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**CHALLENGE** TB

**TECHNICAL HIGHLIGHT**



Photo credit: Warren Zelman

**Introduction of second-line probe assay in laboratory system in Ethiopia**

**BACKGROUND**

Ethiopia is a high-burden TB and MDR-TB country. The incidence of TB is 164/100,000, and about 2.7% of new TB cases and 14% of previously treated TB patients have multidrug-resistant TB (MDR-TB) (WHO 2018). Until recently, Ethiopia used conventional methods for mycobacteria culture and drug susceptibility testing, which take 4-12 weeks to get results and require sequential procedures for the diagnosis. The recently introduced second-line probe assay (SL-LPA) delivers

results in just 24-48 hours, a vast improvement over the conventional method. If the conventional method is used for diagnosis, the result is delayed; during that time, patients may be treated empirically until the result is ready (WHO 2016). The drugs used may have already failed to counter the disease, causing drug-resistant strains to develop and spread, which affects MDR-TB prevention and control efforts.

## STRATEGIC RESPONSE

Following the WHO policy guideline (WHO 2016) on the use of molecular line-probe assays for detecting resistance to second-line anti-TB drugs, Ethiopia started implementation of SL-LPA for patients with confirmed rifampicin-resistant or drug-resistant (DR) TB as the initial test to detect resistance to fluoroquinolones and second-line injectable drugs, instead of phenotypic culture-based drug-susceptibility testing (DST).

## IMPLEMENTATION

Multiple interventions were used to accomplish this goal:

- Assisted EPHI in conducting a baseline assessment for TB culture laboratories to understand the infrastructure and working environment for implementing SL-LPA services
- Provided technical assistance to NTP/EPHI to develop an algorithm for SL-LPA
- Provided technical and financial support to EPHI to organize SL-LPA training for all TB culture laboratories and procured startup SL-LPA kits to begin service in 50 treatment initiation centers located in different regions
- Performed annual calibration of basic molecular lab equipment and annual preventive maintenance of negative pressure, biological safety cabinet certification to ensure and comply with WHO recommended biosafety and ventilation system standards
- Arranged technical assistance to review and recommend that EPHI establish supranational labs of excellence in SL-LPA; also arranged exchange visits to EPHI, the Armauer Hansen Research Institute, and the Uganda supranational laboratory

The Ethiopian Public Health Institute (EPHI), in collaboration with the USAID-funded Challenge TB (CTB) Project, developed an implementation plan that encompassed practical training on SL-LPA (genotypic) for all TB culture laboratories by availing SL-LPA kits, conducting validation of SL-LPA in each culture lab, providing mentorship, and calibrating basic equipment. The goal was to provide better programmatic implementation of new drugs and shorter regimens for treating DR-TB.

Challenge TB supported training of laboratory professional about SL LPA (Photo credit: CTB Ethiopia)



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## Authors

This publication was written by Dr. Gudeta Tibesso with contributions from Dr. Daniel Gemechu.

For more information, please contact [lessons@msh.org](mailto:lessons@msh.org).

## RESULTS AND ACHIEVEMENTS

Seven culture laboratories began providing SL-LPA service in 2017. Currently there are ten SL-LPA sites in the country. Over a two-year period, second-line DST was performed for 386 mycobacterium tuberculosis (MTB)-positive patients. Of these 342 (88%) MTB strains were susceptible to second-line anti-TB drugs, 25 (6.5%) were resistant to fluoroquinolone second-line drugs, and 17 (4.4%) were resistant to injectable second-line drugs. Of all the second-line DSTs performed, 1 (0.26%) patient was found to have extensively drug-resistant TB (XDR-TB) and 42 (10.9%) were pre-XDR-TB cases. Following the SL-LPA results, all patients were enrolled on the appropriate shorter regimen.

## WAY FORWARD

Strong collaboration and coordination among global and local partners ensured the rapid implementation of advanced molecular SL-LPA in seven TB culture laboratories in line with WHO recommendations. This enhanced NTP's introduction of new drugs and shorter regimens for treatment of DR-TB in the country.

The head of the National TB Reference Laboratory stated, "The USAID/CTB project's comprehensive support has enabled the country to initiate SL-LPA service in 10 TB culture laboratories. Thus, the support enabled NTP to implement new drugs and shorter regimens for treatment of drug-resistant tuberculosis."

## References

- 1 WHO. Global tuberculosis report 2018. <http://www.who.int/iris/handle/10665/274453>.
- 2 WHO. The use of molecular line probe assays for the detection of resistance to second-line anti-tuberculosis drugs: policy guidance. 2016. <http://www.who.int/iris/handle/10665/246131>.

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