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The Rapid Expansion of Comprehensive, High-Quality Tuberculosis Services in Ethiopia

HEALTB

FINAL REPORT:
HELP ETHIOPIA ADDRESS LOW TB PERFORMANCE (HEAL TB) PROJECT 2011–2016

WARREN ZELMAN

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ACRONYMS

AFB	acid-fast bacillus
ALERT	All Africa Leprosy, Tuberculosis, Rehabilitation, Research, and Training Center
ART	antiretroviral treatment
BCC	behavior change communication
CB	community-based
CDR	case detection rate
CME	continuing medical education
CNR	case notification rate
CPT	cotrimoxazole preventive therapy
DOT	directly observed treatment
DOTS	directly observed treatment, short course
DQA	data quality assurance
DSM	drug supply management
DST	drug sensitivity testing
EPHI	Ethiopian Public Health Institute
EPTB	extrapulmonary TB
EQA	external quality assurance
FM	fluorescence microscopy
FMOH	Federal Ministry of Health
FNA	fine-needle aspiration
FN	false negative
FP	false positive
GDF	global drug facility
GOE	Government of Ethiopia
HC	health center
HCW	health care worker
HDA	health development army
HEAL TB	Help Ethiopia Address Low TB Performance Project
HEW	health extension worker
HF	health facility
HMIS	health management information system
HP	health post
HSTP	Health Sector Transformation Plan
IC	infection control
IMNCI	integrated management of newborn and childhood illnesses
INH	isoniazid
IPLS	integrated pharmaceutical logistics system
IPT	isoniazid preventive therapy
ISO	International Organization for Standardization
KAP	knowledge, attitudes, and practices
KAPTLD	Kenya Association for the Prevention of Tuberculosis and Lung Diseases
LED	light-emitting diode
LPA	line probe assay
LQMS	Laboratory Quality Management System
MDR-TB	multidrug-resistant tuberculosis
M&E	monitoring and evaluation
MGIT	Mycobacteria Growth Indicator Tube
mHealth	mobile health
MOST	Management and Organizational Sustainabilitiy Tool
MSH	Management Sciences for Health
MTB	*Mycobacterium tuberculosis*
MTP	monitoring, training, and planning approach
NGO	nongovernmental organization
NTP	National Tuberculosis Program
OPD	outpatient department
PATH	Program for Appropriate Technology in Health
PEPFAR	President's Emergency Plan for AIDS Relief
PFSA	Pharmaceutical Fund Supply Agency
PTB	pulmonary TB
PY	project year
RHB	Regional Health Bureau
RRF	requisition and resupply form
RRL	Regional Reference Laboratory
RR-TB	rifampicin resistant TB
SDG	Sustainable Development Goal
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SLD	second-line drug
SMS	Short Messaging Service
SNNPR	Southern Nations, Nationalities, and Peoples' Region
SoC	standard of care
SOP	standard operating procedure
SPR	smear positivity rate
TB	tuberculosis
TB IC	TB infection control
TFC	treatment follow-up center
TIC	treatment initiating center
TSR	treatment success rate
TWG	technical working group
USAID	US Agency for International Development
WHO	World Health Organization
ZHD	Zonal Health Department
ZN	Ziehl-Neelsen

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PREFACE

"The Rapid Expansion of Comprehensive, High-Quality Tuberculosis Services in Ethiopia" is an end-term report of the United States Agency for International Development (USAID)-funded Help Ethiopia Address Low TB Performance (HEAL TB) Project, which was a five-year project implemented from July 15, 2011 to July 14, 2016. The project received a one year no-cost extension through July 2017 for the construction of four multidrug-resistant tuberculosis (MDR-TB) centers and procurement of medical equipment. The results of this no-cost extension are not included in this report and will be shared in July 2017.

The HEAL TB Project was funded by USAID and the President's Emergency Plan for AIDS Relief (PEPFAR) to implement the following main areas: increase political commitment for tuberculosis (TB) program implementation, strengthen laboratory services and systems for TB diagnosis, ensure that standard TB regimens are administered correctly, improve drug supply management systems, improve recording and reporting, strengthen referral linkages, strengthen community TB care, respond to the emergency of MDR-TB, improve TB/HIV services, and strengthen health care systems. Gender and TB was also part of the broad design of the project.

Four organizations implemented the HEAL TB Project: Management Sciences for Health (MSH) as prime, the Program for Appropriate Technology in Health (PATH), the All Africa Leprosy, Tuberculosis, Rehabilitation, Research and Training Center (ALERT) in Ethiopia, and the Kenya Association for the Prevention of Tuberculosis and Lung Diseases (KAPTLD) as sub-partners. PATH was mainly responsible for the community TB part, KAPTLD for gender and TB, and ALERT for training, specifically the introduction of innovative blended training approaches.

The HEAL TB project doubled the population served and health facility coverage, as well as improved the quality of care in all components of TB activities, without an increase in the resources allocated at the signing of the cooperative agreement. This was possible mainly due to innovative approaches in project implementation and stimulation of the health care system at all levels to take the lead role in implementation, rather than creating a parallel implementation structure.

The report is designed to serve as a resource for public health professionals, managers, and partners. It defines the gaps at baseline and presents the strategies followed, results achieved, lessons learned, and recommendations. Program implementation innovations are also covered. The project's peer-reviewed publications and a list of conference abstract are also included.

The report is structured as follows:

- Background
- Section 1. Overview of the HEAL TB Project and Project Strategy
- Section 2. Project Startup and Expansion
- Section 3. Improving TB Case Detection and Treatment Outcomes through Strengthened and Expanded DOT, Short Course (DOTS)
- Section 4. Strengthening Laboratory Services and Systems
- Section 5. Improving TB Case Notification and Treatment Outcomes among Children
- Section 6. Drug Supply Management
- Section 7. Responding to the Emerging Threat of MDR-TB
- Section 8. TB/HIV Collaboration
- Section 9. Health Systems Strengthening
- Section 10. Gender Mainstreaming
- Section 11. Strategic Framework for Capacity Building and Sustainability
- Section 12. Operational Research and Innovations

The report also contains appendices on the materials and tools produced by the project and the supplies and equipment procured, as well as the performance monitoring plan.

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EXECUTIVE SUMMARY

BACKGROUND

In 2010, when the USAID-funded 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 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 MDR-TB was a major concern, but there was no solid program. As for HIV, adult prevalence was 2.3% per the 2010 estimate.[1,2,3]

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, Heal TB 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%.[4]

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 microcopy was published in an international peer-reviewed journal.[5] 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. EHPI 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

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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 prioritization 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.

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BACKGROUND

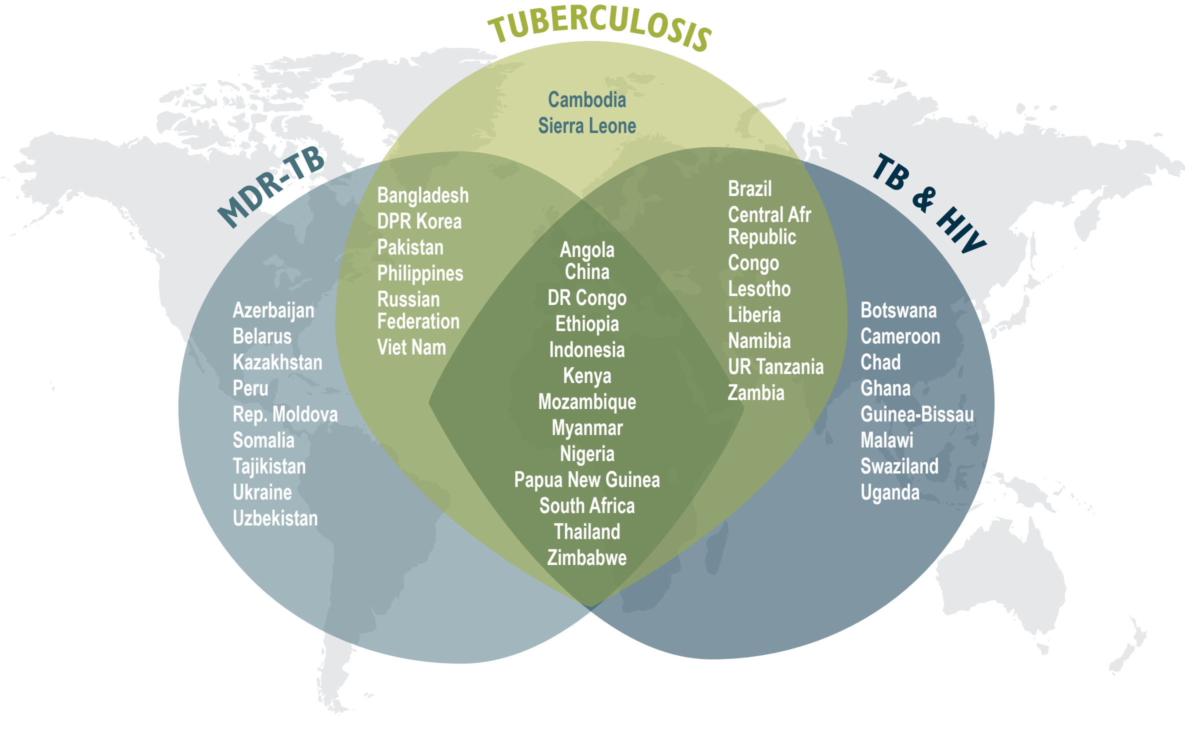
Worldwide, 9.6 million people were estimated to have been affected by drug-sensitive TB in 2014, 12% of whom were HIV co-infected. The case detection rate in the year was less than two-thirds (63%) of the estimated TB cases globally. Since 2000, the global incidence of TB has dropped by an average of 1.5% annually. There were 1.5 million TB deaths in 2014. An estimated 480,000 cases of MDR-TB occurred in 2014 globally, of which only a quarter were detected.[6]

More than one-quarter of the world's TB cases in 2015 were found in Africa; the region has the highest case notification rate, at 281 per 100,000. Africa is one of the WHO regions that failed to meet the target of halving the TB prevalence rate compared with 1990. However, Ethiopia is one of the nine high-TB-burden countries that achieved this target. Similarly, the target of halving the TB mortality rate by 2015 compared with 1990 was not met by the Africa region, while Ethiopia was among the 11 high-burden countries that were able to meet the target.[1]

As shown in Figure 1, despite achieving the global targets of reducing TB incidence and death, Ethiopia continues to be one of the 30 high-burden TB, TB/HIV, and MDR-TB countries,[6] with an estimated incidence of 200,790 in 2014 (207 per 100,000 population). The 2015 WHO report also estimated 194,000 TB cases (200 per 100,000 population) and 32,010 deaths (33 per 100,000 population) due to TB in Ethiopia in 2014. The rate of MDR-TB was estimated to be 1.6% of new TB cases and 11.8% of previously treated TB cases.[1] According to the national TB/HIV surveillance system, TB screening among people living with HIV was reported to be 92.4%. Of these HIV-positive people, 7.8% had active TB. The proportion of TB patients tested for HIV was 86%, and the TB/HIV co-infection rate was 20%.[7]

The year 2015 marked the transition from the Stop TB Strategy to the End TB Strategy, aimed at ending the global TB epidemic. The End TB Strategy is linked to the newly adopted Sustainable Development Goals (SDGs), which aim to reduce the number of TB deaths by 90% by 2030 (compared

FIGURE 1. Countries in the three TB high-burden country lists that will be used by WHO during the period 2016–2020, and their areas of overlap



with 2015), cut the incidence of TB cases by 80%, and avoid TB-related catastrophic costs in the community.[8]

Ethiopia adopted the DOTS strategy in 1997 and the global Stop TB strategy in 2006 with the aim of reducing the TB incidence, prevalence, and mortality by half in relation to the burden reported in 1990. Ethiopia has achieved the Millennium Development Goals for TB in 2015 and currently follows the new End TB Strategy, in line with the Health Sector Transformation Plan (HSTP) of the country. Ethiopia's HSTP is a five-year strategy of the health sector (2015/16–2019/20), which will focus on paving the way for the SDGs.[8,9]

The TB program is managed and coordinated at the national level by the FMOH. The FMOH plays a coordination role for nine regional health bureaus and two city administration health bureaus that are in turn responsible for coordinating zonal health offices. Zonal health offices are in charge of *woreda* health offices (equivalent to district health offices), which manage the health facilities in their catchment areas. The system of health facilities is composed of hospitals, health centers, and health posts, which are accountable for TB prevention, diagnosis, and treatment activities. Hospitals and health centers provide diagnostic services as well as patient management and follow-up. Health posts are the lowest-level health facilities, where community-based TB care—namely community sensitization, referral of presumptive-TB cases, and DOTS—is carried out. There are referral linkages between the health facilities at all levels.[4]

SITUATION ANALYSIS AT THE PROJECT DESIGN PHASE

At the beginning of the project, the Ethiopian population was estimated to be 80 million, with the Oromia and Amhara Regions representing 29.6 and 18.1 million people, respectively. In mid-2016, the Ethiopian population was estimated to be 102.5 million.[10] In 2011, TB was the leading cause of morbidity and second cause of death in Ethiopia, making Ethiopia the 7th of 22 high-burden countries. According to the WHO estimate in 2009, smear-positive TB was 163 per 100,000 population and mortality was 92 per 100,000 population. Ethiopia also had a high HIV burden, including TB/HIV co-infection. Adult HIV prevalence was estimated to be 2.3% in 2010 and declined to 1.1% in 2015.

Progress in case detection of TB in Ethiopia has lagged over many years. The national TB case detection rate (CDR) was low (35.8% in 2009–2010), according to the FMOH. The average TSR, although much higher (at 84% in 2009–2010) did not yet meet the WHO target of 87%. MDR-TB was a rapidly emerging concern. According to WHO, 233 confirmed MDR-TB cases occurred in 2009 in Ethiopia, and there were 146,677 new TB cases notified. These were among the highest numbers in Africa. A WHO briefing for the FMOH on December 14, 2010, counted 152 MDR-TB patients being treated in Addis Ababa and nine under treatment in Amhara. These were the baseline data at the beginning of the project back in 2011.[11]

CHALLENGES AND CONSTRAINTS IDENTIFIED IN 2010

The major challenges and constraints identified were mainly related to health systems and service delivery issues of both demand and supply. On the demand side, there was lack of public awareness about TB in communities; stigma, especially related to TB being associated with HIV, remained strong; physical access to TB services was limited; quality of services was inconsistent; socioeconomic barriers, including transport, child care, and waiting times, hampered access even though treatment following diagnosis was free; and gender-related factors limited women's access to TB services. Public awareness about the disease was low, and health-seeking behavior, especially among women, were proposed as areas for improvement. Inefficient systems also caused long delays in diagnosis and care.

Supply-side issues affected every component of the health system; leadership and management required strengthening to integrate TB into health programming at all levels. TB services suffered from inadequate knowledge and skills among health care workers (HCWs), coupled with high turnover. Poor quality of service delivery—including the organization of case detection within facilities, suboptimal use of the HEWs, poor linkages and referral systems—resulted in missed opportunities for TB detection. Poor management of TB medicines and laboratory commodities seriously delayed diagnosis and treatment. Inadequate recording and reporting hampered analysis and tracking. Service delivery constraints were identified that affected all four technical areas as well:

- **Community-based (CB) TB care:** weak referral system; weak suspect identification because of low skills and knowledge of TB; lack of community empowerment, especially women; lack of linkages between community workers and facilities
- **MDR-TB:** very slow decentralization, with centralized diagnosis of MDR-TB suspects; only one treatment site at national level; re-treatment failures; lack of culture facilities and drug sensitivity testing capabilities in the regions; issue of transportation of sputum specimens
- **TB/HIV:** needed to be strengthened in all health facilities and *woredas*; continue to extend access to ART
- **Infection control:** lack of knowledge of managers, TB focal persons, and frontline health workers; health facilities without IC plans; facilities that required renovation; need to strengthen and expand the HIV/AIDS Care and Support Project's successful IC program

To close these wide gaps, HEAL TB designed a strategy with the FMOH, RHBs, PEPFAR projects, Ethiopian Public Health Institute (EPHI), Pharmaceutical Fund Supply Agency (PFSA), and universities. The project was planned with the target of increasing the CDR to 70% within 18–24 months in selected geographic areas and expanding in the remaining years to achieve an average CDR of 70%, and attain an average TSR of at least 85%. The conceptual framework and results framework (Figures 2 and 3) show how the project approached the challenge to improve and scale up community TB care and strengthen health systems in order to expand access to DOTS, MDR-TB, and TB/HIV services.

FIGURE 2. Ethiopia HEAL TB conceptual framework

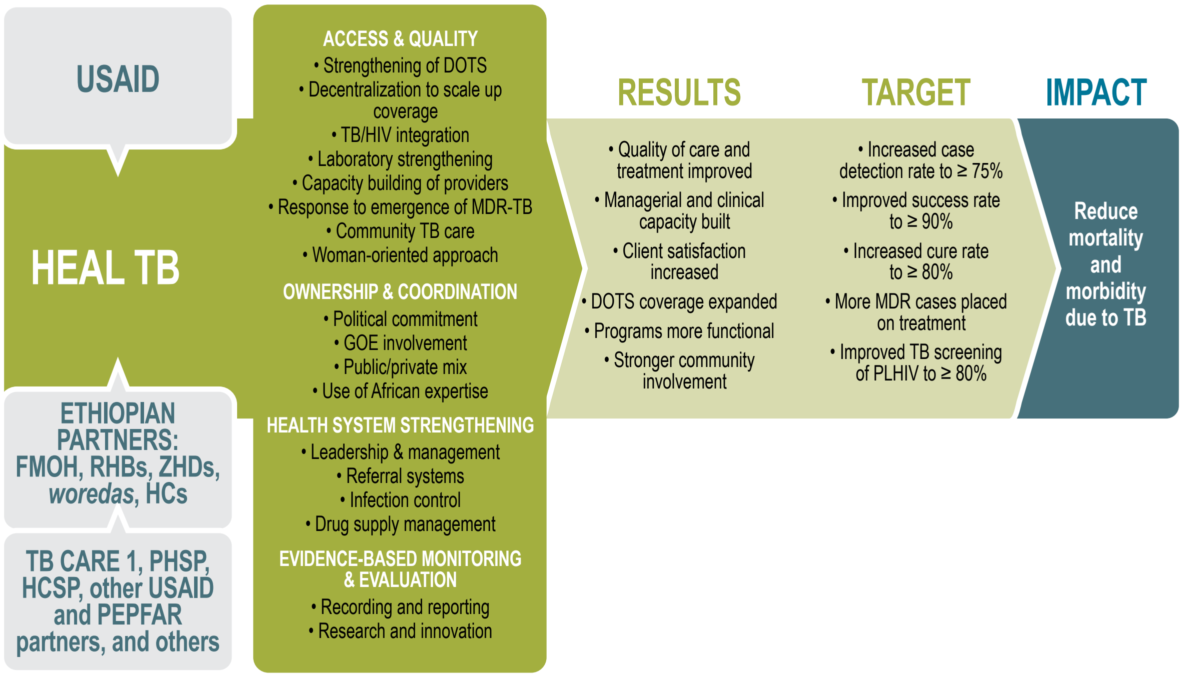
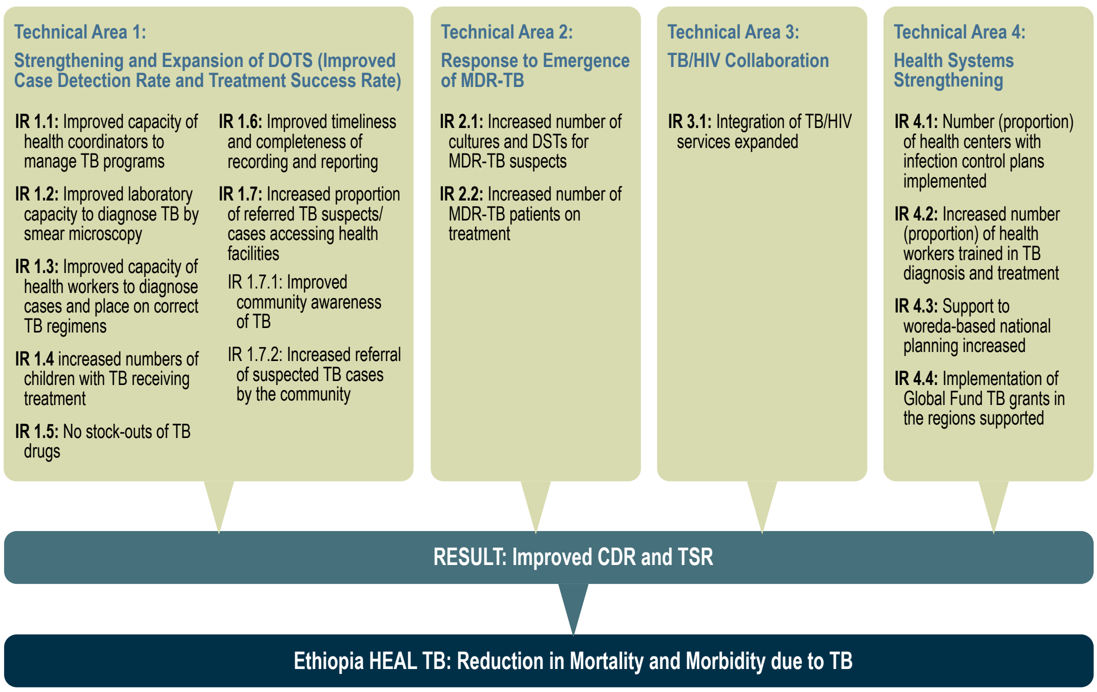


FIGURE 3. Ethiopia HEAL TB results framework



BOX 1. MSH's seven pillars of scaling up comprehensive TB services

1. Increase community awareness of TB, improve referrals, and facilitate service provision to TB suspects referred.
2. Improve the organization of TB cases detection within facilities by strengthening facilities' multidisciplinary teams and streamlining the flow of TB suspects and patients.
3. Provide standard operating procedures, job aids, and posters to all health facilities and improve workers' skills in TB diagnosis.
4. Improve the documentation and monitoring of TB suspects.
5. Screen all people living with HIV for TB.
6. Strengthen laboratory services and management of drugs and supplies.
7. Involve all care providers, including private health facilities and drug outlets.

WARREN ZELMAN

SECTION 1. OVERVIEW OF THE HEAL TB PROJECT AND PROJECT STRATEGY

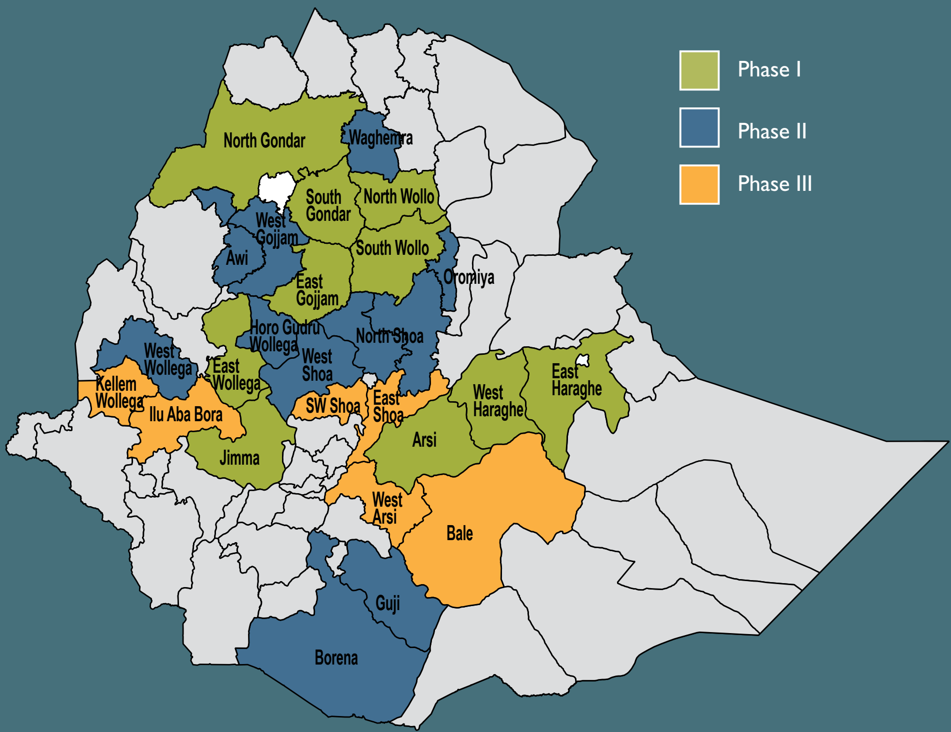
The USAID-funded HEAL TB project was a five-year project awarded to MSH on July 15, 2011, under cooperative agreement number AID-663-A-11-00011. The total award was US$41,996,319. The Global Health Committee was involved for one year in training health workers in MDR-TB on a limited scale in Amhara Region. The project was designed to assist the Government of Ethiopia (GOE) in increasing case detection and improving treatment success rates to reach global targets through a comprehensive package of TB control interventions. The proposed interventions were built on seven pillars of scaling up comprehensive TB services (Box 1, left), which were aligned with the GOE's TB control goals in the five-year HSDP IV. HEAL TB aimed to provide quality DOTS, strengthen referral linkages to the community, and assist the Federal Republic of Ethiopia and targeted regions to improve, expand, and sustain TB services. Through this assistance, the RHBs, zonal health departments, and *woreda* (district) primary health care units improved program management of TB and MDR-TB, provided tighter TB/HIV collaboration, and strengthened the health system.

The core technical strategy of the HEAL TB Project was based on a model of TB care decentralized to the community level and combined with strengthening health care systems, such as leadership and management, and laboratory and diagnostics capacity—complemented by improving health workers' skills in diagnosis and case management, drug supply management, recording and reporting, referral linkages, community TB awareness, and infection control. This systemic approach was envisaged to increase case detection and improve treatment outcomes.

The key innovations proposed at the project's outset were:

- the DOTS package approach;
- introduction of mobile telephone technology into the referral system;
- support for operational research;
- transportation of sputum slides by HEWs and volunteers;
- Model DOTs Learning Centers;
- the MSH Monitoring-Training Planning (MTP) approach;
- MSH Management and Organizational Sustainability Tool (MOST) for TB and TB/HIV;
- TB patient support groups;
- TB treatment kits;
- mobilization of community DOTS supporters through subcontracts to national nongovernmental organizations (NGOs); and
- CME for health workers.

FIGURE 4. HEAL TB MSH intervention zones at the end of the fifth year



Key Achievements Section 2:

- ✔ Creation of a joint plan, strategies, and activities agreed upon with the FMOH, EPHI, Pharmaceutical Fund Supply Agency (PFSA), RHBs, and Regional Reference Libraries (RRLs) from the beginning of the project, which helped to integrate the HEAL TB Project into the government program.
- ✔ *Woreda* health office leading TB program implementation and monitoring, supported by the zonal health department and RHBs. The approach was aligned with the government strategy of *woreda*-led planning, implementation, and monitoring. It avoided donor-driven vertical project implementation approaches, created a sense of ownership of the project within the health care system, and was cost effective and sustainable. The model is applicable to any program.
- ✔ Application of an operational tool—standards of care (SoC) indicators—for gap identification, participatory solution design, progress monitoring, and data quality assurance called developed and applied by *woredas* and zonal TB focal persons. The SoC is being replicated by other MSH TB programs.
- ✔ Innovative training approaches such as Model DOTS centers and blended training approaches.
- ✔ Use of cost savings that allowed the project to expand from a target of 15 zones to 28 zones, from a target of 1,000 health facilities to 2,186, and from 7,000 to close to 10,000 health posts. Also introduced other initiatives and procured multimillion-dollar equipment without a budget increase.
- ✔ Project support for 54 million people to obtain quality TB services.

SECTION 2. PROJECT STARTUP AND EXPANSION

2.1. BASELINE PREPARATIONS AND APPROACHES

After signing the cooperative agreement, the first step taken, beside the recruitment of human resources, was organizing a series of consultative discussions with the FMOH, RHBs, RRLs, PFSA, the Ethiopian Public Health Institute (EPHI), and other projects supporting TB programming. In the consultative meetings, the strategies and activities offered during the proposal phase were discussed in detail and further enriched to accommodate the government's priorities. The main refinements of strategies and activities were:

- A training needs assessment and tools were proposed to prepare for needs-based training.
- HEAL TB proposed using an integrated approach with the government health care system to provide project support (details below).
- The laboratory capacity-building approaches were designed and agreed upon (details under Section 4).
- An approach to TB monitoring was proposed to train one volunteer for every 20 households; it was not accepted because the FMOH was preparing to deploy HDAs. HDAs are volunteers; there is a woman leader for every five households, and for each 30 HDAs there is one leader, who in turn reports to the HEW (details under the community TB section).

Based on these additions, the first-year plan was developed and approved by USAID. In the first phase of the project (July 15, 2011–July 14, 2013), ten zones were included as part of the cooperative agreement and in the second phase, the plan was to expand to five additional zones. With USAID's guidance, a revised strategy was developed to expand to 11 additional zones. In August 2013, after analyzing our pipeline budget, we received approval to cover the remaining seven zones in Oromia. Therefore, in sum, the project-supported zones grew from 15 planned to 28 in total, and the population coverage thus reached 54 million, with the same resources (Table 1 and Figure 4).

TABLE 1. Profile of HEAL TB-supported zones (Jul. 2016)

Phase	Region	Population	No. of *Woredas*	No. of Hospitals	No. of Health Centers	No. of Diagnostic Health Centers	Total Health Facilities	No. of Health Posts
I	Amhara	13,212,167	96	12	518	397	530	2,067
	Oromia	13,715,419	101	15	461	346	476	2,365
	Subtotal Phase I	26,927,586	197	27	978	743	1,005	4,432
II	Amhara	7,186,832	71	7	295	235	302	1,178
	Oromia	9,417,796	93	14	400	287	414	2,154
	Subtotal Phase II	16,604,628	164	21	695	522	758	3,332
III	Oromia *(only)*	10,924,547	110	16	449	285	465	2,203
	Amhara Total	20,398,999	167	19	812	632	831	3,245
	Oromia Total	34,057,762	304	45	1,310	918	1,355	6,722
	Project Total	**54,456,761**	**471**	**64**	**2,122**	**1,550**	**2,186**	**9,967**

2.2. MAJOR TARGETS

In terms of targets for health facilities, the plan was to support 1,000 health facilities, but at the end of 2013 coverage was 2,186 facilities—more than double the target. The MDR-TB support mandate was limited to case notification, but only two hospitals in the country had the capacity to enroll and treat MDR-TB patients. After HEAL TB analyzed the gaps with USAID and the FMOH, USAID asked HEAL TB to support a comprehensive MDR-TB program in the two regions. By 2013, more than 60% of Ethiopian MDR-TB services were supported by the project (Table 2).

TABLE 2. HEAL TB project expansion compared with the original cooperative agreement (Jul. 2016)

Parameter	Original Target	Current Status
Zones	15	28
Health facilities	1,000	2,186
Health posts	7,000	9,967
MDR-TB	Limited scope	22 hospitals
E-health	None	Fully designed
Sample transport	None	Integrated sample transport fully designed; 8 dedicated vehicles designed with cold chain system and operational
Biomedical engineering	None	Significant component, unique in TB
Equipment procurement	Very little	Invested US$ 3.2 million above the original plan

2.3. THE CAPACITY-BUILDING APPROACH

The details of our implementation strategies and capacity building models are presented in each technical area in the following sections. Here, the achievements in terms of mentorship and supervision approaches, training, and the integration with the system are described.

Mentorship and Supervision Approaches

SoC indicators were developed to serve as a tool for baseline assessment, training needs assessment, progress monitoring, mentorship/supervision, data quality assurance, and operational research. The indicators were taken from the standard WHO and national TB indicators. The SoC indicators are not a data collection tool; rather, they strengthened data quality assurance for the health management information system (HMIS) and helped to build the capacity of health workers in using HMIS data for improving the TB program. The SoC indicators included case notification and treatment outcomes, sputum microscopy quality, drug management and stock-outs, MDR-TB, and TB infection control. Cut-off points (percentages) for labeling performance as red (poor), yellow (moderate), and green (better) were developed. The cut-off percentages took into consideration the indicators of critical importance and the implications for progress monitoring. The SoCs initially used 28 indicators, which were later reduced to the 22 most important areas, in order to minimize the burden on supervisors/mentors and give them sufficient time for mentorship. Every HEAL TB team was trained on the SoC indicators and the team cascaded the training to the zonal and *woreda* TB focal persons in turn.

All the baseline data were collected using these tools. The data collectors are the *woreda* TB focal persons, supervised by the HEAL TB field team. The *woreda* TB focal persons supervise and mentor the health facilities quarterly using the SoC indicators (Figures 5 and 6). If there is no progress in the indicator, the TB focal person, with the health facility TB focal person and laboratory or pharmacy staff, identifies the reasons for the faltering indicator and designs an improvement plan. The *woreda* TB focal person also randomizes the AFB smear slides per the national guideline and drops them off at the EQA center for reading. After supervising and mentoring the outpatient department, laboratory, and pharmacy, the *woreda* focal person debriefs the head of the health facility and the persons in charge of different units on the findings and actions taken. The gaps identified with the improvement plans are documented in the health facility logbook specifically prepared for TB program purposes, and both parties sign it to testify that action will be taken on the gaps identified. If the gap identified is related to training, supplies, or equipment, the *woreda* TB focal person reports to the Zonal Health Department (ZHD) for action.

At the end of each quarter, the *woreda* TB focal person presents the *woreda*'s TB program progress in a meeting with the zonal team and HEAL TB experts (Figure 5). The HEAL TB team is embedded in the zonal health office, and all their activities are jointly planned and implemented with the zone. The zonal TB focal person, with the HEAL TB laboratory and TB officers, plans to supervise health facilities with poor performance reported by the *woreda* TB focal persons, as well as one or two health facilities with reported good performance. When he or she visits these facilities, the responsible *woreda* TB focal person joins the team and uses the SoC to validate the information given by the *woreda* TB focal person. He or she also discusses improvements with the health facility team. The RHBs decided to pay US$7.50 per day for *woreda* TB focal persons for transport and lunch allowance, which is less than the government per diem rate, but it worked well, with high staff motivation. The RHBs decided on this amount because it is a rate they can sustain without external support. HEAL TB covered the cost for five years, and the RHBs promised to allocate as many resources as possible. The SoC indicators and progress appear in Annex C.

Support and Coordination at the National and Regional Levels

At the national level, the HEAL TB senior management team participated in the various technical working groups (TWGs) led by the FMOH, such as the TB, MDR-TB, laboratory, and drug supply management groups. The TWGs assist the government in planning, implementation, monitoring, and evaluation of the program. The TWGs are also responsible for developing guidelines, implementation strategies, and tools. All bilateral, multilateral, and NGO partners are also part of these TWGs. At the regional level, there is a technical task force led by the RHB TB managers and at this level all partners are also represented. The task force is mainly responsible for facilitating implementation, assisting in regional planning, and sharing experiences. It is also a forum that helps to avoid duplications and maximize the use of resources. Figure 7, on page 16, shows the integration models of HEAL TB with various levels of the government structure and other partners.

Trainings

HEAL TB has been implementing different training approaches besides the on-site mentorship approach described above. These training approaches were the traditional off-site training, on-the-job training using model DOTS centers, the blended training approach, and continuing medical education (CME) sessions.

Off-site trainings. In the traditional classroom trainings, trainees are identified through our supervision/mentorship approaches described above. Training of trainers was

FIGURE 5. HEAL TB capacity-building interface with the health care system at regional level

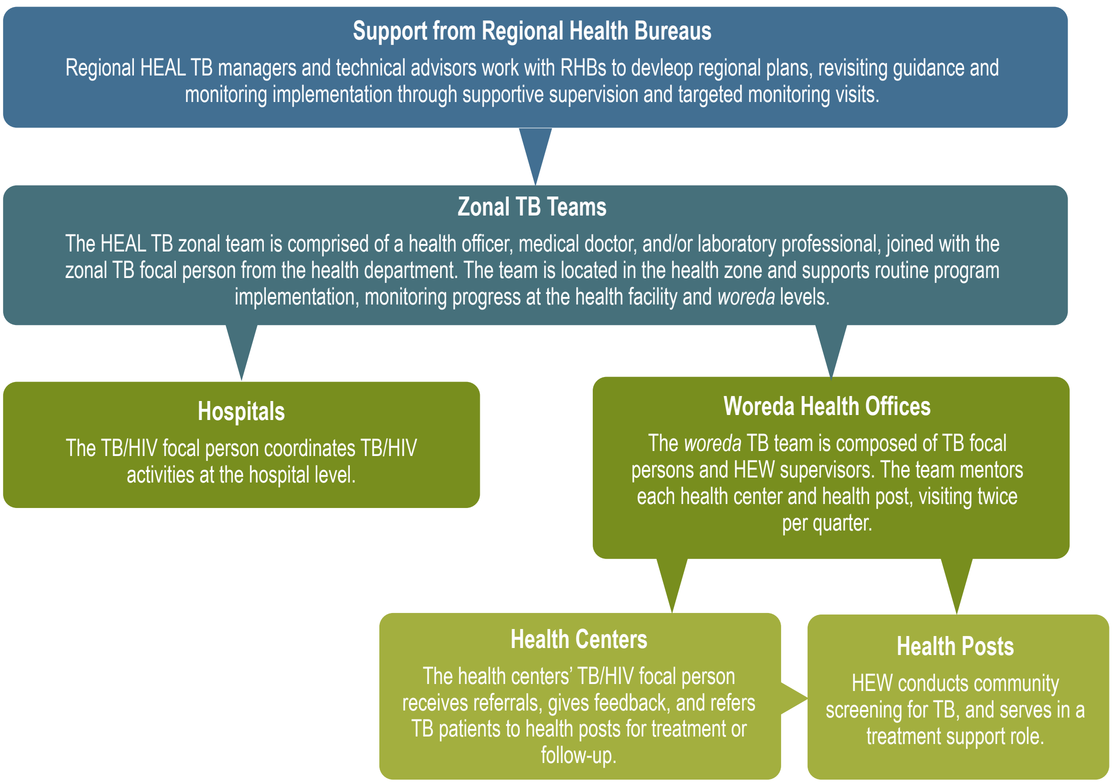


FIGURE 6. *Woreda*-led mentorship/supervision

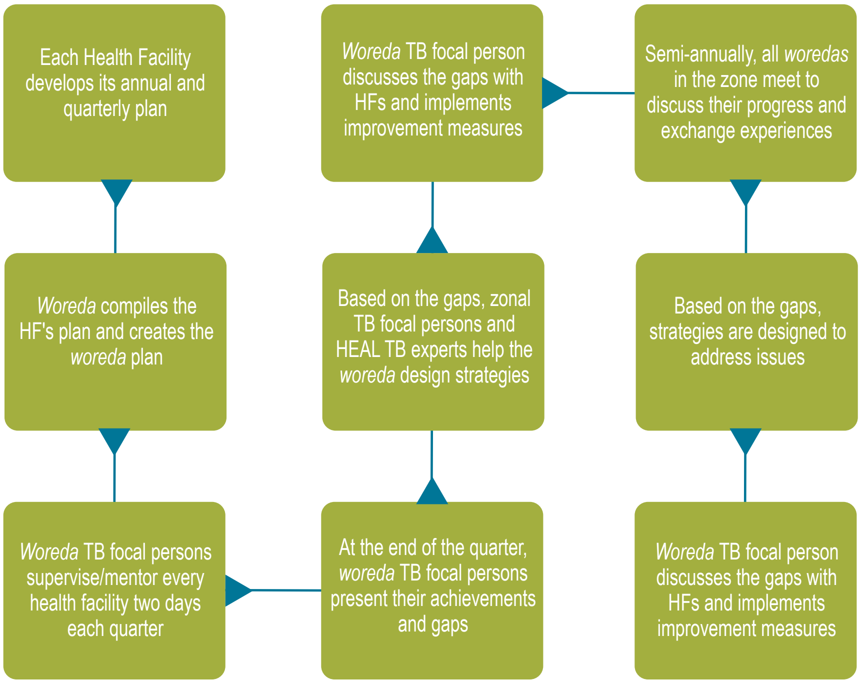
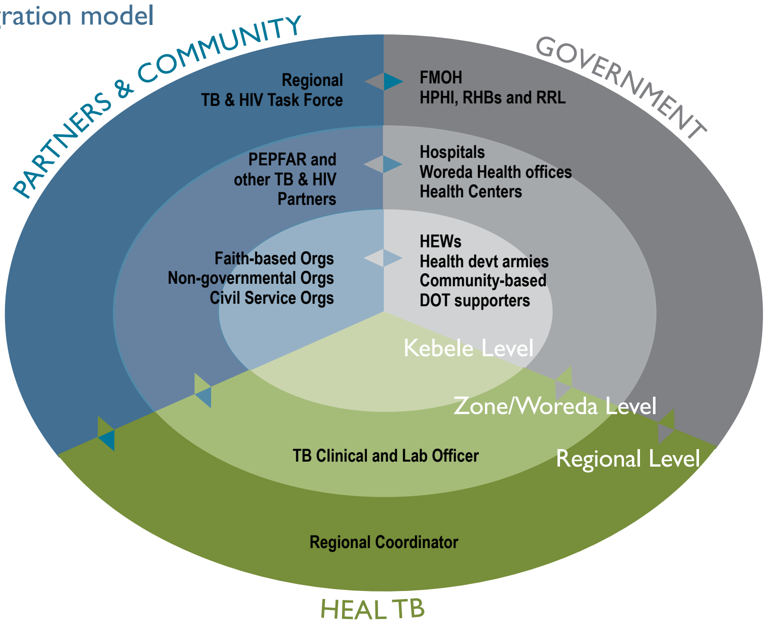


FIGURE 7. HEAL TB integration model



also conducted in health facilities and universities. In total, 23,038 health workers were trained in five years in different categories (Table 3, next page). The trainings listed in Table 3 do not include short trainings such as those on GeneXpert and culture, training for TB program managers, and so on.

Trainings in model DOTS centers. Model DOTS centers are health facilities that receive the same type of support but, because their performance is exceptional, they can serve as on-site training centers for poor-performing professionals in other health facilities. It was planned to establish 10 Model DOTS centers, but at the end 20 centers were established. More than 2,000 health workers and managers were trained in these centers. The RHBs decided to pay a modest per diem for trainees.

Blended learning approach. HEAL TB supported the piloting of a blended learning approach in collaboration with the FMOH. The preliminary findings suggest that blended training is as effective as traditional training (Box 2, next page). In addition, HEAL TB, again in collaboration with the FMOH, organized a blended-learning launch workshop, attended by representatives from over 32 universities. Continuing with the pilot blended-learning approach, HEAL TB supported ALERT in strengthening distance-learning facilities by providing two sets of videoconferencing equipment. An e-learning manager was seconded to ALERT to support the operationalization of the videoconferencing facility. The videoconferencing facility will be used to strengthen the blended-learning training and CME activities in line with FMOH's new directive of institutionalizing in-service trainings.

TABLE 3. Health workers trained from Jul. 2011 through May 2016

Selected Trainings	Target	Achieved
Comprehensive TB/Leprosy and TB/HIV	5,180	6,152
AFB microscopy and EQA for lab professionals	3,408	2,614
Laboratory Quality Management System		330
Integrated Pharmaceutical Logistics System and TB drug supply management for pharmacy store persons	240	2,720
Training community-based TB care (old and new)	3,380*	1,600
MDR-TB clinical and programmatic management	NA	434
Microscope maintenance	NA	66
Woreda and Health Extension Package coordinators' orientation	NA	1,500
Total		15,416

* Note: The government trained all HEWs in the country through the Global Fund, and HEAL TB provided technical support. Nearly 20,000 HEWs were trained in the two regions.

Quarterly and semi-annual review meetings. Every quarter, the *woreda* TB focal persons compile their mentoring SoC data from their respective health facilities and discuss the data with the zonal TB focal person and HEAL TB zonal clinical and lab officers. They discuss the progress of each indicator for each health facility, identify bottlenecks for the progress of activities, and design improvement plans. After completing the reviews under the zonal TB focal person's leadership, and with assistance from HEAL TB, zonal teams identify health facilities with poor performers and plan a supervision visit. During the supervision, the *woreda* TB focal person of the respective health facility also accompanies the zonal team. The team then uses the SoC to calculate each indicator and check if the report by the health facility and *woreda* TB focal person is correct. The supervision has three purposes: to check the capacity of the *woreda* TB focal person, monitor the performance of the health facilities, and discuss the actions to be taken with the health facility management.

BOX 2. Preliminary results of the blended training approach

Background: We carried out a comparative study, using the Kirkpatrick training evaluation model. The test group received materials to read on their own for three weeks, followed by a three-day face-to-face off-site training. The traditional group received a six-day off-site workshop. Training materials were tailored to the specific modality of training, but the same content, as developed and endorsed by the Ministry of Health, was used. Health workers with no recent training in the updated national TB/HIV guidelines from the two selected zones participated in the study. The evaluation criteria included participant satisfaction, learning, behavioral changes, and impact according to the four-level Kirkpatrick training evaluation model. We compared levels of satisfaction between the two groups using a 32-item questionnaire and computed pre- and post-test results between and within the two groups using a one-way ANOVA test.

Results: At the time of this analysis, complete data were available for 209 trainees (63 from the traditional group and 146 from the test group). The two groups did not differ in terms of education and work experience and had similar levels of satisfaction (57 in the traditional group vs. 55 in the test group). The mean pre-test result was higher for the traditional group (56.2 vs. 51.2), while their post-test result was similar (66.7 vs. 63.5; $F = 1.73$; $p > 0.1$). Also, the test group had higher mean (SD) improvement in post-test performance (15.6 vs. 10.1; $F = 7.52$; $p < 0.01$). The unit cost per trainee was lower in the test group (US$116.80 vs. US$235.00).

Conclusion: Participants in the test group had a similar level of satisfaction with the training approach and a more improved level of knowledge. The cost and time taken to deliver the blended approach was lower by about one-half. This approach could be a more efficient way of delivering in-service trainings, but further analysis is needed to compare behavioral and service delivery outcomes between the two groups.

Semi-annually, the *woreda* TB focal persons and zonal TB focal persons, through the facilitation of HEAL TB regional managers and teams, present the progress of implementation of the TB program of each zone to the RHBs. In the review meeting, participants learn from the strengths and weakness of the other zones. Major program challenges are also presented, so that the RHBs can plan interventions.

The approach we implemented together with the RHBs helped to motivate the health facilities, *woreda* health offices, and zonal health departments to monitor program implementation objectively and take timely corrective measures to close gaps. This approach avoided unnecessary interference by NGO staff and built ownership and confidence in the health care system. In the initial phases of the project, most of the mentorship was covered by the HEAL TB team and almost all the officers were traveling throughout the month. It was an expensive and parallel system, which made the health care system dependent upon project staff for mentoring. By implementing *woreda*-led and zonal-led supervision/mentorship instead, the project also saved resources because supervision/mentorship by government personnel was cheaper (US$7.50 per day as compared to US$40–50 by HEAL TB staff). This GOE-led approach assisted HEAL TB to save resources and expand its support to more zones, expand MDR-TB services, and provide new diagnostic technologies such as GeneXpert.

2.4. LESSONS LEARNED ABOUT CAPACITY BUILDING

The systemic capacity-building model designed and implemented by HEAL TB under the leadership of the RHBs is in line with the FMOH plan and it is sustainable, cost efficient, and effective. Creating a parallel project structure would have been expensive, making the health care system dependent on donors, and would not be a good approach to build the capacity of health workers and managers. With moderate support, health care managers can now perform better, because they have the technical know-how, decision-making power, and accountability for successes and failures. Based on our assessment and reports, by the end of the project, the technical and managerial capacity of the TB program in the health facilities, *woredas*, zones, and regions was strong. With targeted support in the coming project, the foundation laid by HEAL TB can be sustained.

The second lesson is that off-site trainings are expensive and disrupt health facilities' work, because health workers are absent for many days. Trainings are also not sufficiently linked to performance. As a result, health workers participate in trainings as a means of relief from duty. The blended approaches we piloted with ALERT and the FMOH, coupled with the Food, Medicine and Healthcare Administration and Control Authority-designed accreditation mechanism, can be a good alternative to decrease the cost of training, avoid service interruptions, and motivate trainees to attend for a good purpose, because their training will be linked with license renewal. Creating Model DOTS centers as practical sites for weak performers is another good means of training, because the person attached to the model center will observe and practice with the mentor, which can be more beneficial than off-site trainings for acquiring skills.

WARREN ZELMAN

MSH STAFF

Key Achievements Section 3:

- ✔ In five years, the project supported the diagnosis and treatment of 265,842 TB patients.
- ✔ The case notification rate declined approximately 18% nationally but only 8% in the HEAL TB-supported Amhara and Oromia Regions. This is because of improved knowledge of health workers in screening all patients visiting the health facilities for TB, introduction of contact screening, mapping high-risk population groups and designing focused interventions, and strengthening community TB care using HEWs and HDAs.
- ✔ The TSR increased from an average of 88% to 95%.
- ✔ The cure rate improved from an average of 74% to 88.5%. The gap between the TSR and cure rate is also narrowing. The result is high by global standards. If the high TSR and cure rates can be sustained for a couple of years, the incidence of TB and MDR-TB will decline because sources of infection are curtailed as most patients are cured.
- ✔ 100,816 (96.4%) of the bacteriologically confirmed TB index cases were screened for TB and 1,162 (11.5%) TB cases were identified, producing a yield of 1,152.6 per 100,000 population, which is eight times higher than the project CNR (135 per 100,000).

SECTION 3. IMPROVING TB CASE DETECTION AND TREATMENT OUTCOMES THROUGH STRENGTHENED AND EXPANDED DOT, SHORT COURSE (DOTS)

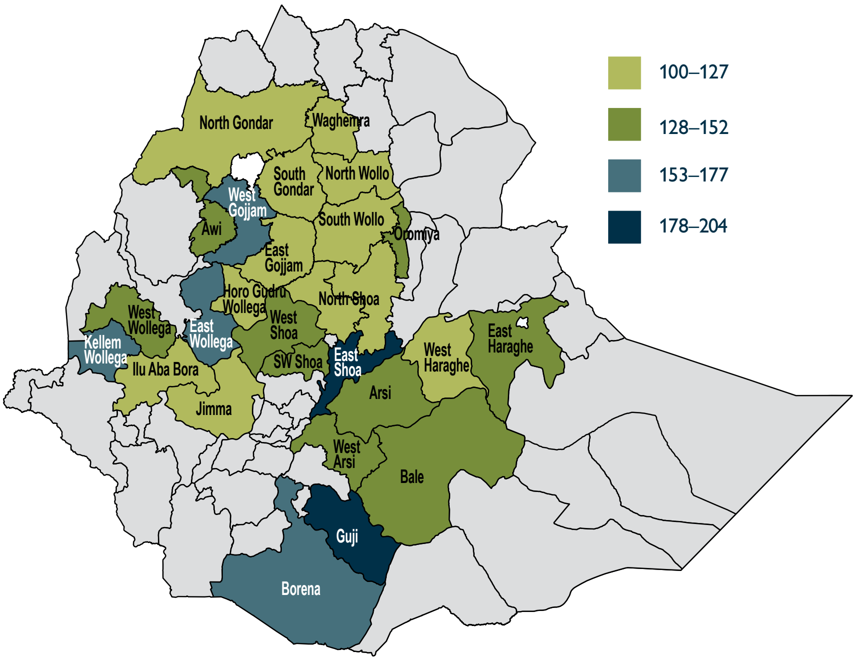
3.1. BASELINE GAPS AND CHALLENGES

At the start of the project, the following key gaps and challenges were identified:

- Inaccurate estimates and declining trends in the CDR: The start of HEAL TB coincided with the release of the results of the national TB prevalence survey in 2011, which reported much lower TB prevalence estimates for the country compared with the WHO's estimate, leading to a revision of the country's case detection target.[12] At the design of the project the CDR was estimated to be 35.8%, but with the new incidence estimate, the rate was around 58%. WHO excluded CDR from the indicator list; the project reported case notification rate (CNR) although it is no longer a reportable indicator.
- Low treatment success and cure rates: In Phase I project zones, the overall baseline TSR was 85%, with a cure rate of 53%. Hospitals had high transfer-out rates, reaching 17%. The situation in Phase II and III zones was a little better because of the spillover effect from Phase I zones. The baseline cure rates for Phase II and III zones were 71% and 79%, respectively, while the TSRs were 88% and 90%, respectively.
- Data quality: At baseline, the DQA result showed that underreporting was as high as 35% and over reporting reached 15%.
- Weaknesses in the community-facility linkage and continuum of care: At baseline, community TB care was in its infancy and there were no tools to ensure adequate linkages between health facilities and community TB care. Based on the baseline assessment in Phase I project zones, only 21% health posts were providing TB treatment.
- TB contact screening was not practiced and TB screening of outpatient department (OPD) visitors in health facilities was very limited: At baseline, contact screening of TB patients was not a strategy for case identification for the nation and project areas. There were no tools and procedures in place for contact tracing. OPDs were also not screening visitors for TB.
- Low level of community awareness about TB: According to the baseline survey of knowledge, attitudes, and practices (KAPs), basic knowledge of TB symptoms, transmission, and cure were low. For example, knowledge of the availability of free TB treatment was 45.2% in urban areas and 26.8% in rural areas.

Other drawbacks related to case finding during the start of the project were the limited capacity of health workers and program managers, shortage of job aids, poor diagnostic capacity, and high stock-out rates. Overall, there was limited implementation of TB case finding approaches.

FIGURE 8. Geographic distribution of TB cases (CNR per 100,000 population) (Oct. 2014–Sep. 2015)



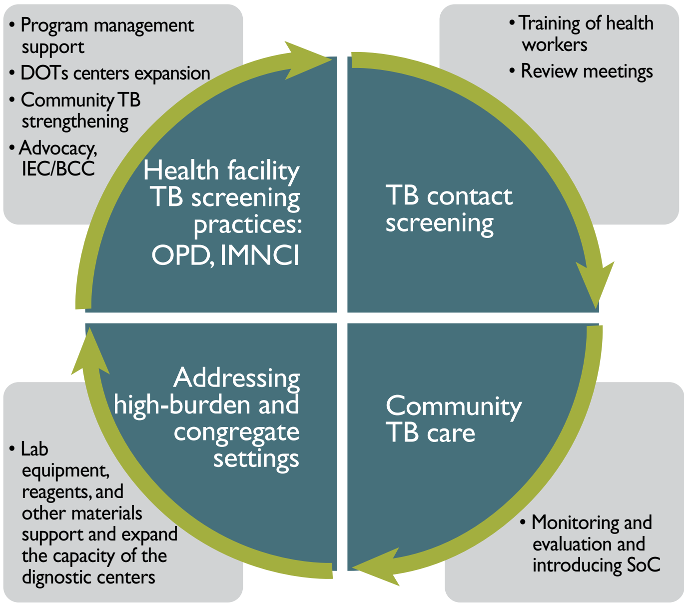
3.2. MAJOR STRATEGIES TO INCREASE CASE NOTIFICATION

While the bulleted points below focus on case notification, they should be interpreted within the broader strategy of expanding DOTS centers; increasing program managers' capacity in planning, implementation, monitoring, and evaluation; expanding laboratory services both in microcopy and GeneXpert; training health workers and volunteers; and introducing innovative monitoring and mentoring tools such as the SoC indicators. These focused case notification approaches were:

- Strengthening of OPD screening of all patients: All health workers were oriented on TB screening, and the FMOH revised the existing OPD register to include TB screening. The mentors/supervisors monitored the performance of the OPDs quarterly and also checked the yield of presumptive TB and TB disease.
- Contact screening: The second strategy was introducing screening of contacts of index TB cases. A contact screening register was developed and given to all health facilities in the two regions for the first time, and was fully implemented in the two HEAL TB-supported regions.
- Mapping of TB high-risk and high-burden areas and application of a tailored approach: As we obtained more information through the HMIS and the SoC, we started to map the load of TB by district based on the case notifications. We initially assumed that districts and zones with low case notification were low performers and those with high case notification were better performers. However, experience showed that areas with high case notification, in most cases, were high-TB-burden areas and areas with low case notification, after all the efforts, remain low except East Wollega zone, which changed to a high case notification zone (Figure 8). The reasons for the differences among zones could include population density, HIV prevalence, and, in some areas, such as in North Gondar, Guji, and Borean zones and urban areas, a large number of migratory laborers. Community-level screening for high CNR was designed, and the yield was very high (presented under 3.4).
- Prison TB services: Another case notification strategy followed was establishing screening and DOT for prisons. Prison health workers were trained to screen new inmates at entry, create referral linkages for presumptive-TB cases to the nearest public health facilities for diagnosis and treatment, and implement TB infection control in prison cells.
- Community TB strengthening and expansion: The final major strategy for increasing case notification was engagement of HEWs in TB screening and referral of presumptive-TB cases, and decentralization of DOT to the health post level. All HEWs, in collaboration with FMOH and RHBs, received refresher training and registers for screening and treatment. The details of the community TB strategy and results are presented in 3.4.
- Urban TB program introduction: In the major towns of the two regions, urban HEWs were trained to screen for TB in their day-to-day visits to households. The focus was on the poorest and most crowded areas of towns.

Figure 9 summarizes the case notification strategies applied in HEAL TB.

FIGURE 9. Summary of case notification strategies applied in HEAL TB



3.3. RESULTS

Case Notification Rates for All Forms of TB

Over the five years, the project supported diagnosis and treatment of 265,842 cases (all forms of TB), 107,579 in Amhara and 158,263 in Oromia (Table 4).

Figures 10–12, next page, show trends and seasonal patterns in the number of notified TB cases by region and phases of implementation. The number of new cases through the years is stable, although case finding increased because of the strategies mentioned above. Nationally, the incidence and prevalence of TB are reported to be decreasing, as shown in the FMOH report (although a new TB prevalence study might be needed to substantiate the program-level decline in cases), and the stable numbers in HEAL TB-supported areas could be because of the increased effort. One clear seasonal trend that we saw in the last five years was an increased number of cases in the dry season from January to June and a decrease from July to September. Seasonality in TB caseload is also reported in the northern hemisphere countries, where there is a peak in early spring and a trough in winter.[13] In the same studies in Spain, the Netherlands, and Portugal, factors predicated for development of the disease in the winter were a low level of vitamin D and impaired immunity, which enhance the disease. As opposed to the general belief that vitamin D deficiency is rare in the tropics, our study in Amhara Region showed that 46% of the subjects studied were vitamin D deficient and vitamin D deficiency was higher for TB patients, at 61% (HEAL TB research finding). The other possible seasonal factor could be that during the dry season, farmers have more time and resources to seek medical care. Yet it is difficult to believe these reasons for seasonal variation, since the incubation period from transmission to development of disease is a minimum of eight weeks.[14] Further investigation of seasonality effects on TB disease control is needed.

TABLE 4. Summary of case notification data, all forms (Jul. 2011–Jun. 2016)

	Amhara	Oromia	Total
Phase I	81,840	87,561	169,401
Phase II	25,739	37,720	63,459
Phase III	NA	32,982	32,982
Total	107,579	158,263	265,842

FIGURE 10. Trends in case notification by phase of implementation and region, Phase I zones (baseline and Jul. 2011–Jun. 2016)

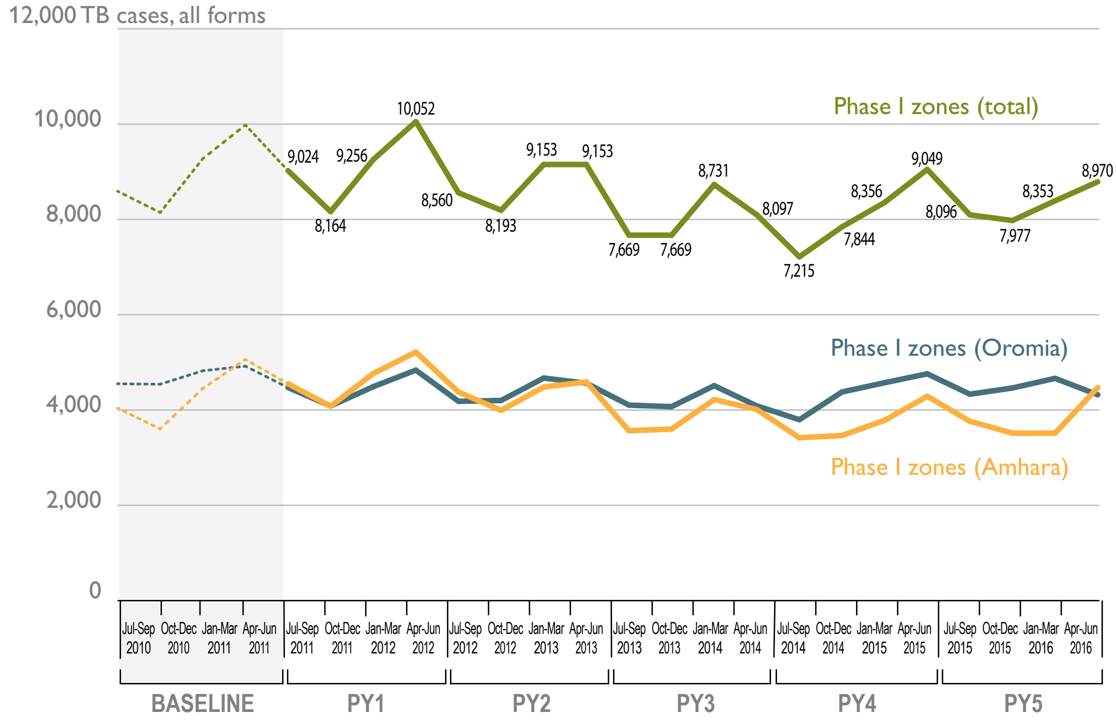


FIGURE 11. Trends in case notification by phase of implementation and region, Phase II zones (Oct. 2013–Jun. 2016)

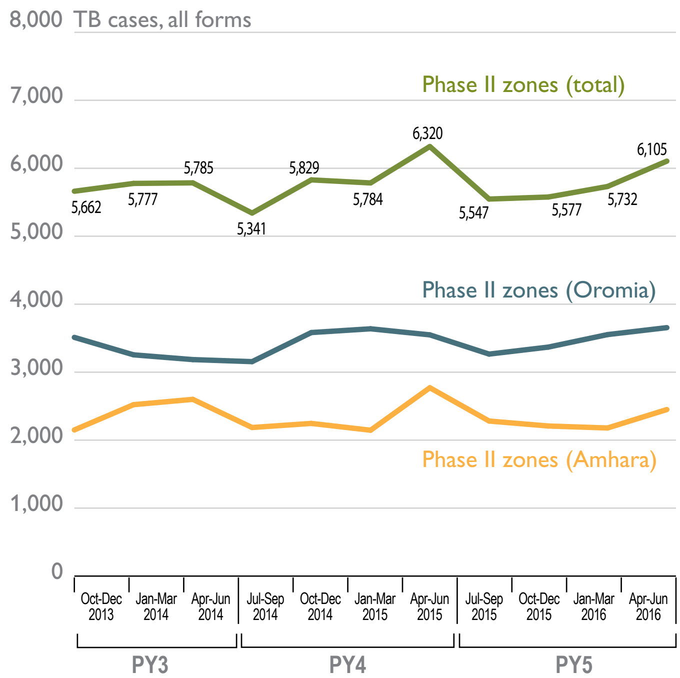


FIGURE 12. Trends in case notification by phase of implementation and region, Phase III zones (Jul. 2014–Jun. 2016)

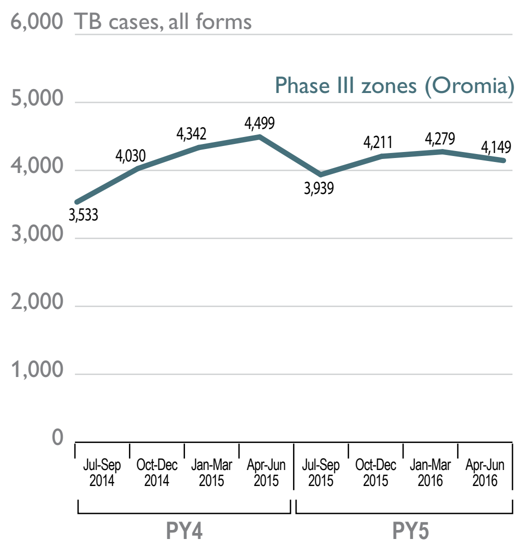
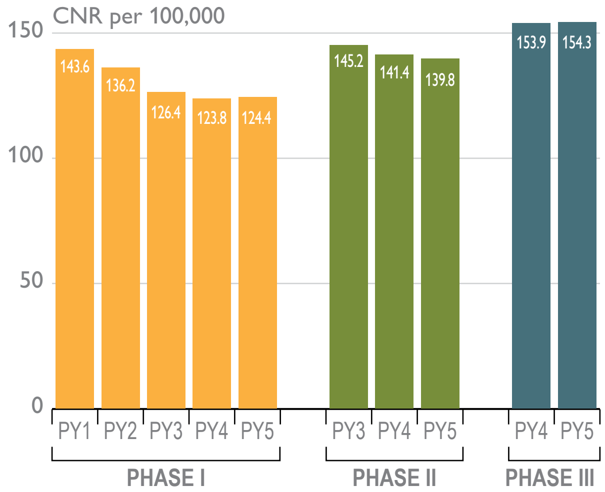


FIGURE 13. Trends in case notification rates for all forms of TB in the HEAL TB project–supported regions of Amhara and Oromia



The CNR for Phase I zones is declining while remaining more stable in Phase II and III health facilities (Figure 13). In our observation, the Phase I zones are the strongest in terms of programming and must have consistently strong TB control efforts to reach this declining trend in number of TB cases. A case in point is South Wollo zone, where with a population of over 2 million, house-to-house TB screening yielded only 30 patients. Although understanding of the decline requires more systematic investigation, it appears that the decline was due to the expansion of health facilities, introduction of strong community health services, the decline in HIV prevalence, and expansion of ART, with a concomitant increase in life expectancy.

At the national level, the declining trend was similar to that observed in HEAL TB-supported regions, but the magnitude of decline in the previous three years was 50% less in HEAL TB-supported regions compared with baseline values in 2010–2011. The FMOH reported a 17.6% reduction in the number of notified cases (from 122,592 to 100,998) when HEAL TB-supported Phase I zones were excluded.[15]

In Phase I HEAL TB-supported zones, however, there was 8.2% reduction over the same period (Table 5). This clearly shows the effectiveness of interventions through HEAL TB in detecting more TB cases, compared with the non-HEAL TB intervention sites.

Trends in New Bacteriologically Confirmed TB Case Notification

New bacteriologically confirmed TB cases constituted 69,963 (41.3%) of all forms of TB reported in the five years in the ten zones in Phase I. In Phase II, the bacteriologically-confirmed cases amounted to 20,976 (33.1%), and in Phase III zones it was 10,866 (36.9%). The relationship between bacteriologically confirmed cases and extrapulmonary TB (EPTB) could be a result of very good TB treatment outcomes reducing infectious pulmonary TB. It could be also a proxy indicator for the effectiveness of disease control interventions (Table 6 and Figure 14, next page).

TABLE 5. Comparison in the reduction of all forms of TB with the national report

Year	Amhara	Oromia	Total
2010-2011	159,017	36,425	122,592
2014-2015	134,343	33,345	100,998
% reduction in 4 years (95%CI)	15.5% (15.3-15.7)	8.5% (8.2-8.7)	17.6% (17.4-17.8)

FIGURE 14. New bacteriologically confirmed TB cases notified in HEAL TB-supported zones (2010–2016)

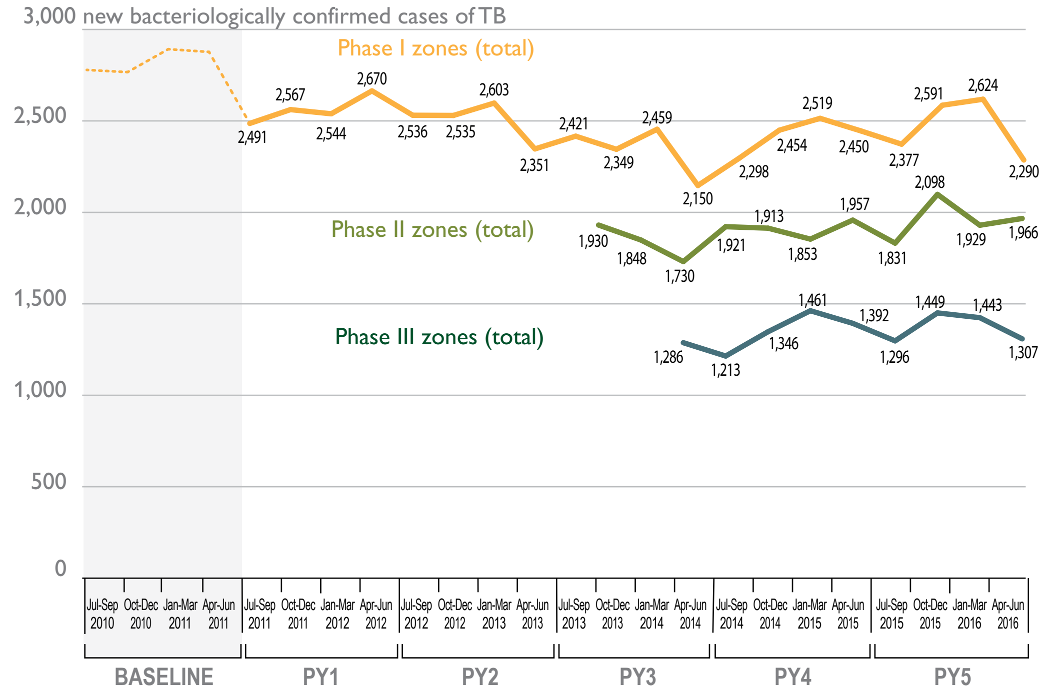


TABLE 6. Trend in bacteriologically confirmed TB cases in Phase I, by year and region (2011–2016)

Region	Bacteriologically Confirmed TB Cases Notified: Amhara	Oromia	Total	Change in Annual TB Case Notification	% Change from Prior Year
Baseline	4,369	6,972	11,341		
PY1	4,404	5,868	10,272	−1,069	−9.43
PY2	4,157	5,868	10,025	−247	−2.40
PY3	3,792	5,587	9,379	−646	−6.44
PY4	3,548	6,173	9,721	342	+3.65
PY5	3,349	6,533	9,882	161	+1.66
Total	23,619	37,001	60,620		

The proportion of bacteriologically confirmed TB cases, as well as EPTB cases, among all forms of TB reported, showed regional variations. In Amhara, bacteriologically confirmed pulmonary TB (PTB) contributed to close to one-fourth of all forms of TB, while half of the cases were EPTB. In Oromia, bacteriologically confirmed PTB contributed to close to one-third of all forms of TB, while EPTB contributed to one-third of all forms of TB (Figure 15, next page). We do not have a clear explanation for the high EPTB in the Amhara Region, and this phenomenon requires further investigation.

Of all forms of TB reported, 12.3% were in children under 15 years of age; 66.5 % of the patients were in the age group of 15–44 years old; 4% of the cases were elderly patients over 65 years. There was a preponderance of cases in males, with a male-to-female ratio of 1.2. The national 2015 report also cited data showing that children under 15 years of age constituted 13.5% of the TB cases notified in the year.

FIGURE 15. Classification of TB cases among all forms of new TB case notification (Jul. 2014–Jun. 2016)

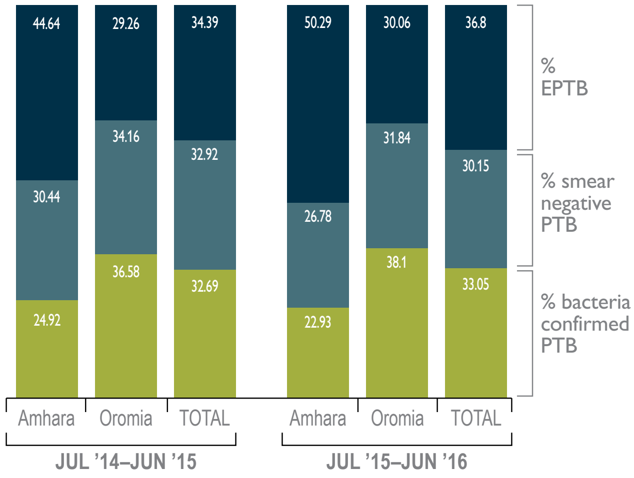
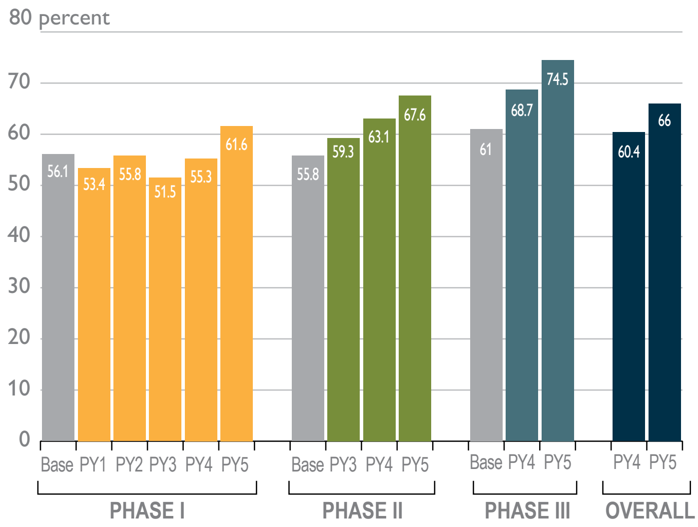


FIGURE 16. Trends in CDR over five years, compared to baseline



Trends in the Case Detection Rate

Although the CDR is no longer considered a valid indicator of TB program improvement, especially in the situation where a decline in notified TB cases is expected, it is noteworthy that the overall CDR of 65% in the fifth year is almost 10% higher than the baseline. As expected, the CDR is the highest in Phase III zones, followed by Phase II and Phase I zones. The CDR in Phase I, II, and III zones in PY5 increased by 11.4%, 7.1%, and 8.4%, respectively, as compared to PY4 (Figure 16). The increase in the last two years could be due to the engagement of HDAs/HEWs, stronger TB contact screening, the improved capacity of health workers screening for TB, and improved diagnostics including expansion of GeneXpert services. There is a difference in CDRs between zones and in our view, long years of better performance in case notification in some zones might have resulted in decreasing the transmission of TB. There will still be some missed cases in every zone; however, knowing the strengths of the interventions, underperformance of the health care system is an unlikely explanation.

New Interventions for Case Notification

TB contact screening. TB contact screening was started in the second year of the project; it was not a standard practice before then. In fourth year of the project, a total of 104,556 household contacts of 37,164 index smear-positive cases were registered, of which 100,816 (96.4%) were screened for TB. Among TB contacts screened, 1,162 (11.5%) TB cases were identified, producing a yield of 1,152.6/100,000 population, which is eight times higher than the project CNR (135 per 100,000). The yield has been consistently decreasing in the past three years. The reasons for this decrease are not yet clear and this needs further investigation. There is a need to monitor the quality of the screening to ensure the consistency of the yield (Table 7, next page). We also compared the yield of TB among contacts of those currently enrolled on TB treatment (active) and among contacts where the index cases completed treatment one to three years earlier (retrospective). The yield among active contacts was 10 times higher and that of the retrospective contacts four times higher than the prevalence of TB in the general population.[16] We recommend that both approaches be implemented, because they are high-yield strategies for case notification.

TABLE 7. Yield of contact investigation and isoniazid preventive therapy (IPT) coverage for children out of smear-positive TB cases in HEAL TB's zones (2012–2015)

Variable	Year 2	Year 3	Year 4	Year 5	Total
Number of health facilities implementing contact screening	275	753	1,553	1,538	NA
Number of index smear-positive TB cases	1,718	7,138	18,009	10,299	37,164
Household contacts registered	4254	20,851	49,207	30,244	104,556
Close contacts, under-5 children	528	2,435	5,442	2,907	11,312
Household contacts screened for TB	4050	19,852	46,922	29,992	100,816
Percent screened among household contacts (%)	95.2	95.21	95.36	99.17	96.4
Number of under-5 children evaluated for TB	457	2,154	5,089	2,884	10,584
Percent under-5 children evaluated for TB out of the contacts (%)	86.6	88.46	93.51	99.21	93.5
Number of presumptive-TB cases identified	269	1,105	1,358	657	3389
Proportion of presumptive TB identified (%)	6.6	5.57	2.89	2.19	3.3
Number of under-5 children presumptive-TB cases identified	84	247	221	81	633
Proportion of presumptive TB identified among under-5 children (%)	18.4	11.47	4.34	2.81	5.9
Number of under-5 children eligible for IPT (screen TB negatives)	442	1,907	4,868	2803	10,020
Number of under-5 children started on IPT	55	507	1,880	1,390	3751
IPT coverage for under-5 children (among eligible) (%)	12.4	26.59	38.62	49.59	37.4
Number of TB cases identified among contacts	117	449	464	132	1,162
Number of smear-positive TB cases identified	26	167	246	87	526
% yield among contacts screened for all ages	2.9	2.26	0.99	0.44	1.15

Screening of OPD visitors for TB improved. Screening of all OPD visitors in the health facilities was initiated in 2012. By the last quarter, December 2015, 92.2% of OPD visitors were screened for TB, compared to a baseline of 10.5%. The presumptive-TB case percentage at the beginning was 0.4% and increased gradually to 3% (Figure 17). The smear positivity rate (SPR) ranged from 4.3% in Phase I health facilities (HFs) to 6.1% in Phase III HFs. Some zones, such as Borena and Guji in Oromia, had higher SPRs (14.1% and 13.3%, respectively), which is significantly higher than the average SPR for all zones combined. Borena and Guji also had higher CNRs, and a similar trend was observed in the yield of TB in contact investigation. The result shows that the TB burden differs depending on the geographical area, thus requiring area-specific strategies for active case finding.

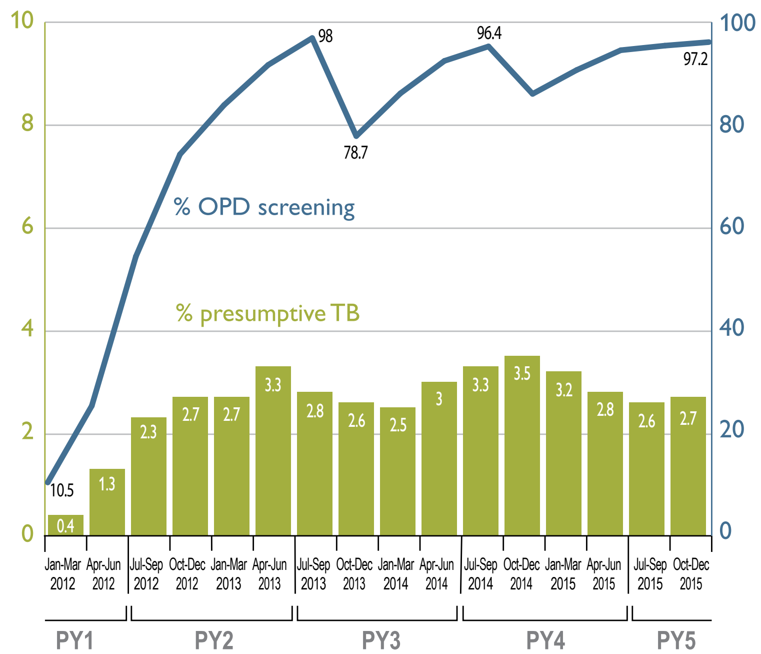
TB screening for all patients who visited the OPD for any complaint has been one of the TB case finding strategies scaled up in HEAL TB-supported regions. The latest achievement in terms of TB screening in OPDs was found to be 97.2%, a nine-fold increase compared to the baseline rate of 10.5%. The trend in OPD screening showed that there was a decline between October–December 2013 and October–December 2014, which was due to the introduction of new, poorer-performing zones in Phase II and Phase III of the project. However, the latest quarterly report (96.5%) signifies that all the three phases attained similar levels of performance. The proportion of presumptive TB was 0.4% at baseline, while the latest report was 2.7% (Figure 17). The yield of TB is low compared to the wider-scale implementation, and operational research is recommended to check the quality of screening, as well as its cost-effectiveness and efficiency. Blanket screening of all visitors to HFs is also a good strategy for case notification.

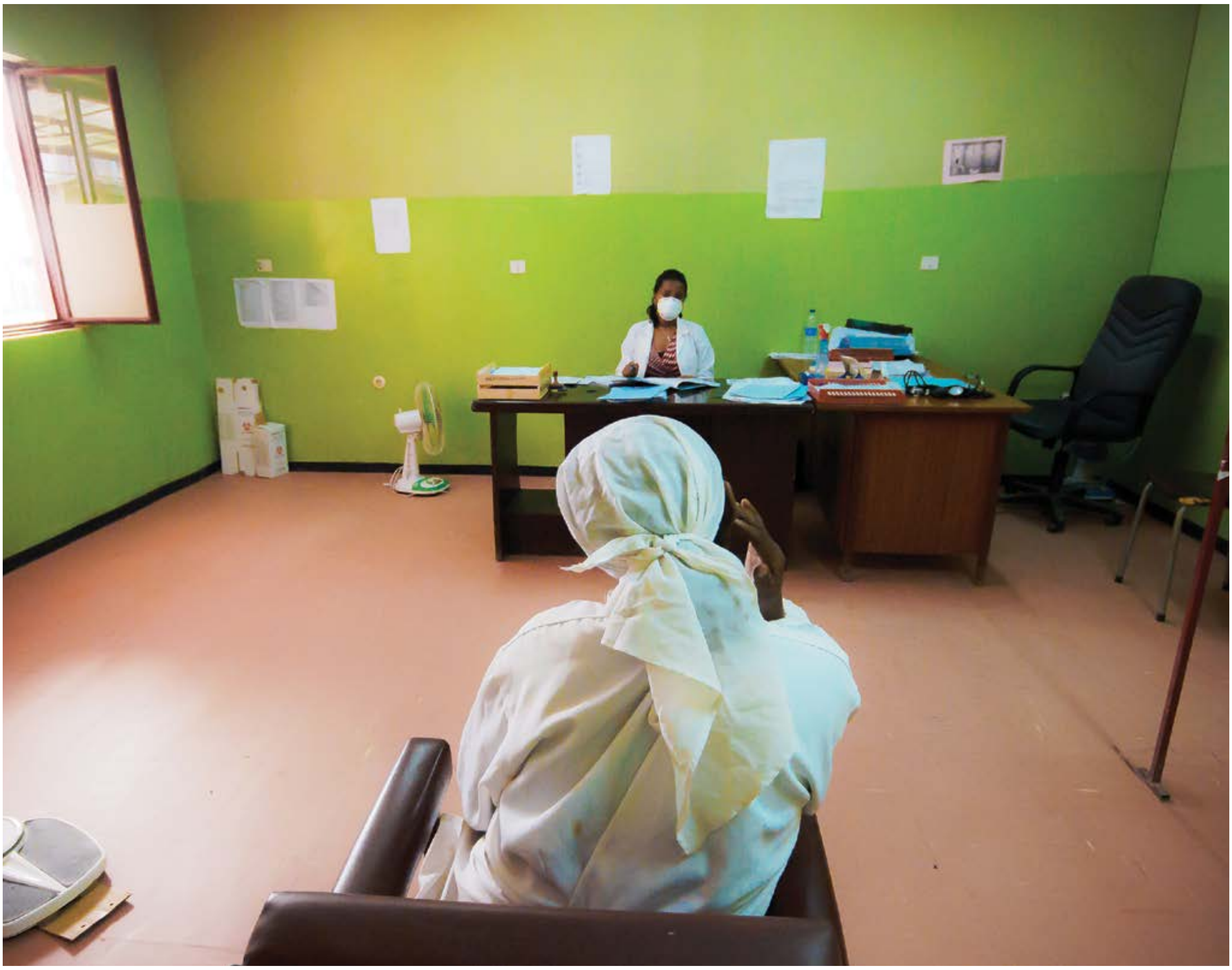
TB/diabetes. A draft CME manual was developed by a consultant diabetologist and two days of CME was given on TB/diabetes co-occurrence and management to 25 medical doctors from selected Oromia and Amhara hospitals. The training also served as a test of the draft manual, and discussion with the FMOH is underway to develop it as a national CME training manual. See Box 3 for the results of the pilot of integrating TB and diabetes.

BOX 3. **Results of the pilot of integration of TB and diabetes**

We piloted the screening of diabetes patients for TB in 2014 and 2015 in selected health facilities to determine the yield of TB. A total of 5,195 and 7,893 diabetes patients were screened for TB in 2014 and 2015, respectively. The bacteriologically confirmed TB cases were 6.8% and those clinically confirmed were 2%. Nationally, the percentage of bacteriologically confirmed TB cases is about 5.9%, but in our findings among diabetic patients it is 15 times higher. In conclusion, TB among diabetic patients is high and we recommend to the FMOH to develop an integration strategy for TB and diabetes.

FIGURE 17. Trend of OPD screening and presumptive case identification (Jan. 2012–Dec. 2015)





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BOX 4. **Results of the survey of knowledge, attitudes, and practices**

The study included a cross-sectional survey of 1,920 members of the general public, qualitative interviews with 15 TB patients and 20 HCWs, and four focus group discussions with representatives of the general public. The study was conducted in 10 zones of the Oromia and Amhara Regions.

The summary of the results of the KAP survey show that almost all respondents (94%) had heard of TB and 79% cited cough as a primary symptom. Nearly three-quarters (72%) knew that TB is transmitted through the air, and 92% knew that TB can be cured. About half (56%) knew that TB can affect anyone, and only one-third (32%) knew that TB treatment is free in Ethiopia.

Knowledge was consistently lower in rural compared with urban areas, and in Amhara compared with Oromia. For example, only 27% of rural respondents knew that TB treatment is free in Ethiopia, compared with nearly half of urban respondents (45%). Compared with rural respondents, urban residents more often cited television as a source of information about TB and other health issues. For example, TV was the preferred source of TB information for 33% of urban residents, but only 5% of rural respondents.

Conversely, HEWs were the preferred source of information for 44% of rural residents, but only 19% of urban respondents. In addition, more people in Amhara get information about TB and other health issues from friends, relatives, and health care professionals than from HEWs, whereas the inverse is true in Oromia. Most respondents (85%) felt they were "somewhat or very well informed" about TB. The percentage of respondents with a high perceived-knowledge level was higher in Oromia than in Amhara. Also, nearly half of respondents (48%) felt they were "at high risk" or "somewhat at risk" of becoming infected with TB. The perceived risk was higher in Oromia than in Amhara.

About half of respondents (49%) felt others would think less of them if they had TB, but less than one-third (29%) stated that they would be embarrassed or ashamed. Although most (72%) felt that they would not have a problem finding a marriage partner if they had TB, most respondents believed that a TB diagnosis would adversely affect their sexual relations.

3.4. COMMUNITY TB

Gaps and Challenges at Baseline

At the lowest level of the health care system are the health posts managed by HEWs. There are two HEWs per *kebele* for a population of 3,000–5,000. The HEWs have 16 health care packages, including TB, to be implemented at the community level. The HEWs are a model in many respects, and their contributions to health service improvement are noted in many publications.[17] The HEAL TB community TB strategy was therefore designed to use HEWs as core implementers. Their role is to screen community members for TB, including contacts-of-index TB cases, administer DOT, and trace patients who miss their treatment (Figure 18). However, implementation of this role was not strong at the beginning of the project for three main reasons: the HEWs' knowledge of TB was limited, DOTS had not been decentralized to HEWs by HFs, and HEWs were overwhelmed with many responsibilities. Supervision and monitoring by HFs was not systematized, and TB was not as strong a focus as maternal health. Other gaps in TB control efforts were identified in our baseline knowledge, attitudes, and practices (KAP) assessment, which helped us to refine our strategies (Box 4). Figure 18 shows the structure of community-based TB services.

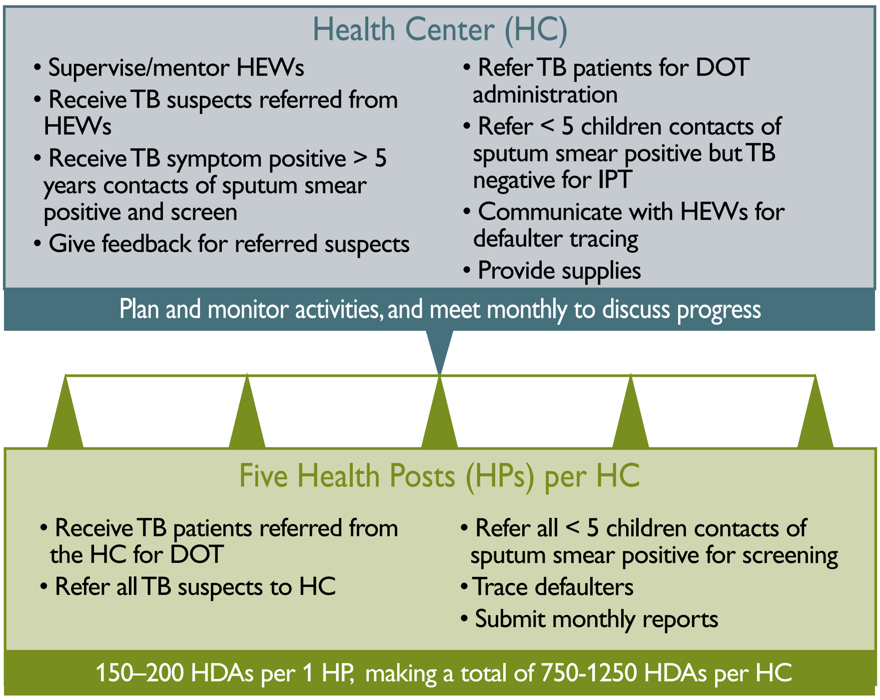
Strategies Designed

Training HEWs in community TB care and systematized on-site support and monitoring were the strategies designed to build their capacity. A supervisory tool, the SoC indicators, was developed for health center HEW supervisors to mentor/supervise and measure the performance of HEWs. The *woreda* health extension program focal persons were also trained to support the HEWs and introduce regular supervision. Through these mechanisms, HEW capacity in screening and decentralizing DOT increased, which in turn eliminated some of the long daily trips of patients to health centers or hospitals to receive DOT.

The other strategy implemented was for HEWs to prepare sputum smears from presumptive-TB cases on site in remote places, such as pastoralist areas, instead of sending patients to HFs. The HEWs' sputum smear-making was not approved initially, although there was a successful experience in the research set up by the TB REACH project.[18] In PY5, the process of HEWs making sputum smears and conducting referrals was piloted in Borena pastoralist communities and the results are presented below.

At the proposal stage, HEAL TB had planned to add TB monitors (volunteers) to assist the HEWs because they are busy with multiple duties. TB volunteer monitors were proposed as one volunteer for every 15–20 households. The concept of this voluntarism was taken from previous strategies in the country implemented for family planning and trachoma prevention.[19] The traditional voluntarism in that model was designed from studying the traditional medical practitioners in rural areas. These volunteers were envisaged to be educators

FIGURE 18. Health center linkage with health posts for community-based TB control



of their families and neighbors on TB prevention, to screen for TB, and to serve as treatment supporters. In the case of the traditional medical practitioners, voluntarism works well, because the following factors are fulfilled:

- The volunteer work does not require day-to-day attendance and does not take many hours, disrupting work and livelihoods.
- The tasks are not too many; most of the traditional volunteers have one or two tasks to carry out.
- Traditional medical practices of an urgent nature that are more in demand, have many practitioners, and serve a limited population; an example is the traditional birth attendants, located in every village. Bonesetters are few, because their services are less-frequently needed and not as urgent.
- There is some traditional obligation to serve for free, such as among blood and clan relationships.
- There is recognition of the practitioner in the community, which gives them respect.
- If they are recognized and respected, the community also supports them in labor or cash (none obligatory), which makes the traditional practitioners relatively well-to-do and gives them power in their community.

Considering these proven practices, a volunteer model was proposed, but at the implementation phase the FMOH determined to introduce HDAs, a volunteer concept similar to the proposed volunteer TB monitors. The HDAs were deployed late in the project, but in the last year under the leadership of the RHBs the HDAs were also engaged in screening TB in households assigned to them.

Another strategy proposed to improve the referral linkages between HFs and HEWs was the establishment of a mobile health (mHealth) system. HEAL TB has designed the mHealth system and it is functional, although it was implemented in the last year of the project. The next project can use the system and demonstrate the results.

3.5. RESULTS

Contribution of the Routine Health Extension Program to Case Finding and Treatment

In the last five years, a total of 337,719 presumptive-TB cases were referred. The proportion of health posts referring TB suspects increased by 18.3%, while the contribution of community TB care toward overall TB case notification increased from 0.7% in PY1 to 8.3% in PY5 (a 12-fold increase) (Table 8).

Sputum Smear-Making Results of HEWs and Nurses for Non-Diagnostic Health Facilities

One of the bottlenecks for increasing case notification is the inaccessibility of the diagnostic HFs for presumptive-TB cases, and some areas (pastoralist and commercial farm areas) required special interventions. After approval from the RHBs, training on sputum smear making and referral of slides was given to HEWs in Borena zone and nurses in non-diagnostic

TABLE 8. Community-based TB care performance (Oct. 2011–Dec. 2015)

Indicators	Oct. 2011-Sept. 2012	Oct. 2012-Sept. 2013	Oct 2013-Sept 2014	Oct 2014-Sept 2015	Oct.2015-Dec. 2015*
Number of HPs in the catchment	4,452	4,452	7,639	9,623	9,747
Number (%) of HPs referring TB suspects	812 (18.2)	2,004 (45)	4,040 (52.9)	6,023 (62.59%)	7,040 (72.2)
Number of TB suspects referred from HPs	5,786	22,867	82,939	148,694	47,086
Number of active TB diagnosed from TB suspects (% yield)	255 (4.3)	915 (4)	3,648 (4.4)	4,772 (3.2%)	1,362(2.9)
Number of TB cases referred to HP for DOT	645	2,066	7,758	11,602	3,097
Number (%) of HPs providing DOT	912 (20.5)	NA	3,150 (41.2%)	3,027 (31.45%)	3,257 (33.4)
Contribution of community to the total TB (%)	0.7	2.7	5.5	6.5	8.3

Data are available through December 2015.

HEAL TB has provided clinical TB training for nearly 300 health care providers in East Gojjam zone of Amhara Region. Of the trainees, 58 came from health centers lacking diagnostic capabilities.

Sample Collection and Transportation System Enables Non-diagnostic Health Centers to Diagnose TB

Melkamu Belete, 22, visited four health facilities over six months for cough, fever, and loss of appetite. Yet no one tested him for TB. Instead, each facility sent him home with antibiotics that failed to cure him. Despite worsening symptoms, Melkamu eventually gave up and stopped seeking medical advice.

Then Melkamu's younger sister, Yelemset, began complaining of similar symptoms. With the help of relatives, Yelemset traveled to the Kuy Health Center, where she was diagnosed with TB. After placing her on TB medication, the team at Kuy Health Center notified the staff at their partner facility, Gerems Health Center, that Yelemset was being treated for TB. A health worker from Gerems followed up in her home and screened her family members for TB. Finally, Melkamu had a proper diagnosis.

Gerems Health Center, along with 14 other non-diagnostic health facilities in East Gojjam zone, have been part of a sputum sample collection and transportation project supported by HEAL TB. This initiative allowed health facilities without microscopes to send samples to facilities with microscopes for testing: a low–cost and life-saving solution.

Today, Melkamu's health has improved significantly. "I was desperate and about to stop going to school [because I was so ill]. I am glad that I started treatment. I am now strictly following my medication," said Melkamu.

TABLE 9. Slide referrals for presumptive-TB cases by HEWs/nurses and yield of TB by region (Jan.-Dec. 2015)

	Region		
Indicators	Amhara	Oromia	Total
Number of presumptive-TB cases with slides smear fixed and sent	7,605	893	8,498
Number of presumptive-TB cases with three slides	7,355	874	8,229 (96.8%)
Number of total slides sent to diagnostic health facilities	22,209	2,644	24,853
Number of total slides processed at diagnostic health facilities	21,966	2,644	24,610
Number of positive slides	261	258	519
Slide positivity rate (%, 95% CI)	1.19 (1.05, 1.34)	9.76 (8.68, 10.95)	2.11 (1.93, 2.29)
Number of TB patients diagnosed	85	89	174
Yield of TB (%)	1.12(0.9, 1.39)	9.97 (8.12, 12.17)	2.05 (1.76, 2.38)

TABLE 10. Slide referrals for presumptive-TB referral and yield of TB by professional category (Jan.–Dec. 2015)

	Smear Referral Done By:		
Indicators	HEW	Nurse	Total
Number of presumptive-TB cases with slides smear fixed and sent	328	8,170	8,498
Number of presumptive-TB cases with three slides	287	7,942	8,229
Number of total slides sent to diagnostic health facilities	900	23,953	24,853
Number of total slides processed at diagnostic health facilities	900	23,710	24,610
Number of positive slides	27	492	519
Slide positivity rate (%, 95% CI)	3.00 (2.07,4.33)	2.07 (1.9, 2.26)	2.11 (1.93,2.29)
Number of TB patients diagnosed	9	165	174
Yield of TB (%, 95% CI)	2.74 (1.34,5.33)	2.02 (1.73,2.35)	2.05 (1.76,2.38)

HFs. In Oromia, the HEWs smear making has started in the pastoralist communities of Borena and Guji; in Amhara, it was implemented in the non-diagnostic health centers. Non-diagnostic health centers are facilities where the RHBs were not able to assign lab professionals because of the shortage of professionals in the country. A total of 457 HEWs and nurses were trained on sample collection and referral. Of 8,498 presumptive-TB cases referred, a total of 174 (2.05%) new TB cases were diagnosed, with the yield among those screened being significantly higher in Oromia; all were linked to a TB clinic (Tables 9 and 10 and Box 5). The SPR is similarly larger in Oromia Region because the zones selected in the region are of high burden. A total of 8,229 (96.8%) of the patients gave three sputum specimens for lab testing.

Mining Areas

Six *woreda* coordinators have been trained and deployed to coordinate case finding and treatment observation in the Gujie and Borena zone traditional gold-mining areas. The overall prevalence of TB identified was 1,565.8/100,000 (Table 11), which is lower than the yield of the contact screening results reported in Table 7 (page 28), where the maximum yield obtained was 2,888/100,000 population. In our published paper on the results of household contact screening using GeneXpert as a primary test for pulmonary presumptive cases, the yield was 4,532.6/100,000 population.[20] We conclude that if GeneXpert had been used in the mining areas for all the presumptive cases, the notified TB patients could have been higher.

In consultation with the RHB, it was decided to test all presumptive PTB cases with GeneXpert, but because of transport issues, we were able to transport only the sputum samples of MDR-TB-presumptive cases. Motorbikes were bought for this purpose and will be supplied for all *woredas* in the two zones. The other significant finding is the high percentage of MDR-TB cases (7.2%) among all TB cases diagnosed. All of the diagnosed TB patients (165) were tested for HIV and 6 (3.6%) were found to be to HIV co-infected.

Per the assessment done in the last year of the project, thousands of workers from all over the country travel to these traditional gold-mining areas. There is no proper shelter, so the workers live in very crowded temporary shelters. Sex workers also travel to these areas because there is a high cash flow. The other challenge for TB control is that these workers move from one mining field to another and seasonally go back to their birthplaces. This mobility makes it difficult to do TB treatment follow-up. The crowded living and working environment, possibly high HIV transmission, and mobile population require a special strategy, and the HEAL TB–designed strategy for these areas is recommended to continue with the new Challenge TB Project. HEAL TB has also designed an e-health system which will help to follow the patient even if he moves from one place to another. In addition, we have deployed volunteer peer educators and treatment supporters among the mining workers and sex workers, which should be strengthened in the future. Because of the high influx of workers to the area, TB notification in the Gojie and Borena zones is always high and requires a more focused TB-control approach for both the mining areas and settler communities (see Figure 8, page 22, on the CNR per zone).

BOX 5. **Task shifting in TB laboratory service delivery: The experience of slide fixing and transportation by nurses and community health workers in two regions of Ethiopia**

Background: The USAID-funded HEAL TB project has been supporting comprehensive TB case identification, diagnosis, and treatment services in two regions of Ethiopia. However, some health centers were not providing AFB microscopic services because of a shortage of laboratory professionals; pastoralist communities, because of their way of life, have limited access to health facilities. To tackle these challenges, nurses in non-diagnostic health centers and HEWs in pastoralist areas were trained in sputum collection, fixing of sputum smears, and transport of slides of presumptive-TB cases.

Intervention: A total of 457 nurses and HEWs (318 in Oromia and 139 in Amhara) were trained on TB symptoms and signs and the basic skills of collecting and fixing sputum smears. Nurses and HEWs transported the fixed sputum smear slides weekly to the nearest diagnostic health facilities. The diagnostic health facilities stained and read the slides, and, if positive, asked the nurse or HEWs to send the patient to start treatment.

Results and lessons learned: A total of 8,498 presumptive-TB cases were identified either by nurses or HEWs from January to December 2015. Three hundred twenty-eight (4%) of the presumptive-TB cases slides were referred by HEWs and the rest were by nurses. More than 97% of them (8,229) were able to provide three samples, which is slightly higher than the finding in health facilities (93%). From the presumptive-TB cases, 24,610 slides were processed at the diagnostic health facilities, and 519 slides were positive (smear-positivity rate [SPR] = 2.11%). The rate of SPR was higher in Oromia than in Amhara ($p < 0.05$). A total of 174 TB cases (85 Amhara, 89 Oromia) were diagnosed and initiated on anti-TB treatment. The SPR and yield among presumptive-TB cases referred by HEWs and by nurses was not significantly different ($p > 0.05$).

Conclusions: Use of non-laboratory professionals in sputum slide smearing and fixing, with a proper referral system, could serve as an alternative approach to improve service accessibility for people who live far from diagnostic health facilities.

TABLE 11. **TB cases identified by screening mining workers in Guji and Borena zones (Dec. 2015–Jun. 2016)**

Activity	Number	Percent
Estimated number of mining workers in the area	42,678	
Number of workers screened for TB	10,538	24.6
Mining workers with presumptive TB	981	9.3
Mining workers tested for TB	948	96.6
Total TB cases diagnosed	165	17.4
■ Number of bacteriologically confirmed TB cases diagnosed	104	63
■ PTB smear negative diagnosed	33	20
■ EPTB diagnosed	16	9.7
■ Rifampicin-resistant TB (RR-TB)	12	7.2
Overall prevalence of TB	1,565.8/100,000 population	

TABLE 12. TB screening results of commercial farm workers in West Armachiho *woreda* of North Gondar zone, Amhara Region (Aug.–Sep. 2015)

Indicator	Number	Percent
Number screened for TB	20,705	
Number of presumptive-TB cases identified	769	3.7
Number linked and examined at health facilities	645	
Total TB cases diagnosed	17	1.4
■ Smear-positive pulmonary TB cases	6	
■ Smear-negative pulmonary TB cases	5	
■ Extrapulmonary TB cases	6	
Overall prevalence of TB	82.1/100,000 population	

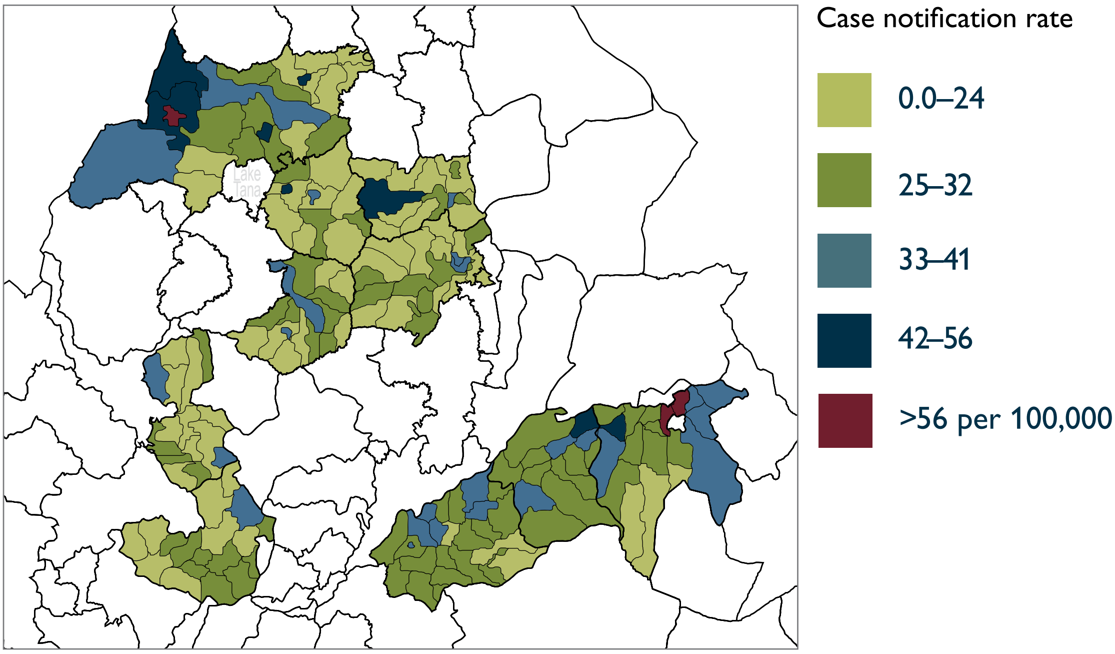
TABLE 13. TB screening results of HDAs: pilot in Minjarena Shenkora *woreda*

Indicator	Number	Percent
Total number of household members screened	16,821	—
Total number of presumptive-TB cases identified	70	0.4
Total number of presumptive cases referred to HFs for diagnosis	63	90
Total number of TB cases diagnosed	7	11.1

MSH STAFF

More than 2 million copies of leaflets on TB prevention, screening, and treatment in the Oromiffa and Amharic languages were produced and distributed to HDAs in the two regions.

FIGURE 19. Mapping of heterogeneous disease transmission within *woredas* of Phase I project zones



Commercial Farms

In North Gondar zone in Amhara Region, the TB disease burden is high in certain *woredas*, namely West Armachiho, Metema, Quara, Genda Wuha, and Tegede, because it is a commercial farm area where nearly 1 million laborers work seasonally. We trained lay volunteers to screen migrants, and the prevalence of TB was 82.1/100,000 (Table 12), which is lower than the number in the routine report for West Armachiho *Woreda*. The quality of screening should be checked.

The two pilots in the mining and commercial farm areas have shown that TB distribution in the country is not uniform and that the mapping of *woredas* based on the routine data and surveillance can help to locate high-TB-burden areas. We applied the *woreda*-based mapping of TB, and our findings showed that routine data for two to three years offer a proxy indicator of the disease burden of the area (Figure 19).

Piloting the Use of Health Development Armies in Community-Based TB Care

HEAL TB supported RHBs in developing and piloting household-level TB screening and a referral strategy through the HDAs. During the pilot phase, HEWs documented the family members based on the family folder kept at health posts and then oriented HDAs on how to screen the family members for TB symptoms in their respective catchment areas. The preliminary results from four health centers are shown in Table 13.

Drawing on the experience from the pilot work, the two RHBs have scaled up the strategy to all health posts in the two regions. Over 2 million copies of family register cards were printed and distributed to the two regions. We recommend better registering the TB notification results of the HDAs, if it is a strategy to be replicated in other areas. One challenge that we anticipate is the coordination and motivation of HEWs to supervise this cadre of volunteers and another, major challenge is the number of responsibilities that HDAs have for many programs. These volunteers' motivation, organization, and retention mechanisms should be studied to determine the best way to sustain their vital activities.

Improved Awareness about TB

HEWs and HDAs were also involved in community education. In the two regions, close to 20,000 HEWs were trained in TB education as part of the integrated refresher training and HDAs received an orientation brochure on TB. HEWs then oriented the HDAs on TB education and screening in the two regions. By involving HEWs and HDAs, many millions of households are expected to be reached, although there has been no reporting system to capture all the data. More than 2 million copies of leaflets on TB prevention, screening, and treatment in the Oromiffa and Amharic languages were produced and distributed to HDAs in the two regions (see photo, left).

Production and dissemination of messages on TB control.

HEAL TB supported the production and dissemination of basic TB-control messages aired through TV and school

ALI GALGALO

In the Borena zone of Oromia, billboards with TB messages by the respected leader Aba Geda were displayed in five marketplaces.

HEAL TB and the FMOH jointly prepared a quarterly bulletin for HEWs, to keep them informed on TB control.

mini-media targeting the general public and the school community respectively. Messaging focused on knowledge, attitudes, and misconceptions about TB, as well as on improved TB case detection, to boost treatment adherence.

Working through traditional leaders. In the Borena zone of Oromia, billboards with TB messages by the well-respected traditional leader Aba Geda were displayed in five marketplaces (see above).

Job aids and tools for community TB care printed and distributed. HEAL TB supported FMOH in printing TB treatment supporters' cards and presumptive-TB cases registers for the Oromia and Amhara Regions as part of the health post family folder. The printing of 663,400 and 1,402,200 cards for the Amhara and Oromia Regions, respectively, was completed and were distributed to the regions.

HEW bulletin. HEAL TB and the FMOH jointly prepared a quarterly bulletin targeting HEWs to keep them informed on updates of TB control. A total of 18,000 copies of the bulletin (see above) were printed and distributed to the two regions (9,000 copies in Oromiffa for Oromia and 9,000 copies in Amharic for Amhara). The second and third issues were drafted but, because of a delay in getting comments from the National TB Program, we could not print them during the project period.

Lessons and Recommendations to Improve Community TB Care

- The decentralization of community DOTS—consisting of household-level screening, referral of presumptive-TB cases to diagnostic centers, provision of DOT for patients, and training of HEWs to locate those lost to follow-up—is working well and many patients are getting their treatment at the HP level, which reduces the daily travel burden of patients to HCs. The practice should be expanded. HEWs' involvement in community TB screening is progressing remarkably well and should be continued.
- The supervision and monitoring of HEWs are assigned to health center staff, with overall coordination by the HEW program coordinator at *woreda* level. The links between the HEW program coordinator and health centers are weak, however, and require more support for better community TB-program implementation.
- The recent involvement of women HDAs (one HDA for five households) is encouraging. In the rural areas, these households are families and share many things. They can educate the households while doing their usual daily work and in their usual social interactions. Because they are family members, they have a responsibility to advise relatives with TB symptoms to seek care. Because the HDAs are women, it is easy for them to ask for information from their peers. The HDA model has advantages and should be supported to create better-informed communities. But if these volunteers are overloaded with assignments in all health areas, this model is unlikely to succeed.
- Mapping of *woredas* using routine data as a proxy indicator for the burden of disease provides information to create geographically-focused strategies. The practice started in HEAL TB should be expanded nationally to tailor strategies based on the disease burden.
- Mining and pastoralist areas have a high disease burden and require more intensive support. GeneXpert should be a primary test for these areas to increase the CNRs and ultimately to reduce the disease burden.

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"Trainings…were the backbone of interventions carried out at the community level. Having the knowledge base has enabled me to know how to solve the community's TB burden. This in turn brings me happiness and motivates me for better results."

—Zenebech Ararso

Health Extension Workers bring Personal Connection to TB Case Detection and Treatment

Identifying individuals with the disease and getting them treatment rapidly are the keys to controlling TB. However, many patients struggle to adhere to treatment guidelines, and too often patients are lost to follow-up. This is often due to lack of transportation, funds, or social support.

Ethiopia had trained female HEWs to provide basic preventive services in all rural villages. HEAL TB linked to this system and trained HEWs in TB identification, prevention, and treatment, for the first time.

Zenebech Ararso, 27, is an HEW assigned to the Dugda Lungo health post in Illu *Woreda*, Oromia, seven kilometers from the Asgori Health Center. She works hard to be available to her clients, members of her own community.

Zenebech convinced one of her clients, Abraham Shiberu, to be tested for TB. However, when diagnosed, he was not able to walk the 14 kilometers to and from the Asgori Health Center every day for treatment. The TB focal person at the health center followed up with Zenebech, and the two brainstormed how to get Abraham directly observed treatment closer to home. They arranged for Zenebech to treat Abraham at the Dugda Lungo Health Post, rather than a more formal facilty.

"I'm so thankful for Zenebech's assistance, because she helped me get referred to the health post nearby," said Abraham. "Now I don't have to worry about the distance, being hungry, and paying for transport." Under direct supervision from Zenebech, Abraham adhered to his treatment.

Zenebech now observes treatment for several patients. She regularly updates their treatment cards, tracks their progress, and refers them to the health center for follow-up examinations.

3.6. TUBERCULOSIS TREATMENT OUTCOMES

The TSR has increased from a baseline of 88% to 96.6% in Phase I zones. In Phase II project zones, the baseline was 78.8% and increased to 95.1% after two years of support. In Phase III, the TSR increased from 90% at baseline to 93.7% in less than two years of support. The cure rate for Phase I and Phase II zones increased significantly compared to the baseline: 71% to 93% in Phase I and 71.0% to 86.1% in Phase II. In the seven Phase III zones, the cure rate increased from 79% to 86.5%. Notably, project support narrowed the gap between cure and treatment success through significantly improved quality of follow-up with TB patients on treatment (Figure 20). The project-level 94% TSR and 88% cure rate in HEAL TB-supported zones are higher than the national averages of 92.5% TSR and 81.6% cure rate (National Tuberculosis Program (NTP) HMIS data). These reports are checked for accuracy through an on-site and *woreda*-level data quality assurance mechanism.

FIGURE 20. Trends in TSR and cure rate during project years

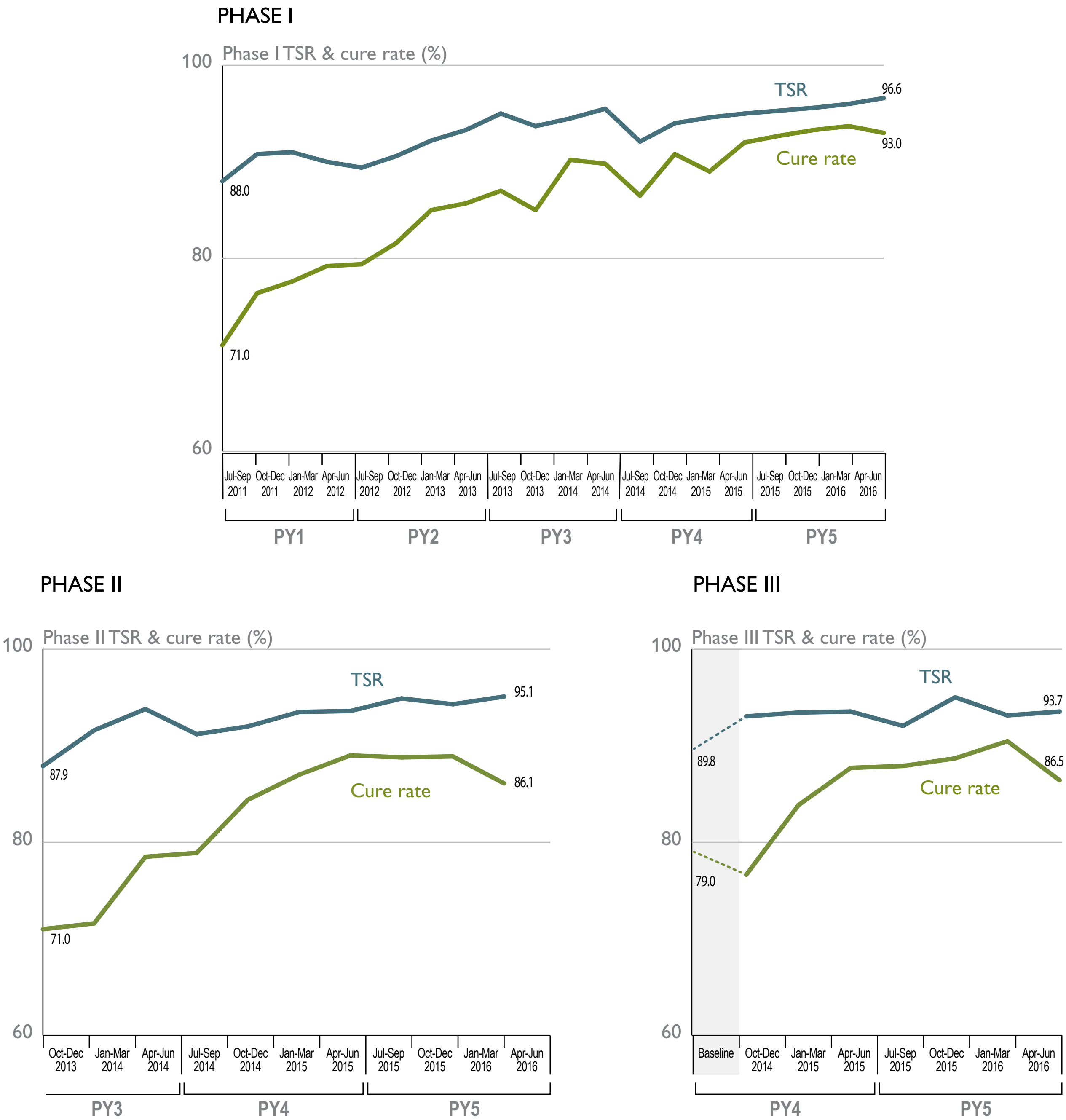
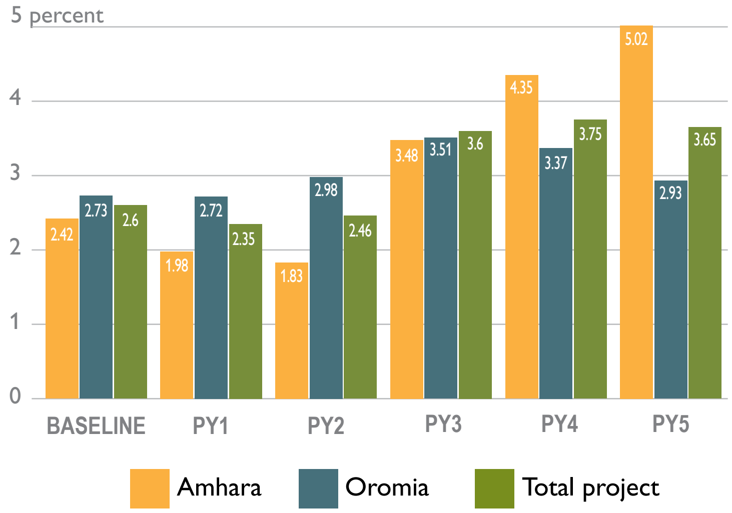


FIGURE 21. Trends in detected re-treatment cases over five years



Unfavorable outcomes at the project level in the latest quarter included those lost to follow-up (0.7%), deaths (2.3%), treatment failure (1%), not evaluated (0.5%), and diagnosed with MDR-TB (0.6%). Overall, this is an excellent achievement. If the strategy used in the last four years continues to be followed, it will contribute to further decline in the incidence of drug-sensitive and MDR-TB.

Re-treatment Cases

Another priority area of HEAL TB is improving the quality of DOT by improving the treatment outcomes of TB re-treatment patients. The proportion of re-treatment in the project-supported regions ranged between 2.35% and 3.65% (Figure 21). Two-thirds of re-treatment cases were secondary to relapse, while 8.5% and 4.1% were due to treatment failure and those lost to follow-up. One-fifth of the cases were previously treated cases where the patients had self-reported anti-TB treatment in the past but there was no documentation of this treatment. The overall proportion of re-treatment cases is in the lower range in the two regions compared with reports elsewhere (12% in Malawi, for example). The HMIS data do not capture the treatment outcomes for re-treatment cases and they are not included in this report. Of the presumptive-MDR-TB cases tested, the majority were identified from re-treatment cases or among patients whose sputum smear microcopy did not covert to negative at the third month. In five years' time 26,067 MDR-TB-presumptive cases were tested and we expect that the majority will be re-treatment cases.

3.7. LESSONS LEARNED AND RECOMMENDATIONS

The project was able to exceed the targets of 90% for TSR and 85% for cure rate. This is due to the project working through the continuum of TB care from screening, to improvement of DOT, to strengthening of AFB microscopy capacity and quality, to *woreda*-led mentorships. If the results are sustained in the coming 5–10 years, the country will reduce the MDR-TB load, because high cure and treatment success rates contribute to preventing MDR-TB, and can achieve the WHO End TB Strategy.

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Key Achievements Section 4:

- ✔ A decentralized external quality assurance (EQA) system for AFB microscopy was implemented, whereby RRLs conduct EQA for hospitals, and hospitals for health centers. Using this approach, the EQA centers grew from 4 to 102 and all health facilities with AFB services (1,550) had EQA services.
- ✔ The percentage agreement between positive and negative slides with EQA readers has surpassed 95% and 99.5% respectively, which are excellent results. There was no EQA system when the project began.
- ✔ GeneXpert was introduced in 49 hospitals by HEAL TB and other funders. HEAL TB built the capacity of laboratory professionals and designed a sample transport mechanism and on-site mentorship. Although the utilization rate is not optimal because of sample transport issues, it was improving as compared to 2014 baseline data.
- ✔ The project introduced MGIT liquid culture to five laboratories; there was previously none in the two regions.
- ✔ E-specimen/e-health and sample transport systems were developed and implemented. The e-specimen system works with both short messaging service (SMS) and the internet. It allows health facilities to request sample pickup by a courier and receive the results in real time. Eight vehicles with freezer systems were bought for and made functional for sample transport. The full implementation strategy was designed with EPHI.

SECTION 4. STRENGTHENING LABORATORY SERVICES AND SYSTEMS

4.1. BASELINE GAPS AND CHALLENGES

Not all health centers had microscopy services at the beginning. In Phase I project areas, 465 (65%) of 691 HFs at that time had microscopy services, and in Phase II and III HFs the diagnostic centers were 54% (388/719) and 62% (277/447) of the HFs, respectively. There was no proper quality assurance of AFB microscopy, there were shortages of reagents, and the distribution of reagents was erratic. The bottles used were transparent, which exposed reagents to ultraviolet rays, thus compromising the quality of the regents.

The Adama and Bahir Dar RRLs were able to provide solid culture and line probe assay (LPA), but there was no liquid culture in either area, which is critical to obtain DST results for MDR-TB within a few days, since the solid culture takes up to eight weeks.

In terms of laboratory professionals, there were no regular refresher trainings to update them on new diagnostic technology, and most new graduates had limited capacity even in basic AFB microscopy.

4.2. STRATEGIES

EPHI had designed a decentralized model of EQA for AFB slides, whereby EPHI conducted panel tests for RRLs, RRLs conducted a blind EQA reading for hospitals, and hospitals provided an EQA reading in the same blind fashion for health centers (Figure 22). Although this strategy was not implemented, HEAL TB operationalized it in the two regions. The first task was training all laboratory professionals on AFB microscopy reading and internal and external quality assurance procedures. The HEAL TB field laboratory professionals then conducted on-site mentorship to make sure that all AFB slides were properly registered, labeled, and stored and instituted appropriate internal quality assurance for AFB. EQA was then started in hospitals and health centers with good internal quality results. Hospitals with good EQA results in their work were identified to serve as EQA centers for the catchment health centers. Currently, 102 health facilities in the two regions serve as EQA reading centers, up from only four at the beginning of the project. A standard operating procedure was developed together with EPHI and the two RHBs, and a minimal fee for EQA slide reading was established.

In addition to the training of laboratory professionals, all *woreda* TB focal persons were trained on randomization of AFB slides from their catchment health facilities. Every quarter, the *woreda* TB focal persons visit the health facilities, supervise/mentor clinical activities, randomly select slides for

FIGURE 22. Laboratory network for TB external quality assurance

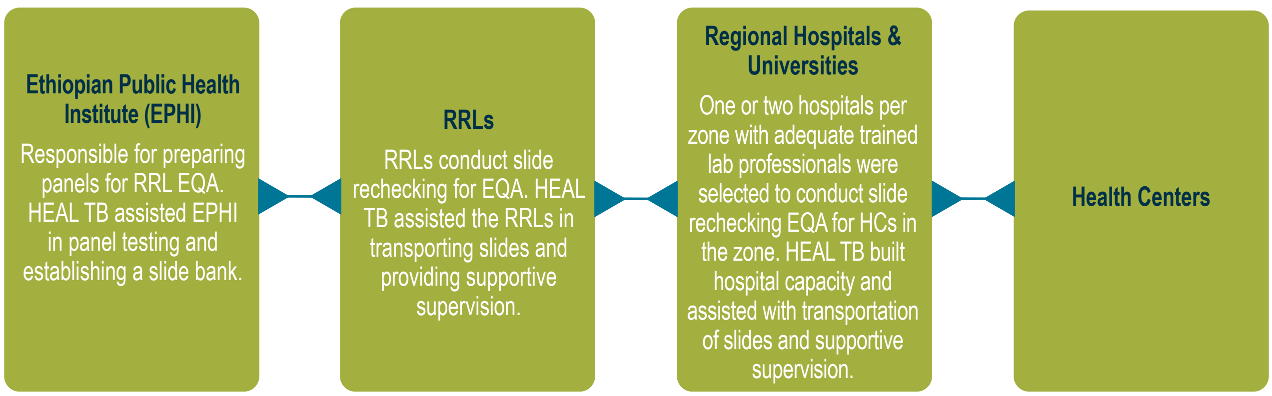
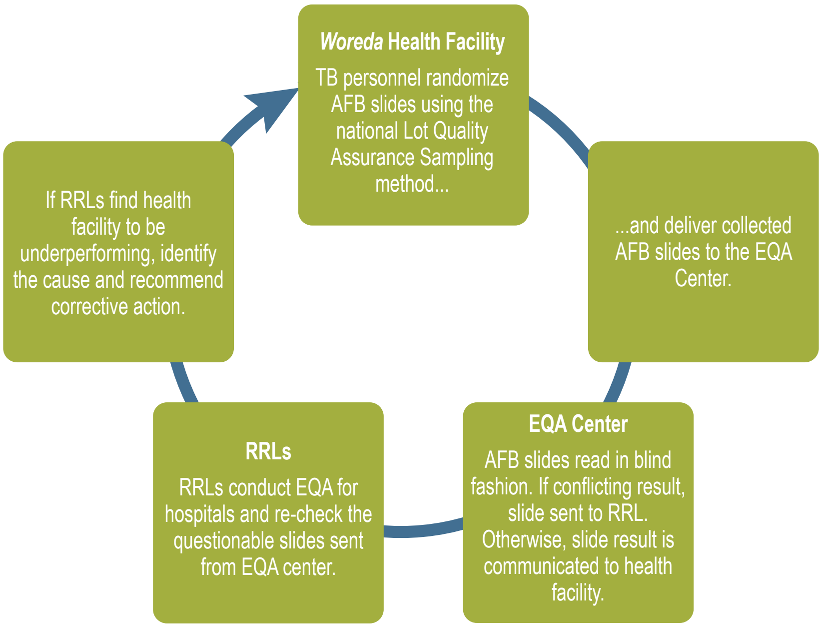


FIGURE 23. HEAL TB-supported decentralized EQA cycle



EQA, and deliver the slides to the EQA sites for reading. Per the national EQA guidelines for AFB microscopy, the sample size is determined based on the annual AFB slide load of each facility, and the *woreda* TB focal persons use the predetermined sample size for each facility.[21]

If the EQA results are discordant, the RRL or EQA experts travel to the specific health facility to identify the cause of the discordancy. The laboratory mentors apply an SoC tool to improve the quality of TB-related laboratory services in the health facility. The mentoring team assesses the status of laboratory performance using indicators of standards of laboratory service, identifies the cause of the discordance, and designs an improvement plan (Figure 23).

The other strategies applied were diversifying the TB diagnostic types. The FMOH had procured lots of fluorescent microscopes, but they were not in use. Under the leadership of EPHI, fluorescence microscopy (FM) implementation guidelines were developed, trainings given to laboratory professionals, and reagents bought and distributed to all FM-designated HFs in the country. More than 880 ZN microscopes were also procured and supplied for health facilities that had laboratory professionals but no microscopes. Reagent bottles appropriate for the reagent type were also procured for the RRLs.

The other new diagnostic technology included in the system was GeneXpert, a DNA-based TB diagnostic tool. HEAL TB bought 18 machines and the FMOH supplied 33, bringing the total number of GeneXpert machines in the two regions to 51. HEAL TB laboratory advisors played major roles in the installation of GeneXpert machines as well as their calibration in the two regions. We also trained lab professionals on the use of the new diagnostic tool, internal quality, and how to minimize invalid results and errors.

One bottleneck in MDR-TB diagnosis was the limited number of culture facilities—only two labs for the two regions—and the lack of a proper sample transport system. Hence, there was delay in diagnosis, the quality of culture results was unreliable, and results did not reach the health facilities in a timely way. In addition to the introduction of GeneXpert for diagnosis, five laboratories (Bahir Dar, Adama, Gondar University Hospital, and Hawaas and Harar RRLs) were supplied with MGIT liquid culture machines, and the staff were trained. To address the sample transport issues, we initially supported the transport of sputum samples using project vehicles, and at times used the post office. In our assessment, the post office had no capacity to transport biological samples, deliver on time, and transport the samples at the required temperature. To improve sample transport in a sustainable manner, a sample transport system developed. The system comprises vehicles with freezers, an e-health system, trained couriers, and health care facilities mapped with diagnostic facilities. The vehicles' freezer system has two compartments: one operates at 0–8°C and the other is a deep freezer that can maintain up to −20°C. The e-specimen system works both through SMS texting and internet at the same time, which will be used for sample pickup requests and real-time result notification. It also has a feature to inform patients (if they are mobile users) that their results are ready and they should visit the health facility.

Finally, a Laboratory Quality Management System (LQMS) to improve service quality and accessibility initiatives was introduced in the culture labs and 28 hospitals for International Organization for Standardization (ISO) accreditation. Staff were trained, necessary materials and registers provided, and on-site mentorship introduced to prepare the sites for accreditation. Most were ready for certification before the project closed.

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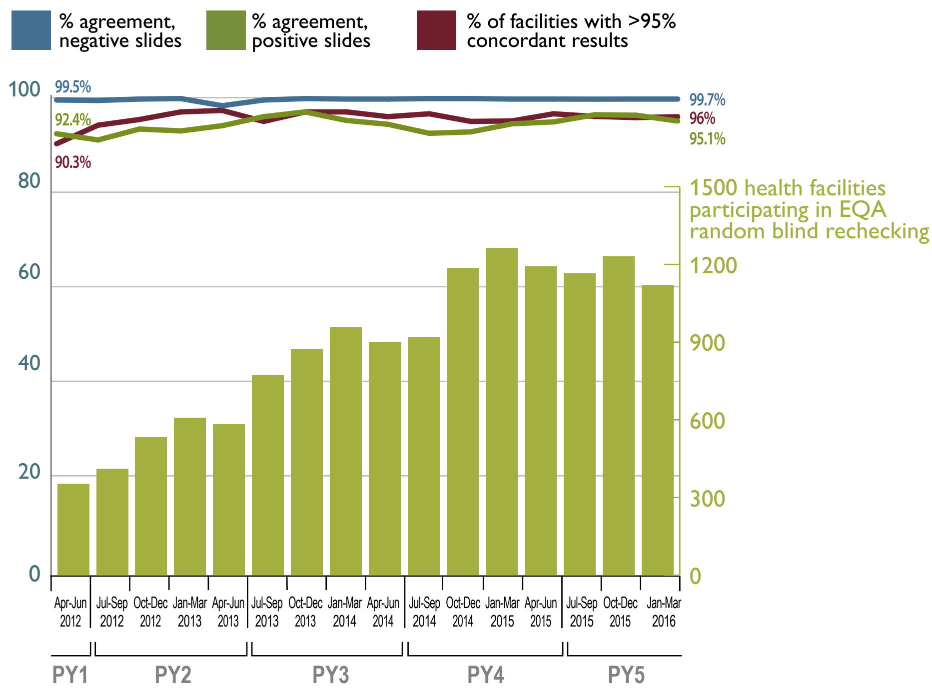
TABLE 14. Results of external quality assurance for AFB microscopy using random blind rechecking (Apr. 2012–Mar. 2016)

Indicator	April-June 2012	July-Sept. 2012	Oct.-Dec. 2012	Jan.-Mar. 2013	April-June 2013	July-Sept. 2013	Oct.-Dec. 2013	Jan.-Mar. 2014	April-June 2014	July-Sept. 2014	Oct.-Dec. 2014	Jan.-Mar. 2015	April-June 2015	July-Sept. 2015	Oct.-Dec. 2015	Jan.-Mar. 2016
Total number of health facilities participating	353	411	533	607	583	773	872	957	899	918	1,186	1,264	1,193	1,165	1,231	1,121
Total number of slides collected for EQA	13,354	16,184	21,682	27,450	23,507	30,673	37,114	41,332	36,954	38,041	50,508	50,031	44,154	40,960	45,943	44,602
Number of positive slides sampled	912	994	1,189	1,308	1,147	1,598	1,822	1,830	1,565	1,884	2,343	2,761	2,163	2,305	2,526	2,563
Number of negative slides sampled	12,442	15,190	20,493	26,142	22,318	29,099	35,297	39,493	35,389	36,157	48,165	47,270	41,991	38,655	43,417	42,039
Percentage agreement of positive slides	92.4%	91.1%	93.4%	93.0%	94.1%	96.0%	97.0%	95.2%	94.4%	92.5%	92.8%	94.5%	94.9%	96.4%	96.3%	95.08%
Percentage agreement of negative slides	99.5%	99.4%	99.7%	99.8%	98.3%	99.5%	99.8%	99.7%	99.7%	99.8%	99.8%	99.7%	99.7%	99.68%	99.7%	99.70%
Percentage of health facilities with > 95% concordant result	90.3%	94.2%	95.4%	97.0%	97.3%	95.0%	97.0%	97.0%	96.0%	96.6%	99.7%	95.1%	96.6%	96.05%	95.8 %	95.99%

FIGURE 24. Trends in AFB EQA enrollment and concordance rate



BOX 6. Results of the pilot of LED external quality assurance in Amhara Region

Background: There is no conclusive evidence globally to apply blind rechecking quality assurance for auramine-stained LED FM sputum smears.

Objective: To examine the blind rechecking applicability of LED FM sputum slides before and after re-staining

Methods: We applied two approaches of EQA piloting for LED FM sputum smear slides that were done and read by microscopic centers and were stored for 3–5 months in a closed slide box. In the first approach, the positive and negative slides were sampled and read in an EQA center in a blind fashion with three experienced microbiologists, before re-staining and after re-staining. In the second approach, slides were randomized and read by the EQA centers without re-staining. A concordant result is considered as agreement between the blind rechecking readers.

Results: A total of 625 slides (525 negative and 100 positive) were read. The false positive (FP) and false negative (FN) rate before re-staining were 2.2% for both. After re-staining, the FN was 3.1% and the FP was 1.5%. Twelve slides were labeled as FN before the re-staining reading, and after re-staining the FN slides decreased to 8 slides. Two slides were FP, which increased to three slides after re-staining. In the second approach, staining only discordant slides with the EQA center, the FP and FN rates were 0.08% and 0.02%, respectively. The sensitivity and specificity were also 98.7% and 99.9%, respectively.

Conclusion: The auramine stain fading after three months is almost negligible in the setting of the Amhara Region of Ethiopia. Slides that changed from negative to positive after re-staining might have faded or not properly stained by microscopic centers. The fading can also occur with ZN microscopy. We recommend applying blind rechecking without re-staining for LED microscopy in the Ethiopian setting, with close follow-up of the results to gather more evidence. We recommend re-staining only the discordant slides and re-reading the result.

4.3. RESULTS

AFB Microscopy and Its External Quality Assurance

More than 1,550 diagnostic facilities provided AFB microscopy services in the two regions by the end of the fifth year of the project. The coverage is more than 100%, as per the WHO criteria of 50,000 population per microscopy service. About 85% used the classic ZN method, while the remainder used LED FM. HEAL TB facilitated technical support to all facilities, including the provision of mentoring and supportive supervision by HEAL TB zonal laboratory specialists, regional laboratories, EQA centers, and *woreda* TB focal persons. The mentoring activities focused on proper internal quality control and microscope preventive maintenance, EQA slide storage, documentation, supply management, and technical support to zonal health departments for the zonal laboratory quality system.

By the end of the last quarter of PY5, 1,220 HFs were participating in the random blind rechecking EQA scheme, 1,121 (91.9%) were HFs using the ZN method, and 99 (8.1%) were using LED microscopes. In total at the end of the project, 102 EQA centers had been established from four at baseline. In the last quarter, over 95% of facilities had a documented concordance rate of ≥ 95% (Table 14 and Figure 24). A few facilities contributed more than 5% of the discordant slides. As the LED FM service has expanded, the number of HFs participating in ZN random blind rechecking has decreased. The result is dramatic from two angles: first, that there was no EQA system at baseline; and currently almost all HFs in the two regions participate in quarterly EQA, which is not strong in non-HEAL TB-supported regions.

LED Microscopy Services and Their EQA

LED microscopy services have been implemented in both regions. EQA for FM was not well established and national EQA guidelines recommend only panel testing and on-site evaluation due to the fading of auramine over time. However, due to the limited capacity of RRLs for panel testing preparation and the lack of logistical support and personnel, EQA for LED FM is not implemented nationally. It is an expensive endeavor to prepare and distribute panel tests, which will not be manageable with the current government capacity. HEAL TB piloted random blind rechecking for LED microscopy services following the ZN EQA approach in the Amhara Region in January 2015, which showed results similar to those of the ZN smear slides (Box 6). Based on a successful piloting of the random blind rechecking approach for LED microscopy, HEAL TB supported the roll-out of the random blind rechecking approach for LED microscopy EQA.

HFs using LED FM for AFB microscopy started participating in the random blind re-checking EQA program. Currently, 298 HFs are providing AFB/LED diagnosis in both the Amhara and Oromia Regions. After the consultative meeting with the EPHI and RRLs, HEAL TB assisted HFs in participating in the LED FM random blind rechecking program.

Slides from FM health facilities in the Amhara Region were collected and rechecked; the positive and negative agreement rates were 97.8% and 99.9% respectively. The discordant slides were re-stained before the final report to exclude discordance due to fading. The discordant trend was not different from that of ZN smear slides (Table 15).

GeneXpert Services

By the end of PY5, there were 51 GeneXpert machines in the two regions. Trainings have been provided for laboratory professionals, including HEAL TB zonal lab specialists. Basic GeneXpert training was provided to 49 heath facilities in the two regions. Minimum packages essential for a GeneXpert laboratory were also provided for each laboratory. To maximize the use of GeneXpert, an orientation on the new diagnostic tool was given to all zones and 2,186 HFs in the two regions.

HEAL TB has continued to provide extensive support for the efficient utilization and improved accessibility of GeneXpert. Eighteen GeneXpert machines, 35,000 cartridges, 250,000 falcon tubes, and 18 power backup systems were procured and distributed to HFs to ensure service provision at all levels. Performance monitoring tools and job aids were developed and distributed to all GeneXpert sites. The GeneXpert test was completed for a total of 20,318 samples, of which 4,322 (21.3%) were HIV-positive clients and 2,660 (13.1%) were children under 15 years of age. Power blackouts sometimes occurred while GeneXpert tests were being processed. There has been a reduction in errors and invalid reports following the distribution of uninterruptible power supply backups, in addition to improvements in lab professionals' experience in GeneXpert procedures. A total of 2,091

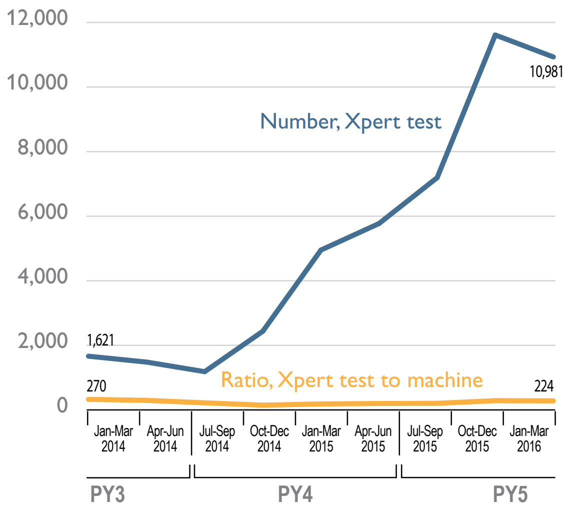
TABLE 15. Results of external quality assurance using random blind rechecking for LED AFB microscopy in Amhara Region (Oct. 2014–Mar. 2016)

Indicator	Oct.-Dec. 2014	Jan.-March 2015	April-June 2015	July-Sept. 2015	Oct.-Dec. 2015	Jan.-March 2016
Number of HFs that participated in EQA	64	76	126	116	147	99
Total number of slides collected for EQA	3,724	4,431	7,400	6,016	9,022	5,734
Number of negative slides	3,535	4,237	6,979	5,753	8,621	5,461
Number of positive slides	189	194	421	263	401	273
Number of false positive slides	1	10	18	4	6	6
Number of false negative slides	2	11	25	8	13	7
Positive agreement rate (%)	99.47	94.85	95.72	98.48	98.50	97.80
Negative agreement rate (%)	99.94	99.74	99.64	99.86	99.85	99.90

TABLE 16. Performance of GeneXpert in Amhara and Oromia Regions (Oct. 2014–Mar. 2016)

Indicator	AMHARA			OROMIA			Total
	HIV-positives	Non-HIV or HIV status unknown	Subtotal	HIV-positives	Non-HIV or HIV status unknown	Subtotal	
# of total samples	5,406	12,557	17,963	2,883	22,121	25,004	42,967
# of samples with valid result	5,216	11,102	16,318	2,837	19,961	22,798	39,116
■ # rifampicin-sensitive	630	1,511	2,141	495	2,924	3,419	5,560
■ # rifampicin-resistant (%)	38 (0.73)	161 (1.45)	199 (1.22)	29 (1.02)	212 (1.06)	241 (1.06)	440 (1.12)
■ # not detected	4,517	9,355	13,872	2,297	16,690	18,987	32,859
# Indeterminate	31	75	106	16	133	151	257
# Error/Invalid/No result (%)	190 (3.51)	1,455 (11.59)	1,645 (9.16)	46 (1.60)	2,160 (9.76)	2,206(8.82)	3,851 (8.96)

FIGURE 25. Trend in GeneXpert uptake (Jan. 2014–Mar. 2016)



(10.3%) tests came back with an invalid result or error since October 2014, mostly due to power interruptions or sample processing errors.

Of the 18,227 tests with valid results, 3,260 (17.9%) were positive for MTB. Of these 3,260 MTB-positive cases, 296 (9.1%) were rifampicin-resistant (RR) and the remaining 2,964 (90.9%) were rifampicin-sensitive (Table 16). Over the period, the performance of GeneXpert has improved slightly.

However, the GeneXpert machines are still underutilized compared to their ideal daily capacity (Figure 25). On average, one machine was performing 49 tests per month in the fourth quarter, which is a significant improvement over the average of 30 per month in the first quarter. At full capacity, however, one GeneXpert machine can perform a maximum of 16 tests in a single day. The performance of GeneXpert centers was noted to be variable, and a maximum of 145 monthly GeneXpert tests were reported by one of the referral hospitals. Hence, the utilization of GeneXpert tests needs to be assessed based on the demand for services (possible targets in the catchment area), rather than the full capacity of GeneXpert machines. The orientation provided to over 2,000 HFs on GeneXpert is thought to have improved its utilization in the subsequent quarters. A possible challenge in GeneXpert utilization is transporting the samples to hospitals with GeneXpert. Until a point-of-care modality is developed, it will be difficult to transport sputum samples and maximally utilize this expensive equipment.

To expand diagnostic capacity in the East Amhara, the project distributed 25 microscopes and trained 242 laboratory technicians in microscopy and quality assurance monitoring.

Microscopes and Diagnostic Training Increase TB Case Detection in Ethiopian Region

When the community health worker knocked on his door, Endiros Tadiswal was relieved. The 19-year-old boy had been ill for six months.

After examination, the health worker referred Endiros to the Yekoso Health Center for TB testing. However, when Endiros arrived at the health center, the staff explained that they did not have a microscope to examine patient samples for TB. They referred Endiros to the closest diagnostic facility, 15 km away. Too weak to walk, Endiros returned home discouraged and afraid.

Soon afterward, HEAL TB began working in Endiros' community in Amhara. The project donated a microscope and diagnostic starter kits to the Yekoso Health Center and trained two laboratory technicians to use the equipment and ensure efficient and accurate TB diagnoses.

Endiros was among the first patients to be tested for TB at Yekoso Health Center; as expected, his results came back positive. Trained to conduct contact screening, the clinician then asked Endiros to bring friends and family members with TB symptoms to the facility for testing, too. Within days, Endiros' father, Tadiswal Abebe, also tested positive for TB. The health center enrolled both of them in treatment.

Today, Endiros and his father are feeling stronger and have gained weight. "The relief we feel now surpasses the suffering we have been through," said Endiros. "We are so happy and, at the same time, grateful to have TB diagnostic services at the nearest facility."

Support from Regional Laboratories and TB Culture Centers

TB culture DST services. RRLs at Bahir Dar and Adama are routinely performing solid and LPA TB culture tests. Both regional laboratories provide follow-up and diagnostic services. Only three labs—the national reference laboratory, St. Peter's Hospital, and Jimma University Hospital—had the capacity to perform MGIT liquid culture in Ethiopia until recently. HEAL TB has introduced liquid culture technology into regional labs. Liquid culture technology is significantly faster, with the average time to detection being 10 to 14 days, as opposed to 8 weeks for solid culture. It is also up to 20% more sensitive than solid culture. At present, five MGIT machines have been procured and installed at Adama, Harari, Hawassa, Bahir Dar RRL, and Gondar University. Lab professionals were also trained in culture and DST for these lab facilities. Start-up reagents and accessories were also procured. The machines were validated by the EPHI and an MSH international consultant.

At both Adama and Bahir Dar regional laboratories doing solid culture and DST (LPA), a quality assurance mechanism was introduced. HEAL TB provided technical support to ensure the implementation of LQMS and adherence to national and WHO guidelines. Since October 2014, a total of 3,363 samples were referred to the two culture centers, of which 87.5% (2,941 and 3,363, respectively) were collected from follow-up MDR-TB patients (Table 17).

The following activities were performed in relation to sample transport:

- HEAL TB zonal laboratory advisors have been supporting and ensuring sputum referral linkage services for TB culture and GeneXpert laboratory services.
- Eight vehicles were purchased and a cold chain system established, which were fully functional by the end of June 2016.
- Under the leadership of the EPHI and FMOH, a draft specimen referral manual was prepared for the integrated specimen transport implementation. RHBs and RRLs were represented at the meeting.
- Eight couriers and a coordinator for sample transport were hired.

During implementation, it was planned for each vehicle to be assigned to a cluster of zones. A health facilities map was to be created and a schedule for sample collection for each HF developed, together with HFs and RRLs. Then, health facilities collect all the samples to be transported one day before the sample transport vehicle's scheduled date. The sample transport covers all the HFs in one route in four to five days and delivers the samples to the testing laboratories. EPHI already has a budget for sample transport and it will be covered by the institution. A tool was developed to measure sample quality, cost per sample, and result notification time. This system will be transferred to Challenge TB for full implementation.

TABLE 17. Number of MDR-TB suspects, DST/culture results (Oct. 2014–Mar. 2016)

Indicator	Oct. 2014–Sept. 2015			Jan.–March 2016		
	MDR-TB suspects	MDR-TB case follow-up	Total	MDR-TB suspects	MDR-TB case follow-up	Total
Number of samples transported to culture and DST sites	422	2,941	3,363	79	752	831
Number with results (culture and LPA/DST)	469	2,255	2,724	63	802	865
Number of culture samples processed	370	2,827	3,197	56	872	928
Number of culture positive results with results received	46	193	239	16	40	56
Number of samples processed for DST by LPA	117	N/A	117	19	0	19
Number of new MDR-TB confirmed cases diagnosed among suspects using DST and LPA	33	N/A	33	9	0	9
Number of MDR-TB suspects with monoresistance to rifampicin	1	N/A	1	0	0	0
Number of MDR-TB suspects with monoresistance to isoniazid	5	N/A	5	1	0	1

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BOX 7. Comparison between fine-needle aspiration cytology and GeneXpert for the diagnosis of TB lymphadenitis in Ethiopia

Background: Lymphadenitis is the most common form of EPTB in Ethiopia. Fine-needle aspiration (FNA) offers a feasible and safe option for specimen collection for cytological examination, culture, and GeneXpert tests. Cytology microscopic reading is an old diagnostic tool, which is simple, rapid, and easy to perform. However, FNA cytology is performed in only a few hospitals in Ethiopia due to a limited number of pathologists, and GeneXpert might offer an alternative testing method.

Methods: A cross-sectional study was conducted in a tertiary hospital between September 2014 and February 2015 to compare the cytological results of the senior pathologists with results obtained using GeneXpert. A senior pathologist took a split sample of FNA from each patient clinically suspected of TB lymphadenitis. The cytology smears were stained with Wright's stain and read by the same senior pathologist. A senior microbiologist ran the GeneXpert test following the standard procedure. Both the pathologist and the microbiologist were blind to the results of each other. We calculated the concordance rate of the two test results using Kappa statistics.

Results: A total of 118 TB lymphadenitis-suspected patients were included in this study, with a male-to-female ratio of 0.72. From the total of 118 TB lymphadenitis suspects, 89 (75.4%) and 64 (54.2%) were diagnosed as TB by cytology reading and GeneXpert, respectively. Four (6.3%) of the TB patients diagnosed by GeneXpert were found to have rifampicin-resistant TB. Out of 89 patients diagnosed as having TB lymphadenitis by cytology, 63 (70.7%) were diagnosed as having TB by GeneXpert. The cytology labeled 29 of the suspects as "no TB," of whom 28 (96.6%) were also negative for TB by GeneXpert. The agreement level between the two tests was moderate (Kappa 0.52, $p < 0.001$). The TB positivity rate was significantly less in caseous aspirate samples as compared to pus (cytology 65.3% versus 88.3% and GeneXpert 38.8% versus 70.5%, respectively).

Conclusions: GeneXpert was able to detect a larger proportion of the TB cases than cytology. The test was also able to pick up rifampicin-resistant TB cases, which the cytology test could not do. In settings where there is no pathologist to provide cytology services, the new diagnostic tool could fill the gap. Getting enough samples for caseous aspirates was a challenge, and the low yield among caseous cases could be due to insufficient samples.

Summary of readings of FNA cytology and GeneXpert testing the diagnosis of TB lymphadenitis

	GeneXpert TB	GeneXpert non-TB	Total
Cytology TB	63	26	89
Cytology non-TB	1	28	29
Total	64	54	118

E-Health Information System

Specimens were transported to testing laboratories either by laboratory personnel or by the post office. This resulted in unacceptably long turnaround times, and the contamination rate for sputum cultures was very high because the temperature during transportation was not regulated. The lack of communication channels among the RRLs, post office, district health offices, and HFs complicated specimen referral and result notification. Facility and district staff often did not know that results had arrived at the postal outlet or were ready for pick-up at the regional laboratory, and, consequently, the results remained at the postal outlet or regional laboratory for weeks. There was also no communication between facilities and districts and the reference laboratory when results were missing. To address the current challenges in specimen referrals, HEAL TB, in collaboration with the EPHI and RHBs, has developed e-health information technology.

The design of the SMS and web-based information is complete and the pilot was completed in selected HFs. The information system forms part of an integrated sample transportation system for sputum culture, GeneXpert, viral load testing, CD4, dried blood spot, and other lab tests. HEAL TB, in collaboration with EPHI, conducted an orientation for participants from three regional labs and eight zones (four from each region). The participants were drawn from three RRLs, 24 HFs, eight MDR-TB TICs, eight GeneXpert centers, and 24 post offices. The system is working well and work is underway to implement it in all HFs in the two regions.

The e-health system has also an SMS message feature to link the HEWs for referrals and other consultations for TB as well as any activities of the HEWs, such as maternal referrals, ambulance calls, etc.

Piloting of TB Lymphadenitis Fine-Needle Aspiration and Gastric Aspirates for Diagnosis of TB Using GeneXpert

In collaboration with Addis Ababa University's Pathology Department, Gondar University, and Bahir Dar RRL, a research study to compare the results of FNA cytology for presumptive-TB lymphadenitis cases with the results of GeneXpert was conducted. The study showed that cytology identified more TB cases than GeneXpert, although the specificity of cytology is low compared to that of GeneXpert. The preliminary results are presented in Box 7, left. We also compared the results of culture for diagnosis of lymphadenitis, but the culture results were even lower than those from GeneXpert. Our cold-chain system could explain the low yield from culture.

We also piloted gastric lavage taking by nurses and physicians from children under five years of age in two hospitals for GeneXpert test. Out of 86 presumptive-TB cases tested with GeneXpert, 25 (29%) were found to be *Mycobacterium TB* positive (Table 18). In addition to the safety of lavage conducted by nurses and physicians, its yield is very high. We recommend training nurses in all HFs to conduct lavage for children under five years and send the samples for GeneXpert testing.

Training on ISO 15189 Standards and the Laboratory Quality Management System

There is a growing need to strengthen TB laboratory services, as well as to improve access to high-quality microscopy, culture, DST, and new diagnostics. The major barrier, however, is developing capacity and ensuring quality in systems where there are few or no laboratory standards. With this in mind, HEAL TB and EPHI organized a consultative meeting with RHBs and RRLs and agreed to introduce LQMS in TB laboratories and accredit them with ISO 15189 standards. HEAL TB and EPHI trained RRL quality officers and HEAL TB laboratory specialists in ISO 15189 standards in order to facilitate accreditation initiatives in selected hospital laboratories in the Amhara and Oromia Regions. In the first round, four regional laboratory quality officers and 28 HEAL TB lab advisors were trained to mentor and support 28 hospital laboratories selected from the Amhara and Oromia Regions. Following these, a total of 330 laboratory professionals were trained in both regions in LQMS. The other activities accomplished were:

- printing and distribution of supporting documents (log book, request forms);
- providing monthly monitoring and timely feedback;
- mentoring of facilities by HEAL TB zonal teams; and
- supporting finalization of facility documents (lab quality manual, safety manual, different SoPs, and technical documents).

TABLE 18. Results of gastric aspirate piloting in two hospitals

Activity	Shashemene Hospital	Gabo Hospital	Total
Number of presumptive-TB cases/samples collected through gastric lavage	44	43	86
Number of samples with GeneXpert test	44	43	86
MTB cases detected by GeneXpert	14	11	25 (29%)

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4.4. LESSONS LEARNED AND RECOMMENDATIONS

- High-quality ZN AFB microscopy services can be successfully expanded. Almost all microscopic centers in the two regions have quarterly EQA, with 95% of health facilities scoring more than 96%.
- The decentralized EQA system is a cost-effective and sustainable approach, of which RHBs have already assumed management. Although RHBs are operating EQA by themselves, they still need some support, especially to ensure that the *woredas* have collected slides quarterly, delivered them to EQA sites, EQA sites read the slides on time, and feedback is sent to microscopic centers. Reporting software for EQA results is needed, and this should be supported.
- With the expansion of LED microscopy, many of the high-TB-load diagnosis facilities dropped ZN and shifted to LED. Random blind rechecking for LED has been shown to work as well as it does for ZN AFB microscopy. The concordance rate for results from LED AFB are not different from those of ZN AFB; hence, we suggest that LED be included in the national AFB microscopy EQA guidelines.
- MGIT and other culture facilities are expanding and trainings have been given, but more technical support will be required in the coming years. The integrated sample transport system designed by HEAL TB with EPHI will further improve the quality of samples and reduce contamination.
- Accreditation of 28 hospital TB labs is in the final stage. The approach we followed is low cost and the experience can be replicated in the coming years.
- Integrated sample transport will help the country to create hub centers for major lab tests and the sample transport system will maintain the quality, efficiency, and timely delivery of samples to these hub labs. The operating cost will be lower than what EPHI pays currently; according to the current estimate, EPHI requires US$9 million for sample transport annually. We estimate that our model might require one-fourth of that funding or less. The introduction of cold-chain vehicles and e-specimen into the country's specimen referral system will contribute to the future direction of the FMOH/EPHI on standardization of the service at all levels. We recommend supporting the model for some time and developing it further before handing it over to EPHI.
- The current GeneXpert expansion has improved TB diagnosis, but the machines are not being used to their full capacity. It will be difficult to use this full capacity, because sample transportation from peripheral facilities is expensive. Unless cheaper point-of-care machines are developed, we do not recommend buying more GeneXpert machines for the two regions.
- FNA can be taken by nurses from the presumptive lymphadenitis cases, if training is given for GeneXpert test. But we do not recommend training lab technologists for cytology reading because the microscopic readings' concordance with those of the senior pathologists is very low.
- Gastric aspirating for children is possible with nurses and the yield of TB from the lavage using GeneXpert was very high.

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Key Achievements Section 5:

- ✔ HEAL TB, in association with Gondar University, introduced continuing medical education (CME) on childhood TB for physicians and mid-level health workers. The NTP has scaled up use of the CME module to the whole country.
- ✔ The project introduced contact screening as an entry point to screen children for TB and for IPT.
- ✔ The percentage of children diagnosed and treated, out of all cases notified, ranged from 11.5% to 13%, which fall within the range of global recommendations for childhood TB case notification.
- ✔ By the end of 2015, out of eligible under-five children screened for TB, 53% without TB symptoms received IPT and 80% completed six months of IPT.

SECTION 5. IMPROVING TB CASE NOTIFICATION AND TREATMENT OUTCOMES AMONG CHILDREN

5.1. BASELINE GAPS

At the beginning of HEAL TB, there were no age-disaggregated data to measure the childhood TB disease burden and gaps. Health workers were not well oriented on diagnosis and treatment of childhood TB; as a result, childhood TB was not well incorporated into integrated management of newborn and childhood illnesses (IMNCI). IPT was not used for TB index contacts, although it is included in the national TB guidelines. Most of the pulmonary smear-positive TB diagnosis is done with microscopy for adults, but children do not produce sputum and they are not benefiting from the inexpensive and most-available AFB microscopy services.

The second diagnostic method is an X-ray, but only hospitals provide the service and, for that matter, most hospitals have no radiologists to interpret X-ray films. Cytology and histological diagnostic methods are limited to three to four hospitals in the two regions. Pediatric drug formulations are in tablet form and are difficult for young children to swallow. During the project's life, we were able to assist the system to overcome some of these challenges, although the major ones, such as diagnostics and medicines, require major technological innovations and child-friendly drug formulations.

5.2. STRATEGIES

Development of a National Roadmap for Childhood TB at National and Regional Levels

HEAL TB was an active member of the Childhood TB Technical Working Group to develop a national roadmap for prevention and control of childhood TB in Ethiopia. The roadmap outlines a five-year strategic plan (2015–2020) focusing on intervention opportunities for childhood TB prevention and control. The roadmap emphasizes the integration of childhood TB into IMNCI programs at both the facility and community levels. Furthermore, HEAL TB has piloted a childhood TB CME module intended for mid-level health workers; the NTP benefited from HEAL TB experience to make this module part of its national CME guidelines. We also assisted in revising the HMIS to included age-disaggregated data.

Training, Mentorship, and Supervision

Childhood TB, which had been de-emphasized, was integrated into the national comprehensive TB and leprosy training. A CME manual was developed with Gondar University and CME was piloted in the two regions before the manual was endorsed as the national standard.

The *woreda* TB focal persons and HEAL TB field team included the IMNCI clinics in their mentorship visits. They also mentored contact screening and introduced IPT.

Contact Investigation as an Entry Point for Childhood TB

As described under Section 3, screening contacts of TB index cases was not practiced in the country. HEAL TB introduced this contact-screening approach and included children under five years of age with presumptive TB. Children identified were referred for diagnosis and those without symptoms were started on IPT.


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5.3. RESULTS

Diagnosis of TB in Children

About 11.5% in the last quarter, and 12.5% in previous years, of new TB cases (all forms) notified were children below the age of 15 years (2.53% in the 0–4 year age group and 8.91% in the 5–14 year age group). The proportion of children seems low despite the capacity building of health workers, mentorship, and introduction of GeneXpert as a first diagnostic test. See Figure 26 for the full age and sex distribution of new TB cases (n = 18,358), based on HMIS data.

Support for Use of GeneXpert for Diagnosis of Childhood TB

To ensure better awareness of GeneXpert and improved utilization of GeneXpert for childhood TB diagnosis, different approaches were used to improve the knowledge of health managers and health workers. Orientation workshops, on-site presentations at HFs, and CME were among the methods employed. In total, 698 children were diagnosed with TB (of whom 22 had RR-TB), of 5,829 children under 15 years age tested for TB using GeneXpert as an initial diagnostic investigation. GeneXpert detected a significant number of TB cases in children, including the RR cases, which could have been missed without the introduction of GeneXpert (Table 19).

CME and On-Site Training of Health Workers by Zonal and *Woreda* TB Focal Persons to Detect and Treat TB in Children

Twenty-five rounds of CME on childhood TB were conducted in the Amhara and Oromia Regions in fiscal year 2016. The CME was aimed at improving health workers' knowledge on how to manage childhood TB, TB/HIV co-infection, and TB/malnutrition cases at their respective HFs, as well as how to identify and refer severe forms of childhood TB. The CME was attended by 470 participants, including pediatricians, general practitioners, health officers, interns, medical students, and nurses. The CME was given by pediatricians and academic faculty from Gondar and Jimma universities.

TABLE 19. Yield of TB among children tested using GeneXpert in Amhara and Oromia Regions (Oct. 2014–Mar. 2016)

Type of case	Total Xpert Tested	Rifampicin Resistant	Rifampicin Sensitive	Indeterminate	MTB Not Detected	Error/ Invalid/No Result
Presumptive MDR-TB	1,111	14	135	8	897	76
Presumptive drug-sensitive TB	4,718	8	502	31	3,993	293
Total	5,829	22	637	39	4,890	369

FIGURE 26. Age and sex distribution of new TB cases (all forms), percent (Apr.–Jun 2016)

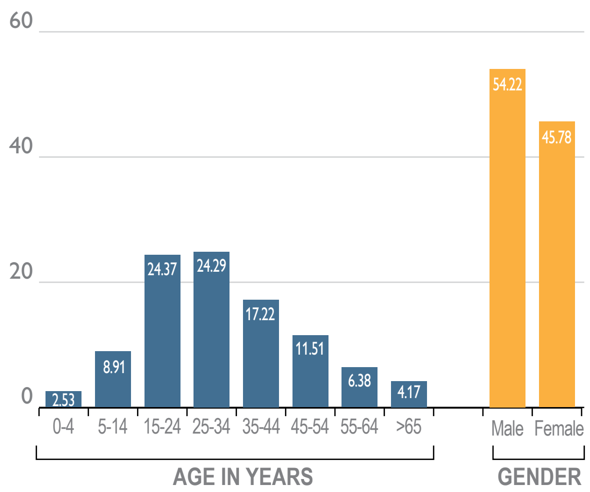
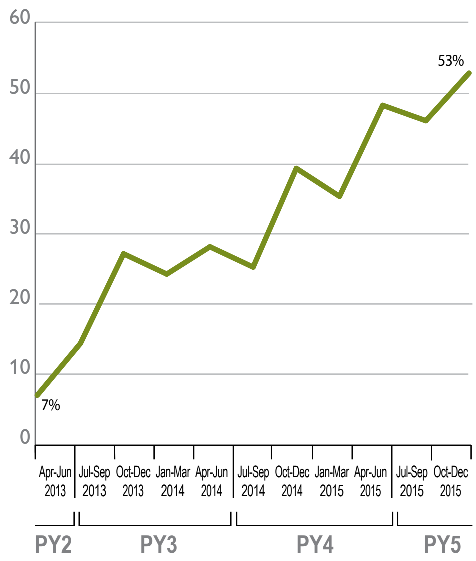


FIGURE 27. IPT coverage among eligible under-five child contacts of index TB cases



HEAL TB also worked with pediatricians from local universities in the two supported regions, with the aim of creating a pool of trainers and regional consultants/experts in the area of pediatric TB. Such an approach will enable RHBs in the future to utilize these experts for childhood TB-related trainings and consultations.

Contact Investigation for Children Who Are Contacts of PTB Index Cases and IPT for Children Under Five

HEAL TB supported routine contact investigation of index TB cases with a focus on children, since they are one of the key at-risk populations. In the last four years of the project, a total of 37,164 smear-positive index cases with pulmonary TB were reached and 10,584 under-five child contacts were screened for TB; 633 were labeled presumptive TB. There were 10,020 children eligible for IPT, of whom 3,832 (38.2%) were put on IPT.

Although the trend in IPT is encouraging, more work is required to screen all children, administer IPT to all eligible children, and improve the isoniazid (INH) supply.

Community Awareness of Childhood TB

To improve public awareness of childhood TB, a TV spot message was developed and it was broadcast for over a month. The message focused on contact investigation, early diagnosis of childhood TB, and the importance of adherence to preventive and curative treatments.

5.4. LESSONS LEARNED AND RECOMMENDATIONS ON CHILDHOOD TB IMPLEMENTATION

Children under 15 years constituted 12.3% of all TB cases reported. This is comparable to the reports of many countries, but diversifying diagnostic means such as gastric and nasopharyngeal aspirates for GeneXpert and improved X-ray diagnostics should be an area of focused support. Introducing tele-radiology for a country like Ethiopia, where there are few radiologists, is a viable option.

Using contact screening as an entry point, HEAL TB supported IPT initiation for 53% of eligible children, which was a 6.5 fold increase from the baseline of 7% (Figure 27). This was achieved through strengthened capacity building for health workers, providing tools and site-level technical support, and ensuring adequate supply of isoniazid. The isoniazid completion rate was 80.3% per the reports collected from 28 health facilities.[22] This suggests that contact screening should be strengthened as an entry point for childhood TB care. More effort is needed to improve the IPT uptake and completion rates.

With improvement in diagnostic methods, we expect more children with TB to be diagnosed. The new pediatric anti-TB formulation is a good opportunity to solve the treatment challenges in children and its introduction to the country should be given priority.

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Key Achievements Section 6:

- ✔ All health facilities in the two regions implemented an integrated pharmaceuticals logistics system, which helped to reduce drug stock-outs from a baseline of 22% to 2%.
- ✔ HEAL TB assisted the FMOH in quantifying and implementing TB drug kits in 2,186 health facilities in the two regions.

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SECTION 6. DRUG SUPPLY MANAGEMENT

6.1. BASELINE GAPS

The rates of stock-outs of tracer drugs were very high: according our baseline study, 22% of the health facilities reported a stock-out within three months of the baseline data collection. Although the PFSA had designed an integrated pharmaceuticals logistics system (IPLS), health workers were not trained in the system and there were no proper stock-out monitoring or timely refill requests by health facilities to PFSA. Since health facilities were not requesting the proper amount of drugs, there were overstocks and expiry in some and undersupply and stock-outs in others. At the national level, quantification was done but was not strong. To fill these gaps, HEAL TB designed the following strategies to work with the FMOH, PFSA, RHBs, and health facilities.

6.2. STRATEGIES DESIGNED

The main focus at the health facility level was to train health workers in proper stock recording, monitoring, and reporting. The IPLS was designed by PFSA for this purpose, and pharmacy professionals working in the health facilities were trained in its use. The *woreda* TB focal persons and zonal teams were also trained to mentor/supervise the health facilities in IPLS implementation. The IPLS is designed to regularly update the stock balance and request drugs based on the morbidity data of the health facility. Stock-out monitoring logbooks, bin cards, and other supplies were also given to the two regions.

The other strategy proposed by the project was to pilot TB drug kits in the project areas. HEAL TB discussed the drug kit with the NTP and PFSA, which decided to implement it nationally rather than pilot it. HEAL TB assisted in developing guidelines for the kit, piloted its use, trained HFs on TB kit implementation, and monitored the implementation. The HEAL TB-supported regions implemented the drug kits earlier than the rest of the regions.

The other major challenge was the quantification of drugs nationally. MSH played an active role on the quantification team established by the FMOH and PFSA. In addition, QuanTB software for quantification, developed by the USAID-funded, MSH-led global Systems for Improving Access to Pharmaceuticals and Services (SIAPS) project, was introduced to the country. Experts in FMOH and PFSA trained on the new quantification software and the country used it for monitoring stock and quantifying the country's need for TB drugs.

6.3. RESULTS

TB Drug Stock-Outs

HEAL TB has been supporting the comprehensive implementation of IPLS for the last five years. As a result, a remarkable improvement has been registered in its implementation across all HFs in both the Oromia and Amhara Regions. The percentage of facilities using the requisition and resupply form (RRF) reached 93.2%, from a baseline of 11% five years ago. The inventory control and management of anti-TB drugs have also improved as a result of IPLS implementation, and the percent of HFs updating bin cards reached 78.1% from a baseline of 25% (Table 20).

Reducing stock-out rates of anti-TB drugs has been a key indicator. As a result of the comprehensive IPLS support, the stock-out rate of selected tracer adult anti-TB drugs has decreased remarkably. The current stock-out rate in Phase I HFs is 1% and the rates in Phase II and Phase III HFs are 11.4 and 3%, respectively. The stock-out rate in Phase II was higher because of significantly higher numbers of stock-outs in Wollega zone due to security problems. When we excluded the zone from the analysis, the stock-out rate in Phase II zones was found to be 2%. The HEAL TB and RHB team provided priority support to the affected zone. There has been a significant improvement in RRF implementation and bin card updating in the last quarter of 2015 (Table 20). At the project level, the stock-out rate for major tracer drugs declined from 22% at baseline to 2% in PY5 (Figure 28).

IPLS Recording and Reporting Tools

HEAL TB has played an active role in regularly updating, revising, and printing IPLS recording and reporting tools. As a result, all HFs in HEAL TB-supported zones received a continuous supply of IPLS recording and reporting tools through the HEAL TB Project. The following items were supplied to the two regions:

- RRFs for both hospitals and HCs
- Internal facility reporting and resupply forms for both hospitals and HCs
- Health post monthly reporting and resupply forms
- Bin cards for all HCs and hospitals

Training of Health Professionals in IPLS

HEAL TB has been engaged with PFSA and the RHBs of the Amhara and Oromia Regions in identifying gaps in IPLS training. Following the identification of gaps, HEAL TB actively supported the PFSA, RHBs, and relevant partners in addressing the gaps. HEAL TB has supported the training of 2,720 health care workers in IPLS from selected HFs in the Amhara and Oromia Regions. Orientation on the implementation of TB patient kits, integrated with the IPLS training sessions, has also been provided to 1,163 trainees.

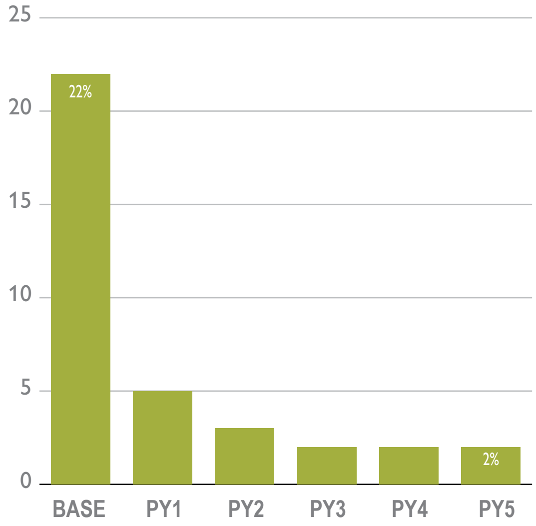
HEAL TB, in collaboration with the PFSA, supported national training of trainers on IPLS for a total of 40 participants (36 male and 4 female). These participants were drawn from 6 RHBs (Amhara, Oromia, Southern Nations, Nationalities and Peoples' Region [SNNPR], Tigray, Diredawa, and Harari), PFSA central, and all PFSA hubs in the nation.

TABLE 20. Performance of drug supply management indicators in HEAL TB-supported zones, by phase

	Phase	Jan.–March 2015	April–June 2015	July–Sept. 2015	Oct.–Dec. 2015
HFs implementing RRFs	I	860 (95.4%)	917 (97.2%)	878 (93.9%)	916 (94.4%)
	II	621 (92.7%)	662 (94.4%)	669 (94.7%)	654 (94.2%)
	III	299 (71.7%)	347 (85.9%)	384 (89.1%)	381 (89.2%)
	Total	1,780 (89.5%)	1,926 (94%)	1,931 (93.2%)	1,951 (93.3%)
HFs implementing bin cards	I	823 (91.3%)	825 (87.5%)	783 (83.7%)	815 (84.0%)
	II	481 (71.9%)	526 (75%)	529 (74.9%)	547 (78.8%)
	III	234 (56.2%)	279 (69%)	307 (71.2%)	314 (73.5%)
	Total	1,538 (77.4%)	1,630 (79.6%)	1,619 (78.1%)	1,676 (80.2%)
HFs with stock-outs	I	3 (0.3%)	20 (2.1%)	7 (0.75%)	10 (1.0%)
	II	13 (1.9%)	5 (0.7%)	37 (5.2%)	79 (11.4%
	III	13 (3.1%)	9 (2.2%)	6 (1.4%)	13 (3.0%)
		29 (1.5%)	34 (1.6%)	50 (2.4%)	102 (4.9%)*

*2.0%, excluding Wollega zone, which had higher-than-normal stock-out reports (60/66 HFs), due to security issues.

FIGURE 28. Percentage of health facilities with stock-outs of major TB drugs



Support to the FMOH, PFSA, and Other Partners in the Implementation of Global Drug Facility TB Drug Kits in Ethiopia

From the introduction and implementation of TB patient kits in Ethiopia, HEAL TB has been playing an active role as a member of the core technical working group. The project supported the FMOH in revising the draft guidelines for the introduction and implementation of TB patient kits in Ethiopia. The implementation of TB patient kits was well monitored and supported as a priority in all HEAL TB-supported regions. Over 95% of the HFs in the Amhara and Oromia Regions are currently implementing TB drug kits, while there were none at the beginning of the project. TB drug kits are well integrated into the IPLS and, thus far, there have been no reports of drug stock-outs in HFs using the TB drug kits.

Following the national TB quantification training workshop, an update of QuanTB has been completed as part of the regular support for the supply planning process. This update considers the central stock on hand and that in the pipeline. Informed decisions are being made based on the findings of the forecasting and quantification exercises.

HEAL TB has also supported the FMOH and PFSA in the procurement of paper boxes, plastic envelopes, and cartons for the preparation of 102,000 TB patient kits from reconstituted, existing loose anti-TB drugs. The preparation of TB patient kits from the loose anti-TB drugs is currently ongoing. Thus far, 48,000 TB patient kits have been prepared and distributed to all regions in Ethiopia. In line with improving drug storage management at TB units, HEAL TB has distributed 260 lockable cupboards to select HFs in the Amhara and Oromia Regions.

Support for the National TB/HIV and Pharmaceutical Logistics Technical Working Group and Related Missions

As a member of the national Pharmaceutical Logistics TWG, HEAL TB is actively participating in the bimonthly PFSA Partners' Forum. HEAL TB has worked closely with the FMOH and PFSA in several technical areas, including:

- Provision of technical support on the preparation of TB patient kits through reconstitution, which supports the supply and distribution to HFs.
- Support for the PFSA in the revision of the national SOP for IPLS. Printing of 10,000 copies of the second edition of the national IPLS SOP.
- Support for the revision and printing of the second edition of *Medical Supplies and Reagents Manual for Ethiopia.* Printed 5,000 copies of the manual.
- Support for the development of draft guidelines for the distribution of small-volume drugs such as streptomycin, pediatric anti-TB drugs, and second-line drugs (SLDs).

Support for the Establishment of an Internal Quality Control Laboratory at PFSA

HEAL TB procured, installed, and provided training on Fourier-transform infrared, high-performance liquid chromatography, and fume hood machines worth US$400,000.

Support to the FMOH and PFSA in Forecasting and Quantification of Anti-TB Drugs

HEAL TB supported the FMOH and PFSA in the forecasting and quantification of anti-TB drugs (both first-line drugs and SLDs using the QuanTB tool, which has forecasting and quantification features along with an early warning system). National experts were also trained on QuanTB software.

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6.4. LESSONS LEARNED AND RECOMMENDATIONS

- Improved quantification and scheduled distribution of TB drugs have greatly reduced stock-outs of drugs. The QuanTB software has eased the quantification exercise and drug monitoring in the country. This practice should continue.
- The IPLS implementation as part of the *woreda* and zone supervision and mentorship has resulted in timely replenishment of drugs and avoidance of stock-outs at the HF level.
- TB drug kits have simplified the drug request process and minimized disruption of treatment once the patient is put on DOTS.

After 18 months, the TB drug stock-out rate at 691 facilities had declined from 22% to 0.2%.

New Tool Reduces TB Drug Stock-Outs

For over a decade, the GOE has worked to improve TB screening and case detection. However, increasing the number of diagnoses then created another challenge—moving enough medicine to treat the newly diagnosed patients. Health facilities experienced frequent stock-outs of TB drugs, leaving many patients without treatment for long periods. This service gap not only exacerbated many patients' illness, but also contributed to transmission as well as development of drug-resistant TB strains.

In 2011, to address this challenge, HEAL TB began assisting the National TB Program to implement the IPLS. IPLS integrates drug requisition, distribution, and reporting information into a single, streamlined mechanism to manage drug supply.

In addition, IPLS includes a forced order-delivery system that allows Ethiopia's PFSA to distribute drug quantities based on health facilities' monthly reports. This allows health facilities to maintain supplies, avoid expiration and stock-outs, and ensure that all patients receive full treatment regimes.

HEAL TB started supporting the implementation of IPLS in the 10 zones of Amhara and Oromia Regions, where 22 percent of health facilities had recorded anti-TB drug stock-outs in 2011.

In collaboration with the Amhara and Oromia Regional Health Bureaus and the PSFA, HEAL TB has trained 691 facility staff on IPLS operations, provided IPLS recording and reporting tools, distributed 355 lockable drug cabinets, conducted quarterly supportive supervision visits to ensure staff are accurately implementing the system, and held regular regional meetings for implementers to share best practices and lessons learned.

The GOE has committed to scaling up the IPLS to improve management of TB and HIV drugs in other regions as well.

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Key Achievements Section 7:

- ✔ HEAL TB implemented a mixed model of MDR-TB care, whereby patients are admitted for a month or two until they tolerate the treatment and discharged to the nearest health center for MDR-TB DOT. Patients return to MDR-TB hospitals every month for follow-up checkups, including follow-up cultures.
- ✔ In the two regions, the number of MDR-TB hospitals (treatment initiating centers) expanded from 1 to 22.
- ✔ HEAL TB-supported regions were able to enroll 1,005 new MDR-TB patients, from a baseline of 50.
- ✔ The TSR is above 75% and the cure rate is 65%. These outcomes place Ethiopia among the better performers in the world.

SECTION 7. RESPONDING TO THE EMERGING THREAT OF MDR-TB

7.1. BASELINE GAPS

In 2011, when the HEAL TB project began implementation, Gondar University Hospital in Amhara Region was the only MDR-TB hospital and there was none for Oromia Region. The two MDR-TB centers of Gondar and St. Peter (Addis Ababa) were overworked and had many patients on their waiting lists. Although support for the treatment of MDR-TB patients was not the primary focus during the first year of the project, this area received more emphasis from the second year onwards.

Several gaps and challenges were identified at baseline and during the early phase of implementation. The key challenges were:

- Presumptive MDR-TB case identification was low, and there was weak or no dedicated and standardized means of sputum sample transport to testing centers.
- There were only two laboratories to diagnose MDR-TB in the two regions (Adama and Bahir Dar).
- Long turnaround time and sometimes lost test results contributed to delayed initiation of treatment and monitoring of treatment outcomes, including death.
- Many patients were on waiting lists for treatment after diagnosis, since there were only three MDR-TB treatment centers, one in Amhara and two in Addis Ababa.
- There was no systematized patient follow-up mechanism for the few patients started on treatment.
- Poor infection control practices and the presence of MDR-TB patients who were not on treatment in the community led to higher disease transmission.
- Awareness about drug-resistant TB among health care workers and the public was low.

7.2. STRATEGIES

HEAL TB, under the leadership of the FMOH and RHBs, implemented the following strategies (Figure 29). The first strategy was designed to increase case notification. To do this, all TB focal persons in 2,186 health facilities received training on screening of MDR-TB presumptive cases, sputum transport, and linking of patients to MDR-TB centers. The main focus was on conducting AFB for all smear-positive pulmonary TB cases enrolled on treatment at the second, third, and fifth months and end of treatment for new patients and re-treatment patients. A mandatory sputum referral was introduced for culture or GeneXpert for those patients whose smear failed to convert at three, five, and six months and for

FIGURE 29. Presumptive MDR-TB case registration, reporting, sample collection, and patient follow-up in HEAL TB-supported regions

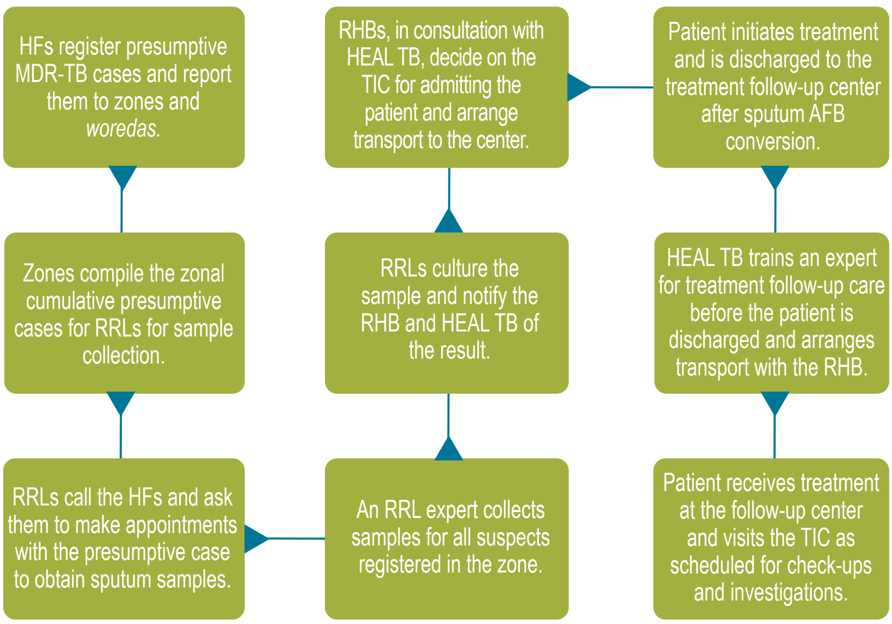
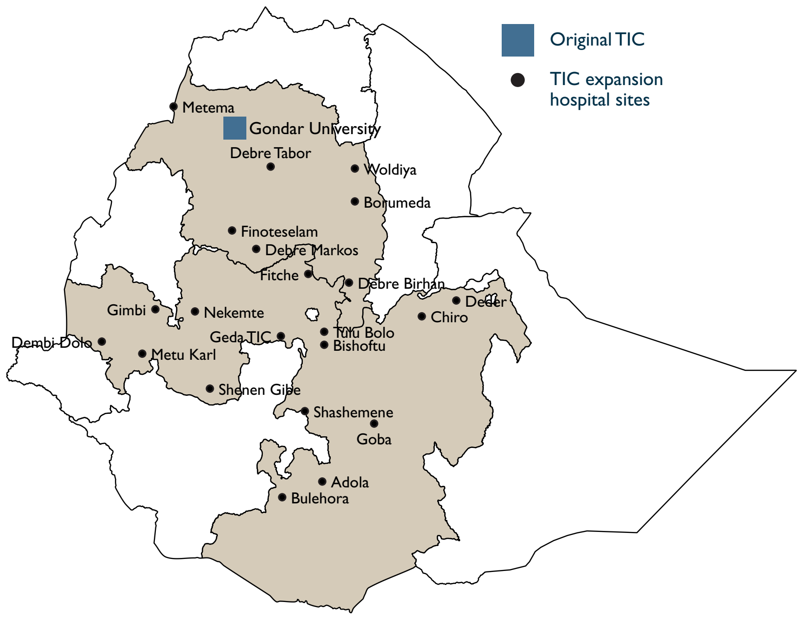


FIGURE 30. Expansion of MDR-TB TICs in Amhara and Oromia Regions



all re-treatment. As described in Section 4 prior, the diagnostic facilities expanded, new diagnostics such as MIGIT and GeneXpert were added, and quality assurance mechanisms for labs were established.

As described in Section 7.1, there were no health facilities to initiate treatment for MDR-TB patients and many were on waiting lists. Many patients died in the process. Under the leadership of the FMOH, HEAL TB helped to introduce a mixed model of care, whereby patients can be admitted for few weeks to hospitals (treatment initiating centers, TICs) until they are stabilized and then be discharged to the nearest health center (called treatment follow-up centers, TFCs) for DOT, with monthly return of patient to TICs for clinical checkups and to take repeat sputum samples for culture and other lab investigations. To implement this mixed ambulatory model of MDR-TB services, TICs in almost every zone were established and TFCs were established based on patients' referral needs. A monthly clinic day concept was introduced so that all MDR-TB patients could come to TICs on a designated date. The advantage was that the clinical and administration teams allocated the day to receive MDR-TB patients; it was easy to collect all samples and transport them in one batch; patients had a chance to meet other patients and discuss their condition informally; and the administrative team reimbursed the patients for transport and provided nutrition support. The other advantage of the MDR-TB clinic day was that mentors from the RHBs, zones, and HEAL TB were at the TIC to provide technical and administrative support.

7.3. RESULTS

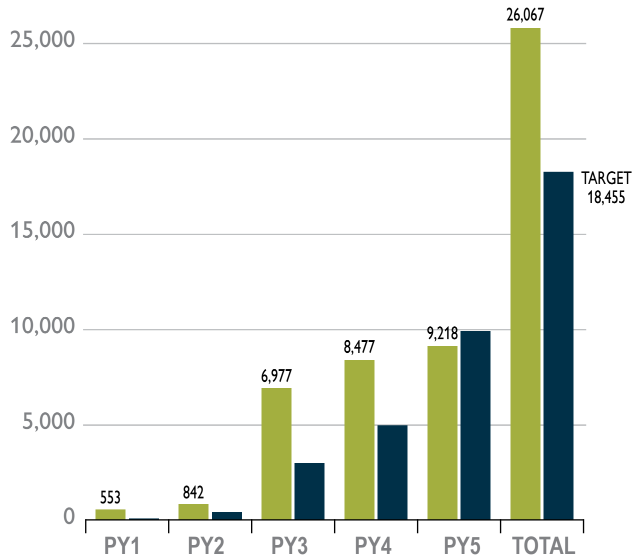
Expansion of Treatment Initiating Centers

In 2011, there were only three MDR-TB centers (TICs) and by the end of the project year, 23 TICs (14 in Oromia and nine in Amhara) were functional (Figure 30). HEAL TB constructed three centers and supported the provision of equipment and furniture to the 23 TICs. More than 400 HFs were providing monthly follow-up to patients who began treatment in TICs. A total of 1,005 MDR-TB patients started treatment in the two regions during the project implementation period.

Orientation Sessions on MDR-TB Suspect Identification and Referral

A zonal-level orientation on MDR-TB and GeneXpert utilization was conducted for each *woreda* and their respective HFs' TB focal persons in all zones of the two regions. A total of 988 and 921 health care workers received this orientation in Amhara and Oromia Regions, respectively. The orientation focused on establishing/strengthening MDR-TB suspect identification and a sample referral system. Following the orientation, the trained TB focal persons carried out an on-site orientation for all health care workers at 2,122 HFs in the two regions. The implementation of the orientation for all workers at HFs is an ongoing process, and there has been significant improvement of awareness in presumptive MDR-TB case identification and sample referral.

FIGURE 31. Cumulative number of MDR-TB presumptive cases identified over five years



In addition to the orientations, the zonal HEAL TB teams actively supported *woreda* TB focal persons, with a focus on hospitals and high-TB-burden health centers, to identify presumptive MDR-TB suspects at HFs and in the community, including contact investigation of confirmed MDR-TB patients.

Cumulative Number of Presumptive MDR-TB Cases Identified

In the last five years, 26,067 (141% of the target) presumptive MDR-TB cases were identified (Figure 31). These achievements were made possible through enhanced MDR-TB case finding strategies and building the capacity of health workers at all levels.

The number of drug-resistant TB cases diagnosed increased progressively from quarter to quarter. The introduction of GeneXpert has improved access to services, resulting in the early identification of drug-resistant TB cases (Figure 32, next page).

MDR-TB Cases Identified through Contact Investigation

Following the introduction of SOPs and tools for MDR-TB contact investigation, a total of 298 MDR-TB index case contacts were screened. The yield was 1.9% for all forms of TB combined and 1.7% for MDR-TB (Table 21).

TABLE 21. MDR-TB contact screening performance (Oct. 2014–Mar. 2016)

Indicators	Amhara	Oromia	Total
Number of index MDR/RR-TB cases enrolled in the previous quarter (Jul.–Sep. 2014)	148	194	342
Number (%) of index MDR/RR-TB cases enrolled in the previous quarter whose contacts were screened for TB	139 (93.92)	159 (81.96)	298 (87.13)
Number of household/close contacts registered	447	546	993
Number (%) of household/close contacts screened for TB	441 (98.66)	512 (93.77)	953 (95.97)
Number of contacts with presumptive TB	14	35	49
Number of contacts screen negative for TB symptoms	427	477	904
Number of susceptible bacteriologically confirmed TB	1	0	1
Number of contacts with drug-sensitive TB diagnosed	0	1	1
Number of contacts with extrapulmonary TB	0	0	0
Number of contacts with MDR/RR-TB	6	11	17
Yield of MDR-TB among those screened (%)	1.36	2.15	1.78

FIGURE 32. Trend in drug-resistant TB cases diagnosed (Jan. 2013–Jun. 2016)

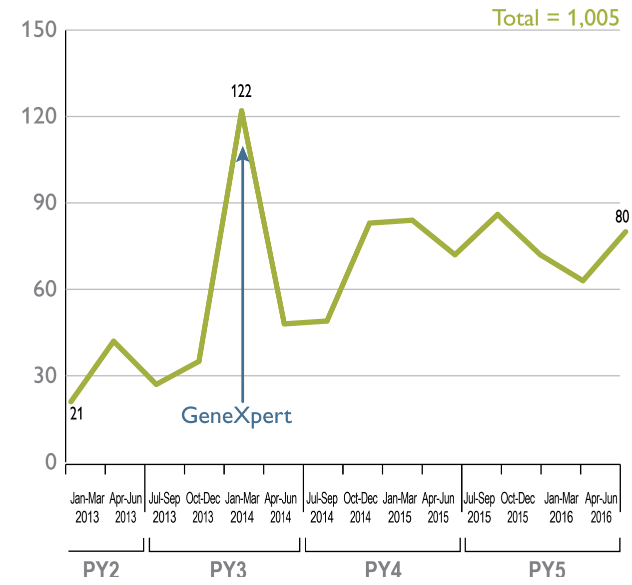
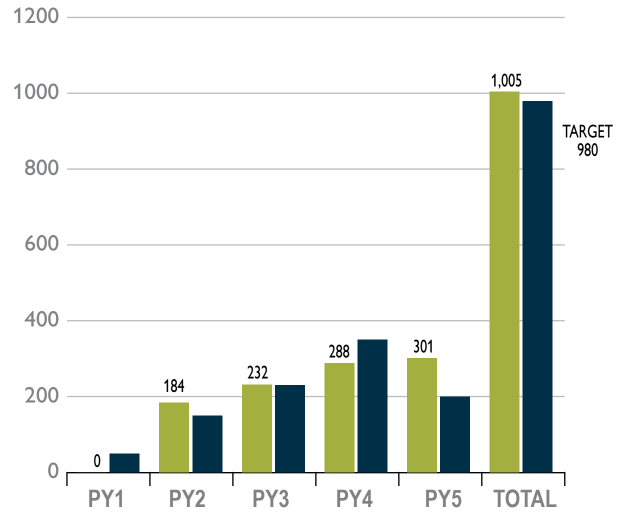


FIGURE 33. Number of MDR-TB patients on treatment with US government support over five years



The prevalence of TB among the MDR-TB contacts was similar to the findings of the national survey for retreated patients.[23] The high yield suggests the need for continued focus on this high-risk group.

Patient Enrollment Rate

HEAL TB's comprehensive case finding effort contributed to the enrollment of 1,005 MDR-TB cases, which is a little above the five-year target (Figure 33). The progressive improvement in patient enrollment rate demonstrates the positive impact of systematized case finding efforts, expanded diagnostic means, and well-coordinated programming.

Quality Improvement Interventions

To improve the quality of patient care, HEAL TB supported robust quality improvement interventions, including clinical seminars and CME for clinicians, cohort review meetings, regular supportive supervision and mentoring, strengthening of sample transport systems, monitoring capacity for drug side effects, and provision of job aids to health workers.

Clinical Seminars and CME

In PY4, HEAL TB supported the FMOH and RHBs in organizing two rounds of clinical seminars and CME, one of which was facilitated by a senior global expert in infectious diseases and MDR-TB. Local MDR-TB experts co-facilitated the sessions. The seminars were conducted as case-based discussions combined with didactic sessions. The FMOH has endorsed the approach as part of the national strategy to build local capacity for sustainable delivery of MDR-TB services.

Patient Support

HEAL TB provided food support and transport fees for patients for Oromia Region for over a year, while Amhara covered the expenses from their budget. In the fifth year, Oromia RHB also took the responsibility of supplying the food and transport fees. MDR-TB patients also receive psychosocial support during follow-up at TFCs and TICs. An audio-visual MDR-TB adherence counseling tool was developed to strengthen patient psychosocial support and to increase patients' treatment adherence. TV sets were provided to all TICs in the two regions.

Supervision and Mentorship

MDR-TB was a key area of focus for monthly supportive supervision by the respective zonal/*woreda* TB officers and HEAL TB team. The areas of focus were MDR-TB case finding and management, particularly in identification of presumptive cases, sample referral, result delivery, and patient enrollment in treatment.

Job Aids for TICs and TFCs

MDR-TB SoC for TICs were developed for quality improvement and shared with both regions. Behavior change communications (BCC) materials and job aids adapted from the second edition of the national Programmatic Management of Drug-Resistant TB guidelines were printed and distributed. An MDR-TB cohort-analysis wall chart (prepared by the FMOH) was printed and distributed to TICs.

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Ethiopia ranks among the world's high MDR-TB-burdened countries. In response to this challenge, HEAL TB worked with local partners to improve infrastructure, screening protocols, and referral networks so the health system is better equipped to diagnose and treat MDR-TB.

Facility Renovations and Staff Trainings Improve MDR-TB Control

Azmara Ashenafi, a 35-year-old woman from the Amhara Region, was diagnosed with TB and placed on treatment with a first line anti-TB drug. Although she took this medicine for months, her symptoms persisted. Eventually, Azmera's cough, fever, and weight loss had become so severe that she sought further treatment at the Muja Health Center.

Since 2012, HEAL TB has been training that health center's staff to screen patients like Azmara for MDR-TB, TB that cannot be treated with the two most powerful first-line anti-TB drugs. Since HEAL TB supported Muja Health Center, the facility was able to offer Azmara appropriate and timely care. First, the newly-trained team collected sputum samples from Azmara and sent them to the Amhara Regional State Laboratory for testing. When her results came back positive for MDR-TB, the staff quickly referred Azmara to the Borumeda Hospital – the closest MDR-TB treatment facility.

HEAL TB also worked to improve infrastructure at TB treatment. At Borumeda Hospital, for example, HEAL TB renovated various rooms and departments so they are fully equipped to provide MDR-TB patients with care and treatment services. Renovations included: ensuring proper ventilation throughout the facility to reduce TB transmission; expanding patient wards to increase capacity; constructing isolation rooms for highly-infectious patients; furnishing patient rooms with beds, mattresses, pillows, bed-sheets, and blankets; and furnishing out-patient departments with tables and chairs.

HEAL TB also trained the staff at the Borumeda Hospital to manage MDR-TB patients and screen those who have been in close contact with the patients. Thanks to this training, the staff tested all of Azmera's family members and found that her three-year-old son, Feseha, was also infected with MDR-TB. The staff immediately began treating the child and both Azmera and Feseha are now stable and in good health.

"I thank the Borumeda Hospital staff and other partners for diagnosing our MDR-TB and providing treatment and other support to save my life and my child's life," said Azmera.

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FIGURE 34. Six-month interim treatment outcomes of MDR-TB patients

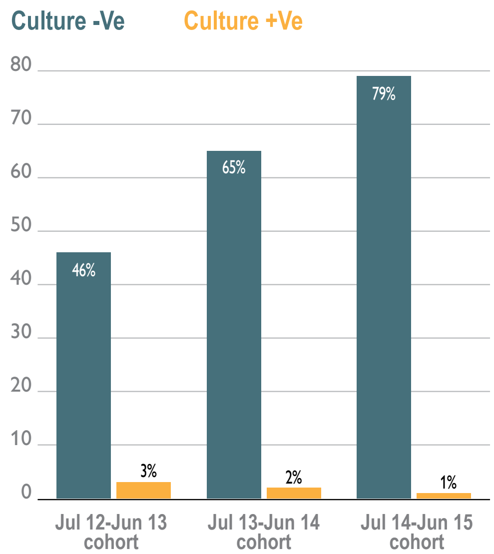
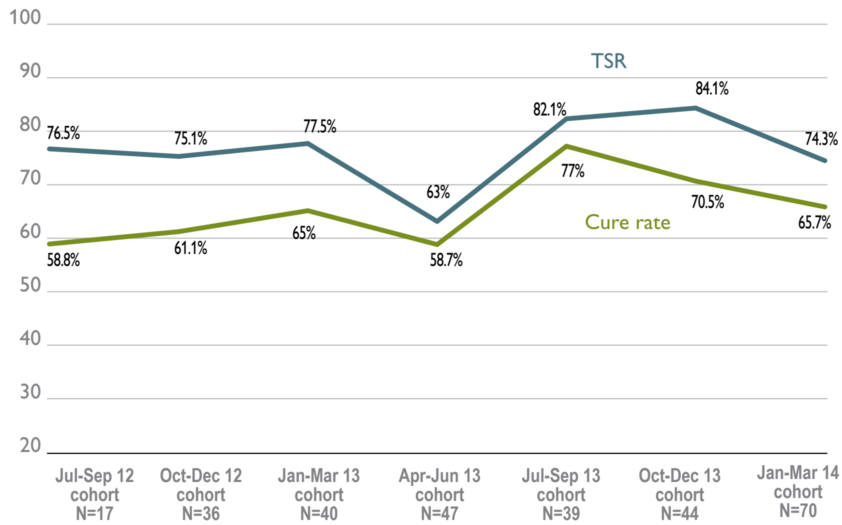


FIGURE 35. Final MDR-TB outcomes for MDR-TB cohorts on SLDS (Jul. 2012–Mar. 2014)



Supply of Materials, Drugs, and Reagents

Different sizes and types of N-95 respirators were imported and distributed to TICs and TFCs. A total of 32,000 N-95 respirators (five types) were procured and distributed to sites on the basis of need. HEAL TB supported TICs and TFCs in the provision of SLDs to avoid stock-outs and provided ancillary drugs to fill gaps.

Additionally, HEAL TB provided technical support for ancillary laboratory investigations, including electrolyte machine installation and maintenance. Supplies for some ancillary investigations were procured and provided to TICs based on demand (e.g., electrolyte reagents).

MDR-TB Treatment Outcomes

Six-month interim treatment outcomes. The total number of MDR-TB patients evaluated was 1,005, and the culture conversion rate for those who completed six months of treatment increased from 46.4% in the 2012–13 cohort to 79% in the 2014–15 cohort (Figure 34). The project-level culture conversion rate at six months is more than twice the national culture conversion rate (33.9%) reported in 2014–15. Over the same period, the proportion of patients without culture results at six months declined from 36% to 10%. The proportions who died, were lost to follow-up, and were not evaluated in the October 2013–September 2014 cohort were 9.4%, 6.5%, and 9.8%, respectively. The capacity building provided to health workers, MDR-TB clinic days, close mentorship, SOPs, and improvement in sputum referral could have contributed synergistically to the improvement in the interim outcomes.

Final Treatment Outcomes

In the most recent cohort of July–September 2013, the treatment success rate was 82.1%, with 77% reported to be cured while the proportions of deaths and those lost to follow-up were 15.4% and 2.5%, respectively (Figure 35). Final treatment outcomes were computed for 161 patients for one year for patients enrolled during October 2012–September 2013. The cure rate for the annual cohort was 65.2% while the TSR was 73.9%, with 14.9% deaths and 8.7% lost to follow-up. The national cure rate was 43.8% and the TSR 69.1%, both lower than the data from the two HEAL TB regions. The TSR was also higher than the global average of 50%, according to the 2014 *World TB Report*. This achievement can be attributed to the critical interventions put in place through USAID's investments under the leadership of the RHBs and FMOH.

7.4. RESULTS, LESSONS LEARNED, AND RECOMMENDATIONS

- By the end of PY5, the number of TICs increased 22-fold (from only 1 to 23), the annual number of sputum samples processed increased 20-fold, and there was a 12-fold increase in patient enrollment.
- The project helped enroll 1,005 new MDR-TB patients in five years, from only 50 at baseline. There were many patients on waiting lists at the beginning, but there are none at the time of this report. The approach of having AFB microscopy for smear-positive patients at the end of the second, third, fifth, and sixth months and doing tests for MDR-TB for those patients who did not convert to AFB negative has helped to find more MDR-TB patients. The other approach was to test all re-treatment cases for MDR-TB. These approaches should be used in the future and, coupled with the high cure rate (more than 90%), incidence of MDR-TB can be expected to decrease.
- TSRs have reached as high as 82.1%, and cure rates have reached 77%, with fluctuations in every quarter's cohorts. The results far surpass the global average of 52% in 2015.
- The yield of MDR-TB contact screening was 12 times the prevalence estimate for drug-sensitive TB in the general population. The contact yield is almost identical to the national survey result for re-treatment TB cases and should be applied nationwide in all TICs.
- The mixed ambulatory and inpatient model of care, coupled with the monthly follow-up clinic days, proved to be a practical approach for improving access to and quality of MDR-TB services.
- The monthly clinic day has contributed to patients getting monthly checkups in a structured manner with transport reimbursement and food supplies. Because all patients come on the same day for follow-up, they have a chance to discuss their illness with peers, offering a psychosocial benefit. The approach also permitted sputum and other lab test collection and transport in one batch as opposed to single test transport when patients were coming for follow-up on different days. It is recommended that this approach continue.
- The treatment outcomes are improving from quarter to quarter because of continued training of MDR-TB clinicians and case-based CME sessions. The improved counseling and follow-up of patients for treatment adherence is also a factor, and all of these practices should be supported in the future.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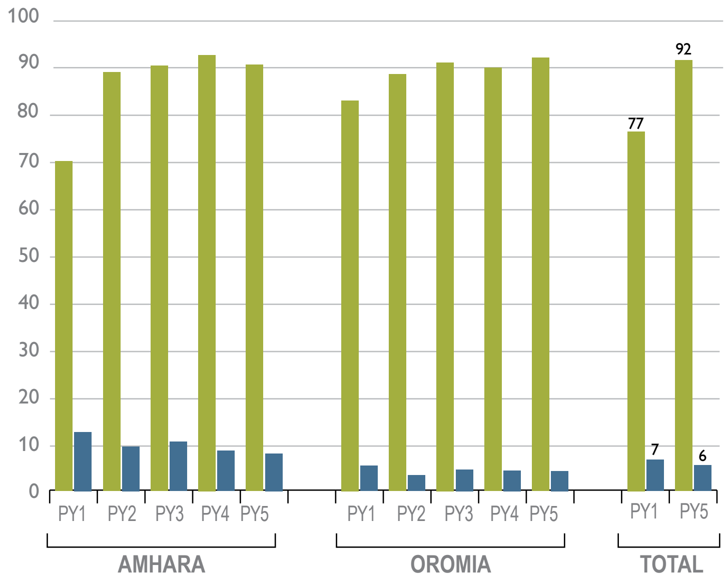
Key Achievements Section 8:

- ✔ The percentage of TB patients tested for HIV increased from a baseline of 77% to 92% by the end of the project.
- ✔ Of all TB/HIV co-infected persons, nearly 89% enrolled on ART by the end of 2015.
- ✔ Ninety percent of TB/HIV co-infected patients received CPT.

FIGURE 36. Annual percentage of HIV testing for TB patients and TB/HIV co-infection rate, HMIS Data (2011–2016)



SECTION 8. TB/HIV COLLABORATION

8.1. BASELINE GAPS

The major gap at the beginning of the project was that the testing of TB patients for HIV was around 70% and the referral linkages for TB/HIV co-infected patients were weak. ART initiation was also CD4 dependent until the mid-point of the project, when the FMOH decided to treat all TB/HIV co-infected patients with ART, irrespective of their CD4 counts.

8.2. STRATEGY

The main strategy designed to test all newly diagnosed TB patients for HIV was to mentor health workers on counseling of patients repeatedly when the patient comes daily for DOT. When the patient is willing, TB focal persons provide the HIV testing services at the TB clinic.

The TB focal person then refers HIV-positive patients to an ART clinic, either within the same facility or at other health facilities providing ART services. Then the TB focal persons ask the patients if they have started ART and CPT when they come for their daily DOT.

8.3. RESULTS

HEAL TB supported the counseling and testing of TB patients for HIV. TB/HIV co-infected patients diagnosed at non-ART HCs are referred to the nearest ART referral center. HEAL TB provided GeneXpert machines and cartridges to high-burden HFs. HEAL TB also provided on-site support to ART clinics for TB screening, IPT, and CPT administration.

HMIS data showed that 92% of TB patients (all forms) notified in the last year were tested for HIV in the project-supported sites, up from a baseline of 77%. The testing rate was comparable in the two regions. The country-level percentage of HIV testing among TB patients in 2014–2015 was 79.9%, and the performance in the project-supported regions is significantly higher. These rates are among the highest across the regions; in comparison, Tigray region had a rate of 67.8%, and SNNPR had a rate of 57.4%, although both regions have health systems comparable to those of the HEAL TB-supported regions. The overall project TB/HIV co-infection rate was 7% at baseline and 6% at the end of the fifth year. The rate of HIV is high in Amhara, compared to Oromia Region. The higher TB/HIV co-infection rates in the Amhara Region are congruent with the higher HIV prevalence rates in the region (Figure 36). The co-infection rate

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FIGURE 37. Annual TB/HIV co-infection rate by zone, HMIS data (Oct. 2014–Sept. 2015)

(Average for total project area was 5.5%)

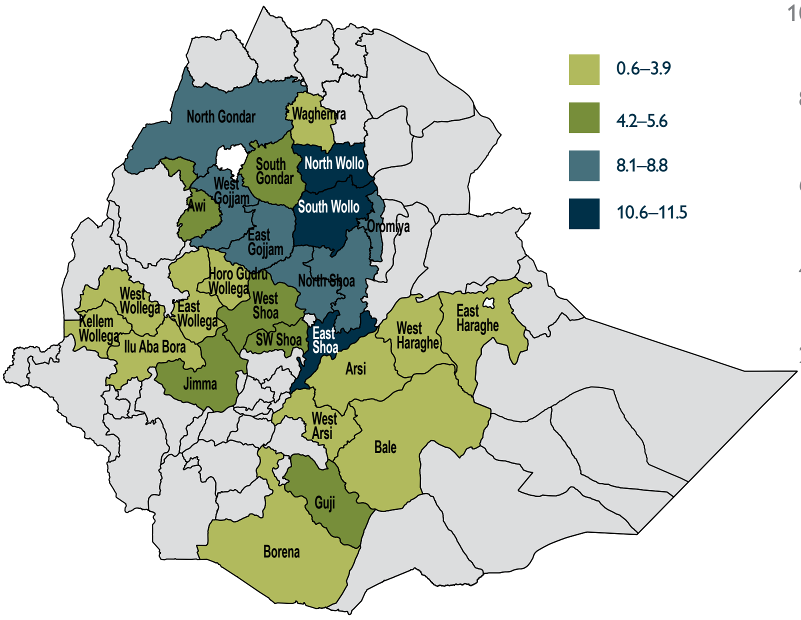
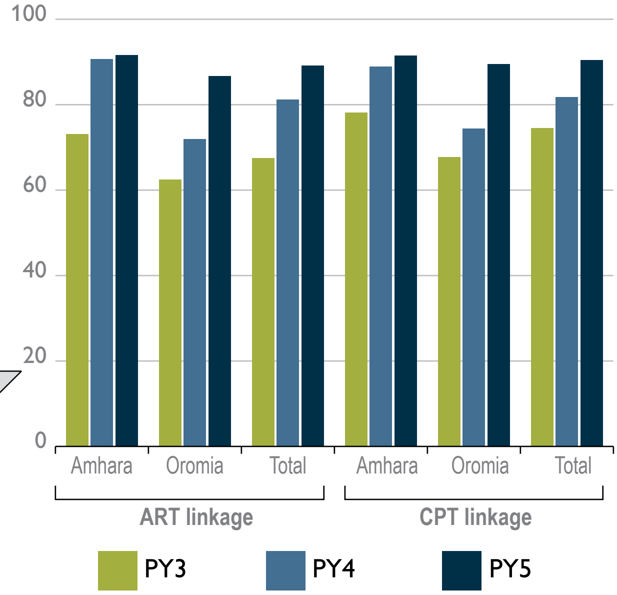


FIGURE 38. ART and CPT coverage (%) among TB/HIV co-infected patients (Jan. 2013–Dec. 2015)



was higher in some zones, specifically North Wollo (11%), South Wollo (10.6%), and East Shoa (11.5%). The lowest co-infection rate was recorded in the East Hararghe zone (0.6%) of the Oromia Region (Figure 37).

Enrollment of TB/HIV Co-infected Patients in HIV Care

Data from December, 31, 2015 showed that 88.6% of TB/HIV co-infected patients who were registered in the quarter were enrolled in chronic HIV/ART-care services; this is slightly higher than the 82.4% in the preceding quarter. The reported CPT uptake was 91.5%, which was slightly more than the preceding quarter. The performance in terms of ART uptake and CPT coverage in all three phases was comparable, as demonstrated by the latest quarterly SoC data (Figure 38).

8.4. LESSONS LEARNED AND RECOMMENDATIONS

- HIV testing and linkage to care has surpassed project targets, but more work is needed to better integrate TB and HIV services in selected areas with high risk factors for dual epidemics.
- Eighty-nine percent of TB patients diagnosed with HIV were put on ART in the fifth year, up from a baseline of 75% in the third year. CPT coverage is also more than 91%. The close monitoring of the *woreda* TB focal persons using the SoC is one reason for the improvement in enrollment. The SoC-led monitoring of activities by the *woreda* and the zonal and regional approach should be part of the system and the FMOH should make it a national tool.
- The screening of HIV/AIDS patients for TB and provision of IPT are required for PEPFAR implementers, but collaboration was not as strong as we wanted because of different organizations' interests. The introduction of GeneXpert, a sample transport system, and results notification benefit the HIV/AIDS program, so interagency coordination is critical. The completion of IPT is as important as its initiation, so there should be a strategy to monitor and report this indicator from the HIV side. The contact-screening approach we implemented in TB can serve also as an example to test sexual partners and families of HIV index cases.

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Key Achievements Section 9:

- ✔ 123 biomedical technicians were trained on basic preventive maintenance and repair for equipment, including microscopes.
- ✔ The trained technicians were able to salvage an estimated US$1.2 million worth of equipment.
- ✔ Infection control systems were implemented in more than 70% of health facilities.

SECTION 9. HEALTH SYSTEMS STRENGTHENING

9.1. IMPROVED INFECTION CONTROL

Baseline Gaps

At baseline, TB IC at health facilities was not known in most health facilities and not systematized in the few facilities that practiced it. In addition, few health facilities had IC plans, and health care workers lacked adequate knowledge about TB IC. In Phase I, of 691 health facilities only 60 (8.9%) reported the presence of an IC plan and there were almost none in the Phase II and III expansion zones. There was no triaging of coughing patients, and no health facility TB IC committees to organize interventions. In many health facilities, there were no separate TB rooms for service provision. The other major stumbling block in TB IC is that health facilities' design did not address TB IC during construction, which requires more investments and is beyond this project's scope.

Although the FMOH had TB IC guidelines, they had not been implemented and were designed mainly to increase knowledge rather than to operationalize procedures at health facility level.

Strategies to Improve TB Infection Control

HEAL TB took the following three major initiatives to improve the TB IC in health facilities: (1) provide training for all health workers on TB IC; (2) produce SOPs; and (3) conduct on-site mentorship.

1. Train health workers: HEAL TB trained one focal person per health facility to provide on-site training to all health workers in the 2,186 health facilities, establish TB IC committees, and monitor the implementation of TB IC in the health facilities.
2. Produce SOPs for operationalizing TB IC in health facilities: As shown in Figure 39 below, the SOP for TB IC was designed following the patient pathway from gate to exit, including disposal of infectious specimens. At each patient contact point, health workers were trained on how to practice TB IC measures including assessments. The SOP was prepared in Amharic to include administrative workers. (The SOP and monitoring tools appear in Annex C.)

FIGURE 39. The patient pathway guided TB IC implementation in health facilities

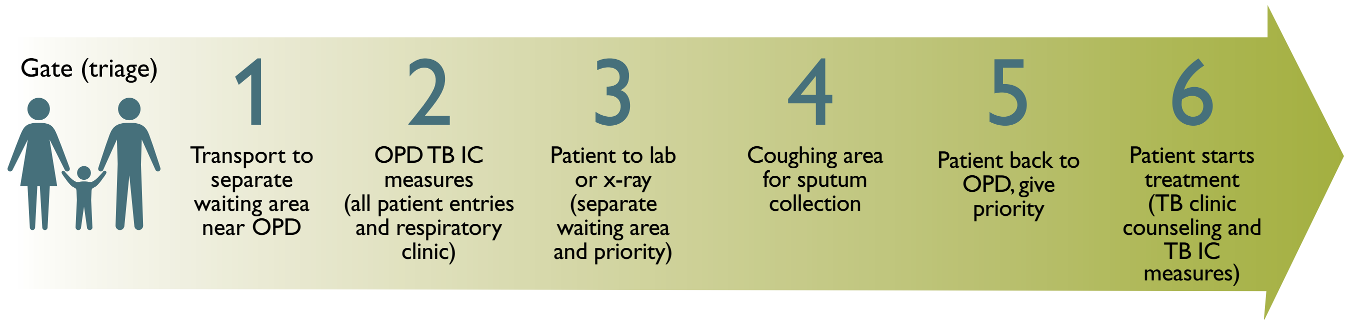
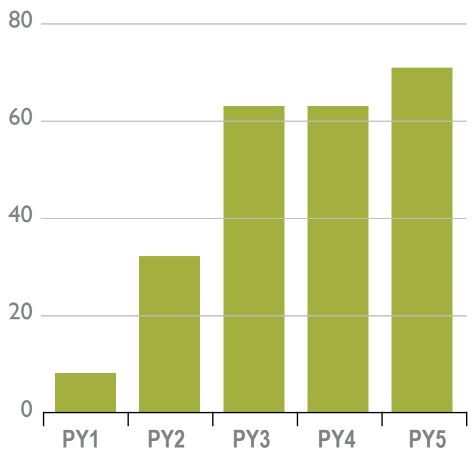


FIGURE 40. Percentage of health facilities with TB infection control plans



3. **Conduct on-site mentorship:** As part of the mentorship strategies described above, *woreda* TB focal persons monitor the implementation of TB IC in all health facilities and monitor its progress as well.

Results

Orientation on TB infection control and provision of materials. The project trained a focal person in all 2,186 health facilities and every health worker, including admin-strative staff and cleaners, received on-site training on TB IC. The orientation included practical demonstrations, drills, and case scenarios. Each health facility received the SOP and TB IC monitoring registers.

Orientation for zonal TB program managers on TB IC. A session on TB IC was given to all *woreda* TB focal persons and Health Extension Program coordinators from the 28 zones' TB focal persons in the two regions. Practical issues in IC, minimum TB IC packages for HFs, measurement of the ventilation status of a room, and respirator fit testing were among the topics covered.

Implementation of TB IC. Per the last quarterly report (Table 22 and Figure 40), 70.4% HFs had a TB IC plan, 72.5% had functional TB IC committees, and 72.6% were implementing prioritization and triaging of coughing patients. There was significant improvement in TB IC plans, from 8.9% at the beginning of the project to 70.4% in the last report. Phase I and II HFs were found to have better performance, while Phase III HFs had the lowest performance. Phase III HFs have demonstrated significant improvement compared to the previous quarter. However, they still need intensive support to improve their TB IC performance.

TABLE 22. TB infection control performance among health facilities in the project-supported zones (Oct.–Dec. 2015) (HFs SoC)

Indicator	Phase I	Phase II	Phase III	Total
TB IC plan	720 (74.2%)	515 (74.2%)	237 (55.5%)	1,472 (70.4%)
Functional TB IC committee (functional multidisciplinary team)	701 (72.2%)	551 (79.4%)	264 (61.8%)	1,516 (72.5%)
Prioritization of coughing patients (triage)	759 (78.2%)	520 (74.9%)	240 (56.2%)	1,453 (72.6%)
Total HFs	970	694	427	2,091

Development and distribution of implementation manual of TB IC. A total of 2,320 TB IC manuals (870 in Amharic and 1,450 in Oromiffa) were printed and distributed to HFs in the two regions.

HF risk assessment. The analysis showed that 60 hospitals and 11 HCs participated in the assessment (24 in Amhara and 47 in Oromia). A total of 60 (84.5%) HFs had TB IC committees, whereas only 41 (57.7%) had documented TB IC plans. Two-fifths of the HFs had an allocated budget for TB IC, and 55 (77.5%) reported practicing cough triage. Three-fourths of the respondents perceived that TB suspects at HFs could be a source of infection to others. Only six hospitals conducted surveillance on TB disease among staff. The incidence of TB among health workers was 460.3 per 100,000 per year, which was 6.5 times higher than the general population incidence. The result of the risk assessment was used for TB IC program support. It will also serve as a baseline to compare improvements following the interventions.

TB IC activity audit. Data were collected via checklists from all zones supported by HEAL TB. The audit showed that most zones managed to orient all *woreda* TB focal persons on facility TB IC risk assessment and how to plan TB IC activities in HFs. The distribution of TB IC manuals and planning templates to HCs was achieved by *woredas* in 16 zones of Oromia and five of Amhara.

TB IC material and equipment support. The project procured over 100,000 N-95 masks for TICs and TFCs, and 66 Vaneometers and 66 fit test apparatus were purchased and distributed to major hospitals.

9.2. LESSONS LEARNED AND RECOMMENDATIONS

The project has brought changes in health workers' knowledge and practices related to IC in the last five years. We have also introduced an SOP to standardize implementation, with some variation depending on the health facility set-up. In PY2 and PY3, our focus was on increasing knowledge but IC practices were not standardized. As an example, triaging was performed at the gate, waiting area, or card room because there was no standard until we realized that it should take place at the gate before the presumptive cases mix with other patients. By the end of the project, we had a very good model SOP to implement. The other lesson was that the risk of TB among health workers is very high, which could be the result of low awareness of the need for IC and poor design of health facilities.

We recommend implementing our designated SOP and monitoring its progress as part of other TB activities.

9.3. STRENGTHENING THE BIOMEDICAL ENGINEERING SYSTEM

Baseline Gaps

Biomedical engineering was not part of the original cooperative agreement, but we encountered the following challenges as we started implementation. Biomedical engineering is an almost forgotten part of the health care system in the FMOH. There was no clear national policy or strategy for it, and few biomedical technicians in few hospitals. These technicians are not well trained and did not have even simple tools to conduct preventive maintenance and basic repairs. In recent years, biomedical engineers have started to graduate but still the system lacks a clear strategy and plan for biomedical engineering to engage the few human resources in addressing the huge maintenance and repair needs of the country.

Initiatives to Address Some of the Challenges

A consultative meeting on biomedical engineering implementation in Ethiopia. At the request of the RHBs and as approved by USAID, HEAL TB started a biomedical engineering activity on a small scale. A consultative meeting was held in the second year to discuss the status of implementation of biomedical engineering in the country. The conclusions from the presentations of the two regions and EPHI showed that the biomedical engineering component of the health care system has not been addressed, and capacity in this area is weak in the country. The RHBs recommended that commitment at all levels (from facility to RHB) be mandatory to avert the medical equipment maintenance and management challenges in the regions. All health institutions in the regions need to develop comprehensive inventories of all the biomedical equipment that they currently own. Moreover, adequate funding should be made available to implement the program and facilitate the establishment of a regional biomedical equipment maintenance workshop. Finally, an equipment management and maintenance strategy for the country is a first step to address the huge challenges that Ethiopia is facing in this area. HEAL TB discussed these gaps with the FMOH, but because there is no responsible department or expert, we could not design a national strategy to integrate biomedical engineering into the health care system strategy of the country.

Training for biomedical technicians. HEAL TB, in collaboration with the Oromia and Amhara RHBs, trained 123 regional- and facility-level biomedical technicians. Follow-up and support were provided for microscope maintenance with regional maintenance units and MSH zonal lab specialists. Microscope spare parts were purchased and distributed. Two hundred toolkits bought and distributed to technicians in the two regions. Microscope spare parts were also bought and provided. We collected partial data on the equipment restoration completed by these trained technicians and estimate the market value [or savings] at about US$ 1.2 million.

Lessons Learned and Recommendations

The country does not have a clear strategy and policy on biomedical engineering. Thus, the FMOH has no clarity about where to assign the newly graduating engineers in the health care system, and the number of engineers required for the country is not known, nor is the composition of the experts required known. Workshop requirements and equipment referral systems have not yet been established. Training needs are not documented and guides do not exist. No plan and budget form part of the health care plan. We recommend to USAID to design a stand-alone biomedical engineering assistance project, as it is a priority for the country and USAID is investing millions of dollars for equipment purchases annually for use in Ethiopia.

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Key Achievements Section 10:

- ✔ A review was conducted of the literature and a baseline assessment created to understand how gender influences the demand for and supply of TB services.
- ✔ A mainstreaming strategy was developed based on the assessment.

SECTION 10. GENDER MAINSTREAMING

10.1. MAJOR FINDINGS OF THE ASSESSMENT

Gender and Risk

TB infection and disease risk behaviors for men include smoking tobacco, chewing khat, ingesting alcohol, and spending time in overcrowded social places. In the case of women, the risk was said to be associated with their gender roles—of being the ones who have to cook together in places that are poorly ventilated, both at home and on social occasions such as funerals and weddings. It was noted that even though women do the cooking, there are some communities where there are still restrictions on what women can eat, especially with regard to protein intake for pregnant women. Poverty worsens the malnutrition problem, especially among pregnant women, which makes them more vulnerable to TB infection and disease. In some communities, during situations of food scarcity, men not only get disproportionately more food but also the best food available, and are fed first as the heads of households, leaving women and often children to depend on leftovers. Other identified risk factors associated with gender were low family planning coverage, which makes many women have too many pregnancies in rapid succession with little time to recover between pregnancies. Frequent pregnancies may enhance the malnutrition problem in women of reproductive age.

Due to high illiteracy rates and high poverty levels, women tend to have lower access to prevention information when compared to men. The lack of information about TB by women may also be compounded by the less frequent attendance by women, as a result of preoccupation with domestic chores, at community meetings where health information on diseases such as TB is shared. Women may also be less free to attend such meetings if they have to ask their husbands for permission to participate in these meetings.

Gender and Health-Seeking Behavior

Culturally, in most Ethiopian communities, men and husbands are the decision makers, especially at the household level, which may affect women's ability to make decisions about their own health. It was noted, however, that with more women community health workers working with women at the household level, this is changing and more women are adopting positive health-seeking behavior. Women's domestic workloads may, however, still pose significant challenges to health care seeking and may contribute to delayed care seeking and therefore delayed TB diagnosis. These perceptions will need to be confirmed in well-designed studies on TB health care-seeking practices among men and women in Ethiopia. Additionally, the higher illiteracy rates among women may lead to poor understanding of TB symptoms, which could contribute to delays in seeking care. Delays in TB diagnosis are known to contribute to a higher rate of disease complications, including deaths.

Gender and TB Prevention

Unlike the issue of health-seeking behaviour, where women seem to be at a disadvantage, women may be advantaged by their contact with the health care system for maternal and child health services such as family planning and antenatal and postnatal care. However, this advantage may not be significant for those with TB, because many of these services have not yet integrated TB prevention messages and TB screening. The role of religious institutions as places for passing on prevention messages was seen as an important one that requires strengthening.

Gender and Case Finding, Diagnosis, Treatment, Care, and Support (Access and Treatment Outcomes)

One possible explanation for the higher TB case finding among men is that as the decision makers and the ones with more access to resources and information, men are more likely to seek medical attention, compared to women and girls, when TB symptoms set in. They control the resources and need not seek permission or ask to use resources for anything, including for their own health, as opposed to women, who must often get permission to seek care and ask for resources to facilitate care seeking. Women are also the ones who look after the sick at home, which not only exposes them to infection, but may also hinder early care seeking when their own heath is threatened. In some cases, women require permission

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from their husbands for some medical procedures like X-rays to be carried out, which may delay diagnosis. There are also gender issues related to treatment. Women may interrupt treatment if they get pregnant and may also have drug-drug interactions related to taking oral contraceptives.

For men, even if they have more power and resources to seek care and treatment than women, there are higher chances of treatment interruption due to gender-related behavior such as tobacco smoking, drug abuse, khat chewing, and alcohol consumption, which may contribute to poor judgment with regard to treatment adherence. Occupational opportunity costs may also play a role in reducing the likelihood of men to adhere to clinic and treatment schedules. Unlike women, who more often work at home and have a greater chance of interacting with community health care workers when the latter visit households, men mostly work away from home and may have less interaction with community health care workers.

10.2. CORE PRINCIPLES OF OUR STRATEGY

- Gender equity in access to health services including TB services
- Respect for social and cultural norms that promote gender equality, while discouraging those norms that may lead to inequality between men and women in the delivery of health interventions including TB interventions
- Promotion of societal/community (by both men and women) ownership of health services, including TB services
- Recognition that men and women are different biologically and socially with regard to willingness to transform gender relations

10.3. KEY COMPONENTS

- Ensure early TB diagnosis for men and women (or increase effectiveness of TB case finding and diagnosis for men and women).
- Address and prevent gender-related treatment interruption (promoting adherence).
- Combat gender-based TB stigma and discrimination.
- Promote TB data disaggregation by sex and age to monitor burden of disease and treatment outcomes in men and women during their lifecycles.

10.4. RESULTS

In the first year of the project, we conducted a multi-stakeholder workshop and consultations to consolidate what had been learned from the literature review and the field visits. Following that a gender mainstreaming strategy was developed.

The strategy was implemented by creating awareness among health workers and HEWs to consider the particular needs of men and women in their services. As mentioned above, in community TB care, orienting thousands of women HDAs in TB screening, and having them serve as treatment supporters and promoters of TB prevention will address some of the gender disparities we have observed.

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SECTION 11. STRATEGIC FRAMEWORK AND INDICATORS TO ENSURE THE SUSTAINABILITY OF CAPACITY-BUILDING ACTIVITIES: RECOMMENDATIONS FOR UPCOMING USAID PROJECTS AND THE GOVERNMENT

11.1. BACKGROUND

While there is no single agreed-upon definition of sustainability in the heath or development sector, the most popular definition of sustainability is the 1987 UN-sponsored Brundtland commission report, which defined sustainable development as "development that meets the needs of the present without compromising the ability of the future generation to meet their own needs." The same report and others posit that the three main pillars of sustainability are social, environmental, and economic.[24] A review of research papers on sustainability in health shows that nine factors are critical for sustainability: (1) funding stability for making long-term plans based on a stable funding environment, (2) political support, both internal and external, which will have a role in funding, (3) initiatives and acceptance of new policies and strategies, (4) organizational capacity to effectively manage the program, (5) program adaptation, (6) program evaluation, (7) communications, (8) public health impacts related to effects on health attitudes, perception, and behaviors, and (9) strategic planning.[25]

These conceptual frameworks tell us that sustainability involves many areas and raise the question of whether sustainability is within reach for a single short-term project such as HEAL TB. It is expected that short-term, focused projects should be able to contribute to the bigger sustainability plan of the country, but it might not be possible to fully claim the responsibility of sustainability in a project with limited scope.

There is also no universally accepted indicator of sustainability to measure whether work is sustainable or not, in terms of time frame or place and from the perspectives of people or patients. There is also a tendency to consider that capacity building is the same as sustainability. In our view, capacity building can be a part of a sustainability strategy, but having very good capacity by itself cannot sustain the services required. A case in point is that a health facility might have the best-qualified health professionals and diagnostic means, but may lack the reagents and drugs to sustain the best services.

Capacity is defined as "the ability of individuals and organizations or organizational units to perform functions efficiently, effectively, and sustainably." Capacity building is "an evidence-driven process of strengthening the abilities of individuals, organizations, and systems to perform core functions sustainably, and to continue to improve and develop over time."[26] It is believed that capacity is directly linked to improved performance in the health sector and that capacity plays a critical role in sustaining performance over years. However, there have been few frameworks and tools to monitor and evaluate the effectiveness of capacity-building interventions in the health sector. Several attributes distinguish capacity from other forms of technical assistance, including its being context-specific, dynamic and volatile, and multidimensional.

It is not the aim of this report to discuss sustainability in detail, but to consider what we implemented and make recommendations for the future. HEAL TB designed capacity-building approaches that enable sustainability if the same or a reduced level of resources was allocated after the end of the project. The principles we followed at the design stage were the following:

- Inasmuch as possible, integrate the project within the government's policies and strategies and implement it within the existing health system, rather than creating a parallel structure. We endeavored to carry out all activities not by ourselves, but rather with the full involvement of the system's leaders, so that we could address the gaps identified together.
- Create innovative approaches that can be applied within the existing system and help to build the capacity of the TB program and others. A case in point is the integrated sample transport system, in which both TB and HIV programs require transportation of samples to higher-level labs, but there was no mechanism to transport samples at the required temperature and in a timely way. A sample transport courier system with digital technology to provide results was designed. Using the courier not only improved the quality of sample transport but also reduced the cost, because the system can transport samples en masse. Furthermore, it will help the country in the future to establish a few specialized laboratories instead of buying equipment for many labs, which has implications for the budget, human resources needed, equipment maintenance, and supplies.

- Our designs should be patient-centered, meaning that they should be able to reduce patients' time, discomfort due to impersonal, bureaucratic services, and indirect costs. The mixed model of MDR-TB services, and community TB services, described in the above sections are examples.
- No matter how it is defined, sustainability should be designed at the beginning of the project, with regular revisions and updates in the sustainability plan as experiences are gained.

With these principles in mind, HEAL TB designed its capacity-building approaches at the beginning of the project and as we gained more experience, together with the FMOH, RHBs, EPHI, PFSA, RRLs, zones, *woredas*, and HEWs, many areas of implementation were modified and new ways of doing things developed, piloted, implemented, and monitored. In PY5, we evaluated again which parts of the implementation had gone well and which needed strengthening, which will be inputs for the government and other USAID-funded projects working in TB. The following strategic framework was discussed with USAID.

11.2. PURPOSE OF THIS STRATEGIC FRAMEWORK

The overall purpose of this strategic framework was to ensure that the investments made through HEAL TB in strengthening regional TB program activities will be sustained and continue to provide effective and quality services to beneficiaries after the end of the HEAL TB Project activities.

11.3. KEY ACHIEVEMENTS TO ENSURE SUSTAINABILITY

MSH, through its USAID-funded HEAL TB project, as it does in many other projects globally, has been working to build and strengthen local capacity to effectively run and sustain TB control programs at the national and subnational levels. During the first two years of project implementation, HEAL TB focused on direct site-level technical support, which resulted in dramatic improvements in performance indicators. In addition to the direct site-level support, HEAL TB put considerable effort into improving the health infrastructure for TB control, including equipping and furnishing health facilities and training health care workers. Beginning in PY3, HEAL TB's scope of work and geographic coverage were expanded to cover nearly half of the Ethiopian population (Table 23).

This huge expansion in the project's scope of work with the same level of funding demonstrates the efficiency gains achieved through a redesigned technical assistance model that effectively built the capacity of zonal and *woreda* TB focal teams to mentor and support the health facilities in their catchment area. In this decentralized technical assistance model, HEAL TB's major areas of technical support included:

- deploying zonal HEAL TB teams (an MD or Health Officer and a lab specialist), who sit within the zonal health departments and work as integral part of the team;
- conducting capacity building needs assessment;
- filling gaps (materials and supplies) as needed;
- providing orientation, training, and tools for supportive supervision and mentoring;
- co-organizing and participating in quarterly review meetings; and
- making joint site visits to selected sites to ensure that capacity-building activities are translated into optimal supportive supervision at the service delivery and patient levels, including community-level activities. Table 24 summarizes progress in major areas of sustainability.

The redesigned model was well received by the local health authorities and the NTP. In this section, we outline the framework and indicators of success for the redesigned capacity-building model.

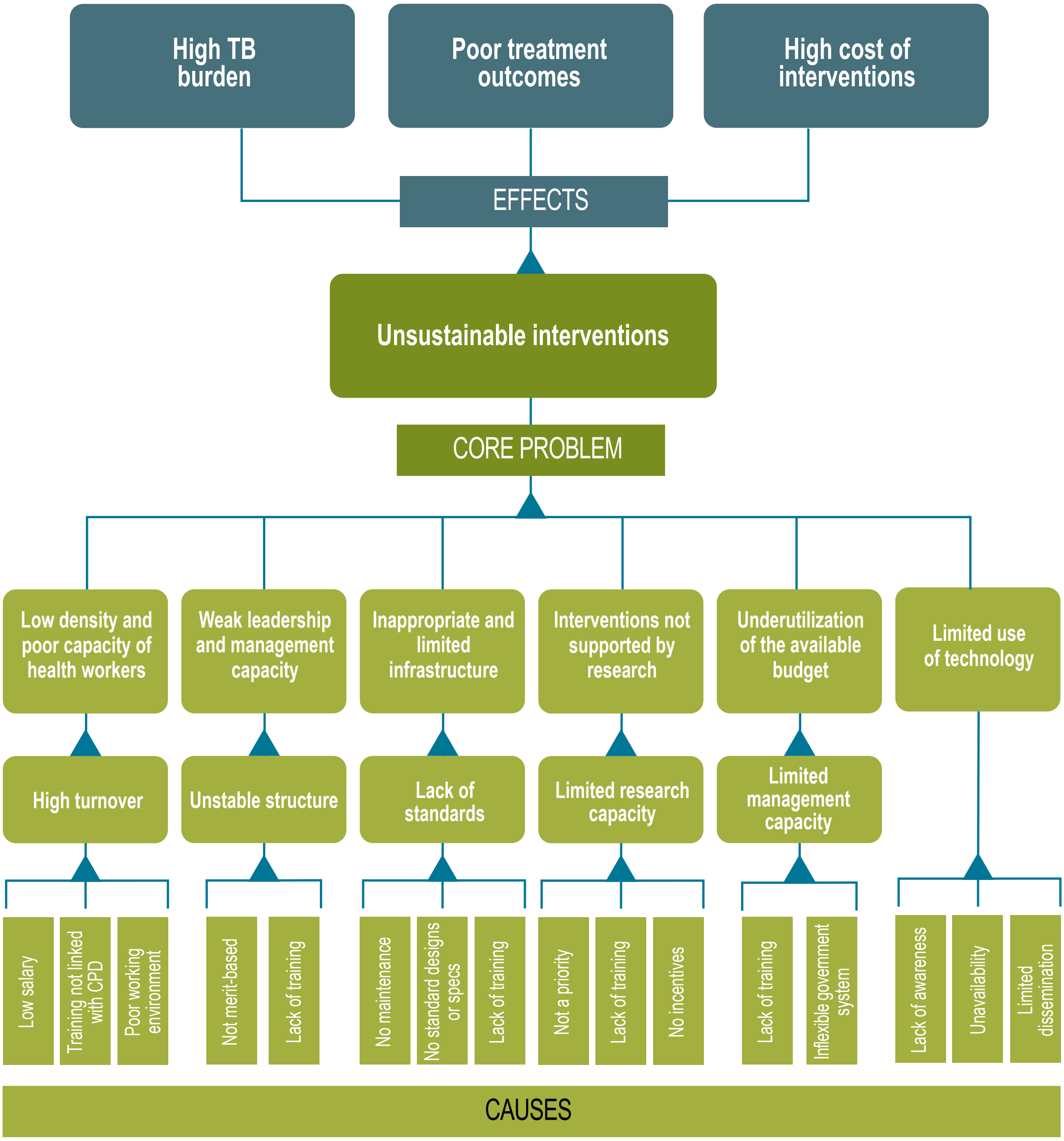
TABLE 23. HEAL TB-supported institutions and populations as of July 2016

Units	Number
Number of zones	28
Number of *woredas*	471
Number of health centers	2,122
Number of hospitals	64
Number of health posts	9,967
Population (millions)	54.5

TABLE 24. Summary of the progress of the HEAL TB project toward sustainability

Sustainability issues	Project performance
Human resources for health	■ Blended learning piloted and rolled out as a standard training approach ■ ALERT training center spearheading blended training initiatives, which the center will continue ■ Human resource information system for health workers trained in TB program management underway ■ Project support for creating a pool of trainers in TB program management, laboratory services, etc. ■ Huge number of clinical and laboratory staff and HEWs trained on TB
Leadership and management	■ Advocacy for TB to be a priority, making it a routinely reportable priority disease ■ Successful advocacy to RHBs on the need to assign laboratory specialists to zonal health offices ■ *Woreda* TB focal persons now fully in charge of mentoring HFs using the SoC tool—which was initially carried out by HEAL TB staff ■ Zonal and *woreda* HP coordinators now engaged to oversee TB-related activities at HPs ■ HEAL TB staff at national, regional, and zonal levels who continue to actively engage their counterparts in project planning, implementation, monitoring, and evaluation to ensure ownership and continuity of leadership at all levels ■ SoC management tool used in all *woredas* in the two regions; FMOH NTP team approached to use it at national level ■ Support to the FMOH in the printing of register cards for treatment supporters and presumptive-TB cases and their inclusion in the family folder ■ Political and religious leaders involved to foster ownership, trust, and continuity ■ Creation of working relationships among sectors in TB program implementation, such as the FMOH and telecommunications companies; engagement of teaching institutions in research and capacity building ■ EQA decentralized from RRLs to referral hospitals, which increased coverage and ensured continuity of services ■ HEAL TB technical staff actively engaged in the national TWGs for policy formulation as well as preparation of the national strategic plan, roadmap, and guidelines that will help the national program over the years
Financing	■ RHBs starting to cover the cost of TB program activities such as EQA ■ Health facilities starting to use their regular budget for the renovation of health facilities, payment for internet line, etc.
Infrastructure	■ Evaluation on TB IC done by international consultant and feedback given to FMOH and RHBs on the gaps ■ HEAL TB engineer working with government counterparts to improve infrastructure, revise the FMOH-approved HF design, and build the capacity of government staff ■ Renovation of TICs done in some HFs that ensures the continuity of MDR-TB treatment and follow-up in those centers ■ Training on equipment maintenance provided in both regions and trainees on board for maintenance
Technology	■ Integrated sample transport introduced and at a pilot stage using SMS and internet technology ■ Video-conferencing established ■ Blended learning using electronic reading materials ■ GeneXpert expansion that improved access to services and reduced turnaround times ■ Use of computers for EQA, MDR-TB database, IPLS, etc. ■ Training of pharmacy staff on QuanTB software, a new forecasting and quantification tool
Service delivery	■ SOPs for different aspects of TB program introduced to standardize TB program implementation ■ Lab capacity built at regional level on DST ■ Integrated sample transport ■ Decentralization of TICs that improved access to health services at zonal levels ■ Decentralization of DOTS to HPs and treatment supporters
Research and innovation	■ Involvement of teaching institutions in operational research and creation of demand and networking that will continue in the future ■ FMOH and RHB staff empowered by being part of publications and abstract presentations ■ Publication of project experiences in peer-reviewed journals to be used as a resource at national and global levels ■ Involvement in the selection of priority TB research agenda with the FMOH ■ Support for the TB Research Advisory Committee conference, where a number of research findings and emerging issues were shared among experts from all regions of Ethiopia ■ Evidence generated by the project used to improve practices (e.g., the introduction of iLED EQA) ■ Introduction of innovative approaches such as enhanced case finding, retrospective TB contact screening, smear preparation, and referral, which can be applied on a larger scale in the subsequent years ■ Model DOTS and TB IC health facilities introduced that will serve as a resource in the years to come

FIGURE 41. Problem tree analysis of causes and effects of unsustainable TB program interventions



11.4. REMAINING THREATS TO AND GAPS FOR SUSTAINABILITY

Through a consultative process that involved major stakeholders, we identified major threats to sustainable TB program interventions in HEAL TB-supported regions. Broadly, the challenges can be categorized into: human resources for health, leadership and management, financing, infrastructure, technology, and research and innovation (Figure 41).

Suggested Reponses to the Threats

In Figure 42 on the following page, we depict the solution tree derived from the problem analysis. This also formed the basis for the strategic objectives and indicators detailed below.

11.5. GOALS AND OBJECTIVES

Goal

To ensure the sustainability and continuity of key interventions started through USAID/HEAL TB investments.

Objectives, Strategies, and Activities

Objective 1: Strengthen TB program leadership and management capacity

- Help RHBs design well-studied structures where the TB program will have a dedicated coordination unit or directorate.
- Support short-term trainings in TB program leadership and management.
- Continue to transfer skills and tools in the areas of planning, monitoring, and evaluation.
- Institute the SoC as a standard monitoring and evaluation (M&E) and capacity-building tool within the RHB structure.

Objective 2: Strengthen human resource capacity at regional, zonal, *woreda*, and service delivery levels

- Continue to support RHBs and local universities to institutionalize in-service training.
- Provide technical and material support to roll out blended/on-site learning approaches and link them with continuing professional development.
- Support RHBs in the design of retention mechanisms for health workers:
    - Standardize criteria for transfer/rotation of health workers.
    - Strengthen human resource information system (HRIS).
    - Institute recognition/reward mechanism for staff working in TB clinics.
    - Improve the work environment through improved IC interventions.
    - Promote merit-based promotion.

Objective 3: Improve financing for TB program support

- Advocate for increased budget allocation by the GOE through better resource mapping.
- Assist in designing mechanisms for generating local revenues for TB program support.
- Provide short-term trainings in financial management.
- Coach and support government staff to modernize the financial management system.

Objective 4: Improve health infrastructure

- Assist RHBs in defining building designs that are infection-control-friendly.
- Support proper needs identification, specification, and standardization of equipment used in TB program management.
- Institute regular equipment maintenance systems.
- Support establishment of specialized equipment/lab services.

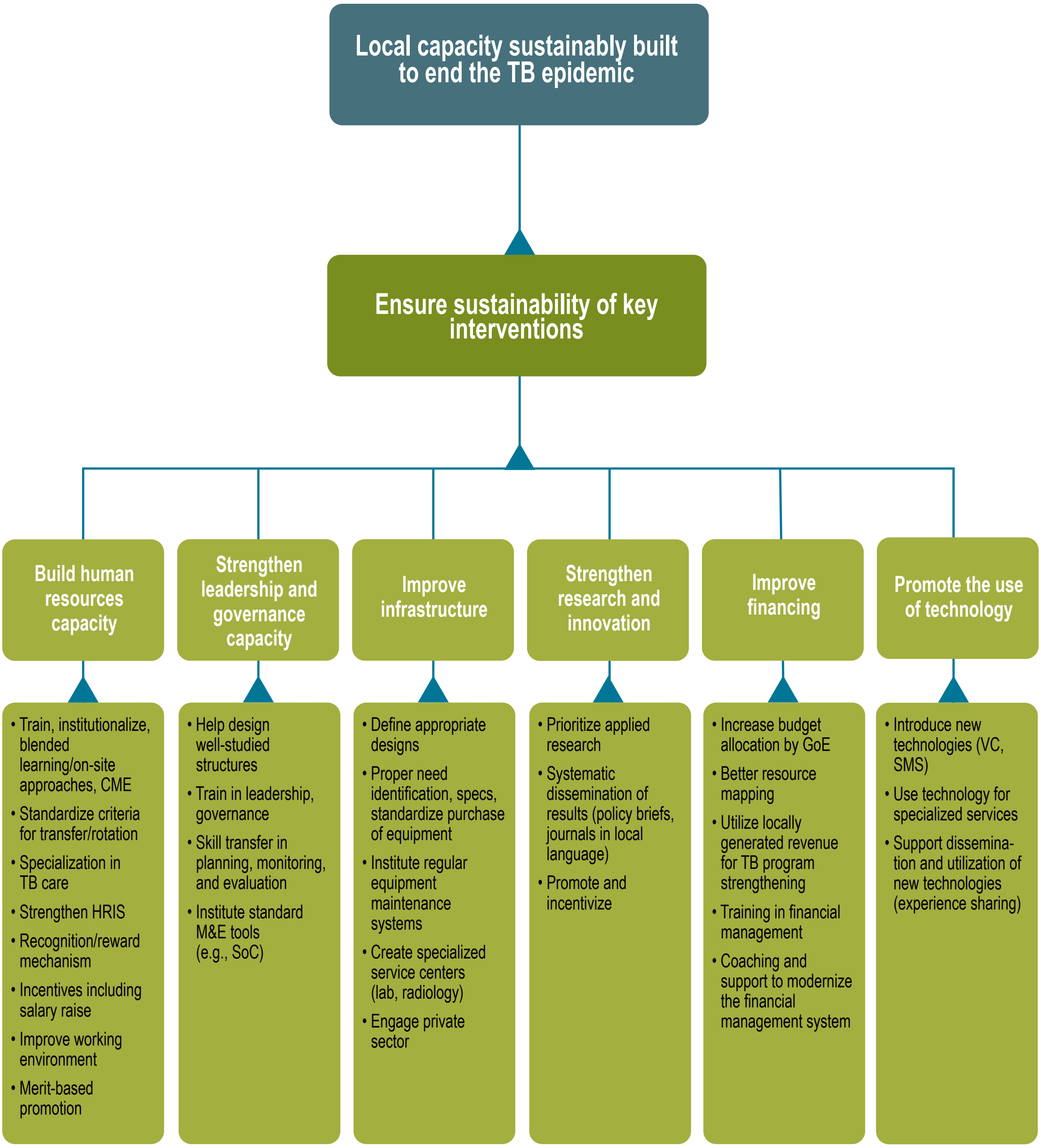
Objective 5: Promote the use of technology in TB service delivery

- Provide support to introduce new technologies for TB service delivery and program management (e.g., videoconferencing for training and SMS/internet system for case notification and delivery of results).
- Support dissemination and utilization of new technologies by organizing experience sharing and skills transfer forums.

Objective 6: Strengthen evidence generation and innovation for evidence-informed decision making at local level

- Assist in prioritizing implementation research as part of the routine work in TB programs.
    - Support systematic dissemination of evidence generated through HEAL TB.
    - Prepare policy briefs and TB updates in local languages.
- Promote and incentivize research.

FIGURE 42. Solution tree, derived from the problem tree (Figure 41)



Objective 7: Strengthen key but recently-introduced TB program components

Some recently introduced program components are still in a very early stage of development. They therefore require continued direct technical support. These program areas include:

- MDR-TB program support
- Childhood TB services
- TB in "hot spots," including pastoralist communities and mining/farming areas
- Newly introduced TB diagnostic tools
- Contact screening

Strategies and activities to support these areas include:

- Continue to provide robust direct technical support in strengthening the MDR-TB service delivery.
- Support the FMOH and RHBs in improving childhood TB case finding and treatment outcomes, including IPT using contact screening as an entry point,
- Support implementation of innovative case-finding strategies in "hot spots," and contact screening.
- Continue to assist with the roll-out of GeneXpert and iLED.

11.6. MONITORING AND EVALUATION FRAMEWORK

Traditional M&E focuses more on measuring performance and less on measuring the process through which performance is achieved. The M&E of capacity building often does the reverse—it focuses more on measuring the processes and other qualitative aspects of the capacity-building interventions. The M&E of capacity building should normally be an integral part of the overall M&E plan, but lack of standardized approaches and indicators for capacity building makes the M&E of capacity building more difficult to measure. In Table 25, we outline selected capacity-building output and outcome indicators.

TABLE 25. Proposed output and outcome indicators for capacity-building objectives 1-6

Objective	Capacity output indicators	Outcome indicators
Objective 1: Strengthen TB program leadership and management capacity	■ Number/proportion of RHBs, zonal health departments, *woreda* health organizations, and PHCUs with clearly defined structure for TB program management	■ Strengthened local management capacity to run strong TB program at all levels
Objective 2: Strengthen human resource capacity at regional, zonal, *woreda* and service delivery levels	■ Number/proportion of RHBs, ZHDs, and WHOs with a full-time TB focal person ■ Number/proportion of HFs with adequate number of trained health workers retained in TB clinics for at least two years after assignment	■ Evidence of improved TB service quality from routine program reports
Objective 3: Improve financing for TB program support	■ Number/proportion of RHBs allocating budget from government sources for TB service delivery ■ Proportion of HF's internal revenues being used to improve TB services	■ Core functions of TB programs implemented with limited external support
Objective 4: Improve the health infrastructure	■ Number/proportion of RHBs implementing standardized designs for HF buildings and equipment	■ Evidence of decreased occupationally acquired TB infections
Objective 5: Promote the use of technology in TB service delivery	■ Number/proportion of eligible HFs implementing GeneXpert ■ Number/proportion of ZN microscopes replaced by iLED	■ Improved case detection due to improved diagnostic techniques
Objective 6: Strengthen evidence generation and innovation for evidence-informed decision making at local level	■ Number/proportion of RHBs with dedicated budget for TB research and budget ■ Number of research outputs produced	■ Evidence of locally generated evidence being used to improve TB program functioning

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SECTION 12.
OPERATIONAL RESEARCH AND INNOVATIONS

12.1. BACKGROUND

In the first year of the project, broad operational research priorities were identified. We defined the objective of generating knowledge to design evidence-based interventions and to assist performance and decision-making by the FMOH, USAID, and the HEAL TB Project. The operational research priorities identified by the FMOH, in collaboration with stakeholders, for the period 2012–2015 are shown in Table 26, on the next page. Taking the national research priorities into consideration, HEAL TB implemented studies on many of the questions listed in that table. Research strategies were designed in collaboration with the FMOH, RHBs, RRLs, and universities. Research was implemented mainly through monitoring routine implementation through the robust data collected using the SoC indicators and HMIS, as well as specially designed targeted research studies.

12.2. RESULTS

Twenty-one articles have been published, or are forthcoming, or are drafted at the time of this report. In the coming year, we will publish more articles from the data accumulated over the last five years. Seventy abstracts have also been presented in international forums, such as the annual conference of the International Union against Tuberculosis and Lung Disease, national TRAC conference, and others. The research articles helped the project, RHBs, and the FMOH to make informed decisions, introduced new innovations, and shared experiences with national and international audiences. The publications and program innovations are listed in Table 27, page 99. Detailed descriptions of the program innovations are provided in earlier sections. The list of abstracts appears in Annex D.

12.3. LESSONS LEARNED AND RECOMMENDATIONS

- Operational research agendas should be developed at the beginning of the project and be updated with more information as it is gathered. The research agendas should be able to answer questions about project implementation challenges and respond to the needs of the FMOH.
- Operational research studies should not be stand-alone projects, rather integrated with project implementation. With the same program implementation resources, the data collected are more reflective of the routine implementation challenges and success. The findings acquired through routine implementation can better inform implementation.
- There is still a need for research studies to be designed that use data other than those available from the routine data collection system, and for this type of research, involving universities and interested researchers in the country can help to develop a national pool of experts for the country.

TABLE 26. National TB operations research priorities of the FMOH for 2012-2015

Key Areas	Priority Questions
1. Improved case detection and diagnosis	■ How can case finding best be enhanced in different settings? ■ What are the health system, community, and patient barriers for case finding? ■ What are the burden and predisposing factors for TB in congregate settings? ■ What is the best way to implement contact tracing and screening? ■ Which high-risk populations should be screened for drug-susceptible and MDR-TB? ■ How can diagnosis and treatment of TB in children be improved? ■ How can new diagnostic services be brought nearer to the community? ■ How can the use and scale-up of new diagnostic tools be optimized? ■ What is the best way to develop capacity in quality assurance for peripheral laboratories and scale it up?
2. Sustainable collaboration with all care providers for TB control	■ What are the barriers for optimal public-private partnerships in TB control? ■ What are the potential contributions of different care providers in TB control?
3. Prevention of TB in people living with HIV, and joint treatment of HIV and TB	■ What are system and client factors affecting uptake of INH prophylaxis? ■ How can we best rule out active TB in high-risk populations by screening? ■ How "early" is ART initiated in TB/HIV co-infected populations? ■ How can joint TB and HIV interventions be best integrated and delivered at different levels? ■ What are the barriers to adherence to treatment of TB/HIV co-infected people?
4. Access to and delivery of treatment for drug-susceptible and M/XDR-TB	■ How can new technologies (e.g. mobile phones) be effectively used to improve treatment adherence? ■ What is the best model of service delivery (e.g., DOTS vis a vis socioeconomic condition, role of treatment supporters, quality of care, etc.)? ■ What are the best practices in the management and scaling up of MDR-TB? ■ What are the best strategies for scaling up MDR-TB management in Ethiopia? ■ What are the barriers for an efficient pharmaceutical and lab reagent supply?
5. Improved community participation and investigation of the effectiveness of community level interventions	■ What sort of communication strategy is effective in improving community participation in TB control? ■ What are the barriers and enabling factors for community-level interventions (HEWs, HDA performance, etc.)?
6. Capacity-building for operational research	■ What sort of funding mechanism is needed for capacity building in operations research at the national level?
7. Optimization of infection control to reduce TB transmission	■ How can we assess the adoption and implementation status of infection control measures? ■ What is the best combination of infection control interventions in reducing TB transmission?

TABLE 27. Published and draft manuscripts of the HEAL TB Project

Title	Published/submitted/draft
Sileshi B, Deyessa N, Girma B, Melese M, Suarez P. Predictors of mortality among TB-HIV co-infected patients being treated for tuberculosis in Northwest Ethiopia: a retrospective cohort study	*BMC Infectious Diseases* 2013, 13:297
Hirpa S, Medhin G, Girma B, Melese M, Mekonen A, Suarez P, Ameni A. Determinants of multidrug-resistant tuberculosis in patients who underwent first-line treatment in Addis Ababa: a case control study	*BMC Public Health* 2013, 13:782
Kibret KT, Yalew AW, Girma Belaineh G, Melese M. Determinant factors associated with occurrence of tuberculosis among adult people living with HIV after antiretroviral treatment initiation in Addis Ababa, Ethiopia: a case control study	*PLoS One* 2013, 8(5): e64488. doi:10.1371/journal.pone.0064488
Jerene D, Melese M, Kassie Y, Alem G, Daba SH, Hiruye N, Girma B, Suarez P. The yield of a tuberculosis household contact investigation in two regions of Ethiopia	*Int J Tuberc Lung Dis.* 2015, 19(8):898–903
Mekonnen F, Tessema B, Moges F, Gelaw A, Eshetie S, Kumera G. Prevalence of MDR-TB and risk factors in West Armachiho and Metema *woredas* of North Gondar	*BMC Infectious Diseases* 2015, 15:461
Melese M, Jerene D, Alem G, Seid J, Belachew F, Kassie Y, Habte D, Negash S, Ayana G, Girma B, Haile YK, Hiruy N, Suarez PG. Decentralization of external quality assurance using blind rechecking for sputum smear microscopy in Ethiopia	*PLoS One* 2016, 11(3): e0151366. doi:10.1371/journal.pone.0151366
Umubyeyi AN, Bonsu F, Chimzizi R, Jemal S, Melese M, Ruttoh E, Mundy C. The role of technical assistance in expanding access to Xpert® MTB/RIF: Experience in sub-Saharan Africa	*Public Health Action* 2016, 6: doi.org/10.5588/pha.15.0069
Tadesse Y, Gebre N, Daba S, Gashu Z, Habte D, Hiruy N, Negash S, Melkieneh K, Jerene D, Haile YK, Kassie Y, Melese M, Suarez P. Uptake of isoniazid preventive therapy among under-five children: TB contact investigation as an entry point	*PLoS One,* 2016, 11(5): e0155525. doi:10.1371/journal.pone.0155525
Dememew ZG, Habte D, Melese M, Hamusse SD, Nigussie G, Hiruy N, Girma B, Kassie Y, Haile YK, Jerene D, Suarez G. Trends in tuberculosis case notification rates and treatment outcomes following four years of focused interventions in ten selected zones in two regions of Ethiopia	*Int J Tuberc Lung Dis.* 2016 Sep; 20(9):1192-8. doi: 10.5588/ijtld.16.0005
Gashu Z, Jerene D, Ensermu M, Habte D, Melese M, Hiruy N, Shibeshi E, Hamusse SD, Nigussie G, Girma B, Kassie Y, Haile YK, Suarez P. The yield of community-based "retrospective" tuberculosis contact investigation in a high burden setting in Ethiopia	*PLoS One*, 2016; 11(8): e0160514. doi:10.1371/journal.pone.0160514
Habte D, Melese M, Hiruy N, Gashu Z, Jerene D, Moges F, Yifru S, Girma B, Kassie Y, Haile YK, Suarez PG, Tessema B. The additional yield of TB among TB contacts with GeneXpert test and the contribution to reduce the TB incidence	*Int J Infect Dis*. 2016, 49:179-84.
Hamusse SD, Teshome D, Hussen MS, Demissie M, Lindtjørn B. Primary and secondary anti-tuberculosis drug resistance in Hitossa District of Arsi zone, Oromia Regional State, Central, Ethiopia	*BMC Public Health* 2016, 16:593
Delays in tuberculosis diagnosis and treatment in pastoralist versus non-pastoralist communities in three agro-ecologically different zones in Oromia Region of Ethiopia	Accepted by *Pan African Medical Journal*
Decentralized, ambulatory model of care for management of multi-drug resistant tuberculosis in resource-limited settings: successful example from Ethiopia	Submitted for publication
Vitamin D deficiency among smear positive pulmonary tuberculosis patients and their tuberculosis negative household contacts in Northwest Ethiopia: a cross-sectional study	Submitted to *Annals of Clinical Microbiology and Antimicrobials*
The yield and feasibility of tri-directional screening for TB, diabetes and HIV in four public hospitals in Ethiopia	Submitted for publication
Standard of care indicators as mentorship, quality control and performance improvement tool in tuberculosis program management	Submitted to *Health Policy and Planning*
The pattern of rpoB gene mutations from *Mycobacterium tuberculosis* isolates of pulmonary TB patients using Xpert® MTB/RIF in Amhara and Oromia Regions, Ethiopia	Drafted
Comparison of the yield of drug sensitive and MDR-TB contacts	Drafted
Results of blind rechecking for LED fluorescence microscopy in Ethiopia	Drafted
Comparison of TB lymphadenitis yield using FNA cytology and GeneXpert	Drafted

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APPENDICES

Appendix A. Performance Monitoring Plan and Achieved Results, July 15 2011–July 14, 2016

Indicator		PY1 Target	PY1 Actual	PY1 %	PY2 Target	PY2 Actual	PY2 %	PY3 Target	PY3 Actual	PY3 %	PY4 Target	PY4 Actual	PY4 %	PY5 Target	PY5 Actual	PY5 %
Result 1 (Expected Outcome 1): HEAL TB performance shall assist the regional/zonal TB programs to reach a minimum case detection rate of 70% and treatment success rate of 85% of detected cases in the respective																
Technical Area 1.1. Political Commitment																
1.1.1	No. people covered by USG-supported health financing arrangements	23,500,000	23,500,000	100	25,700,000	25,600,000	100	41,000,000	50,800,000		50,000,000	54,546,761	101	55,000,000	54,546,761	100
1.1.2	Number of *woreda* annual operational planning meetings conducted	193	163	84	187	188	100	361	348	96.3	471	471	100	471	n/a	n/a
Technical Area 1.2. Strengthening Laboratory Services and Systems																
1.2.1	Total number of HFs capacitated to provide TB microscopy diagnosis	691	484	70	691	691	100	1,301	1,614	124	1,600	1,550	97	1,550	1,550	100
1.2.2	Number of laboratory professionals trained in AFB microscopy, internal and external quality assurance	1,180	1,071	90.7	n/a	870	n/a	1500	1175	78	528	368	70	200	0	0
1.2.3	Percent of USG-supported laboratories performing TB microscopy with over 95% correct microscopy results	70	90	n/a	95%	97.20%	n/a	95%	96%	n/a	95%	96.10%	n/a	95%	96%	n/a
1.2.4	TB microscopy laboratory coverage in USG-supported areas	90	70	n/a	100%	100%	n/a	100%	>100%	n/a	100%	>100%	n/a	100%	>100%	n/a
1.2.5	TB laboratory quality assurance for smear microscopy in USG-supported areas	691	353	51	691	607	87.8	1,041	957	92	1,600	1,550	97	1,264	1,550	122
1.2.6	Number of health posts that collected sputum smear from TB suspects	3,380	*not approved by FMOH*													
Technical Area 1.3. Ensuring that Standard TB Regimens are Administered Correctly																
1.3.1	Number of Health Centers and Hospitals providing DOT (treatment)	691	691	100	691	691	100	1301	2186	168	1600	2186	136	2,185	2,186	100
1.3.2	Number of health care workers trained on DOTs with USG funding	1,180	1,052	89.1	2,000	1,660	83	1,500	2,042	136	2,000	2,071	103	500	822 (additional 990 got refresher)	>100
1.3.3	Number of medical and para-medical practitioners trained in evidence-based clinical guidelines (HWs and HEWs)	3,380	0	0	n/a	n/a	n/a	0	0		0	0		0	n/a	
1.3.4	Number of Health Posts able to screen for TB	3,380	0	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a		n/a	n/a	

Indicator		PY1			PY2			PY3			PY4			PY5		
		Target	Actual	%	Target	Actual	%	Target	Actual	%	Target	Actual	%	Target	Actual	%
1.3.6	Case notification rate of new sputum smear positive pulmonary TB cases per 100,000 population in USG-supported areas	82	44.6	n/a	65	40	n/a	65	34	n/a	55	42	76	55	44	80
	Case notification rate of all forms of TB cases per 100,000 population in USG-supported areas													146	135	92
1.3.7	Percent of the estimated number of new smear-positive pulmonary TB cases that were detected under DOTs (i.e., case detection rate)	50	*estimated incidence rate for Ethiopia is not available to calculate the case detection*	n/a	n/a	n/a	n/a	n/a	n/a	n/a	146	135.2	n/a	n/a	n/a	
	CDR of all forms of TB cases (based on incidence rate (estimate) provided by WHO)							70%	54.10%	n/a				n/a	n/a	
1.3.8	Percent of the registered new smear-positive pulmonary TB cases that were cured and completed treatment under DOTs (i.e., treatment success rate) in USG-supported	90	90.3	n/a	85%	92.50%		90%	92%	n/a	90%	94%	n/a	90	95.20%	
Technical Area 1.4. Drug Supply Management																
1.4.1	Value of pharmaceuticals and health commodities purchased by USG-assisted governmental entities through competitive tenders*	TBD	n/a		n/a	n/a		n/a	n/a	n/a	n/a	n/a		n/a	n/a	
1.4.2	Number of USG-assisted service delivery points experiencing stock-outs of specific trace drugs (%)(adult preparation)	0	1.4	n/a	<2%	0.20%		<2%	2%	n/a	<2%	2%	n/a	<2%	2%	
1.4.3	Number of pharmacy professionals trained on IPLS	240	325	135	n/a	n/a		n/a	n/a		n/a	n/a		n/a	n/a	
1.4.4	Number of HFs practicing TB drug kits (requires FMOH approval)	60	0	0	*Number per PFSA supply*	*Prep stage*		*Number per PFSA supply*	1,600	n/a	n/a	n/a		2,186	2,077	95
Technical Area 1.5: Recording and Reporting																
1.5.1	Number of people trained in monitoring and evaluation (health workers)	2,360	2,444	103	n/a	n/a		n/a	n/a		0	n/a		n/a	n/a	

Indicator		PY1			PY2			PY3			PY4			PY5		
		Target	Actual	%	Target	Actual	%	Target	Actual	%	Target	Actual	%	Target	Actual	%
1.5.2	Number of HEWs trained in monitoring and evaluation (para-medics)	3,380	0	0	2,000	2,717	135	n/a	n/a		0	n/a		0	n/a	
1.5.3	Number of Regional annual reports, disaggregated by zone, *woreda* and HF, developed	1	1	100	2	1	50	2	2186		2	2		2	n/a	
Technical Area 1.6: Strengthened Referral Linkage																
1.6.1	Number of TB suspects referred to health facilities from HEWs	32,800	5,876	18	20,000	22,867	114	50,000	82,939	165	200,000	148,694	74	100,000	77,500	77
1.6.2	Number of health posts providing DOT for TB patients (%)	1,500	14.10%	n/a	2,500	n/a	n/a	5,000	3,150	63	50%	31.50%		50%	33.40%	
1.6.3	Number of TB patients referred to health posts for community DOTS from hospitals, health centers and private health facilities	4,000	645	16	4,000	2,066	52	4,000	9,758	243	5,000	11,602	232	5,000	5,946 (two quarters reported	
Technical Area 1.7: Improving Community TB Care																
1.7.1	Number of para-medical practitioners trained in evidence-based clinical guidelines (HEWs)	3,380	0	n/a	2,500	1,660	66	n/a	n/a	n/a	0	n/a		561	0	0
1.7.2	Number of para-medical practitioners trained in evidence-based clinical guidelines (community DOTS supporters)	76,800	0	n/a	n/a	n/a		n/a	n/a	n/a	n/a	n/a		n/a	n/a	
1.7.3	Number of health posts screening for TB	3,380	0	n/a	2,500	2,004	80	7,000	9,442	135	9842	9967	101	9,967	9,967	100
Technical Area 1.8: Engaging Private Health Sector in DOTs (Public Private Mix-DOTS)																
1.8.1	Number of TB cases reported to the National TB Program by USG-assisted non-MOH sector¥	TBD	0	n/a	*This area was removed from HEAL TB's role.*											
Result 2 (Expected Outcome 2): Identify re-treatment failures, expedite sputum for culture and DST and map location of MDR-TB cases																
2.0.1	Number of MDR-TB cases on treatment with USG support	50	0	n/a	150	155	103	230	254	110	350	325	93	200	215	107
2.0.2	Number of samples for culture or DST sent to the Regional labs and/or EPHI	55	300	545	400	1,040	260	3,000	8,109	270	n/a	n/a		n/a	n/a	
2.2	Number of samples for culture or DST/ GeneXpert (presumptive MDR TB)	n/a	n/a		n/a	n/a		n/a	n/a		5,000	9,597	191	10,000	6,729(two quarters reported)	67

Indicator		PY1			PY2			PY3			PY4			PY5		
		Target	Actual	%	Target	Actual	%	Target	Actual	%	Target	Actual	%	Target	Actual	%
Result 3 (Expected Outcome 3): Improved TB/HIV Collaborative Activities																
3.0.1	Percent of all registered TB patients who are tested for HIV through USG-supported programs	70	89	n/a	90	93.25	n/a	90	89	n/a	90	93.70	n/a	90	90.10	
3.0.2	Number of people trained in TB/HIV	1,180	1,052	89	n/a	n/a	n/a	n/a	n/a		n/a	n/a		n/a	n/a	
Result 4 (Expected Outcome 4): Health Systems Improved																
4.0.1	Number of baseline or feasibility studies	1	1		n/a	n/a		n/a	n/a		n/a	n/a		n/a	n/a	
4.0.2	Number of information gathering or research activities	TBD	2		6	3	50	6	6	100	6	5 (one published, the rest submitted)	100	1	2	
Technical Area 4.1: Improving Infection Control																
4.1.1	Number of healthcare facilities with TB IC plans implemented	23	60	260	150	48	32	150	837	558	1,500	1,281	85	1,200	1,472	122
Technical area 4.2 Capacity Building of Health Care Providers																
4.2	Capacity building of health care providers	no target														
Technical area 4.3 Support proper TB and TB/HIV planning																
4.3.1	Number of *Woreda* annual operation planning meetings conducted													471	n/a	
Technical area 4.4 Support implementation of GF TB grants in the region																
4.4.1	Number of medical and para-medical practitioners trained in evidence-based clinical guidelines (Global Fund supported)	no target			This technical assistance area is canceled from HEAL TB as per the first year discussion with USAID.											
4.4.2	Number of people trained in monitoring and evaluation (Global Fund supported)															
4.4.3	Number of people trained in other strategic information management (Global Fund supported)															
4.4.4	Number of *Woreda* annual operational planning meetings conducted where Global Fund resourcing was discussed															

Appendix B. Standards of Care (SoC)

(1) The similarities and differences of the traditional supervisory approach and the SoC approach

Traditional Checklist Approach of Supervision	Objective Performance Measuring through SoC Approach
Supervisor usually starts by interviewing the implementer; the information is primarily dependent on information given by the implementer.	The mentor/supervisor starts by actually measuring the performance of the implementer through a set of standard indicators.
The depth of gap or challenge identification is mainly passive and dependent on the information provider, e.g., checks what is reported, but does not check him/herself in depth.	Gap/challenge is identified by the supervisor/mentor, e.g. the supervisor calculates the past quarter performance of cure rate, compares with what was reported, and if it is low, finds out the reason.
Usually, the gap/challenge of the health facility is mainly found through an interview of the implementer.	The gaps or challenges are identified by the mentor/supervisor, and the implementer can add or explain. As an example, the lab mentor re-checks five negative and five positive slides with the same microscope used by the health facility. If there is discordance, s/he identifies the cause. It may be the microscope, the reagent, the smear quality of the health facility lab, or some human resource issue.
The approach is more supervisory and, in most cases, does not identify the true challenges.	The SoC approach is one of mentorship, and identifies objectively the cause of the gap on site. As in the example above, if there is a problem with the microscope, s/he may recommend changing the microscope; if it is reagent problem, s/he may establish an internal quality system, and if it is a human resource issue, sh/e may recommend training.
The supervisory approach does not measure the progress of activities, as it is dependent on information from the implementer.	Progress is more accurately measured, as indicators are collected by the mentor/supervisor.
On-site capacity building is limited.	With a mentorship approach, capacity building is intertwined with indicator data collection. As an example, a high cure rate reported by the health facility could be actual performance, or health workers may have confused treatment completion with cure. The mentor on the site resolves differences and oversees the formulas.
The supervisory approach has limited motivational effect on the implementer.	The mentor/supervisor calculates each indicator together with the implementer, identifies the reason for the under- or over-performance, designs solutions jointly with the implementer, and monitors the progress periodically together. It motivates staff to perform well.
The supervision is usually done by managers or related professionals even if not specialist on the subject.	The mentor/supervisor is a specialist.

(2) SoC indicators reference sheet (sample)

TB Standards of Care		Code	Quarterly measure	Numerator/Denominator	Source	Results of quarterly measure		
V	All patients should be monitored for response to therapy, best judged in patients with pulmonary tuberculosis by follow-up sputum microscopy (two specimens) at least at the time of completion of the initial phase of treatment (two months), at five months, and at the end of treatment.	C8	Cure rate (new smear positive cases)	No. of sputum smear (SS) positive TB cases cured during the reporting period Total No. of SS positive patients registered a cohort (evaluated during the last quarter)	TB register	<80	80-85	>85
		C9	Cure rate (re-treatment)	No. of re-treatment TB patients cured in the reporting period No. of re-treatment patients registered in a cohort (evaluated during the last quarter)	TB register	<80	80-85	>85
		C10	Sputum conversation rate at the end of intensive phase of treatment (of patients registered in the previous quarter)	No. of new SS positives cases registered in the previous quarter and became SS negative at the end of the intensive phase of treatment Total no. of new SS positive pulmonary TB cases registered for treatment in the previous quarter	TB register	<85	85-90	>90
		C11	Proportion of SS positive TB cases that weren't examined at the end of the intensive phase (of patients registered in the previous quarter	No. of new SS positive TB cases registered in the previous quarter that weren't examined for AFB at the end of the intensive phase Total no. of new SS positive pulmonary TB cases registered for treatment in previous quarter	TB register	>4	1-4	0
		C12	Proportion of SS positive pulmonary TB cases that weren't examined at the end of 5th month (of patients registered in the previous quarter)	No. of new SS positive TB cases registered in the specified period that weren't examined at the end of the 5TH month of treatment. Total no. of new SS positive cases that were registered for treatment in the previous quarter and who completed 5th month treatment				
VI	HIV counseling and testing is indicated for all TB patients and all HIV patients should be screened for TB during every visit.	C13	Percentage of TB patients whose HIV test result is recorded	No. of TB patients registered who had an HIV test result recorded in the TB register (last quarter) No. of newly registered TB patients during the last quarter	TB register	<90	90-99	100
		C14	Percentage of TB patients who are known HIV positive cases	Number of HIV positive TB patients in the last quarter No. of TB patients tested for HIV who were registered for treatment during the last quarter with test result recorded				
VII	All patients with TB and HIV co-infection should be evaluated to determine if ART is indicated during the course of TB treatment.	C15	Percentage of co-infected patients who were linked to chronic care	No. of TB/HIV co-infected patients linked to chronic care (ART clinic) in the last quarter (among new TB pts registered) Total No. of HIV-positive TB patients registered during the last quarter (among new TB patients registered)	TB register	<95	95-99	100
		C15a	Percentage of co-infected patients who were started on ART	No. of TB/HIV co-infected patients who were on ART (among new TB patients registered) Total No. of HIV-positive TB patients registered during the last quarter (among new TB patients registered)				
VIII	An assessment of the likelihood of drug resistance, based on history of prior treatment, exposure to a possible source case having drug-resistant organisms, and the community prevalence of drug resistance, should be obtained for all patients.	C16	No. of re-treatment cases (treatment failure, relapse, treatment failure after lost to follow-up)	Same	TB unit register	<75	75-90	>90
		C17	Proportion of re-treatment cases for whom sample is referred to DST sites (relapse, re-treatment after lost to follow-up, treatment failures) in the previous quarter	No. of re-treatment cases for whom sample is referred to DST sites in the last quarter Total no. of re-treatment cases (relapse treatment after lost to follow-up, failure cases) previous quarter	MDR suspect registration book			

(3) Summary sheet sample for SoC quarterly performance)

Code	Quarterly measure of SoC (clinical quality indicators)	Q1	Q2	Q3	Q4
C1	Percent/proportion of patients screened for TB in all adult OPD in the quarter				
C2	Percentage of presumptive-TB cases identified/detected among adult OPD visitors in the quarter				
C3	Proportion of sputum smear (SS)-positive TB cases among newly registered TB patients in the last quarter				
C4	Percentage of SS-positive patients with successful treatment (TSR) during the quarter				
C5	Lost to follow-up rate; SS-positive TB cases evaluated in the last quarter				
C6	Percentage of TB Rx interrupters during intensive phase among patients enrolled during the previous quarter				
C7	Proportion of new TB patients enrolled in the previous quarter with appropriate dose/regimen				
C8	Cure rate (new SS-positive cases)				
C9	Cure rate (re-treatment cases)				
C10	Sputum conversation rate at the end of the intensive phase of treatment (of patients registered in the previous quarter)				
C11	Proportion of SS-positive TB patients who weren't examined at the end of the intensive phase (previous quarter)				
C13	Percentage of TB patients whose HIV test result is recorded (new and re-treatment patients)				
C15	Percentage of co-infected patients who were linked to chronic HIV care (ART clinic)				
C18	Level of accuracy of reporting for number of new SS positive patients (previous quarter)				
C19	Level of accuracy for number of new SS negative pulmonary TB patients (previous quarter)				
C20	Level of accuracy for no. of new EPTB cases (last quarter)				
C21	Level of accuracy for no. of TB patients tested for HIV (new and re-treatment-RDF)				
C23	Level of accuracy for # of cured (among new SS-positive cohorts)				
CI1	% screened among close contacts SS-positive index cases				
CI2	% TB cases identified among presumptive-TB cases of close contacts of SS-positive TB cases				
Quarterly Measure of SoC (drug supply management indicators)					
DM1	Stock-out days of adult RHZE				
DM2	Stock-out days of adult RH				
DM5	Percentage of bin cards updated for anti-TB drugs (adult RH and RHZE)				
Quarterly Measure of SoC (laboratory quality indicators)					
LAB1	% of suspects with 3 samples collected in the reporting quarter				
LAB2	Percentage of positive slides among new slides examined in the quarter				
LAB3	Percentage of positive slides graded in the reporting quarter (see calculation)				
Quarterly Measure of SoC (community TB care quality indicators)					
CTBC1	Proportion of health posts reporting CTBC activities to the health facility (CTBC report)				
CTBC2	Percentage of health posts referring TB suspects during the quarter				
CTBC3	Number of presumptive-TB cases referred from health posts during the quarter				
CTBC4	Percentage of TB cases detected among TB suspects referred from health posts				
CTBC5	Number of TB cases referred to health posts for follow up of treatment by HEW (follow up DOT)				

(4) SoC sample logbook, health facility action points

Name of *Woreda*____________________ Name of Health Facility____________________________

Date______________________

Service area	Major strengths	Major challenges	Corrective action		
			Agreed action points	Responsible Person	Time Frame
Community TB care					
TB IC and HSS					

Appendix C. TB Infection Control

(1) Sample Comprehensive TB Infection Control Plan

Name of Health Facility______________________________ Year______________________________

No.	Applicable Procedure	Activities	Place	Responsibility		Timeline	Budget estimate	Source	Measure of success (target)	Remarks
				Position	Name					
Managerial Activities										
M1	The facility will strengthen/ establish Infection Prevention (IP) Committee, which also oversees TB infection control; a TB IC focal person will be assigned, with accountability to the CEO/Medical Director.	—establish IP committee OR —strengthen IP committee	office level	CEO/Medical Director			N/A	N/A	IP committee & TB IC focal person present	It has no cost
M2	The IP committee will undertake facility TB risk assessment, using standard checklist; this will be an annual routine.	—conduct risk assessment for first time OR —conduct repeat risk assessment	various service delivery points	IP committee			N/A	N/A	Updated facility risk assessment document available	It has no cost
M3	The IP committee will develop a written TB IC plan based on the facility TB risk assessment; revision will be made on yearly basis. The plan will be incorporated to the main facility work plan and it will be posted on the main notice board for easy referencing.	—prepare TB IC plan for the first time OR —update TB IC plan	office level	IP committee			N/A	N/A	Updated & budgeted TB IC plan available	It has no cost
M4	All staff will be oriented on TB IC before work assignment and sensitized each year	—conduct TB IC orientation for all staff OR —orient new employees as they come OR —sensitize all staff (yearly)	office level	Trained CEO/ Medical Director and Trained Matron					100% of staff trained at any given time	The TB IC focal person will act as a facilitator
M5	Patients and visitors will be offered oral and written information on TB IC	—print, photocopy, and distribute brochures on TB IC to patients and visitors —post reminders —replace reminders when lost/torn	Waiting area(s)	IP committee or TB IC focal person		ongoing			Health education given on TB IC, daily, by health workers	
M6	Implementation of the TB IC annual plan will be regularly monitored using the following indicators: TB suspects missed at entry, proportion of staff oriented on TB IC, TB incidence among staff, and proportion of smear-positive TB patients who received timely anti-TB treatment	—print, photocopy, and bind staff training log	Staff clinic	Matron/Head Nurse/Staff clinician		ongoing			—# of TB suspects found at OPDs, but missed at triage, should be progressively decreasing —at least a yearly 50% decrease in the incidence of TB among staff	Find additional indicators under M4 & A6
M7	Operational research will be conducted on major gaps identified, following implementation of the TB IC plan	—collect and analyze data —write article	office level	Any interested staff					At least 1 research article produced per year	There are different research journals in Ethiopia and abroad (online) in which to publish
Administrative Controls										
A1	All clients will be screened for TB symptoms at triage & OPDs. Additional screening will be offered to medical in-patients and their caretakers	—print, photocopy, bind, and distribute TB screening log								

No.	Applicable Procedure	Activities	Place	Responsibility		Timeline	Budget estimate	Source	Measure of success (target)	Remarks
				Position	Name					
A2	TB suspects & TB cases will be identified and placed in separate waiting areas; they will not be allowed to walk on the path to ART room or sit with PLHIV	—renovate existing waiting room/ward OR —construct new additional waiting room/ward OR —put benches under shades for separation purposes OR —other options								
A3	TB suspects will get service priority at OPDs, laboratory, and X-ray department	—fast tracking	OPDs, laboratory & X-ray dept	OPD clinicians, lab & X-ray professionals		ongoing	N/A	N/A	TB suspects observed getting service priority	It has no cost
A4	Chronic coughers will be educated on how to cover their mouth and nose while sneezing and coughing; each cougher will be given a container with lid to spit into	—provide daily health education —distribute sputum collection material for coughers	Waiting area(s), medical/ TB/MDR-TB wards	Triage officer/ assigned HW/ assigned cleaner		ongoing	N/A	N/A	TB suspects observed covering their mouths and noses while coughing and sneezing; no one observed spitting on the floor	It has no cost
A5	Sputum smear result will be ready within 2 days; the result will be communicated to the clinician before noon	—provide prioritized service	Laboratory	Laboratory personnel		ongoing	N/A	N/A	The majority of TB suspects get sputum smear results in less than 48 hours	No additional cost
A6	Initiation of anti-TB treatment will be carried out on the 3rd day of HF visit, by engaging clinicians and lab personnel on duty	—adequate counseling —prompt initiation of standard anti-TB drug regimen	TB room	TB focal person		ongoing	N/A	N/A	Diagnosed SS+PTB cases put on anti-TB treatment within 3 days of appearance	No additional cost
A7	TB cases will get supervised treatment 7 days a week, by assigning duty clinicians on weekends, and holidays	—assign duty clinician —provide treatment on weekends & holidays	TB room	assigned duty clinician		ongoing			All TB patients get supervised treatment until completion	
A8	TB patients will have scheduled sputum follow-up tests, while on treatment. The aim is bacteriologic cure	—do sputum follow-up examinations per the schedule	TB room laboratory	TB focal person, laboratory personnel		ongoing	N/A	N/A	Follow-up sputum examination done for all new SS+ cases on the 2nd, 5th, and 6th months; on the 3rd, 5th, and 8th months for previously-treated cases	No additional cost
A9	A special staff clinic and staff clinician will be designated	—designate a room as a staff clinic	office level	IP committee					A special staff clinic designated	
A10	Confidential TB & HIV services will be provided to staff, by staff clinician	—assign staff clinician	office level	IP committee					A special staff clinic assigned	
A11	Staff diagnosed with TB will not be allowed to report to work until sputum smear conversion	—conduct annual TB symptomatic screening —provide sick leave	office level	Staff Clinician Medical Director Personnel (HR)		routine or need-based	N/A	N/A	Staff on anti-TB treatment, not reporting to work until sputum smear conversion	No additional cost
A12	Staff diagnosed with HIV will be linked to chronic care; staff living with HIV will not be assigned to TB room, adult OPD, medical ward or MDR-TB ward	—encourage staff to undergo HCT periodically —link to ART if HIV-positive for chronic care —relocate HIV-diagnosed staff	office level	Staff Clinician ART Clinician Medical Director		routine or need-based	N/A	N/A	Staff living with HIV relocated to less risky areas	No additional cost

No.	Applicable Procedure	Activities	Place	Responsibility		Timeline	Budget estimate	Source	Measure of success (target)	Remarks
				Position	Name					
Environmental Controls										
E1	A stand-alone, cross-ventilated, and spacious room will be assigned to TB-DOTS	—change room OR —renovate room	office level	IP committee					Stand-alone, cross-ventilated room available for TB-DOTS	
E2	Natural ventilation will be maximized by opening windows and doors on opposite sides in all OPDs and wards; signage will be placed to reinforce the message	—install windows —shorten doors —post signs —other	OPDs and wards	IP committee					All OPDs and wards are cross ventilated.	When Vaneometer measurement feasible, each consultation & admission room will have 12 or more ACH value
E3	Separate ward or rooms will be made available for admitting sputum smear PTB cases; care will be taken not to admit PLHIV in the same room as confirmed PTB patient	—renovate ward OR —construct new ward —designate separate admission rooms	medical ward	IP committee					Separate ward or rooms exist for admitting SS+ PTB cases	
E4	Separate sputum collection area will be identified and/or constructed	—identify an open area for sputum collection —construct a well-ventilated sputum collection booth	office level	IP committee					Sputum collection site available	
E5	Overcrowding in hallways, waiting areas and around OPDs will be prohibited	—patrolling	hallways, waiting areas, OPDs	Security guard TB IC focal person		ongoing	N/A	N/A		No additional cost
E6	When available, mechanical devices like Whirly Birds and window fans will be inspected on monthly basis and get fixed by appropriate personnel if found dysfunctional	—regular cleaning of fans —monthly inspection and maintenance	rooms, wards with mechanical ventilation	HF electrician		ongoing			Functioning ventilators	
E7	Seating arrangement in OPDs will be such that air flows in between the health worker and the patient; periodic check of wind direction will be made using incense sticks	—make periodic check of wind direction	OPDs	OPD clinicians IP committee		ongoing			Appropriate seating arrangements seen in all OPDs	
Personal Protection										
P1	Particulate respirators of different sizes and models will be gathered from different sources and made readily accessible	—store respirators in safe place	Matron's office	Matron/Head Nurse		ongoing	N/A	N/A	Particulate respirators are accessible	No additional cost
P2	Staff treating (or caring for) confirmed and highly suspected DR-TB cases in TB room and/or DR-TB ward must wear particulate respirator. Caretakers will also be provided with respirators; the quota for daily users is one or two respirators per week	—wear respirator, if indicated	DR-TB ward, TB room	clinicians cleaners caretakers food catering staff		ongoing	N/A	N/A	Consistent wearing of respirators by staff & caretakers while dealing with DR-TB patients	No additional cost
P3	When the test kit is available, all particulate respirator users will be subject to fit testing before use. The IC committee will ensure adequate pool of trained personnel to perform the test	—do respirator fit test for each user	DR-TB ward, TB room	Matron/Head Nurse, TB IC focal person, any other trained staff		ongoing	N/A	N/A	All users of respirators are fit tested before use and thereafter, as appropriate	Depends on availability of fit test kit No additional cost

No.	Applicable Procedure	Activities	Place	Responsibility		Timeline	Budget estimate	Source	Measure of success (target)	Remarks
				Position	Name					
P4	Patients with DR-TB will use surgical masks while in ART, lab, X-ray unit or ward; the quota is 1-2 surgical masks per week. They will be instructed to dispose used masks in to wastebaskets/ dustbins	—wear surgical masks	DR-TB ward, TB room	DR-TB patients		ongoing	N/A	N/A	Consistent wearing of surgical masks by DR-TB patients while in the ward and moving around	No additional cost

Optional additional control details:

We, the undersigned IP committee members, have read and agreed on the content of the TB IC annual plan.

NAME ______________________________ SIGNATURE ______________________________

NAME ______________________________ SIGNATURE ______________________________

NAME ______________________________ SIGNATURE ______________________________

NAME ______________________________ SIGNATURE ______________________________

(2) Terms of Reference for Infection Prevention Committee

Name of Health Facility________________________________ Year of Establishment ____________________

Date IP committee formed ________________________

Goal: To provide high quality care with adequate safety for patients, visitors and health care providers.

Purpose: This term of reference is to establish the area of operation for the infection prevention committee.

Rationale: Effectiveness of infection prevention practices depend on regular monitoring and follow-up of their implementation. Accordingly, the health facility has formed the IP committee to oversee these activities.

Roles and responsibilities

1. Draft the health facility infection prevention operational plan
2. Monitor and evaluate the performance of infection prevention practice and assess implementation of the operational plan
3. Establish policy for infection control and prevention at the health facility level
4. Establish a system for the surveillance of health facility acquired infection in patients and staff
5. Identify and investigate outbreaks of infection in the health facility
6. Define policy for safe handling and disposal of waste
7. Identify training needs of staff on infection prevention and filling of the gaps

Representation of the Infection Prevention Committee

Name	Position	Department
1. ______________________	______________________	________________
2. ______________________	______________________	________________
3. ______________________	______________________	________________
4. ______________________	______________________	________________
5. ______________________	______________________	________________
6. ______________________	______________________	________________
7. ______________________	______________________	________________

Management

The chairperson:

- Coordinates the infection prevention committee meetings in collaboration with the secretary
- Sets agenda for each meeting in coordination with the secretary
- Reports infection prevention committee activities to senior management of the health facility

The secretary:

- Coordinates with the chair person to set meeting agenda and date
- Takes minutes and send to members of the committee
- Sends documents to members, keep files and archives

Members will:

- Actively participate in all meetings, preparation of action plan, and implementation of all activities

Meeting frequency

Monthly

Weekday ____________________Time______________________

(3) TB IC health facility risk assessment checklist

GENERAL INFORMATION	
Name of Health Facility:	
Category of Health Facility:: ❑ Hospital ❑ Health Center	Facility Ownership: ❑ MOH ❑ NGO ❑ FBO ❑ Other
Address of health facility:	TB-related services provided at this facility: ❑ TB-DOTS ❑ ART ❑ DR-TB ❑ GeneXpert
Region:	
Zone:	
Woreda:	
Telephone number:	

TB Infection Control measures implemented at this health facility

#	QUESTIONS	IF RESPONSE IS	SKIP TO:
Managerial			
1.	Is there an IC committee?	Yes ① No ②	
2.	Is there a TB IC focal person?	Yes ① No ②	
3.	Is there a facility TB IC plan?	Yes ① No ②	4
	3.1. Is the plan part of the facility plan?	Yes ① No ②	
	3.2. Is the plan properly budgeted?	Yes ① No ②	
4.	Is there any staff member who developed TB during the past (one) year?	Yes ① No ②	5
	4.1. If YES, how many staff developed TB?	#__________	
	4.2. Which categories were affected? ❑ Medical ❑ Administrative ❑ Both		
Administrative			
5.	Is the triage near the main gate?	Yes ① No ②	
6.	Do patients with a cough go directly to a separate OPD?	Yes ① No ②	
Environmental			
7.	Is there cross-ventilation in OPDs, including TB clinic?	Yes ① No ②	
8.	Is there cross-ventilation in waiting area(s)?	Yes ① No ②	
9.	Is there cross-ventilation in wards?	Yes ① No ②	
10.	Are there separate wards for TB-DR/TB patients?	Yes ① No ②	
11.	Is there a separate/designated sputum collection area?	Yes ① No ②	

Personal protection			
12.	Are respirators available for staff working in MDR-TB ward?	Yes ① No ②	
	12.1. If YES, what is the distribution quota like? ① 1-2 per week ② 1 per 2 weeks ③ 1 per month ④ Variable		
13.	Are surgical masks available for DR-TB patients?	Yes ① No ②	
#	QUESTIONS	IF RESPONSE IS	SKIP TO:
Laboratory safety			
14.	Is there a written health and safety manual?	Yes ① No ②	
15.	Are used sputum cups decontaminated with a 0.5% sodium hypochlorite solution before incineration?	Yes ① No ②	
16.	Is the sputum smear preparation area cross-ventilated?	Yes ① No ②	
17.	Are sputum containers and contaminated materials disposed/ incinerated in incinerators? (observe)	Yes ① No ②	

Appendix D. Abstracts Presented in National and International Forums between 2012 and 2016

No.	Abstracts presented by HEAL TB team in national and internaltional forums
1	Yield of tuberculosis among children with presumptive TB using GeneXpert MTB/RIF assay in two regions of Ethiopia
2	Experiences and challenges in the scale up of GeneXpert services in Oromia and Amhara Regions, Ethiopia
3	Survival and predictors of mortality among multi-drug resistant tuberculosis patients on treatment in two regions of Ethiopia
4	Geographic variation of tuberculosis case notification in two regions of Ethiopia and its implication on TB program management
5	The yield of TB contact screening in two regions of Ethiopia: Comparing the yield between contacts of bacteriologically confirmed and clinically diagnosed index TB cases
6	TB, HIV, and diabetes mellitus tri-directional screening in four hospitals of Ethiopia
7	Risk scoring system and symptom-based screening as initial steps for detecting diabetes mellitus in TB and HIV clinics in Ethiopia
8	Tuberculosis and pregnancy in a cohort of women receiving antiretroviral therapy in Ethiopia
9	The pattern of rpoB gene mutations from Mycobacterium tuberculosis isolates of pulmonary TB patients using Xpert® MTB/RIF in Ethiopia
10	Correlation of childhood TB case notification with bacteriologically confirmed pulmonary TB case notification: results of two regions of Ethiopia
11	The yield of TB screening in over 16 million outpatient department visitors in two regions of Ethiopia
12	Improved TB/HIV collaborative activities via health system strengthening in two regions of Ethiopia
13	Improved access to MDR TB services via decentralized service delivery model in Amhara and Oromia Regions of Ethiopia
14	Burden of MDR TB among contacts of MDR TB cases: results from routine program implementation in Amhara and Oromia Regions of Ethiopia
15	Incidence of tuberculosis among health workers at public healthcare facilities in two regions of Ethiopia
16	Task shifting in TB laboratory service delivery: the experience of non-laboratory technicians in two regions of Ethiopia
17	Towards zero anti-TB drugs stock-out: focusing on system strengthening brought a difference in two regions of Ethiopia
18	Electronic laboratory specimen (eSpecimen) referral system in Ethiopia: a feasible approach
19	Narrowing the gap between cure and treatment success over four years: sign of improved quality of drug sensitive TB treatment follow up
20	Improved tuberculosis contact investigation and isoniazid preventive therapy (IPT) among under-5 children in two regions of Ethiopia
21	Factors affecting treatment outcome of childhood tuberculosis in two regions of Ethiopia
22	Rapid scale up of MDR-TB services through a decentralized patient management system in Ethiopia
23	Yield of TB lymphadenitis with cytology versus GeneXpert and culture in Ethiopia
24	Contribution of GeneXpert in MDR-TB case finding in Ethiopia
25	The yield of contact investigation in a rural setting in Ethiopia
26	Integrated care for tuberculosis, HIV, and diabetes in four public hospitals in two regions of Ethiopia
27	District-level performance monitoring improves the accuracy of TB program reporting in Ethiopia
28	Progress in TB/HIV collaborative activities in two regions of Ethiopia
29	Comparison of fine needle aspiration cytology and GeneXpert in the diagnosis of TB lymphadenitis in Ethiopia
30	Trends in the rate of follow-up sputum smear examination and conversion rate among smear-positive pulmonary TB patients in two regions of Ethiopia
31	Trends in treatment outcome of new and re-treatment tuberculosis cases in two regions of Ethiopia
32	Tuberculosis drug kit implementation eases drug supply management in two regions of Ethiopia
33	Isoniazid preventive therapy for under-five children in two regions of Ethiopia
34	Prevalence and incidence of smear-positive pulmonary tuberculosis in Hetosa District of Arsi Zone, Oromia Regional State of Central Ethiopia
35	Decentralized MDR-TB service model increases access to case finding in Amhara and Oromia Regions of Ethiopia
36	Blended learning as capacity building option for TB/HIV services: results from a comparative study in Ethiopia
37	High transfer out affecting hospitals' performance of treatment outcomes of new tuberculosis cases in Ethiopia
38	The yield of household contact investigation of MDR-TB index cases in two regions of Ethiopia
39	The yield of TB among contacts of TB patients treated in the last three years (retrospective screening) in Ethiopia

40	Heterogeneous TB case notification rates in Ethiopia: what is the implication for TB control?
41	On-site staff mentoring and assessments improve laboratory service quality and microscopy diagnostic accuracy in Ethiopia
42	Prevalence of smear positive pulmonary tuberculosis among health facility patients and their escorts in Bahir Dar, Ethiopia
43	Routine supportive supervision guided by standard-of-care indicators improved TB service quality in Ethiopia
44	Expansion of microscopic service, staff training, and supportive supervision improve smear microscopy follow-up for smear positive TB patients
45	Predictors of mortality among TB-HIV co-infected patients being treated for tuberculosis in Northwest Ethiopia: a retrospective cohort study
46	Comparison of the yield from contact screening among smear positive versus smear negative tuberculosis patients in North Western Ethiopia
47	Delay in diagnosis and treatment of tuberculosis in different agro-ecological zones in the Oromia Region of Ethiopia
48	Implementation experience of light-emitting diode fluorescence microscopy in TB microscopic centers in the Amhara Region of Ethiopia, 2013–2014
49	Improving TB cure rate of new TB SS+ cases through strengthening local implementation capacity in the Amhara and Oromia Regions of Ethiopia, 2011–2013
50	The impact of the implementation of an integrated pharmaceutical logistic system in reducing anti-TB drug stock outs in two vast regions of Ethiopia
51	Childhood tuberculosis is directly linked to the smear positive tuberculosis case notification rate: results from Amhara and Oromia Regions, Ethiopia
52	Standard of care indicators as a capacity building and TB program improvement tool: an innovative approach
53	Interventions improve TB infection control at hundreds of health facilities in Ethiopia, 2012–2013
54	GeneXpert early implementation experience in Ethiopia: how to plan for implementation and address challenges before further roll-out
55	High yield of TB cases among household contacts of smear positive pulmonary tuberculosis patients using GeneXpert MTB/RIF in Ethiopia
56	Early results from a large scale implementation of health facility based contact investigation in Amhara and Oromia Regions of Ethiopia, 2013–2014
57	Tuberculosis incidence among HIV infected adolescents and children at eight health facilities in Ethiopia
58	GeneXpert MTB/RIF implementation scale up and its contribution to decentralized management of MDR-TB in Ethiopia
59	Biomedical engineering: addressing the neglected component of the health system to reduce its deterrence to TB control efforts
60	Causes of death among MDR TB patients: findings from a mortality audit in four MDR TB treatment centers in Ethiopia
61	The performance of fluorescence microscopy to diagnose tuberculosis lymphadenitis from fine-needle aspirates in Ethiopia
62	District level performance monitoring improved the accuracy of TB program reporting in Ethiopia
63	Capacity building and mentorship improved tuberculosis infection control practices at health facilities in two regions of Ethiopia
64	Integrated care for tuberculosis, HIV, and diabetes in four public hospitals in two regions of Ethiopia
65	High yield of contact investigation among household contacts of smear positive pulmonary tuberculosis patients using GeneXpert MTB/RIF in Ethiopia
66	Early results from a large scale implementation of health facility based contact investigation in Amhara and Oromia Regions of Ethiopia, 2013–2014
67	Implementation experience of light-emitting diode fluorescence microscopy TB in TB microscopic centers in Amhara Region of Ethiopia, 2013–2014
68	Implementation of a decentralized AFB microscopy quality assurance system in the Amhara and Oromia Regions of Ethiopia, 2014
69	Strengthening community-based TB care improves TB case notification rates in Amhara and Oromia Regions, Ethiopia
70	Delay in diagnosis and treatment of tuberculosis in different agro-ecological zones in Oromia Region, Ethiopia

Appendix E. List of Success Stories

No.	Success stories from the HEAL TB project (2011–2016)
1	A mother's wish fulfilled: rolling out TB contact investigation in rural Oromia, Ethiopia
2	TB screening at health facilities reduces missed opportunity for early detection of TB for rural populations
3	Microscopes and diagnostic training increase TB case detection in Ethiopian region
4	Training and monitoring improve tuberculosis in rural Ethiopia
5	New tool reduces TB drug stock outs in Ethiopia
6	Health extension workers bring personal connection to TB case detection and treatment
7	Facility renovations and staff training improve multi-drug resistant TB control in Ethiopia
8	Implementation of TB drug kits eases drug supply management and improves adherence to treatment
9	Sample collection and transportation system enable non diagnostic health centers to diagnose TB