MALAWI TUBERCULOSIS ROADMAP OVERVIEW, FISCAL YEAR 2023

This is an overview of the USAID/Malawi FY 2023 Tuberculosis (TB) Roadmap, implemented with the FY 2022 budget.

In 2021, the estimated TB incidence in Malawi was 26,000, and an estimated 7,700 people died from the disease. Malawi notified 14,385 incident TB cases. DurIng 2021, 52 percent of total notified bacteriologically confirmed individuals with TB were tested for rifampicin resistance. A total of 97 individuals with drug-resistant TB (DR-TB) were put on treatment.

The Malawi Tuberculosis Control Program and the global community share a vision of a world free from TB. To achieve this vision and end all deaths due to TB, the National TB Program (NTP) will work with its development and implementing partners to ensure effective, equitable, and accessible TB prevention, diagnosis, treatment, and care services in Malawi. The NTP has set an ambitious goal to reduce tuberculosis-related incidence by 50 percent and mortality by 75 percent, reducing catastrophic costs incurred by those with TB to less than 20 percent of annual household income by the end of 2025, compared to the 2015 baseline. The National TB Strategic Plan focuses on:

i.   **Improving access to high-quality, person-centered diagnosis, care, cure, and prevention for all forms of TB and patient categories:** This will include expanding use of molecular testing (GeneXpert, TrueNat), etc.) and other newer diagnostics such as LF-LAM urine test for people with HIV; strengthening TB sample transportation system, optimizing use of fully oral and shortened DR-TB treatment regimens, expanding effective case finding approaches such as active case finding, contact investigation, Use of stool-based TB screening in Children, and scaling up TB Preventive Therapy (TPT) to exposed children, people living with HIV (PLHIV), and eligible HIV-negative persons above the age of 5 years.

ii. **Collaborative interventions for TB/ HIV and other co-morbidities in priority populations:** This will include TB/HIV screening for presumptive TB individuals and linkage to appropriate therapy for people diagnosed with TB. The interventions will also focus on TB/HIV screening for key populations that include health workers, prisoners, miners, urban dwellers, migrant populations including refugees, children including the malnourished, the elderly population, diabetics, and PLHIV (for TB).

iii. **Enact bold policies and supportive systems to end TB, including coordination structures, engaging all service providers, and patient social support:** The emphasis will be to strengthen policy guidelines that will help to increase the case notification and care by other stakeholders such as community and private service providers. Policies and guidelines related to protecting individuals with TB from catastrophic costs associated with accessing TB services and Universal Drug Sensitivity Testing (DST) using more sensitive molecular methods will also be strengthened.

iv. **Strengthening program management, monitoring and evaluation, research and innovation:** Development and rollout of Electronic Medical Records System (EMRS) for TB and TB/HIV, capacity building of program management systems including data management and use, and operations research related to digital health will be prioritized. The TB program will

leverage the PEPFAR-funded HIV EMR to develop and implement the TB module, which includes TB/HIV indicators.

The proposed FY 2022 USAID TB budget for Malawi is $5 million. With this level of funding, USAID will support the following technical areas:

REACH
TB diagnosis
The NTP, in collaboration with USAID and other stakeholders, has identified TB diagnostic gaps as contributory 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 2022 funds to strengthen the National TB diagnostic network:

1. Incorporate use of chest X-rays (CXR) in the systematic TB screening algorithms, including use of Artificial intelligence (AI)
2. Improve radiography capacity at selected high-burden health facilities to facilitate systematic TB screening.
3. Continue to expand contact investigation for contacts of all individuals with pulmonary TB in selected districts.
4. Continue to expand the coverage of new TB diagnostics: USAID will complement the Global Fund and PEPFAR contributions to scale-up use of WHO approved genotypic (GeneXpert, or similar) testing capacity. USAID will complement the Global Fund's efforts to provide additional molecular testing platforms (including Truenat and 10-color Xpert) and test cartridges where gaps exist.
5. Expand the implementation of TB/COVID-19 bidirectional testing and contact investigations at selected high burden sites. Specifically, USAID Implementing partners will continue to implement screening algorithms that integrate COVID-19 and TB screening and integrate COVID-19 and TB contact investigation at the participating sites.
6. Provide regular training, mentorship, supervision, and performance reviews to laboratory and TB management personnel on TB diagnostics including the use of new TB diagnostic tools and approaches.
7. Provide External Quality Assurance (EQA) for TB microscopy for sites still using microscopy.
8. Strengthen the utilization and testing proficiency for Culture and Drug-Susceptibility testing (DST) Testing.
9. Maintain the secondment of three laboratory technologists to the National TB Reference Laboratory (NTRL) to enhance the efficiency of Culture and DST labs and support the NTRL's journey to international accreditation status.
10. Strengthen the hub and spoke model for molecular TB testing, including addressing sample transportation and storage gaps.
11. Expand effective TB testing approaches in children, including stool-based sample TB testing on Xpert.

Engaging all care providers

Lack of systematic TB screening, lack of access to effective diagnostic equipment, insufficient knowledge of effective TB control approaches, and poor oversight on service delivery and reporting have contributed to persistent low case notification from private service provider service delivery points.

USAID will continue to strengthen 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 United Nations High-Level Meeting on TB (UNHLM) targets. The following strategies and approaches will be prioritized in FY 2023:

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

Community TB care delivery

An analysis of 2020 case finding has shown that while facility-based finding declined during the COVID-19 pandemic, Community-based case finding through the mobile diagnostic unit (MDUs) and contact investigation increased. With FY 2022 funding, USAID will implement the following strategic approaches:

1. Continue to utilize the Global Fund-supported MDUs to conduct active case finding in selected TB hotspots, including high-density pollution locations, mining communities, and prison facilities.
2. Expand the coverage of TB contact investigation for individuals with pulmonary TB, including DR-TB, using community volunteers, lay health workers, and expert patients.
3. Provide job enablers to community volunteers, including those serving at community sputum collection points.
4. Promote health-seeking behaviors and create demand for TB services.
5. Address 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:

1. Maintain 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 NTP to maintain uninterrupted supply and availability of TB medicines

for both adult and pediatric formulations, improve the quality of DS-TB care and ensure the high performance of the TB/HIV grants through mentorship and identification of areas that

2. Strengthen health facility TB management teams in conducting cohort analyses and action-oriented death audits to identify and address reasons for loss to follow-up and TB deaths

3. Support the NTP to review the merit of shortened regimen for DS-TB, i.e. four month regimen

4. Train and mentor service providers on TB case management approaches including monitoring of treatment adverse events and treatment failure.

5. Scale-up multi-month dispensing of TB drugs to stable individuals with TB to minimize risk of contracting COVID-19 infection at overcrowded health facilities.

Multidrug-resistant TB (MDR-TB) treatment

In its current strategic plan (2021-2025), the NTP has planned to introduce and roll out fully oral regimens for individuals with DR-TB, including fully oral shortened regimens.

With FY 2022 funding, USAID will support the implementation of the following strategic approaches for DR-TB:

1. Continue to support the NTP to rollout the fully oral regimens, including fully oral shortened and individualized regimens based on the consolidated WHO guidelines for the management of DR-TB.

2. Strengthen the TB laboratory and diagnostic network to ensure increased capacity to conduct Drug sensitivity testing, patient monitoring, and test results delivery to carers. Leveraging core funding, USAID/Malawi will help the NTRL to expand the 10-color Xpert MTB/XDR cartridge testing that will bring rapid molecular DST for rifampicin, Isoniazid, fluoroquinolones, and Ethionamide in a single test.

3. Continue to build the capacity of service providers in active Drug Safety Monitoring and management (aDSM) at the district level through on-the-job training and mentorship;

4. Maintain a DR-TB technical advisor seconded to NTP to continue building capacity of National and District DR-TB Management teams.

5. Through USAID implementing partners, ensure that all individuals with DR-TB diagnosed in the districts where they have a presence are linked to treatment in a timely manner.

6. Support district TB teams to conduct cohort analyses of individuals with DR-TB, share lessons learned, and address identified gaps or bottlenecks to achieving high TSR.

7. Through implementing partners and collaborations with other players, ensure that all individuals diagnosed with DR-TB access psychosocial and financial support for transportation to prevent them from incurring catastrophic costs.

8. Through the secondment of a PSM Advisor, ensure uninterrupted supply and availability of first- and second-line TB drugs and culture and DST supplies.

9. Through the secondment of three Laboratory Technologists (via TB LON-1), contribute towards expanding the coverage of Culture & Drug Sensitivity Testing (C&DST) and reduced Turnaround Times for test results.

PREVENT
Prevention

TB infection prevention within the NTP is characterized by the existence of weak TB Infection Prevention Control Teams at district and health facility levels. The emergency of COVID-19 in the country has increased the importance of building the capacity and supporting the implementation of infection prevention interventions at all levels.

With FY 2022 TB funds, USAID will support the implementation of the following strategic approaches for TB prevention:

1. Expand the implementation of contact investigation of contacts of all individuals with pulmonary TB and initiate eligible persons on TPT. Additionally, TB and COVID-19 contact investigations will, where feasible, be integrated through the use of bi-directional screening and investigation algorithms.

2. Continue to collaborate 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.

3. Work with PEPFAR, IMPAACT4TB, and other partners to oversee the implementation of newer, shorter, and more tolerable TPT regimens, including 3HP and 3RH for children. USAID will also work with the National Task Force on TPT to evaluate the feasibility of introducing a 1HP TPT regimen

4. Support the NTP to develop and implement policy and management guidelines for the implementation of TPT for HIV-negative persons over the age of five years.

5. Continue to build 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.

6. Continue to strengthen TB infection control teams at district and health facility levels and undertake minor infrastructural renovations to improve patient/client flow, allow natural ventilation, and maintain ultraviolet germicidal irradiation (UVGI) equipment provided to health facilities through the Global Fund grants.

7. Support the NTP to integrate TB and COVID-19 screening and build on infection prevention practices developed for TB to incorporate COVID-19 prevention.

8. Support semi-annual/annual screening of prison inmates as well as prison entry and discharge.

SUSTAINABLE SYSTEMS

Commitment and sustainability

USAID and the NTP will also leverage the resources of other donors, such as the Global Fund TB/HIV grants, PEPFAR, and the World Bank's Southern Africa TB systems support project to help the National TB program build capacity for self-reliance in TB control.

With FY 2022 funding, USAID will implement the following strategic approaches:

1. Continue to engage senior government officials and the Parliamentary Committee on Health to lobby and advocate for increased domestic financial resource allocation to TB control.

2. Work with the NTP to incorporate USAID, Civil Society Organizations, and other stakeholders' participation in the TB performance reviews at national, district and facility levels.

3. Facilitate the participation of TB stakeholders, including the NTP, Global Fund, USAID Implementing partners, and Civil Society in the development of the TB Roadmap for FY 2023

4. Support new and ongoing Operational Research for TB diagnosis, prevention, and cure as per the national TB research agenda.

5. Continue building the capacity of the national program through secondment of technical advisors at the national level to support training, mentoring, and joint planning and reviews.

6. Build the capacity of District councils to deliver quality and sustainable TB services through existing and new G2G mechanisms.

Capacity and functioning systems

For the past seven years, there have not been any stockouts of first- and second-line TB drugs reported in Malawi. This success is largely due to sustained support from USAID through the secondment of a Procurement and Supply Chain Management Advisor to the NTP and short-term technical assistance that USAID-funded projects continuously offered. USAID continues to build the capacity of the NTP PSM staff in the use of Quan TB and other applicable systems as early warning systems for TB commodity stock and pipeline status.

With FY 2022 funding, USAID will implement the following strategic approaches:

1. Maintain the secondment of a PSM Advisor at the NTP to continue building the capacity of National and District staff in forecasting, quantification, supply planning and inventory management for TB commodities. Supply Chain Management personnel will be mentored on the use of Quan TB and other relevant systems and approaches.

2. Support the NTP in monitoring TB commodities at national, district and facility levels.

3. Facilitate commodity management related trainings and mentorships for national program staff.