



Government of Malawi



Statement of Partnership

This Statement of Partnership (“SP”) reflects the intended cooperation between the Ministry of Health and Population (MOHP) of the Government of Malawi and the United States Agency for International Development in Malawi (USAID/Malawi); collectively these entities will be referred to as the “Parties”. It is issued in accordance with the terms of the Development Objective Assistance Agreement (DOAG) for Malawi signed by the Government of Malawi and the Government of the United States of America (USG), acting through the United States Agency for International Development (USAID) on September 19, 2013, and as amended.

This SP will provide an implementation framework within which USAID will provide, primarily through the TB Implementation Framework Agreement (TIFA), Sustaining Technical and Analytic Resources (STAR), Local Organizations Network (LON), and TB Data, Impact Assessment and Communications Hub (TB DIAH) projects, but also through other national-level systems strengthening and regional-based USG partners, technical support to the Ministry of Health and Population’s (MoHP) National TB Control Program (NTP) for improved tuberculosis (TB) control.

Please indicate your agreement with the terms and conditions of this SP by signing below and returning all originals to USAID. Once all Parties have signed, USAID will distribute one original copy to each Party.

I. Background

TB situation analysis in Malawi

Tuberculosis (TB) remains a major public health problem in Malawi. There have been good achievements over the past two decades in tuberculosis control through the roll out of the Directly Observed Therapy, Short-course (DOTS) strategy. However, the results of the TB prevalence survey conducted in 2014 showed that the TB disease burden in Malawi is significantly higher than initially estimated by the World Health Organization (WHO). The TB prevalence among urban population was more than double the national average. In 2018, the

WHO estimated that 181 new and relapse TB cases occurred per 100,000 population. This translated to about 30,000 new and relapse TB cases occurring in 2018 (Global TB Report 2019). During the same year, nearly 16,000 new and relapse TB cases were reported to the National TB control Program, representing about 53% of incident cases.

Diagnosis and management of pediatric TB is one of the major challenges facing the National TB program in Malawi. Limited capacity is available at District and Central hospitals that diagnose and manage the bulk of pediatric TB. About 10% of reported TB patients are children under the age of 15 years. Child contact investigation of household contacts of pulmonary tuberculosis patients is being implemented in a few selected districts. Sixty-eight percent of eligible child contacts in these districts are initiated on TB preventive therapy. TB preventive therapy for eligible PLHIV is implemented in 5 high TB/HIV burden districts that contribute 55% of TB case notification and 44% of People Living with HIV (PLHIV) on Antiretroviral Therapy (ART). Based on Electronic Medical Records System (EMRS) site data, 81% of patients placed on TB preventive therapy had completed at least six months of treatment by December 2018.

Drug-resistant Tuberculosis is an emerging issue in Malawi. The prevalence of Multidrug resistance (MDR-TB) or Rifampicin resistance (RR) is 0.75% among newly diagnosed TB patients and 6.4% among previously treated TB patients; translating to just over 300 RR/MDR-TB cases per year.

The National TB program's 5-year strategic plan budget is estimated at \$147 million. The large proportion of this budget (43%) is funded by international donors, including the Global Fund, the World Bank, PEPFAR and USAID. About 15% is domestically funded and the remainder (42%) is unfunded gap.

Nearly all (99%) registered TB patients know their HIV status and nearly half (48%) of the are also infected with HIV. Nearly all (99%) HIV positive TB patients diagnosed are put on Antiretroviral and Anti-tuberculosis therapies. The high levels of TB/HIV co-infection call for integration of TB and HIV services at all levels of care to ensure widespread implementation of interventions which reduce the burden of TB among PLHIV and reduce the burden of HIV among notified TB cases. The geographic distribution of TB cases seems to follow the HIV epidemic pattern; with most cases notified from urban and the Southern Region of the Country.

In September 2018, the United Nations General Assembly convened a High-Level Meeting (UNHLM) on ending Tuberculosis. Heads of Governments collectively committed to very ambitious target of treating 40 million people with TB by 2022 (40 by 22 targets). This includes treating 3.5 million children, and 1.5 million people with MDR-TB; and putting 30 million people on TB preventive therapy. Malawi committed to the following country level targets: treating 97,300 people with TB (including 10,000 children and 869 MDR-TB patients); and putting 374,100 people on TB preventive therapy. In 2018, the Ministry of Health diagnosed and initiated treatment for just fewer than 16,000 patients including about 1,600 children and 107 Rifampicin Resistance/MDR-TB patients. This means that if the status quo is maintained, Malawi will not be able to meet its UNHLM targets on ending TB by 2022.

USAID contribution to TB care and prevention

Fighting Tuberculosis (TB) is a top priority for the United States Government and the Government of Malawi. USAID's new TB business model, the "Global Accelerator to End Tuberculosis," will catalyze investments across multiple countries and sectors to end the epidemic while building self-reliance.

USAID has been a leader in the global fight against TB for over two decades and supports anti-TB efforts in more than 50 countries helping to provide TB treatment to more than 13 million people, including over 300,000 suffering from multidrug-resistant TB (MDR-TB). Since 2000, the USAID TB program has contributed to a nearly 50 percent reduction in TB-related deaths and, with our partners; we've saved more than 54 million lives.

USG support is most successful when it is coupled and aligned with strong commitments from other governments and partners. To accelerate action, USAID has announced a new innovative model, "The Global Accelerator to End Tuberculosis" that will leverage additional resources from countries, private sector partners, and other local organizations in order to meet the UN target of treating 40 million people by 2022. It will focus on the countries with high burdens of TB in which USAID already has existing partnerships and align with local communities and partners to deliver performance-based results towards the global target. This is a change in approach to ensure USAID is fighting to end TB effectively and efficiently.

USAID began supporting TB control activities in Malawi since 2003. Targeted support to the National program was provided through the USAID Tuberculosis Coalition for Technical Assistance (TBCTA) managed by KNCV Tuberculosis Foundation. Since then, USAID has provided support to the National TB program through a number of mechanisms, including Tuberculosis Control Assistance Program (TBCAP) Managed by Management Sciences for Health (MSH), TBCARE II Managed by University Research Company (URC), Treat TB managed by the International Union against Tuberculosis and Lung disease, and recently the Challenge TB mechanism managed by KNCV Tuberculosis Foundation. Through these mechanisms, USAID has supported extensive systems strengthening activities including expanding diagnostic and treatment networks, including introduction of new diagnostic technologies such as LED microscopy, GeneXpert and TB Urine LAM; building capacities of NTP staff to provide TB control activities including TB diagnosis, treatment and prevention, TB Infection control; and strengthening quality control and quality assurance systems for diagnosis and care. USAID has also tapped into technical assistance from USAID projects with global institutions such as the Stop TB Partnership, the Global Drug Facility (GDF), and individual consultants to conduct program reviews, assessments and address specific programmatic gaps. Currently, USAID has four Technical Advisors embedded within the National TB Program to help build capacity for Procurement and Supply Chain Management, Programmatic Management of Drug Resistant TB, Laboratory and Diagnostic Network, and support the implementation of the TB/HIV Global Fund grants respectively. Below are the highlights of

achievement from support provided to the Malawi National TB program through the USAID Assistance since 2003.

TBCTA Technical Assistance: Initial USAID support focused on strengthening Directly Observed Therapy Short Course (DOTS) strategy which led to significant acceleration of treatment success rates and case detection rates in the TBCTA-supported districts.

TBCAP: The project strengthened collaboration of TB and HIV units by supporting the TB/ HIV sub-group at the national level, a forum comprised of stakeholders working in TB and HIV. TBCAP also supported the development and printing of national TB/HIV integration guidelines. TBCAP introduced innovative activities to involve communities to increase TB case detection and helped to establish 270 community sputum collection points. TBCAP also supported implementation of the first ever Drug Resistance Survey in Malawi.

TBCARE II: Through this Mechanism, USAID contributed significantly to the expansion and decentralization of TB services through establishment of TB microscopy and treatment initiation sites, further expansion of community sputum collection network using volunteers, procurement and deployment of GeneXpert platforms, and supported the implementation of the first ever TB prevalence Survey.

Treat TB: Through this centrally funded mechanism, USAID has seconded a Technical advisor to the National TB control Program to support implementation of the TB/HIV Global Fund grant. The TA has contributed to improving the performance of the TB/HIV grant with rating improving from B2 in 2016 to A1 by January 2019.

Challenge TB (CTB): Through Challenge TB, three long term Technical Advisors were seconded to the National TB control Program to help build the capacities of NTP staff in procurement and supply Management, Programmatic Management of Drug Resistant TB, and strengthening the TB Reference laboratories and the diagnostic network. Through CTB, USAID refurbished the National TB Reference Laboratory (NTRL); bringing it to WHO Biosafety level 3 and supported Regional culture labs in the Northern and Southern regions of the Country. CTB also enrolled all 72 GeneXpert machines deployed at publicly owned health facilities with GX alert; a diagnostic connectivity and remote reporting system for results, commodity stock and machine operational status. Challenge TB project closed out in September 2019.

USAID support beyond the Challenge TB project: Following the close-out of the Challenge TB project in September 2019, USAID Malawi intends to channel its technical and financial support for TB control in Malawi through several mechanisms in line with the new USAID TB business model; the Global Accelerator to end TB. These include:

The TB Local Organizations Network (LON). Through LON, USAID will partner directly with local organizations in Malawi to implement locally generated solutions to improve TB diagnosis, treatment, and prevention services. Partnering directly with local organizations, including civil society organizations, faith-based organizations, private sector service

delivery provider organizations, and academic institutions, LON will prioritize country empowerment and accountability to improve TB services, and leverage additional resources. LON will build on the capacity and available resources of local institutions to achieve self-reliance of the national TB program.

The Sustaining Technical and Analytical Resources (STAR) mechanism; a central level mechanism awarded to Public Health Institute (PHI) which will identify capacity gaps and deploy technical Advisors to work alongside their national counterparts to make innovative and measurable contributions to TB control in Malawi. So far, Technical Advisors for Procurement and Supply Chain Management and Programmatic Management of Drug Resistant TB have been identified and seconded to the NTP.

The TB Implementation Framework Agreement (TIFA) mechanism; another central level mechanism awarded to JSI Research & Training Institute, Inc. Through TIFA, USAID will create agreements with local government entities to build organizational and technical capacity to improve TB services and to sustain results as we work together to achieve the global target of treating 40 million people with TB by 2022. Through TIFA, the local government entities will be empowered to implement locally generated, context-specific solutions; focus on the scale-up of new technologies with proven results to improve TB case-detection and treatment outcomes and utilize new approaches to increase local ownership. Newly created partnerships with local government entities will identify quantifiable milestones and targets in order to strengthen accountability of local governments and increase ownership of their TB program.

Other central level mechanisms including the TB Data, Impact Assessment and Communications Hub (TB DIAH), Infectious Disease Detection and Surveillance (IDDS) mechanism, and the Global Technical Assistance institutions such as the STOP TB Partnership and the Global Drug Facility (GDF) as well as individual consultants will be considered as it becomes necessary and subject to availability of additional financial resources.

II. Purpose

The purpose of this SP is to establish an alignment between the Malawi MOHP and USAID (the "Parties") to jointly reaffirm our respective commitments to combating TB in Malawi, and to align expectations related to a joint approach to achieve the objectives and targets to which Malawi is committed.

This SP describes the respective **roles** and **responsibilities** that each Party will assume toward the achievement of this purpose, subject to the availability of funds and each Party's applicable laws and regulations. In particular, the Parties agree that the targets and objectives towards combating TB in Malawi will be achieved only by accelerating implementation of the national TB Control strategy and by speeding up the current pace of implementation. Therefore, the Parties will work towards scaling up the implementation of highly effective, strategic interventions, including TB Prevention, diagnosis, treatment and care, policy development and implementation, leadership, supervision, supply chain logistics, operational research, improved

data for decision making and robust monitoring and evaluation systems that contribute to reducing the TB burden, and ending the spread of TB including DR-TB.

This SP further describes the approaches that USAID is committed to support, subject to availability of funds, via technical and operational assistance to the National TB Program, including the secondment of three or more highly skilled TB technical experts to the NTP.

Finally, this SP describes the process by which the interventions implemented under this SP will be established.

This SP defines the process, objectives, and approaches for MOHP and USAID's joint commitment to combating TB in Malawi.

US Government support for TB control includes investments made through the Global Fund, the President's Emergency Plan for AIDS Relief (PEPFAR), the US Centers for Disease Control (CDC), and USAID. Coordination of these investments with those of other donor partners under the leadership of the Ministry of Health and Population is critical to achievement of the UNHLM targets for TB control. This Statement of Partnership provides an implementation framework for USAID's investment in the Government of Malawi's efforts to accelerate progress toward meeting the UNHLM targets for ending TB.

III. Objectives and key technical areas

Objectives

MOHP and USAID are committed to working together in a joint approach to achieve the following objectives:

- I. **Objective 1:** Between 2018 and 2022, diagnose and put on treatment 97,300 TB patients, including 10,000 children under the age of 15 years and 869 MDR-TB patients
- II. **Objective 2:** Initiate 374,100 eligible people on TB Preventive Therapy, including PLHIV and child contacts of pulmonary TB patients as per national guidelines.
- III. **Objective 3:** Sustain high levels of treatment success rate for drug sensitive smear positive TB ($\geq 90\%$) and for DR-TB ($> 65\%$)

Key Technical Areas

To achieve these objectives, a substantial number of interventions guided by the national TB control strategy are needed in multiple technical areas. It is understood that specific approaches outlined below may be altered based on new evidence (both local and international), and that they will assist in reaching the national priorities. With this understanding and flexibility in mind, the Parties nevertheless agree to make a good faith effort to jointly address the following key technical areas that are critical to ending TB in Malawi:

- 1) Enhance the leadership and technical capacity of the TB program at national and sub-national levels to effectively coordinate, guide and manage implementation of TB control activities.
- 2) Implement innovative, proven and effective strategies and tools for improving TB case finding and treatment outcomes to meet national TB strategic plan targets and UNHLM targets for Malawi.
- 3) Strengthen the programmatic management of Drug Resistant TB (DR-TB) at national, facility and community levels.
- 4) Ensure uninterrupted availability of commodities (FL & SL medicines, reagents, supplies, equipment) that have acceptable international quality assurance.
- 5) Improve availability of and access to quality and effective TB laboratory diagnostic services at facility, district, regional and national levels.
- 6) Strengthen private sector engagement and community systems for TB control.
- 7) Improve data collection, analysis, reporting and use of data for decision making through among others supporting e-Health migration and integration
- 8) Enhance (results) monitoring, evaluation and operations research.

IV. Roles and Responsibilities

Jointly, the Parties agree to:

- Monitor progress, share information, review learnings, and evaluate and report on progress;
- Meet on a quarterly basis, or as needed based on mutual agreement to define the specific activities to be undertaken and provide the required guidance to the implementing partners;
- Jointly plan and organize any launch or dissemination events related to the activities mentioned in Section III; and
- Participate in a regular (e.g., quarterly, semi-annual and annual) performance review process.

The following section describes the individual roles and responsibilities of the Parties to the SP:

A. MOHP/NTP

In support of the aforementioned joint commitment to achieving the objectives outlined above, MOHP is committed to:

- Including the commitments and targets agreed to at the High-Level Meeting on TB at the United Nations General Assembly in September 2018 in the National Strategic Plan 2020-2024
- Convening a high-level oversight group (such as an Inter-Ministerial Task Force on TB Control that is already in place) and monitor a **Multisectoral Accountability Framework** for TB involving all key stakeholders;
- Supporting an uninterrupted supply of quality assured TB drugs;

- Building the capacity and access for effective use of data and performance monitoring and evaluation;
- Adopting and implementing relevant national guidelines and policies;
- Convening, participating in and documenting a joint annual action planning process between MoHP, all other relevant partners, and USAID, to assess results and to agree to interventions by government and USAID-funded activities on an annual basis;
- Ensure sufficient workspace and logistics to host USAID-seconded TB Advisors;
- Share routine TB data with USAID in a timely manner in order to further the joint objectives outlined in this SP;
- Conduct regular monitoring and evaluation activities to jointly review performance data, technical reports and accountability records with USAID
- Create at least three additional staff positions to match NTP/NTRL's staffing needs; advocate for increased government-funded staff at NTP/NTRL through either absorption of currently seconded staff or government appointment of new staff to better coordinate and manage TB control efforts at both the National and District levels;
- Work towards attaining international accreditation of the National TB Reference lab and two Regional TB laboratories.
- Advocate with relevant Government agencies to include TB and/or DR-TB patients in existing social protection schemes

B. USAID

In support of the aforementioned joint commitment to achieving the objectives outlined above, USAID is committed to:

- Participating in a joint annual action planning process between MOHP, all other relevant partners, and USAID, to assess results and to agree to interventions by government and USAID-funded activities on an annual basis;
- Providing technical assistance as required to strengthen capacity and achieve results;
- Providing financial support to MOHP, subject to fund availability, to conduct specified activities as agreed in the joint annual action plan;
- Seconding TB experts to key roles within the MOHP to serve as TB Advisors for the NTP;
- Assisting with the improvement of monitoring and evaluation systems and quality of data collection and analysis;
- Supplying MOHP with available equipment and supplies from existing USAID implementing partners;
- Instructing its implementing partners to report on project progress, challenges, and results;

V. M&E Plan

The activities outlined in this SP will be monitored on a quarterly basis at the Inter-Ministerial Task Force on TB Control or designated High-level oversight committee meeting. Within six months of adoption of this SP, the Parties will complete an M&E plan

which will describe the approaches for ensuring effective implementation and achievement of results. The M&E plan will identify appropriate indicators for each level of the results framework; show data sources and describe how the data will be collected and collated to regularly inform performance. The proposed plan will provide preliminary five-year performance indicator targets which will be reviewed and possibly revised during implementation discussions. This M&E plan will not be a standalone plan but will build on the existing MoHP M&E plan and routine reporting systems.

VI. Communications

The Parties expect to collaborate on the development of outreach materials. Public communications should recognize the Parties through appropriate branding in accordance with their respective legal, policy, and procedural requirements. Each Party intends to communicate publicly the contributions of the other in articles, media, and publications or other documents as well as hand-outs and signage at events. The Parties should respect one another's confidentiality policies, with the mutual understanding that the Parties intend to publicize their support and its objectives without disclosing any confidential or proprietary information of the Parties. The Parties will endeavor to share information on their individual policies, procedures, and requirements relating to branding, and other communications-related requirements, so that potential obstacles can be addressed in a timely manner.

<p>All communications should be sent to the Parties at the following addresses: For USAID/Malawi: U.S. Agency for International Development NICO House P.O. Box 30455 Lilongwe, Malawi Attention: Littleton Tazewell, Mission Director, USAID/Malawi Tel: +2651772455 / Fax: +2651773181 (ltazewell@usaid.gov)</p>	<p>For Ministry of Health & Population: Ministry of Health & Population P.O. Box 30377 Lilongwe 3, Malawi Attention: Dr. Dan Namarika, Secretary for Health & Population Tel: +265 1 789 400 (danamarika@gmail.com)</p>
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VII. Terms and Conditions:

1. **No-obligation of funds:** This Statement of Partnership does not effectuate an obligation of funds by any Party. All obligations of funds by USAID to support its undertakings under this Statement of Partnership are intended to be made in other agreements with USAID implementing partners by USAID, consistent with U.S. law and regulations, and in accordance with USAID procurement and other related policies, procedures, and guidelines.

2. **No international status:** It is understood by the Parties that this Statement of Partnership is not an international treaty or international agreement and is not subject to either the Government of Malawi or United States Government's treaty ratification or other

domestic and internal legal procedures for ratification of treaties or international agreements.

3. Non-binding Statement of Partnership which does not supersede existing agreements: The terms and conditions shall govern the undertakings of the respective Parties under this Statement of Partnership; however, this Statement of Partnership shall be considered to be a good faith Statement of Partnership to pursue the goals and objectives identified above for the benefit of the people of Malawi, and is non-binding and not legally enforceable on any party. The Parties entering into this Statement of Partnership maintain their own separate and unique missions and mandates and their own accountabilities. This Statement of Partnership shall not supersede or interfere in any way with other agreements or contracts entered into by the Parties, either prior to or subsequent to the signing of the Statement of Partnership.

4. Assistance Under the Framework Bilateral: All assistance provided by USAID and reflected in this Statement of Partnership is United States assistance within the meaning and terms of the ongoing terms of the (i) Economic, Technical and Related Assistance Agreement between the Government of the Republic of Malawi and the United States of America, dated January 8, 1987 and (ii) the "Development Objective Assistance Agreement for DO1: Social Development Improved" between the Government of the Republic of Malawi and the United States of America, dated September 19, 2013, and as amended from time to time thereafter."

5. Designated Representatives: The primary points of contact and liaison for each party to this Statement of Partnership are as follows:

Dr. Charles Mwansambo, Chief of Health Services, MOHP and **Rachel Goldstein**, Director, Health Office, USAID/Malawi, or their designees are the focal points of contact for this Statement of Partnership.

The Parties may substitute the above points of contacts at their discretion and upon notice to the other Party.

6. Duration: This Statement of Partnership is effective upon signature of the Parties and will remain in effect for a maximum period of five years.

7. Resolution of Disputes: The Parties intend to use the utmost good faith to resolve any issues and disputes that arise under this agreement, bearing in mind that the Statement of Partnership is not for the benefit of the Parties but instead for the people of Malawi.

8. Amendments: This Statement of Partnership may be amended or modified in writing by mutual consent of all Parties, as may be necessary from time to time.

9. Termination: Each Party may, at its discretion, terminate this Statement of Partnership by providing all other Parties, in writing, with 60 days' advance notice, a communication reflecting the intent to terminate the Statement of Partnership.

10. Wind up: In case of termination of this Statement of Partnership by a Party, the Parties intend to consult with each other on how to bring the Statement of Partnership to an orderly end.

11. Authority to sign the SP: By their signatures below, the representatives of the Parties represent that they have the authority to sign the Statement of Partnership.

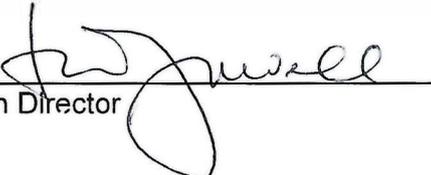
The Parties, each acting through their duly authorized representatives, have signed this Statement of Partnership as of this 18 day of November, 2019

FOR MINISTRY OF HEALTH AND POPULATION, MALAWI

Dr. Dan Namarika 
Secretary for Health and Population,

Witness: Dr. James Mpunga 
National Tuberculosis Programme

FOR U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT/MALAWI

Littleton Tazewell 
USAID/Malawi, Mission Director

Witness: 
Position: Health Office Director / USAID Malawi