



## **MALAWI TUBERCULOSIS ROADMAP OVERVIEW, FISCAL YEAR 2024**

This is an overview of the USAID/Malawi FY 2024 Tuberculosis (TB) Roadmap, implemented with the FY 2023 budget. The roadmap was developed in consultation with the National TB and Leprosy Elimination Program (NTLEP) and with the participation of national and international partners involved in TB prevention and care in the country.

Tuberculosis (TB) remains a major public health problem in Malawi. In 2022, the TB incidence rate was 125 per 100,000 population, translating to 25,000 incident TB cases. An estimated 48 percent of TB cases are among people living with HIV and it is one of the World Health Organization's (WHO's) high TB/HIV burden countries. In 2022, 18,025 TB cases were reported to NTLEP, with eight percent being children aged 0-14 years and 70 percent bacteriologically confirmed pulmonary cases; this data left a gap of 30 percent of incident TB cases in 2022 undiagnosed. Malawi is not considered a high-burden multidrug-resistant TB (MDR-TB) country by the WHO, with a rifampicin-resistant/multidrug-resistant TB (RR/MDR-TB) incidence rate of 3.4 per 100,000 population, translating to 700 estimated incident cases. Among incident TB cases, the estimated proportion of TB cases with RR/MDR-TB is 2.8 percent. TB treatment success rate for drug-sensitive TB (DS-TB) remains high at 90 percent, and for RR/MDR-TB, the treatment success rate has improved to 76 percent in the 2020 cohort.

The Malawi Tuberculosis and Leprosy Elimination Program and the global community share a vision of a world free from tuberculosis (TB), as outlined in the WHO End TB Strategy 2030. The NTLEP set an ambitious goal: reduce tuberculosis-related incidence by 50 percent and mortality by 75 percent and reduce catastrophic costs incurred by individuals with TB to less than 20 percent of annual household income by the end of 2025. The National TB Strategic Plan focuses on the following:

- Improving access to high-quality, person-centered diagnosis, care, cure, and prevention for all forms of TB and patient categories.
- Collaborating on interventions for TB/HIV and other co-morbidities in priority populations.
- Enacting bold policies and supportive systems to end TB, including coordination structures, engaging all service providers, and social support.
- Strengthening program management, monitoring and evaluation, research, and innovation.

The proposed FY 2023 USAID TB budget for Malawi is \$5 million. With this level of funding, USAID will support the following technical areas.



## REACH

### *TB diagnosis*

The NTLEP, in collaboration with USAID and other stakeholders, has identified TB diagnostic and sample transportation gaps as contributing to low TB case detection in the country. In particular, low access to new WHO-recommended rapid molecular tools and over-reliance on microscopy have contributed to a low case detection rate. The following strategies and approaches will be supported with FY 2023 funds to strengthen the National TB diagnostic network:

- Scaling up digital chest X-rays in the systematic TB screening algorithms, including scaling up the use of artificial intelligence (AI).
- Improving radiography capacity at selected high-burden health facilities to facilitate systematic TB screening.
- Continuing expanding TB contact investigation for close contacts of all individuals with pulmonary TB in selected districts.
- Continuing expanding the rollout of new TB diagnostics: USAID will complement the Global Fund's efforts to provide additional molecular testing platforms (including Truenat and 10-color GeneXpert) and provide associated test cartridges where gaps exist.
- Undertaking minor renovations, maintenance, and refurbishment of TB diagnostic facilities and equipment at selected sites to improve access to existing and additional new TB diagnostic tools.
- Providing support to the National program in developing and implementing a new TB diagnostic tool deployment plan, including site preparedness and installations.
- Expanding the implementation of TB/COVID-19 bidirectional testing and contact investigations at selected high-burden sites; USAID Implementing partners will continue implementing screening algorithms that integrate COVID-19 and TB screening and contact investigations at the participating sites.
- Providing regular training, mentorship, supervision, and performance reviews to laboratory and TB management personnel on TB diagnostics, including using new TB diagnostic tools and approaches.
- Providing External Quality Assurance (EQA) for TB microscopy for sites still using microscopy.



- Strengthening the utilization and testing proficiency for Culture and Drug-Susceptibility Testing (C & DST).
- Maintaining the secondment of three laboratory technologists to the NTRL to enhance the efficiency of Culture and drug-sensitive (DS-TB) labs and supporting the National Tuberculosis Reference Laboratory (NTRL's) journey to international accreditation status.
- Strengthening the hub and spoke model for molecular TB testing, addressing sample transportation and storage gaps.
- Expanding effective TB testing approaches in children, including stool-based sample TB testing on GeneXpert.

### *Engaging all care providers and the linkages among care providers*

Lack of systematic TB screening, access to effective diagnostic equipment, insufficient knowledge of effective TB control approaches, and poor oversight of service delivery and reporting have contributed to persistent low-case notifications from private service provider service delivery points. USAID will continue strengthening the capacity of private, not-for-profit providers and private for-profit service providers to improve facility-based case finding and quality of care to contribute towards meeting the NSP and UNHLM targets. The following strategies and approaches will be prioritized in FY 2023:

- Rolling out the FAST (Find cases Actively, Separate safely, and Treat effectively) approach at selected private-not-for-profit and private-for-profit health facilities.
- Building capacity for private health facilities in TB screening and diagnostic skills and linking them to the national sample transporter and GeneXpert/molecular testing hubs.
- Supporting the TB program at the district level to provide quality improvement and control to the private provider's TB diagnostic services.
- Providing mentorship to health facility staff on various aspects of TB, including case and data management.

### *Community TB care delivery*

An analysis of 2020 case findings has shown that while facility-based case findings declined during the COVID-19 pandemic, community-based case findings through the mobile diagnostic units (MDUs) and contact investigation increased. With FY 2023 funding, USAID will implement the following strategic approaches:



- Utilizing the Global Fund-supported MDUs to conduct active case finding in selected TB hotspots, including high-density population pollution center locations, mining communities, and prison facilities.
- Expanding the coverage of TB contact investigation for individuals with pulmonary TB, including DR-TB, using community volunteers, lay health workers, and expert patients.
- Providing job enablers to Community volunteers, including those serving at community sputum collection points.
- Promoting health-seeking behaviors and creating demand for TB services.
- Addressing bottlenecks to accessing TB services, including addressing gender and stigma issues.

## **CURE**

### *Drug-susceptible TB (DS-TB) treatment*

In FY 2023, USAID will prioritize the following strategic approaches to achieve and maintain DS-TB treatment success:

- Maintaining the secondment of the TB advisors to Procurement and Supply Chain Management (PSM) of TB commodities and the technical advisor to support the GF grants implementation at the NTLEP to maintain uninterrupted supply and availability of TB medicines for both adult and pediatric formulations, improve the quality of care for individuals with DS-TB and ensure the high performance of the TB/HIV grants through mentorship and identification of areas that need further technical assistance from USAID and other donor partners.
- Strengthening health facility TB management teams in conducting cohort analyses and action-oriented death audits to identify and address reasons for individuals' loss to follow-up and TB deaths, respectively, and draw and share lessons.
- Supporting the NTLEP in reviewing the merit of a shortened regimen for DS-TB, i.e., a 4-month regimen.
- Training and mentoring service providers on TB case management approaches, including monitoring of adverse treatment events and treatment failure.

### *MDR-TB treatment*

With FY 2023 funding, USAID will support the implementation of the following strategic approaches for DR-TB:



- Continuing supporting the NTLEP in rolling out the fully oral regimens, including fully oral shortened and individualized regimens based on the consolidated WHO guidelines for the management of DR-TB.
- Strengthening the TB laboratory and diagnostic network, ensuring increased capacity to conduct drug sensitivity testing, monitoring of individuals with TB, and test results delivery to carers. Leveraging core funding, USAID/Malawi will help the NTRL expand the 10-color GeneXpert MTB/XDR cartridge testing, bringing rapid molecular DST for rifampicin, Isoniazid, fluoroquinolones, and Ethionamide in a single test.
- Building capacity of service providers in active Drug Safety Monitoring and Management (aDSM) at the district level through on-the-job training and mentorship.
- Maintaining a DR-TB technical advisor seconded to NTLEP to continue building the capacity of National and District DR-TB Management teams.
- Ensuring all individuals with DR-TB diagnosed in the districts where they have a presence are linked to treatment on time through USAID implementing partners.
- Supporting district TB teams in conducting cohort analyses of individuals with DR-TB, sharing lessons learned, and addressing identified gaps or bottlenecks to achieving high-treatment success rate (TSR).
- Ensuring that all individuals diagnosed with DR-TB access psychosocial and financial support for transportation to prevent them from incurring catastrophic costs through implementing partners and collaborations with other players,
- Ensuring uninterrupted supply and availability of first- and second-line TB drugs and C & DST supplies through the secondment of a PSM Advisor.

## **PREVENT**

### *Prevention*

With FY 2023 TB funds, USAID will support the implementation of the following strategic approaches for TB prevention:

- Expanding the implementation of contact investigation of contacts of all individuals with pulmonary TB and initiating eligible persons on TPT, and where feasible, integrating TB and COVID-19 contact investigations will be through bidirectional screening and investigation algorithms.
- Collaborating with PEPFAR partners and other stakeholders to ensure quality TB screening of PLHIV and ensure the provision of TPT to eligible PLHIV in all 28 districts.



- Working with PEPFAR and other partners to oversee the implementation of newer, shorter, and more tolerable TPT regimens.
- Supporting the NTLEP to develop and implement policy and management guidelines for the implementation of TPT for HIV-negative persons over the age of five years.
- Building the capacity of program staff to oversee the implementation of TPT in various population groups, including children under the age of five years and PLHIV and the introduction of TPT for HIV-negative people above the age of five years.
- Strengthening TB infection control teams at district and health facility levels and undertake minor infrastructural renovations to improve individual/client flow, allowing natural ventilation, and maintaining ultraviolet germicidal irradiation (UVGI) equipment provided to health facilities through the Global Fund grants.

## **INNOVATE**

### *Scale up of New Tools*

USAID will collaborate with the NTLEP and other stakeholders regarding introducing new rapid molecular diagnostic tools, such as Truenat, into the TB diagnostic network and algorithm, improving access to rapid molecular diagnostics, increasing bacteriological confirmations and DR-TB testing. Artificial intelligence (AI) software packages for reading chest X-rays can improve the speed and accuracy of TB screening, and with FY 2023 funding, USAID will support the following:

- Introducing and expanding access to artificial intelligence software to new and existing digital X-ray instruments.
- Expanding molecular TB testing (Truenat/GeneXpert).
- Scaling up stool-based TB screening in children.

### *Research*

USAID Malawi realizes the critical role of research in generating information that facilitates evidence-based planning of the TB response. The national program has a research agenda focusing on finding solutions to emerging issues in TB. Over the years, a few studies, including those supported by USAID, have been conducted, contributing to the design of successful interventions in TB control in Malawi. However, inadequate funding has been a bottleneck in research within the national TB program. In FY 2024, USAID will implement research supporting the piloting of TB screening using stool-based samples for TB testing on GeneXpert; the pilot is in progress in some selected facilities.



## SUSTAIN

### *Commitment and Sustainability*

With FY 2023 funding, USAID will implement the following strategic approaches:

- Engaging senior government officials and the Parliamentary Committee on Health to lobby for increased domestic financial resource allocation for TB control.
- Working with the NTLEP to incorporate USAID, civil society organizations, and other stakeholders' participation in the TB performance reviews at national, district, and facility levels.
- Facilitating the participation of TB stakeholders, including the NTLEP, Global Fund, USAID Implementing partners, and civil society organizations, in developing the TB Roadmap for FY 2024.
- Supporting new and ongoing Operational Research for TB diagnosis, prevention, and cure as per the national TB research agenda.
- Building capacity of the national program through the secondment of technical advisors at the national level to support training, mentoring, and joint planning and reviews.
- Building the capacity of the district councils to deliver quality and sustainable TB services through existing and new government-to-government (G2G) mechanisms.

### *Capacity and Functioning Systems*

To build program management and technical capacity, USAID has seconded to the NTLEP three technical Advisors for Supply Chain Management, DR-TB Management, and Global Fund grants implementation. Additionally, USAID has seconded three laboratory technologists to the NTRL to help improve capacity and reduce turn-around times for C & DST, support the NTRL in its efforts to attain international accreditation and provide mentorship to the TB diagnostic network staff. With FY 2023 funding, USAID will support the implementation of the following strategies and approaches:

- Maintaining the secondment of the three Technical Advisors to help build capacity for PSM and DR-TB management.
- Maintaining the secondment of three laboratory technologists at the NTRL and engaging the NTP of newly identified gaps for USAID consideration.
- Build the capacity for TB diagnosis and treatment systems through training and mentorships and continue leveraging PEPFAR resources to build the capacity for implementing TB Prevention Therapy for PLHIV.



- Supporting NTLEP staff in attending relevant training and conferences to learn new diagnostic and management approaches and exchange experiences.
- Mentoring supply chain management personnel on QuantTB and other relevant systems and approaches. QuantTB will also be used as an early warning system, ensuring the continuous availability of TB commodities.
- Supporting the transition to more effective TB regimens and coordinating with other programs on supply chain system strengthening activities and pharmacovigilance.
- Facilitating commodity management-related training and mentorships for national program staff.

*Monitoring and evaluation (M&E) and Health Management Information Systems (HMIS) [and implementation of the Performance-Based Monitoring and Evaluation Framework (PBMEF)]*

The following activities will be implemented with FY23 USAID funding:

- Working with the NTLEP and other stakeholders to finalize the development and incorporate into an existing system an electronic reporting module for TB and TB/HIV indicators.
- Leveraging PEPFAR funds to continue supporting the GxAlert ASPECT connectivity platform for existing and additional GeneXpert and Truenat machines.
- Supporting the national and sub-national level TB program reviews and share lessons learned.
- Supporting the facility, district, and national TB program staff in collecting, analyzing, and using quality-assured TB program data.
- Supporting quarterly and annual TB program epidemiologic assessments at district, zonal, and national levels.
- Scaling up stool-based TB screening in children; it will be available next year.
- Integrating TB screening using 10-color Xpert machines to detect resistance to isoniazid, Rifampicin (first-line), and levofloxacin (second-line).





### *Human resources for Health (HRH)*

Human resources for health (HRH) shortages remain a long-term challenge in Malawi; the NTLEP is not spared from the effects of this gap. Poor quality of TB screening at health facilities and low coverage of contact investigation have been attributed to inadequate HRH<sup>1</sup>.

With FY 2023 funding, USAID will support the following strategies:

- Utilizing task shifting to implement non-technically demanding tasks such as conducting contact investigation, triaging OPD clients during FAST implementation, and collecting and transporting TB samples from selected communities.
- Providing USAID implementing partners to deploy additional lay cadres and engage compensated community volunteers to help administer and triage WHO symptom screening questions and contact investigations of individuals with pulmonary TB.
- Providing on-the-job training and mentorship to TB program staff where there are gaps.

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<sup>1</sup> Ibid 4,8,18, 32