Government of Malawi

Ministry of Health

NATIONAL TUBERCULOSIS & LEPROSY CONTROL STRATEGIC PLAN

2021-2025

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LIST OF ABBREVIATIONS/ACRONYMS

ADSM	Active TB-drug Safety Monitoring and Management (aDSM)
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral drug
BCG	Bacillus Calmette–Guérin Vaccine
BSCs	Biosafety Cabinets
C & DST	Culture and Drug Susceptibility Testing
CBO	Community Based Organization
CCM	Country Coordinating Mechanism
CDC	Centers for Disease Prevention and Control
CHAI	Clinton Health Access Initiative
CHAM	Christian Health Association of Malawi
CMED	Central monitoring and Evaluation Department
CMST	Central Medical Stores trust
CNR	Case Notification Rate
CSCPs	Community Sputum collection Points
CXR	Chest X-Ray
DAHSP	Decent and Affordable Housing (Cement and Malate) Subsidy Programme
DC	District Commissioner
DHA	Department of HIV and AIDS
DHIS	District Health Information System
DHMTs	District Health Management Teams (DHMTs)
DICOM	Digital Imaging and communication in medicine
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment Short Course Strategy
DPHS	Directorate of Preventive Health Services
DRS	Drug Resistance Survey
DST	Drug Susceptibility Testing
ECG	Electrocardiograph (ECG)
EHP	Essential Health packages EMRElectronic Medical Record
EPTB	Extra Pulmonary Tuberculosis EQA Eternal Quality Assurance

e-TB	Electronic TB Data Management System
FASH	Focused Assessment with Sonography for HIV-associated TB
FBOs	Faith based organizations
FEFO	First Expiry First Out
FISP	Fertilizer Input Subsidy Programme
FNA	Fine Needle Aspiration
GDF	Global Drug Facility
GDP	Gross Domestic Product GDP Gloss Development product
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLC	Green Light Committee
GoM	Government of Malawi
GUV	Germicidal Ultra Violet
HCW	Health Care Workers
HCWM	Health-Care Waste Management HIV Human immunodeficiency virus
HMIS	Health Management Information System
HSA	Health Surveillance Assistant
HSSP	Health Sector Strategic Plan
HTC	HIV Testing and Counseling
HTSS	Health Technical Support Services
ICF	Intensified Case Finding
ICP	Infection Control and Prevention
IHP	International Health Partnership
IHR	International Health Regulation
IMCI	INTEGRATED Management of child illness
LED	Light Emitting Diode (Microscopy)
LFA	Local Funding Agent
LIS	Laboratory Information management
LJ	Lowenstein Jensen
LMIS	Logistic management information system
LPA	Line Probe Assay
LQMS	Laboratory Quality Management System
LTFU	loss-to-follow-up
M&E	Monitoring and Evaluation
MAF	Multisectoral Accountability Framework

MB	Multi Bacillary
MDG	Millennium Development Goal
MDHS	Mini Demographic health Survey
MDR-TB	Multi-Drug Resistant TB
MDT	Multi Drug Therapy
MGDS	Malawi Growth and Development Strategy
MNCH	Maternal, Neonatal and Child Health
MNSSP II	Malawi National Social support Program
MoGCDSW	Ministry of Gender, Children, Disability, and Social Welfare
MoH	Ministry of Health
MOHP	Ministry of Health and Population
MSF	Médecins Sans Frontières
NAC	National AIDS Commission
NCDs	Non Communicable Diseases
NGO	Non-Governmental Organization
NHA	National Health Accounts
NLGFC	National Local Government Finance Committee
NSP	National Strategic Plan
NTLP	National TB and Leprosy Control Programme
NTRL	National Tuberculosis Reference Laboratory
OPD	Out Patient Department
PACS	picture Archiving and communication system
PB	Pauci bacillary
PHC	Population and Housing Census
PICT	Provider Initiated Counseling and Testing
PLHIV	People Living with HIV
PMDT	Programmatic Management of Drug-Resistant TB
PMTCT	Prevention of Mother to Child Transmission
PoW	Programme of Work
PPM	Public-Private Mix
PSM	Procurement and supply chain management
PWP	Public works programmes
QA	Quality Assurance
QC	Quality Control

QMD	Quality Management Department
rGLC	regional Green light committee
RR	Rifampicin Resistance
RR-TB	Rifampicin-Resistant TB
SADC	Southern Africa Development Community
SCT	Social Cash Transfer
SDGs	Sustainable Development Goal
SLIPTA	Strengthening Laboratory Improvement Towards Accreditation
SLMTA	Strengthening laboratory management towards accreditation
SRH	Sexual and Reproductive Health
SSN	Sputum smear Negative
SSP	Sputum smear Positive
TA	Traditional Authorities
TB IC	Tuberculosis Infection Control
TB LAM	Lateral Flow Urine Lipoarabinomannan Assay
TFT	Thyroid Function Test
TSH	Thyroid stimulating Hormone
TSR	Treatment Success Rate
TWG	Technical Working Group UBR Unified beneficiary registry
UNHLM	United Nations High Level Meeting
URC	University Research Corporation
USAID	United States Agency for International Development
VDC	Village Development Committees (VDCs)
WFP	World Food Programme WHO World Health Organization
XDR TB	Extensively Drug Resistant Tuberculosis
Xpert	Xpert MTB/RIF rapid molecular test
ZN	Ziehl-Neelsen

FOREWORD

Despite significant progress in TB Control since Malawi adopted the WHO recommended TB DOTS strategy at the beginning of the 1990s, TB remains a major public health concern in the country. Over and above its direct impact on morbidity and mortality, TB continues to impact negatively on Malawi's economic development. It continues exerting significant socio-economic burden on individuals, families and communities across the country. The high HIV prevalence and the resulting high prevalence of TB/HIV co-infection have exacerbated the situation. In 2013, 56% of the notified cases of TB were co-infected with HIV. Just as is the case in other countries in the sub-region, drug resistant TB cases have emerged and Malawi is already recording an increasing number of laboratory confirmed Multidrug Resistant TB (MDR-TB) cases. Recognizing the enormity of TB epidemic, the Government of Malawi (GoM) declared TB an emergency in 2007 in order to raise awareness and advocate for more resources and control actions by all stakeholders. One of the initiatives embarked on as a result of that declaration is Universal Access to TB diagnosis, treatment and care which entailed a shift from centralized institutional DOTS services to more innovative ways of reaching out to all target population groups with quality assured diagnosis and care regardless of socio-economic status and geographical location. Under this concept, community members, civil society groups, community based organizations (CBOs), governmental and non-governmental organizations are all called upon to participate in the fight against TB. The high levels of TB/HIV co- infection calls 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 People Living with HIV (PLHIV) and those which reduce the burden of HIV among notified TB cases. Even though Malawi is one of the countries with low prevalence of MDR-TB, there is a need to put in place measures which prevent the development of drug resistant strains especially through attaining high treatment success rates for both new and previously treated TB cases.

In order to respond effectively and efficiently to the TB epidemic there is an urgent need to strengthen Malawi's health system. Human resources for health (HRH), infrastructure, transport, communication and logistic support, monitoring and evaluation systems, procurement and supply chain systems also remain major challenges for the health sector in Malawi. More efforts are needed to strengthen these in order to improve universal access to essential quality TB and TB/HIV diagnosis and treatment services through the Government of Malawi recommended primary health care approach.

The development of this National TB & Leprosy Control Strategic Plan is, therefore, an opportunity to consolidate the significant gains that Malawi has made in the fight against TB and Leprosy. The Plan seeks to further decentralise quality assured TB diagnosis and treatment services to peripheral facilities and community levels in the public and private sectors; to consolidate programmatic management of drug resistant TB (PMDT); and roll out further implementation of TB/HIV collaborative activities and interventions as part of both TB and HIV Control strategies. In this context, this 5-year plan provides an outline of what the Ministry of Health & Population (MoHP) and its stakeholders would like to see implemented during the period 2021-2025 in order to reduce the burden of TB in Malawi. This plan is aligned with the Malawi Growth and Development Strategy (MGDS) and the Malawi Health Sector Strategic Plan (HSSP). At a global level, it has been aligned with the End TB Strategy. At regional level, the document seeks to help align Malawi's efforts with regional and sub-regional efforts to address emerging cross border challenges that include migrant populations due to political, social and economic reasons through regional commitments and declarations. It is this plan which will consolidate Malawi's efforts towards achieving the UN High Level Meeting Resolutions and set Malawi going towards attainment of End TB targets as part of the UN Sustainable Development Goals (SDGs) aspirations.

To achieve the country's health aspirations and people level results specified in this strategic plan, increased human and financial resources and close collaboration between government ministries, agencies, departments, non-governmental organizations (NGOs), civil society, development partners and the communities themselves will be critical. I am confident that this strategic plan will adequately guide all stakeholders in designing programs for TB and Leprosy control in Malawi.

I call upon all stakeholders and citizenry to join government in its efforts to end the combined scourge of TB and TB/HIV which has the potential of derailing socioeconomic development of the country.

Hon. Khumbize Kandodo Chiponda, MP
MINISTER OF HEALTH

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Dr. Charles Mwansambo,
SECRETARY FOR HEALTH

CHAPTER 1: INTRODUCTION

1.1 Background

1.1.1 Geography

Malawi is a landlocked country with a surface area of 118,484 km2. Administratively, the country is divided into three regions, namely the Northern, Central and Southern regions. The country has 28 districts, which are further divided into traditional authorities (TA) ruled by chiefs. The TAs are sub-divided into villages, which form the smallest administrative units. The Village Development Committees (VDCs) under the TAs are responsible for development activities. Politically, each district is divided into constituencies that are represented by Members of Parliament (MPs) in the National Assembly for purposes of legislations. Constituencies are further divided into wards which are represented by a ward councillor at district assembly.

1.1.2 Demography

Demographically, the country has an estimated population of 17,563,749 million people in 2018 (National Statistical office, 2019) with an average annual growth rate of 2.9%, giving an estimated population of 22,358,192 million people by 2025, with a sex ratio of 94.2 males per 100 females. An estimated 84% of the population lives in the rural areas. Table 1.1-1 below shows the breakdown of the population by age group.

Table 1-1: Demographic population in Malawi – 2018

Population	Number	Percentage
Children age 0-59 months (under five years)	2,552,406	15%
Population age 5- 15 years of age	7,718,587	29%
Population age 15 -64	9,188,275	52%
Population age 65 and above	656,887	4%
Total population	17,563,749	

Source: *National Statistical Office Malawi*

Household size and housing characteristics

According to 2018 Malawi Population and Housing Census (PHC) there were 3,984,929 households in Malawi. Average household size for 2018 PHC was at 4.4 persons per household. The Northern Region had the biggest average household size of 4.8, followed by the Central Region with household size of 4.4 and Southern Region with household size of 4.3 persons per household.

Communication: Of the total households in Malawi (3,984,981), 51.7 % had a mobile phone, 33.6 % had a radio, 11.8 % had a television and 16.4 % had access to the internet.

Transportation: Of the total households in Malawi, 35.8 % had a bicycle, 3.7 % had a motorcycle or scooter, 2.4 %t had a motor vehicle and 2.3 percent had an oxcart.

1.1.3 Social issues and economic development

The country has made significant improvements in social services, such as health, housing, education, water/sanitation and others. There is a strong drive, by government to provide social services health inclusive free at point of use, to reduce financial barriers to their utilization. Government introduced free primary education in 1991 and enrolment increased from 1.9 million to about 3 million. The literacy rate is estimated at 62% and it is higher among men (69%) than women (59%), Self-reported literacy (reading and writing in any language) is 71.6% for males and 65.9% for females (15+ years of age) and life expectancy at birth is 63.7 years and the total fertility rate in 2015/16 was 4.4 children per woman down from 6.7 in 1992 (2016 DSHs). However, there are still many barriers to uptake of social services, mainly on the demand side (lack of decision-making especially among women due to culture and financial dependence on spouses by women, lack of transport among others).

The Gross Domestic Product (GDP) per capita in 2017 was estimated at US$1,200. The GDP growth for Malawi was reported as 4% in 2017 and projected to reach 4.4% in 2019. The national poverty line for Malawi was 51.5% in 2016 which fell gradually from 65.3 % in 1997. The extreme national poverty decreased from 24.5% in 2010/11 to 20.1 in 2016/17. Poverty is mainly driven by low productivity in the agriculture sector; limited opportunities in non-farm activities; volatile economic growth, rapid population growth, and limited coverage of safety net programs and targeting challenges (The World Bank in Malawi, 2019).

In Malawi, the wealthiest households are concentrated in urban areas. Ninety-one percent of the urban population belongs to the two highest wealth quantiles. By contrast, almost half of the rural population (46%) falls in the two lowest wealth quantiles (MDHS, 2015-16)

Malawi remains predominantly an agricultural economy. Agriculture accounts for 35% of the GDP and more than 80% of export earnings (primarily from tobacco sales) and it supports more than 80% of the population. Development aid has played a key role in stabilizing the economy over the past 30 years. In addition, diaspora remittances increasingly contribute to the country's economy (MOH, 2017).

1.1.4 Administrative and health system in Malawi

Malawi has 28 districts and is divided into three regions: Northern, Central and Southern regions. Politically, each district is further divided into constituencies which are represented by members of parliament. Administratively, the districts are subdivided into Traditional Authorities (TAs), presided over by chiefs. The TAs are composed of villages, which are the smallest administrative units and are presided over by village headmen. Villages have Village Health Committees (VHCs) which work with Health Surveillance Assistants (HSAs) on health issues at community level. HSAs are the lowest cadre of health workers employed by the MoHP. They work in the community and are attached to health facilities. Their work is mainly preventive and promotive health service provision even though recently they are more involved in case management of malaria, pneumonia and diarrhea at community level. A group of villages is headed by the Group Village Headman (GVH). At each GVH level there is a Village Development Committee (VDC) which is responsible for development activities.

Malawi has a decentralized system for the public health sector. The Local Government Act of 1998 is the legal framework within which the decentralization policy operates. The decentralization policy seeks to delegate authority, functions and funds from central government including the MoH to District Assemblies. This entails that the District Assemblies are mandated to guide the decision-making process in the public health sector, including planning, budgeting, procurement and expenditure; and to ensure efficiency, effectiveness and equity in the delivery of health services including the general provision of the EHP.

This also involves the provision of health services which has been decentralized and the responsibility for service delivery has been transferred from MoHP headquarters to the local government. Thus, district authorities have been given greater responsibility for managing health services at district and community levels. Although the health sector in Malawi has been decentralized, the central government has not fully devolved its power to levels below it. The challenges affecting health services decentralization in Malawi include shortage of human, financial and material resources; lack of administrative/management skills by staff, among other things.

The public health sector administration has two structural levels: central and district levels. The Ministry of Health has a Minister as a political head while the Secretary for Health is the administrative head of the Ministry. Departments are headed by Directors/Heads of Departments. The functions of the central level include policy making; setting standards for service delivery; planning and mobilizing health resources for the health sector; providing technical support; supervision; coordinating research; monitoring and evaluation, among others. Below the national level, there are five Zone Quality Management Offices namely North, Central West, Central East, South East and South West zones. Their role is to provide technical support to District Health Management Teams (DHMTs) in planning, delivery, supervision and monitoring of health services at district level. The district level constitutes the local government authorities and district hospitals. There are 28 public district hospitals. Each district hospital is headed by a District Health Officer (DHO) supported by a district health management team. The DHO is the overall in-charge of the district health services and reports to the District Commissioner (DC) who is the controlling officer of all sectors at district level.

Health care services in Malawi are provided by three main agencies; the public sector, Christian Health Association of Malawi (CHAM) and the private sector. Within a decentralized context, MoHP is responsible for health services delivery only in central hospitals, whilst the Ministry of Local Government oversees the delivery of health services at district and lower levels. The Government of Malawi's is the major provider of health services, contributing up to 52% of health facilities with CHAM contributing 15% of the health facilities. The rest are provided by the private for-profit sector, NGOs and other providers

1.1.5 The Global Health Development Agenda

There is global recognition of the key role of health in achieving international health Development Goals. Some of the key global commitments that impact on health include:

- United Nations High Level Meeting (UNHLM) Political Declaration on Ending TB. The FIND.TREAT.ALL. #ENDTB joint initiative of the WHO, Stop TB Partnership, the Global Fund shall support countries to achieve the ambitions expressed in the UNHLM Political Declaration

- The UN Sustainable Development Goals (SDGs) which builds upon the MDGs. 17 SDGs were agreed and of these SDG 3: *"Ensure healthy lives and promote well-being for all ages"* is directly related to health. Other SDGs related to health are: Goal 1: End poverty in all its forms everywhere; Goal 2: End hunger, achieve food security and improve nutrition and promote sustainable agriculture; Goal 4: Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all; Goal 5: Achieve gender equality and empower all women and girls; and Goal 6: Ensure availability and sustainable management of water and sanitation for all.

- Implementation of the International Health Regulation (IHR) – to guide the country on key actions needed to assure adherence to international regulations;

- Ouagadougou declaration on Primary Health Care and Health Systems – a re-iteration of and re-dedication to the principles of the PHC approach to improve the health of the people, within the context of an overall health system strengthening approach;

- International Health Partnership (IHP+) on Aid Effectiveness;

- The Abuja declaration made by members of the African Union to commit to raising the health budget to 15% of the national budget.

SDG 3, which is directly related to health, has the following targets:

Target 1: By 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births.

Target 2: By 2030, end preventable deaths of newborns and under five children.

Target 3: By 2030, end the epidemics of AIDS, TB, malaria and Neglected Tropical Diseases, and combat hepatitis, water-borne diseases and other communicable diseases.

Target 4: By 2030, reduce by one-third premature mortality from NCDs through prevention and treatment, and promote mental health and wellbeing.

Target 5: Strengthen prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol.

Target 6: By 2030, halve deaths and injuries from road traffic accidents.

Target 7: By 2030, achieve universal access to sexual and reproductive health care services, including family planning, information and education, and the integration of reproductive health into national strategies and programmes.

Target 8: Achieve universal health coverage, including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all.

Target 9: By 2030, substantially reduce the number of deaths and illness from hazardous chemicals and air, water and soil pollution and contamination.

The Government of Malawi is a signatory to all these global health development agendas and is committed to fully participating in their implementation. As such implementation of these international commitments is well integrated into the strategic focus of the health sector.

1.2 Situational analysis

1.2.1 TB Epidemiology

1.2.1.1 TB mortality

Between 2003-2012, TB mortality per 100,000 increased slightly. Deaths stabilized and started declining in the year 2013, followed by a steeper decline with smaller confidence intervals in the subsequent years. The TB mortality among HIV negative people was 11/100,000 population while among HIV positive people was 19/100,000 Population (WHO, Global TB report, 2018). Malawi currently does not have any national or sample civil registration system collecting vital statistics, including data for cause of death, which would meet the standards defined in the WHO TB surveillance checklist to analyze TB mortality. Therefore, the TB mortality estimates among HIV-negative people published yearly were utilized for the purpose of this NSP (Oterro, Pimpin, & Fukunanga, Oct 2019).

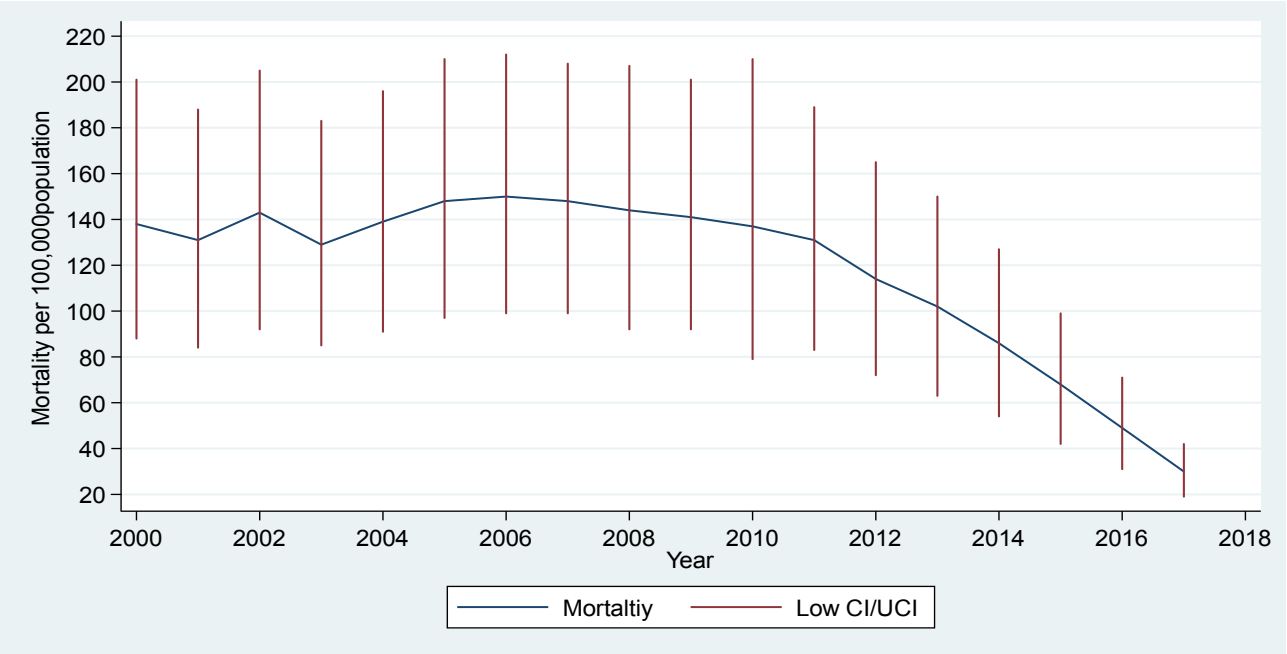


Figure 1-1: *Estimated TB mortality, Malawi 2000-2017*

1.2.1.2 TB incidence and notifications

Since 2006, both incident TB cases and TB notifications have been declining consistently. Incidence estimates were adjusted with the results of the 2014 TB prevalence survey. On this basis, TB incidence was estimated at 131 (95%CI 70-210) per 100,000 population) in 2017. (see figure below).

In 2017, the TB notification rate was within the confidence interval of the estimated incidence. Considering the point estimate for TB incidence, the program notified 69.1% of incident TB cases in 2017. The trends in the graph also show that notifications have not declined at the same pace as TB incidence. This could be a result of strengthened case detection efforts, resulting in a larger proportion of incident cases being notified as compared to some years ago.

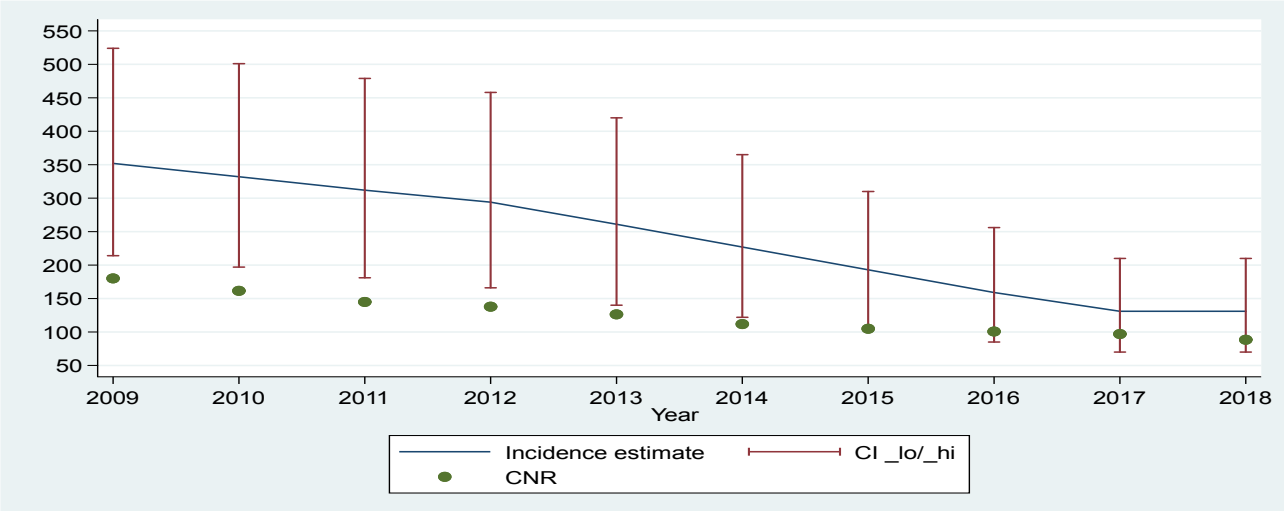


Figure 1-2: *TB incidence and TB notifications of new and relapse cases, Malawi 2000-2018*

Figure 1.2-3 show a declining trend in the rate of new and relapse notifications per 100,000 population from 129 in 2012 to 88 in 2018. Cases slightly increased in 2017 (94 per 100,000 population), which is attributed to the expansion of TB classifications to include relapse cases. Notification rates for bacteriologically confirmed TB cases fell from 46 per 100,000 population in 2012 to 35 per 100,000 population in 2014, albeit with slight increases in 2015 and 2016 (per 100,000 in both years). This could be attributable to the implementation of GeneXpert. The rate of clinically diagnosed TB has substantially and consistently decreased in recent years, from 44 per 100,000 population in 2012 to 19 per 100,000 population in 2018, which likely is a result of both the availability of a rapid molecular test, GeneXpert, and the very high coverage of antiretroviral treatment (ART) achieved in Malawi.

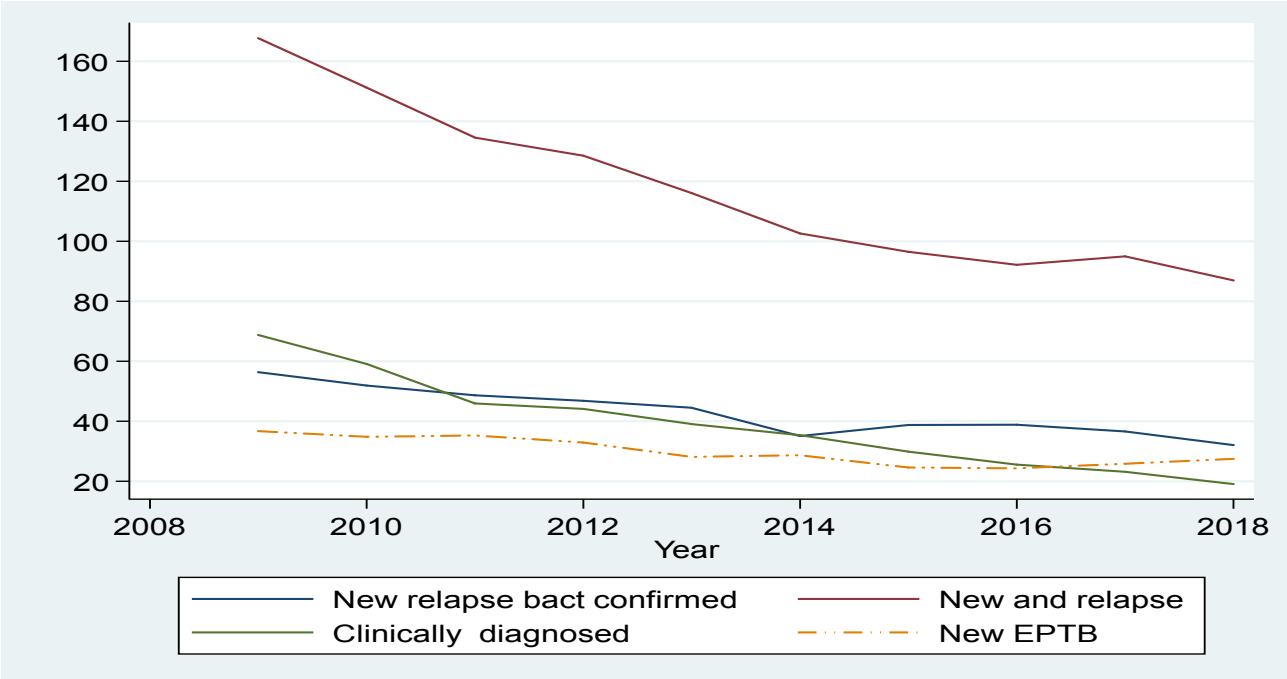


Figure 1-3: *TB notifications per type of TB, Malawi 2012-2018.*

Of all new notified TB 41% were bacteriologically confirmed TB cases. Furthermore, 35% of TB cases were extra pulmonary TB (EPTB) and 24% were clinically diagnosed PTB. Nearly 65% of all TB patients had pulmonary TB.

The diagnosis of EPTB is made through clinical and bacteriological confirmation including FNA, ascetic/CSF/ fluid analysis, LAM and physician clinical skill. EPTB contributes up to 35% of all new and relapse TB patients. The number and proportion of the EPTB has increased from the previous year (2017). Blantyre (51%), Lilongwe (44%), Chiradzulu (41%) and Zomba (38%) were districts with high proportion of EPTB. This may be attributed to the presence of central hospitals and/or partners with the required skill and diagnostic back-up to diagnose EPTB.

In contrast, health center diagnosis relies on smear microscopy where the majority are bacteriologically confirmed (Figure 1.2.4) while majority of patients in referral hospitals are EPTB.

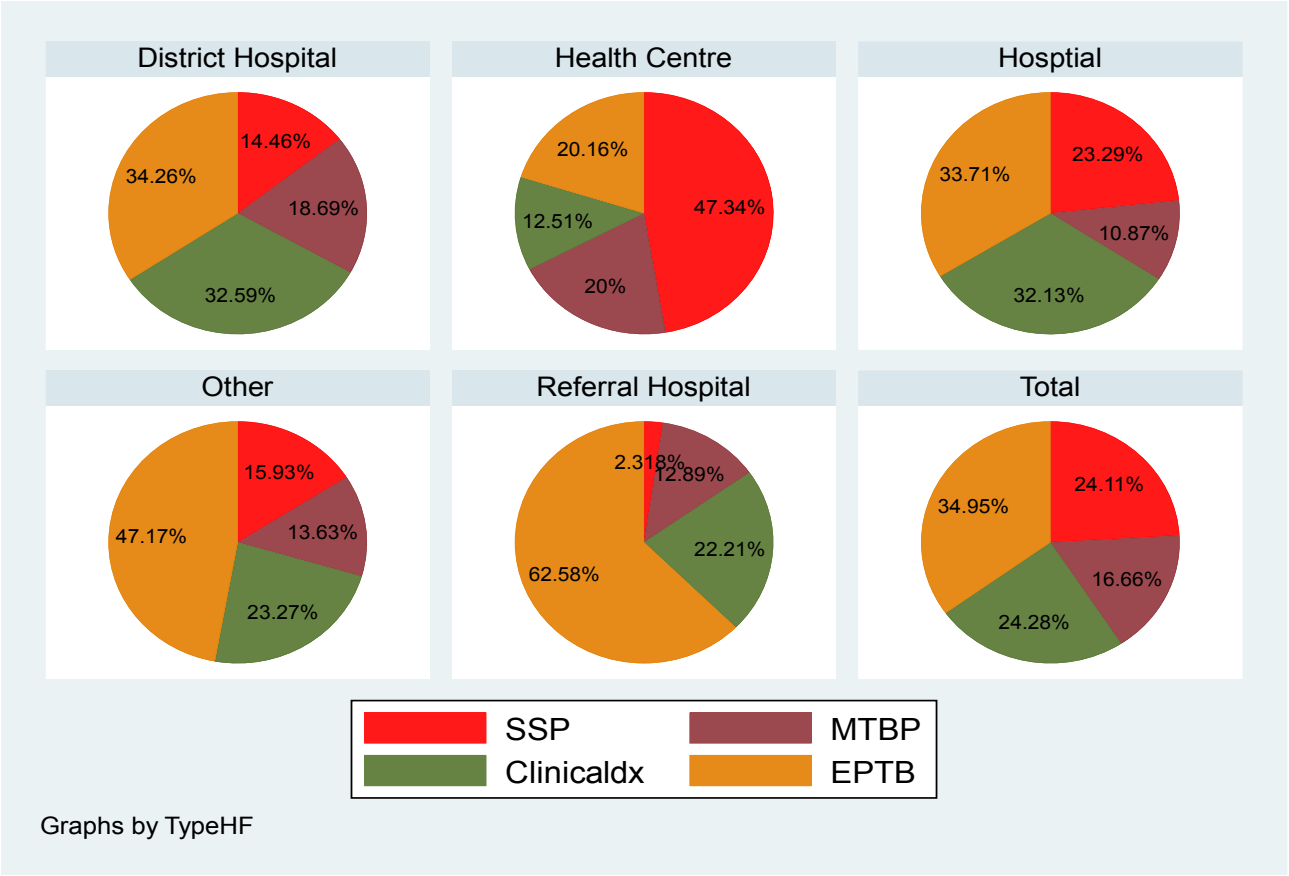


Figure 1-4: *Distribution of notified TB cases by disease category and type of health facility (Jan –Dec 2018)*

1.2.1.2.1 Geographical distribution of TB, TB notifications by zone

Figure 1.2-5 shows the TB notification rates per TB type, in each of the 5 health zones in Malawi. The zones with the rates above the national average, are the South West (165 cases for all TB forms per 100,000 population in 2018), the Central West (90 cases for all TB forms per 100,000 population in 2018). Both zones include the 2 largest cities in Malawi, Lilongwe the capital in the Central West and Blantyre in the South West. The South East reported 66 cases for all TB forms per 100,000 population in 2018, the Northern zone reported 66 cases for all TB forms per 100,000 population in 2018 and the Central East which has the lowest rates in the country with 44 cases for all TB forms per 100,000 population in 2018. Notification rates in the South West, Central West and South East zones have all substantially declined since 2008 while rates in the North and Central East have been stable with minimal declines. Therefore, the decline in the TB rates in Malawi is attributed to declines in the zones with the highest burden namely South West and Central West zones.

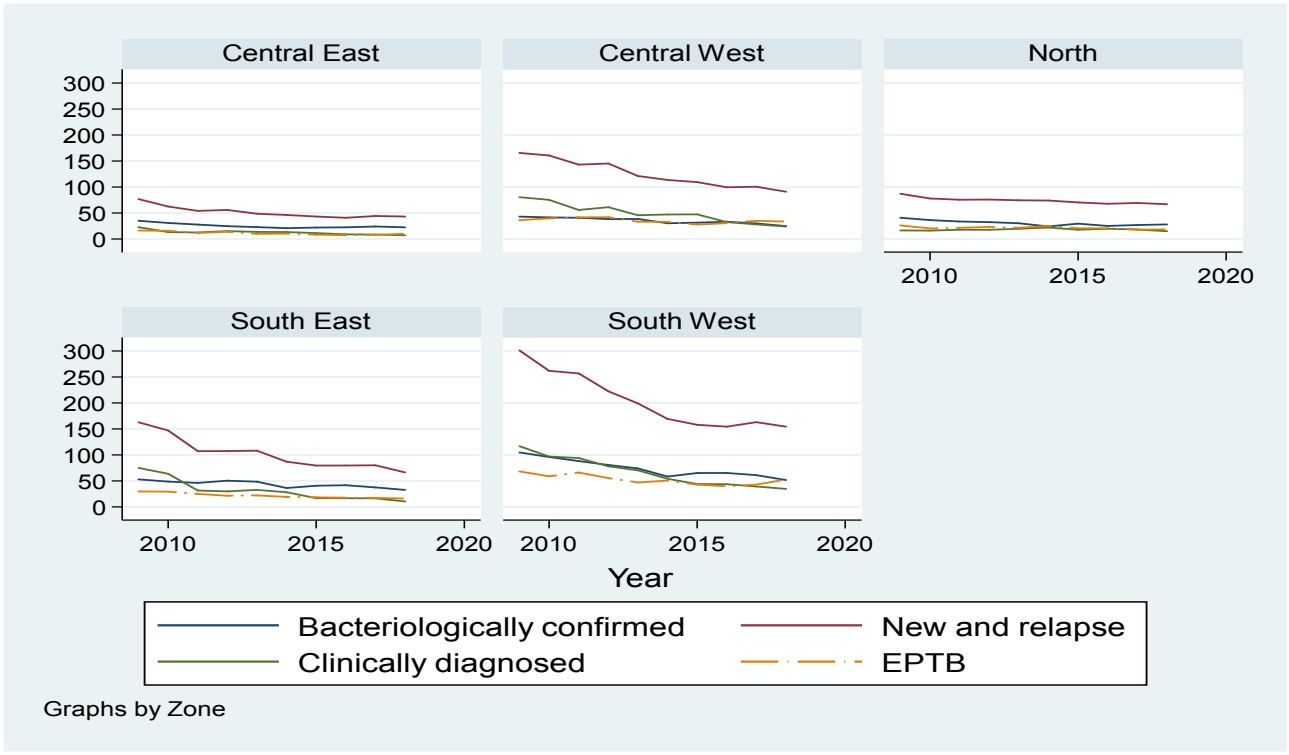


Figure 1-5: *TB case notifications per type of TB per zone, Malawi 2008-2018*.*

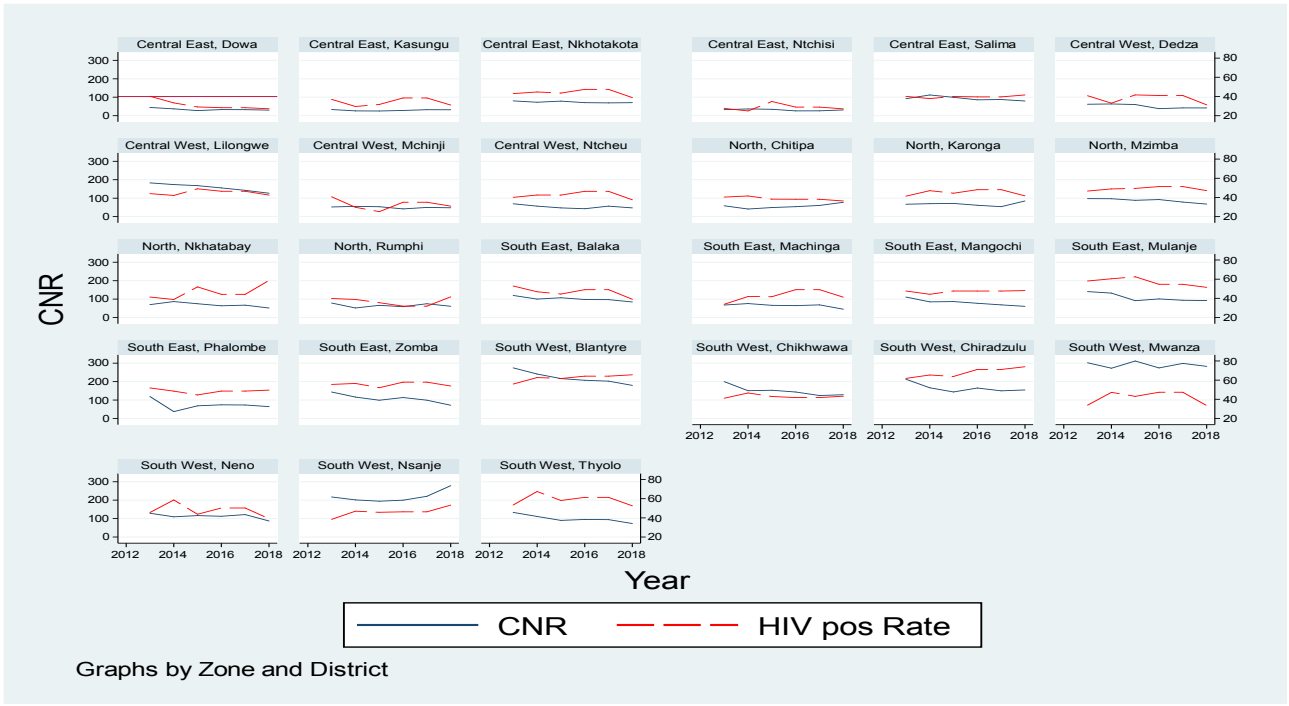


Figure 1-6: *Trend in TB case notification rate (2009-2018)*

HIV prevalence is highest in the South West zone, where highest TB rates are also observed. TB/HIV coinfection in the South West was 56.9% in 2017 (the highest in the country), whereas the Central East zone is lowest at 34.2% TB/HIV coinfection. Both the TB and TB/HIV rates are a mirror image of HIV prevalence in these zones still emphasizing the fact that TB in Malawi is largely driven by HIV.

1.2.1.2.2 Gender and age distribution

In 2018, the majority (62%) of all new and relapse TB cases were men just as has been the case over the previous years. This is consistent with findings of the national prevalence survey which showed that men had higher prevalence compared to women.

Age specific notification rate was highest among those aged 65 years and above in 2018. This contrasts with 2017 when those aged 35-44 years had the highest notification rates.

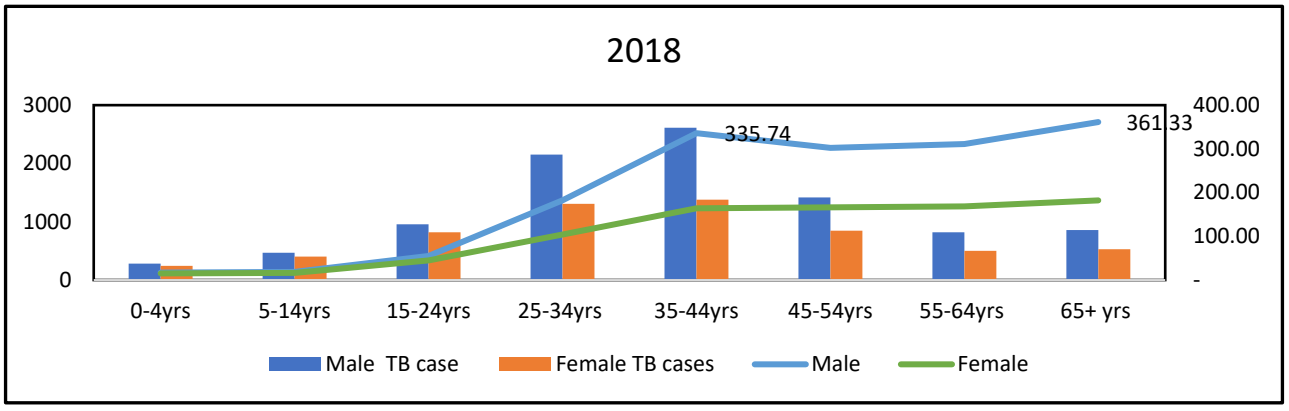


Figure 1-7: ***TB notification by age group and gender (2017-2018)***

1.2.1.3 TB in children

Childhood TB contributes to about 9% of all new and relapse TB cases. The two large cities of Lilongwe and Blantyre contributed 26% and 15% respectively accounting for just less than half of all childhood TB reported in 2018. Contribution of incident (new and relapse) cases range from 16% in Mwanza to 4% in Mulanje. This trend is similar to that for total TB notification as well as EPTB as shown already above. This can be explained by the capacity to diagnose TB in children owing to availability of expertise

as well as diagnostics in these districts that allow for diagnosis and treatment of TB in children. At this point, heterogeneity of TB burden in districts might not strongly account for the inter-district variation due to unavailability of sub national disease burden estimates.

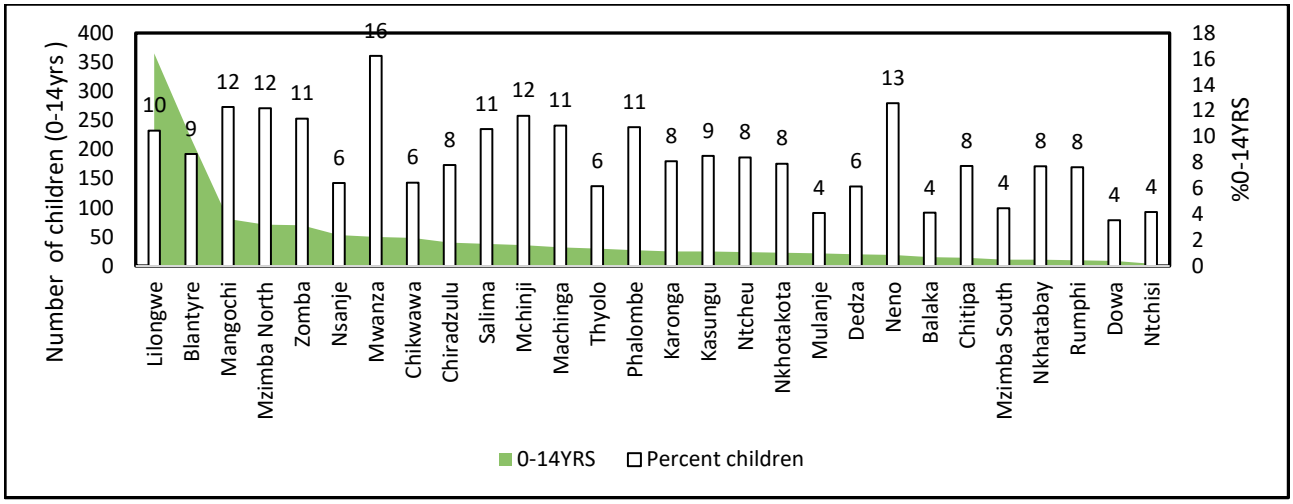


Figure 1-8:. *Proportion of children among all notified TB cases, Malawi. 2018*

Table 1-2: Treatment outcomes of children (0-4 years and 5-14 years) enrolled in 2017

Parameter	0-4 years	5-14 years
Cohort	562	824
Treatment success rate	86.5	89.8
Death rate	6.8	6.2
Rate LTF	2.1	1.3
Not Evaluated	2.5	2.5
Failure	0.0	0.1

Children aged between 5-14 years (89.8%) had higher level of favorable treatment outcome (TSR) compared to those aged between 0 -4 years (86.5%.). Treatment success rate has improved over the past year from 78.2% in 2016 to 86.5% in 2017 for children aged 0-4 years and 84.4% to 89.8% for those aged 5-14years. Children aged between 0-4 years had higher death rate (6.8%) compared to those aged 5-14 years (6.2%).

1.2.1.4 Treatment outcome

The overall treatment success rate (TSR) for new and relapse cases was 86 % with a 4% increase from the previous year. TSR among bacteriologically confirmed cases (88%) was higher than among relapse TB cases (81%) which had high death rate 13.7% and high proportion of not evaluated patients (6.1%). The national average loss-to-follow-up (LTFU) rate was 1.6% and treatment failure rate among new smear positive TB cases was 1.9%. These figures especially for LTFU and treatment failure have remained low over the past few years.

Table 1-3: Treatment outcome of patients enrolled in 2017

	New and relapse	TBHIV	SSP	MTB (new)	Clinical diagnosis	EPTB	Rel	Retreatment (no relapse)
Cohort	16321	7763	4543	1849	4008	4434	1487	430
TSR	85.8	83.7	87.6	88.3	86.8	83.7	80.9	82.6
Death rate	9.7	12.1	4.9	8.0	10.9	13.0	13.7	9.1
Rate LTF	1.6	1.5	2.6	1.7	0.9	1.2	1.7	2.6
Not Evaluated	2.2	1.8	2.9	2.1	1.4	2.1	2.6	3.7
Failed	0.6	0.9	1.9	0.0	0.0	0.0	1.1	2.1

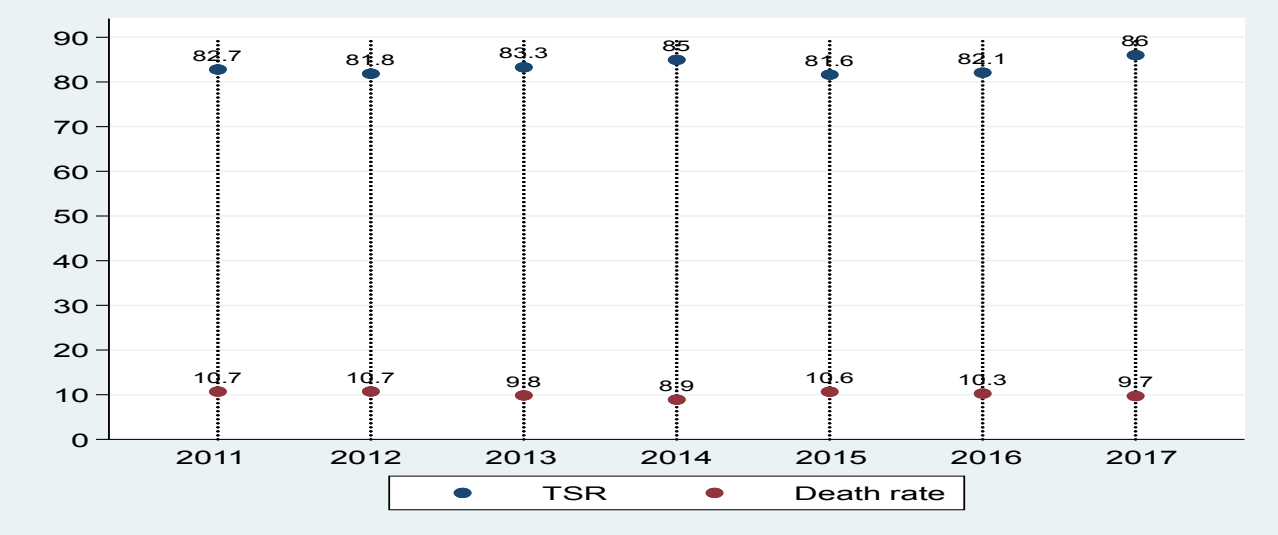


Figure 1-9: *National level trend TSR and death rate (2011-2017 cohorts)*

Out of a total of 7,763 TB/HIV co-infected patients (see Table 1.2-5) evaluated for TB treatment in 2018, 83.7% had successfully completed TB treatment. The TSR has improved by 4 % from TSR reported the previous year (80%). The success rate was comparable to the overall TSR (86%). Death rate among TB/HIV co-infected patients was higher than all forms of TB (12% versus 9 .7%). The undesirable outcome for all forms of TB were related to high rate of LTF and not evaluated patients.

The high death rate among PLHIV can be attributed to their comorbid condition. An improvement in ART coverage among TB patients might have contributed to the improvement in TSR among this group of patients.

Variation was observed among districts and over time in performance related to treatment outcomes. Kasungu, Mwanza, Dedza, Dowa, Lilongwe Balaka and Phalombe had TSR of more than 90%. The least performers were Mangochi (66% TSR), Machinga (74%) and Karonga (79%).

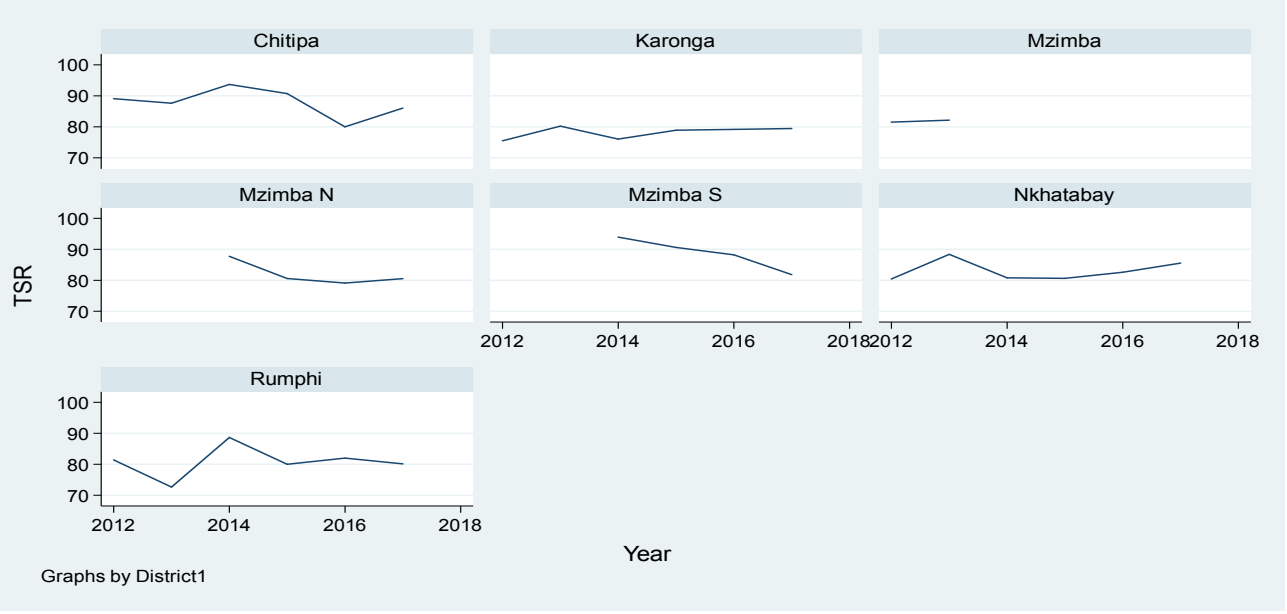


Figure 1-10: ***Trend in treatment success rate by districts (Northern region***

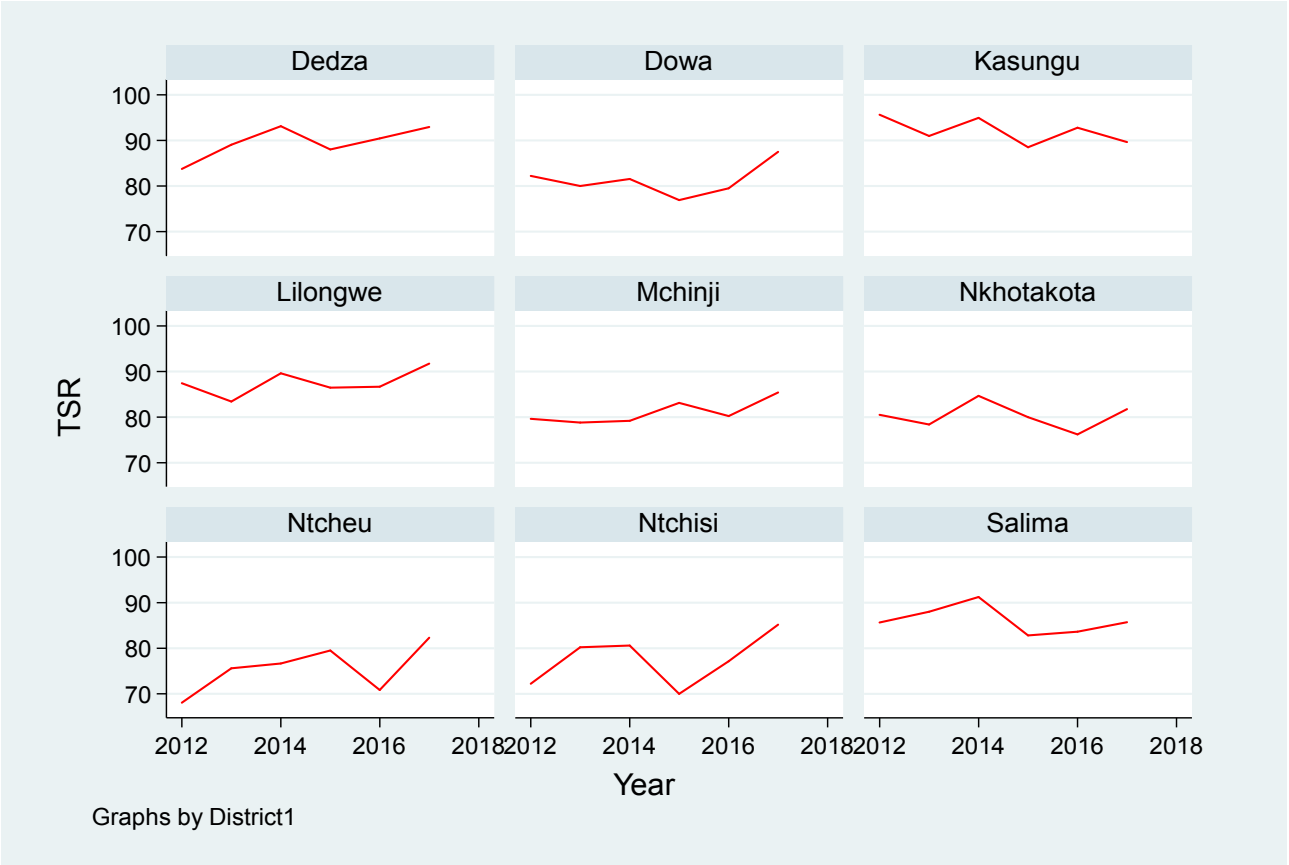


Figure 1-11: *Trend in treatment success rate by districts (Central region)*

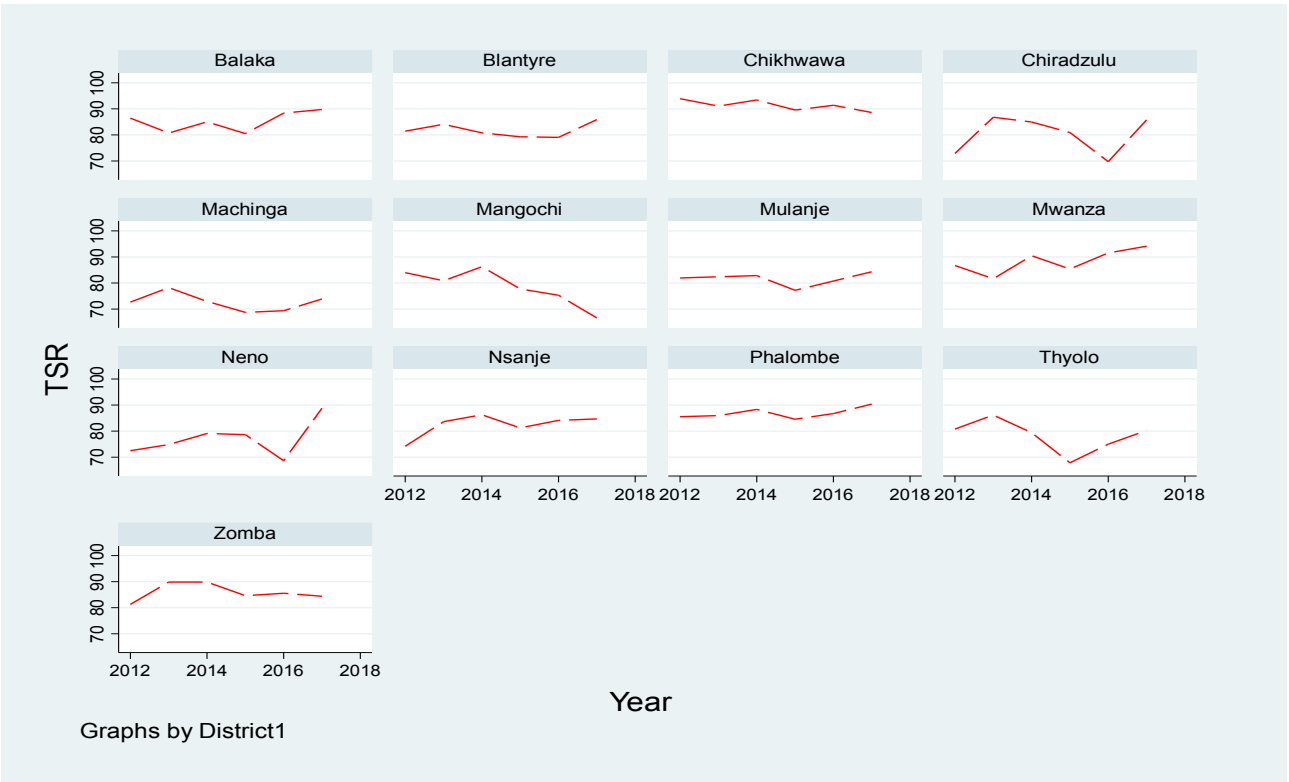


Figure 1-12: *Trend in treatment success rate by districts (Southern region)*

1.2.1.5 Drug resistant Tuberculosis

The country conducted its first Drug Resistance Survey (DRS) in 2013. With a prevalence of 4.8% among retreatment and 0.48% among new patients, the country expected to notify a total of approximately 200 patients annually. The DRS together with the roll out of GeneXpert platforms explain the jump in notification for that year and the subsequent years. It is worth noting that since 2014, patients with Rifampicin resistance (RR) after second confirmation test are treated using second line treatment. This has contributed to a sharp increase in the number of patients on Second Line Drugs (SLD) since 2014.

Table 1-4: Status of DR TB detection and enrollment Malawi (2012-2018)

Parameter	2012	2013	2014	2015	2016	2017	2018
Total anticipated DR TB patients (incident)	176	166	152	198	196	199	182
Notified MDR /RR cases (Eligible for treatment)	27	91	106	107	66	85	126
MDR /RR enrolled for SLD	19	19	65	70	59	59	107
Rate of enrolment of anticipated DR TB cases	11	11	43	35	30	30	59

By districts, 28 (26.2%) MDR/RR cases were reported by Lilongwe followed by Blantyre with 17(15.9%). Twenty-three districts reported at least 1 RR/ MDR case enrolled for second line treatment. The reporting of RR/ MDR cases in these districts might be a result of low burden of TB in general again following trends of TB case notification generally in Malawi.

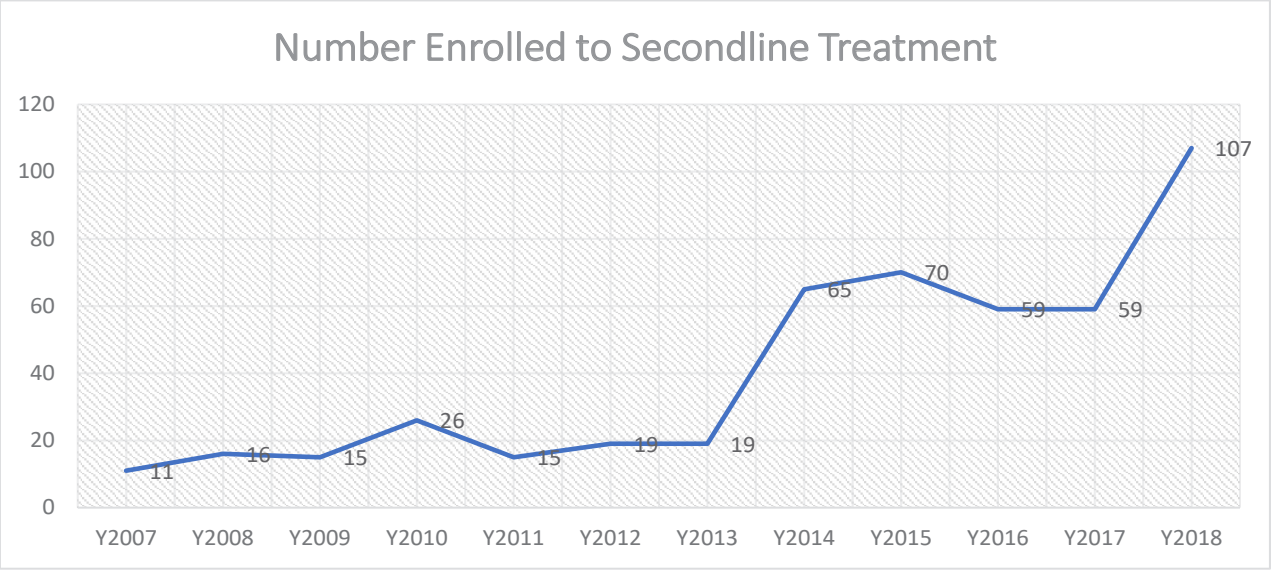


Figure 1-13: *Trend in patients started on second-line TB treatment (2007-2018)*

MDR TB patients are put on treatment as per national PMDT guidelines. During the treatment period, sputum follow up is done monthly in intensive phase of treatment and every 2 months during continuation phase. The treatment success rate (TSR) for MDR TB cases has ebbed and flowed over the past 5 years ranging from 53% in 2013 to 59% in 2016. The death rate among DRTB patients reduced from 37% in 2013 to 29.3% in 2016. Both the high death rate and the high proportion lost to follow up is a concern for the program.

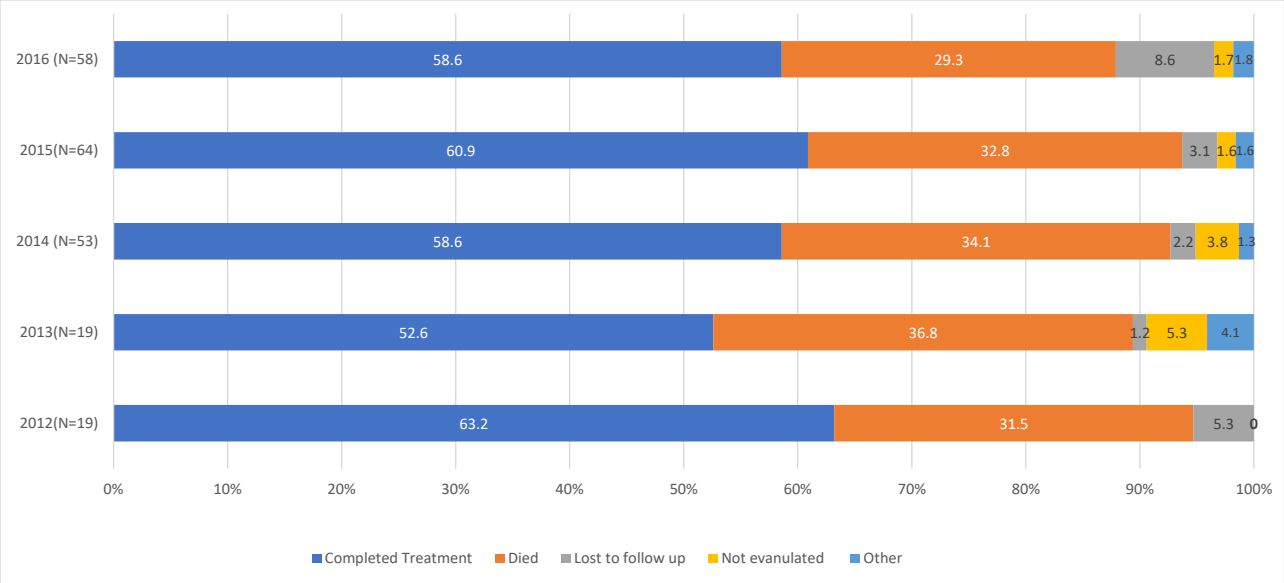


Figure 1-14: *Trend in DR TB treatment outcome (2012-2016)*

1.2.1.6 TB HIV

The trend in documented HIV status among TB patients has shown an increase since 2005 (48%) to 2018 (99) %. The testing coverage exceeded 90% in 2012 while the ART uptake reached to this level in 2014. The co-infection rate also showed a remarkable decline from 70% in 2006 to 48.5% in 2018.

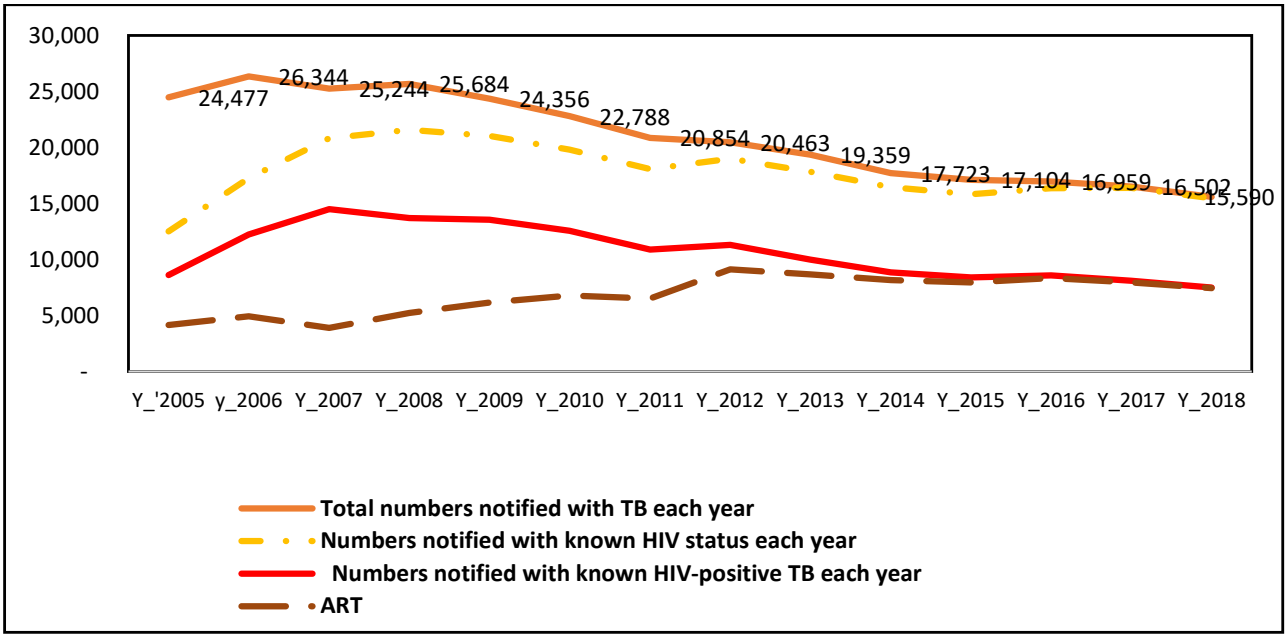


Figure 1-15: *Trend in TB/HIV collaborative indicators (2005-2018)*

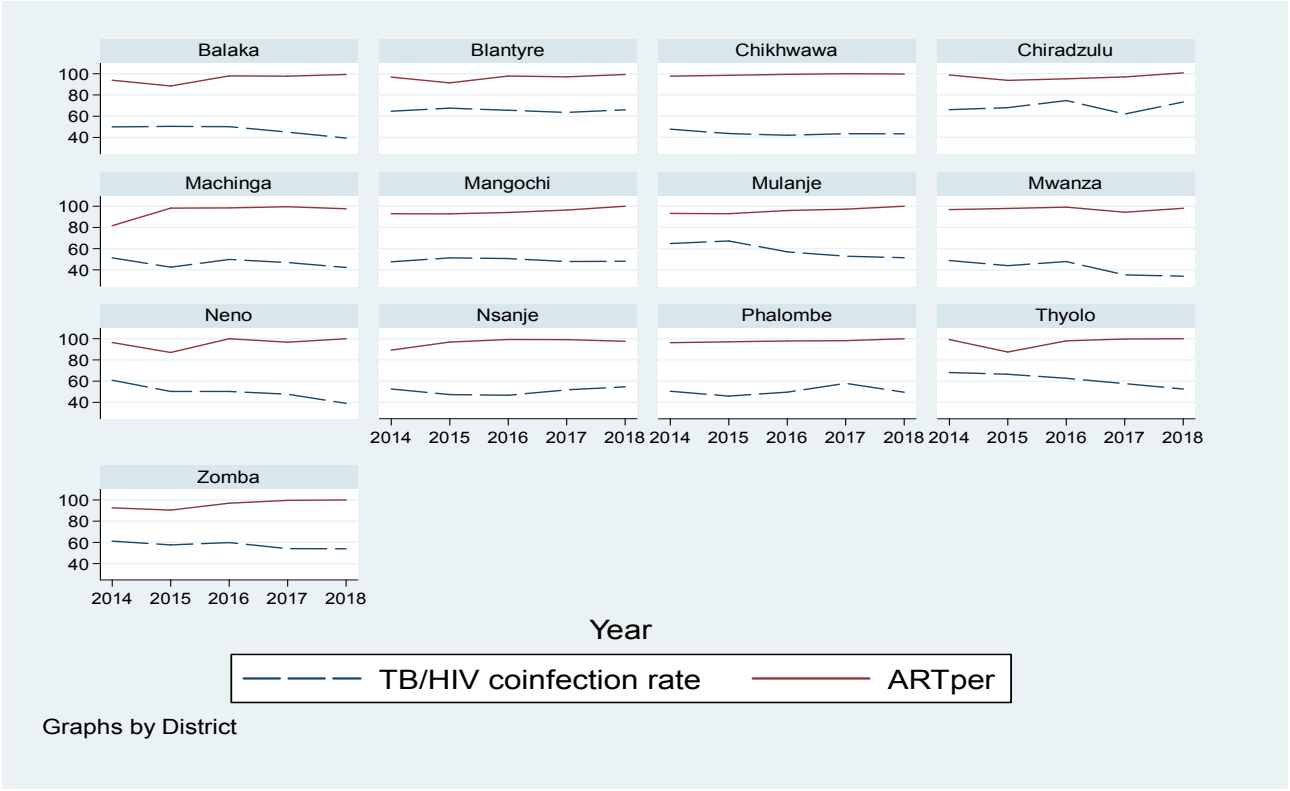


Figure 1-16: *TB HIV co-infection rate and ART uptake among TB patients (Southern region)*

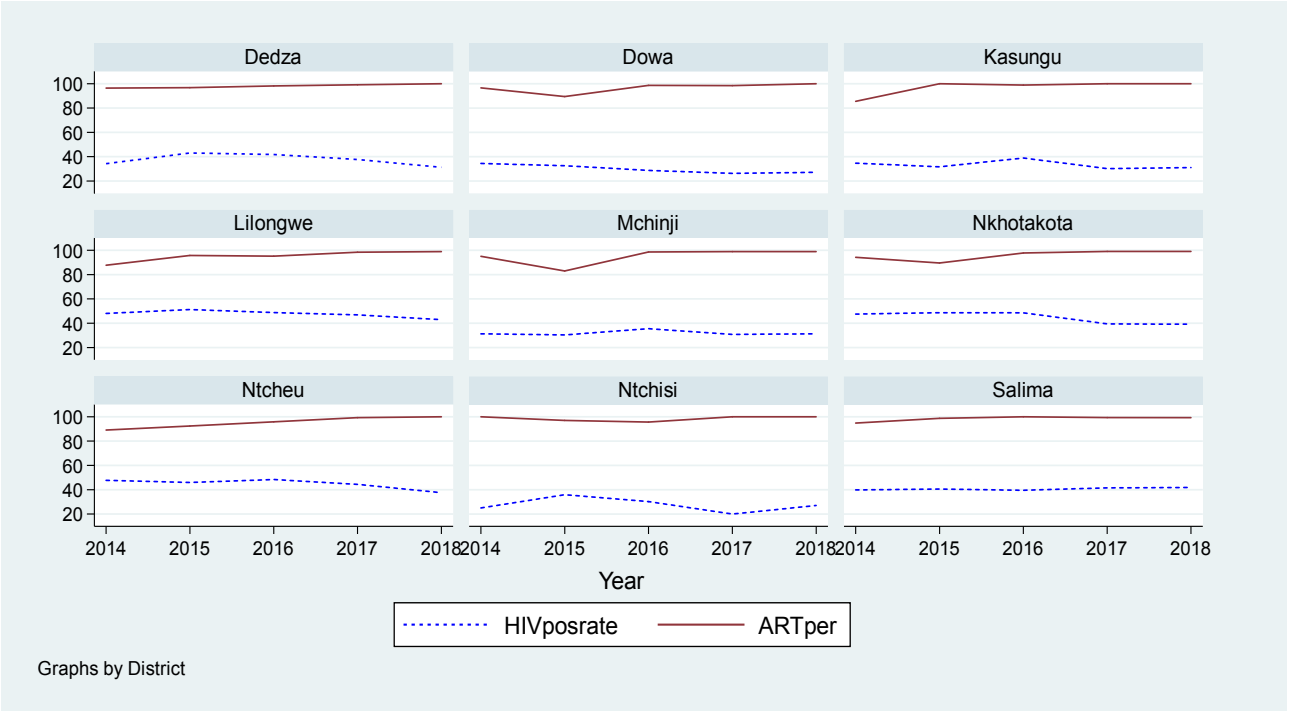


Figure 1-17: *TB HIV co-infection rate and ART uptake among TB patients (Central region)*

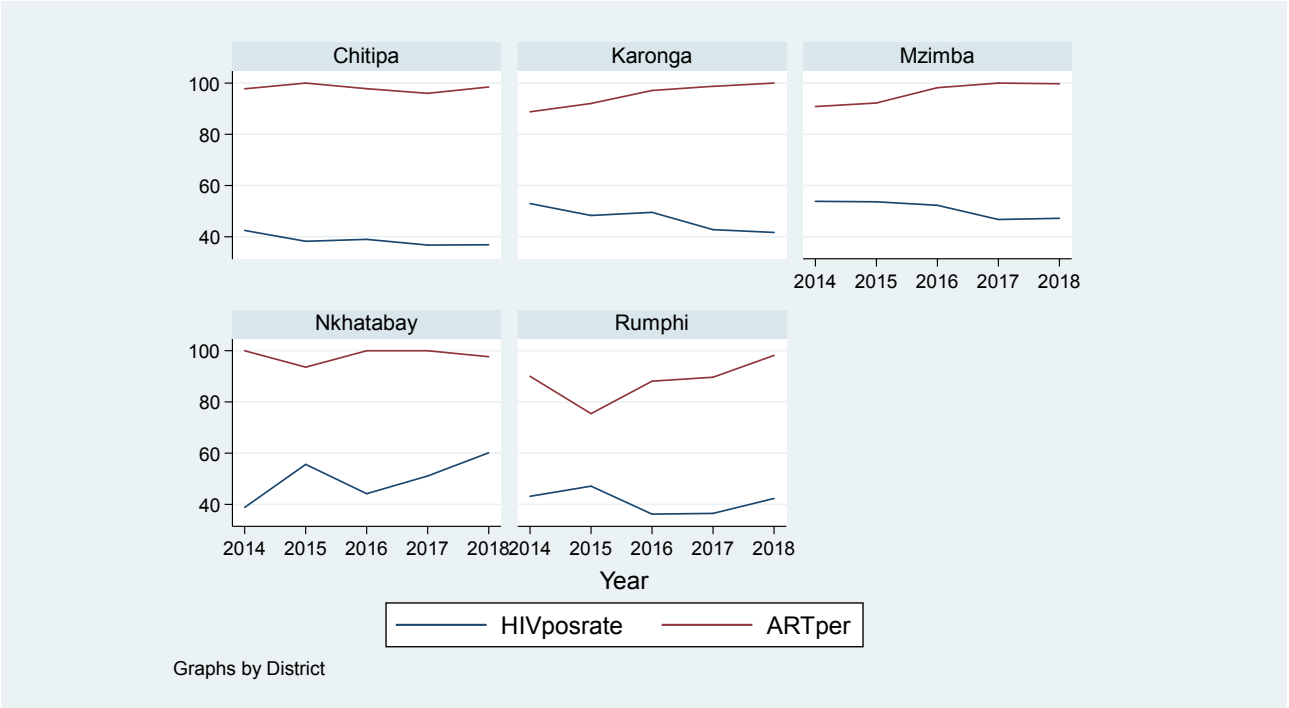


Figure 1-18: *TB HIV co-infection rate and ART uptake among TB patients (Northern region)*

HIV /TB coinfection rate and Coverage of ART

HIV coinfection rate has been on the decline since 2003 when it was at 77% to 48.5% in 2018. Among districts, the highest rate of HIV infection was observed in Chiradzulu with Dedza recording the lowest. Although the national figures indicate a declining trend in rate of coinfection, some districts show an increasing trend (see figure.) This may be attributed to the increased effort in TB case finding among PLHIV in those districts.

Since 2013, national average for ART uptake has increased to 99% from 87% in 2013. Twelve districts (43%) reported 100% ART uptake. Those districts that have not yet achieved this feat are being supported to improve as soon as possible.

1.2.2 Social determinants of health

Over the years, the TB sector has grappled with TB as a health issue. Recently, there has been growing interest in addressing the social determinants of TB. It has been documented that national TB incidence rates appear more closely correlated with social and economic determinants such as the human development index, access to water sanitation, and child mortality than to the success of DOTS. The World Bank for example advises building of social safety nets in settings with high poverty with an aim to:

- Build resilience to risks and shocks
- Advance equity in assets and access to services
- Improve economic and social opportunities

In 2008, the African Union adopted the Social Policy Framework: a framework to guide African Union (AU) Member States as they develop and/or implement appropriate national strategies and programmes. In 2012, World Bank adopted a ten-year plan entitled the Social Protection Strategy (2012– 2022) to support the expansion of Social Protection in Africa. Malawi has put up measures to cushion the poor and marginalized through among others introducing Social Cash Transfer (Ntukula Pakhomo Programme). The Social Cash Transfer (SCT), locally known as Ntukula Pakhomo, is implemented by the Ministry of Gender, Children, Disability, and Social Welfare (MoGCDSW). The SCT is an unconditional cash transfer program targeted at households that are both ultra-poor and labour constrained. The SCT has the objective to reduce poverty and hunger among ultra-poor and labour constrained

households; to increase school enrolment of children in the beneficiary households; and to improve the nutrition, economic, and general well-being of beneficiaries.

Another social protection program is the Public Works Programme (PWP) implemented by the Ministry of Local Government and Rural Development through the National Local Government Finance Committee (NLGFC). PWP are programmes that provide regular payments to individuals in exchange for work, with the objective of decreasing chronic or shock-induced poverty and providing social protection. The PWP targets the ultra-poor households that are not labour constrained and currently focuses on 11-25% of beneficiaries identified by the UBR. The School Feeding Program is implemented by the Ministry of Education and is a response to studies that have shown the disastrous effects malnutrition has on the development of physical and mental capabilities of children. The goal of all school feeding activities is to improve child nutrition, increase children's' ability to concentrate in class, promote enrolment and regular attendance.

The Fertilizer Input Subsidy Programme (FISP) is implemented by the Ministry of Agriculture. The FISP serves two main objectives, which are reducing poverty and ensuring the country's food security by fostering an increase in agricultural productivity levels

Cement and Malata Subsidy Programme seeks to provide affordable access to building materials by the poor. This may have positive effects on reduction of TB transmission through better housing.

1.2.2.2 Human rights and social barriers

Reaching key populations in an equitable manner is a human rights imperative. Social – economic barriers such as stigma and discrimination, gender disparities, social cultural barriers such as negative beliefs and myths that impede access to services, differences in economic status still exists and have a bearing on access of TB service across populations. To tackle these issues, deliberate efforts to address TB key populations and associated stigma, gender and legal environment shall be made. Central to these efforts will be assessments to understand and measure the impact that these factors would have on overall TB programing, by analyzing key indicators on human rights, legal, gender and social – economic aspects building on the Universal Health Coverage goals.

Addressing these barriers from a program point of view, can, increase case detection at facility and community level through increase in health seeking behaviors among patients by means of patient empowerment, decrease default rates through reduction in stigma and access barriers, develop a community of engaged communities with an ability to decrease infection rates within the communities and increase community-led case detection efforts.

Communities and Civil Society are central to ensuring human rights, legal, gender and social barriers are addressed to accelerate Malawi's progress towards achieving the TB UNHLM, End TB Strategy and 2021 – 2025 TB National Strategic Plan targets. CSOs and Affected communities need to be empowered to generate evidence for action through Community Based Monitoring (CBM) to contribute to TB governance, and decision making both at national and sub national levels. This can be achieved if these groups are mobilized and organized in groups and/or networks where information sharing, dissemination and peer support is sustained. Investing in building the capacity and coordination of TB key populations in advocacy, treatment literacy, peer support, monitoring and evaluation, program design, procurement and human rights which together, can create a care – enabling environment for those most vulnerable.

1.2.2.3 Systems for health

Despite tremendous strides made to increase human resources in Malawi, there remains gaps in human resource for health for optimal functionality of the health system. This includes laboratory technicians and technologists', nurses, doctors, clinicians and pharmacists. Even though the Government of Malawi together with its partners have funded human resources for health training at the undergraduate and postgraduate level there is still need to continue investing in this critical resource for the sector.

Health Information Management system is another crucial area that requires special mention in the fight against disease. There are various Health Management Information Systems and M Health or E Health initiatives as Malawi continues to steadily move towards digitalization. The Ministry of Health has created a coordinating mechanism within the Ministry to ensure that all systems are built with compatibility and interoperability of systems old and new; efficiency by cutting out duplication of systems; integration of systems across programs; and the scaling of systems rather than a fragmented project like operations. The systems are being built

with a patient centered approach meaning they are first and foremost for making patient management easier by integrating multiple databases into one system and secondly for aiding the monitoring and evaluation functions of the ministry of health and its myriad user departments second.

In the midst of scarce resources, the country shall ensure that resources are put to the best use and ensure accountability. In this regard, Malawi shall continue to work with other sectors and implement the TB Multi-Sectoral Accountability Framework (MAF) which seeks to ensure accountability at all levels.

1.3 Health sector governance and planning; community systems strengthening to support community response

The NTLP shall take into consideration governance structures in its planning and implementation of this strategy. These include but not limited to public sector management; local participation and community empowerment; civil society, media and private sector interface, and formal oversight institutions among others. This NSP draws inspiration from the Malawi Growth and Development Strategy as an overarching strategic document for the country as well as the Health Sector Strategic Plan. International policies and commitments shall also be referred to, considered and provide guidance to this document. Service delivery in health is guided by regulatory agencies including the professional bodies e.g. medical and nurses councils. Citizens participation and feedback shall also be emphasized and deliberate structures put in place including grievance redress mechanisms. Communities shall be organized and mobilized to play a more effective role in disease control. The media and the private sector and their role in national development has been recognized and they shall be involved at all stages of the implementation of this NSP.

1.4. SWOT Analysis for tuberculosis

Area	Strengths	Weaknesses
TB diagnostic and detection	• The country has the infrastructure and capacity to perform LPA, Ultra Assay and urine TB LAM • Major equipment at the NTRL and regional labs (MGIT, BSCs, air handling unit) are maintained • Service level agreement is available for all GeneXpert machines in the network • A mechanism for EQA for of TB microscopy is in place • A Regular mentorship and on-site support for high volume facilities is in place • Standard Operation procedures are available (sample collection, transportation processing) are available • There is capacity within the country to train laboratory personnel on new and existing diagnostic technologies • External technical support is provided by SNRL-Uganda for TB. • The NTRL has functional laboratory information system LIS (NTRL) and Gx alert for Xpert network (Functional Digital X-ray machines are available in most of the district hospitals and all central hospitals	• Limited access to the existing and new diagnostic technologies • there is a gap in coverage TB microscopy service • Long turnaround time for sample transportation, processing and delivery of result mainly attributed to poor sample tracking system, noncompliance to the SOPs and limited coverage of curriers system • Inadequate Infrastructure for expansion of TB diagnostic service, to peripheral laboratories which do not meet the minimum safety standards • There is Lack of local capacity for maintenance and servicing of heavy-duty laboratory equipment and reliance on external service provider • Sub optimal EQA coverage for TB microscopy (73%) against target of 100%. • Inadequate staffing at NTRL to support testing and supervision activities. • Limited use of chest radiography for diagnosis of TB • Suboptimal use of Gx-Alert

Area	Strengths	Weaknesses
TB case finding in health care setting	• Increasing trend in number of presumptive TB individuals (10% in 2018) Xpert use increased by 64% in 2018 compared to 2017 • Some districts achieved CNR >127/100k (range from 127 to 283 per 100k population • improved coverage of contact investigation and enhanced case finding in most health facilities. • Health workers were trained in systematic TB screening • Availability of presumptive registers and SOPs in all facilities • Prioritization matrix was developed to guide active case finding efforts based on yield, case detection effort and notification data.	• Sub optimal yield form TB screening at health facilities • Low yield among presumptive 5-6% vs 10% target • Lack of dedicated personnel for implementation of TB screening at health facilities • Limited integration of TB screening in other service delivery points (MNCH, Wards, HIV and NCD clinics) • Sub optimal intra and interfacility referral linkage • Low case notification, about 7000-7500 TB cases are missed each year, • Variation in TB notification, Case detection effort (Microscope and Xpert) across districts • The general OPD register does not has information on TB screening status.
Detection: DR TB	• There is capacity to perform for full C & DST services in 3 regions. • All Xpert machines are connected through GX-Alert. • Availability of PMDT guidelines and SOPs • GeneXpert is a primary diagnostic test for nearly 40% of the presumptive TB nationally • Trained HCWs on PMDT	• Low Case detection for DR-TB, less than 59% of estimated DR TB cases identified in 2019. • Low Culture and DST coverage among all notified TB cases (20%). • gap between notified and enrolled DR TB patients • Un-reliable sample transportation system from district to NTRL • limited coverage of Currier services within district (Riders for Health visit facility only 2-3 times a week). • Limited access to GX Alert.

Area	Strengths	Weaknesses
Treatment: DS-TB	• Improved overall Treatment success rate (87%) • Availability of DOT • Reliable system for supply of First line TB medicines	• High death rate among smear negative, EPTB, retreatment and HIV positive individuals. • Low TSR among PLHIV in central hospitals (78.8%)
Treatment: MDR-TB	• Reliable system for supply of SLDs to TB treatment initiation center. • The country transitioned to short and longer full oral regimen • The program has dedicated PMDT unit at central level, • Functional clinical mentors at district level • The program has placed a laboratory monitoring equipment in district hospitals • Core aDSM package is adopted to assist reporting of adverse events • Nutritional and other psychosocial support are in place for patients • Community awareness (documentaries on ex-patients who have treated successfully)	• Low TSR (58%) and high death rate (29%) and high lost to follow up (8.6%). • Patient support system doesn't cover all aspects of required supports • interrupted supply of lab reagents for monitoring electrolytes / TSH • Irregularity of monthly clinical review for DR-TB patient on treatment • Sputum Culture and smear follow up tests are not done regularly or not properly documented. • Insufficient linkage between DR-TB treatment initiating center and diagnostic sites • Inadequate capacity of health care workers to diagnose, report and management adverse events. • Stigma among health care workers and community

Area	Strengths	Weaknesses
TB supply chain Management	• Capacity at national level to carry out quantification and forecasting (program use Quan TB for Pharmaceutical) • Availability and use of stock management tools (stock cards, ordering books, drug balance book) • Adherence to FEFO • Improved supply chain management in terms of accountability, inventory management and traceability • Upgrading of TB warehouse in the South and Central regions. • Availability of tracking mechanism for TB commodities at CMST • Procurement of TB medicines and other supplies from WHO pre-Qualified suppliers. • There is capacity at PMPB to perform quality assurance, pre-registration, pre-distribution, post distribution as well as aggregate analyze informal adverse drug reaction.	• Limited capacity for supply chain management at district and facility level • Sub-optimal traceability of TB Commodities at district level and registration sites • Logistics Management Information System (LMIS) for TB laboratory commodities is not widely used • Limited use of quantification tool for laboratory commodities • Inconsistent use of available data for ordering medicines at facility level • In adequate use of exiting forums to discuss PSM issue at zone and district level • Inconsistent use of document 3 (Drug balance book) and 4 (Drug ordering book) during issuing and ordering of TB medicines. • Limited adherence to min-max level at the regional warehouses (operating on thin level)

Area	Strengths	Weaknesses
Childhood TB	• Implementation of contact investigation • TB screening among HH contacts (91%). • High IPT completion rate (90%). • Availability of Integration with under 5 clinics in selected districts • Better TSR among children >90% than adult. • Pediatric friendly commodities available in all facilities. • Digital Chest X-ray machines installed in all districts	• Lack of advanced technologies to diagnose TB among children. e.g. limited capacity for Sputum induction, gastric Lavage and use of Stool sample for TB diagnostic • Suboptimal contribution of childhood TB to case notification • Suboptimal yield from Contact investigation • Lack of specific diagnostic algorithm for children • Limited integration childhood TB with other service delivery point • Management of TB among children is centralized and No strong referral linkage with peripheral health facilities • Inadequate capacity of HCWs at district and health center level to diagnosis TB in children.
Contact investigation	• Contact investigation and enhanced case finding. • Availability of M+E tools. • Training conducted. • Dedicated focal point. • HR-staff committed to other programs, high turnover of staff.	• Low TB yield from contact investigation intervention (Less than 1%). • Low IPT coverage in children 59%. • Low adherence to SOP's by health workers evidenced by incorrect documentation.

Area	Strengths	Weaknesses
TB/HIV	• Availability of TB/HIV policies • Availability of TB/HIV coordinating mechanism at both facility and national level. • Good performance - HIV ascertainment, ART uptake. • Reduced TB incidence among PLHIV. • HIV screening among TB patient and IPT for newly enrolled to HIV care. • Program introduced LF-LAM to role in TB among HIV patient with advance diseases • Updated policies. • IPT for newly enrolled to HIV care patients.	• Low coverage of HTS among presumptive TB cases. • High death rate among TB-HIV co-infected patients. • Quality of TB screening among PLHIV-Low yield and declining TB cases despite increasing X-pert test among PLHIV. • Suboptimal integration of TB into other service delivery areas • Low coverage of TPT among eligible PLHIV and Children • Low X-pert coverage among presumptive PLHIV (80%) • Only 352 out of 745 Health facilities, provide TB registration services hence challenge in referrals • Although there are challenges related to M&E tools

Area	Strengths	Weaknesses
Key Affected Population	• Introduction of mobile TB diagnostic units equipped with digital X-ray with CAD4TB targeting the key population • The Active case finding approaches contributed up to 9% of the total notified TB cases • Introduction of outreach mobile screening program • Regular technical support and review of the performance in place for ACF • Mapped hotspot sites in the rural area potential for scaling up • Availability of various recording and reporting tools • Introduction of regular TB screening of health workers, Prisoners, refugee, miners and urban poor	• Limited access to TB services among key population • Limited TB awareness among key populations resulted in low health seeking behavior among key population • Inadequate services for health care workers with TB • Limited participation of key stakeholder in addressing the need of key population • Inadequate community awareness on TB • Lack of digitalized data management system • High staff turnover in mobile TB diagnostic unit • Unreliable gadgets for transmission, receiving and reading of image • TB key affected population are not well mapped and defined

Area	Strengths	Weaknesses
Public Private Mix	• Presence of PPMx secretariat at national level to Coordinate the activities • Presence of function PPMx steering committee • Training for private care providers TB • Mapping of private providers and traditional healers • Regular public Private Mix focused supportive supervision • Presence of PPMx action plan and operation guideline • Regular coordination forum for PPMx with stakeholders	• Suboptimal engagement of private health care providers in provision of TB care • Limited engagement of corporate and workplace policies in TB care and prevention • Suboptimal involvement of informal care providers /medicine stores /pharmacies • Inadequate capacity to diagnose and manage TB patient in private sector • Suboptimal linkage between public and private health facilities • Limited engagement of the uniformed services. • Limited resource for implementation of activities in PPM action plan

Area	Strengths	Weaknesses
Engage communities and CSOs on TB	• Improved community contribution (4.8%) on TB case notification • There are more than 1,600 CSCPs • Quarterly review meeting at district and HFs level • Continuous community awareness on TB using CSCPs volunteers • Introduction of TB source book in primary schools • Mapping of hotspot sites for HH • Engagement of Parliamentary TB coccus. • Active engagement of media professional in TB	• Limited coverage of sputum collection points • Low yield and limited coverage of active case finding through house to house intervention • Minimum integration between HIV and TB screening at community level. • Inadequate coordination and engagement of CSOs • TB screening is not integrated in package of IMCI village clinic • Lack of patient centered communication approaches • Inadequate enablers and incentive for volunteers as a result high proportion dropout of CSCPs volunteers • Inadequate number of trained volunteers per sputum collection point • Inadequate supportive supervision and monitoring mechanism for CSCPs

Area	Strengths	Weaknesses
TB infection prevention	• Availability of Personal protective devise (87%), TB-IC guideline and SOPs, trained staff on TB-IC. • Started HCW's screening in 5 districts. • Implementation of FAST Strategy in four hospitals (Mangochi Machinga, Zomba and Chichewa district hospitals). • Regular TB screening in prisons	• Unavailability of functional TB IC committees in some health facilities (30% had no functional IC-committee) • Unavailability of TB IC plans in some facilities (40% registration site had no TB-IC plan) • Limited coverage of GUV systems • Inadequate structures for HCW collection/segregation, storage, transportation, treatment and disposal • Limited knowledge among HCWs on health care waste management
Latent TB treatment	• Implementation of IPT in high TB burden districts among PLHIV • High IPT retention • Contact investigation in place (SOPs)	• Limited coverage to only five priority districts. • Suboptimal coverage of IPT for the following group: - • People living with HIV in non-priority district • Suboptimal implementation of CI. • Misconceptions on IPT-provider/beneficiary on IPT (risk vs. Benefit) would derail scale up.

	Opportunities	Threats
	• Presence of strong political and leadership support • Funding from Global Fund, USAID and World Bank • Presence of various CSOs operating in the community • Availability of global guidance and support through GLC, GDF and STTA • Care of care policy available (2% of chronically ill patients) • Presence of cadres at grassroot level to optimize for TB prevention and care • Ongoing global development of new drugs and diagnostic tools • End TB strategies and UN targets provide ambitious goals to aim for by national program • In-country innovations and pilots with potential for replication and scale-up	• Intermittent Power breakdown, module failure as well as poor maintenance • Poor internet connectivity as well as damage of server • Emerging higher forms of resistance • Natural disasters which led to internal migration and overcrowding • Unpredictability of external funding sources, e.g. Global Fund funding mechanism and funding by other donors • Insufficient financial expenditure for health in the national budgets compromises the allocation to TB • Varying implementation capacity and ownership of the district council level

SWOT Analysis of the Leprosy control programme

Strengths	Weaknesses/gaps
Continued WHO support through provision of free MDT and technical support Presence of trained focal person for leprosy at national level Strong political commitment and leaders ship supporting the elimination of leprosy Presence of skilled coordinator in few districts	Suboptimum leprosy diagnostic services with limited knowledge and skills in case management among health care workers Inadequate involvement of HSAs and other Health care workers in leprosy prevention and control at all levels Low level of Community awareness on leprosy resulted in delay of leprosy patients to present themselves at health facilities High level of stigma and discrimination associated to leprosy Limited Funding for leprosy control activities Poor record keeping and non-reporting by the newly deployed health workers.
Opportunities	**Threats**
Presence of annual commemoration of World Leprosy day Integration of leprosy into other disease control programmes for leveraging resources Integration of the leprosy activities in the context of the essential package of health services UN resolution on the human rights of persons with disabilities Presence of various CSOs operating in the community	Minimal government contribution towards Leprosy control Global financial crisis affecting donor contributions An upsurge of communicable diseases attracting more focus by the donor community Varying implementation capacity and ownership of the district council level

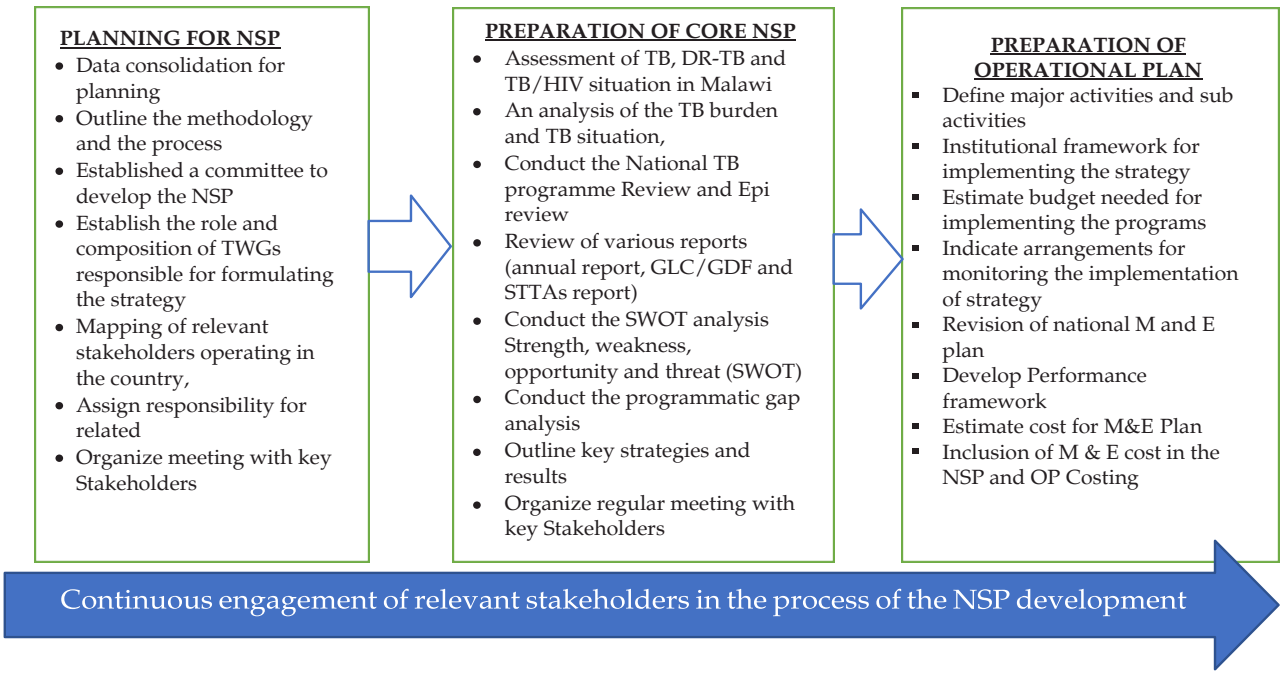
CHAPTER 2: DEVELOPING THE NEW 2021-2025 STRATEGIC PLAN

2.1. National Strategic Plan Development Process

The NSP development process followed the roadmap as outlined in the following diagram. Prior to the commencement of the NSP development process, a stakeholder consultation workshop was held, to which all relevant stakeholders and partners were involved, including representative from CSOs, development and Technical partners, Department of HIV/AIDS, Ministry of Labour, Youth and Manpower Development and Ministry of Natural Resources, Energy and Mines and other MOHP departments. Stakeholders and partners were continuously involved in the process of the NSP development from the inception to completion of the NSP. The development process was guided by national Steering Committee composed of members from CSOs, representative from stakeholders and Implementing partners, WHO, USAID, CDC, Other collaborating line Ministries including the Ministry of Finance, Ministry of Economic Planning and Development, Ministry of Justice, Ministry of Labor, Youth and Manpower Development , Ministry of Natural Resources, Energy and Mines, Ministry of Home Affairs, Ministry of Local Government and the Department of Public Sector Management.

The process was initiated by a review of the available evidence conducted by NTLP. Reviewed documents were 1) WHO External program review, 2) World Bank Mid-term program, 3) 2017 and 2018 annual program reports, 4) Various STTA reports (GDF, rGLC), 5) Various Global Fund/LFA Spot check reports, 6) NSP 2015-2020 and End TB strategic documents.

Goals and strategic objectives are formulated in light of reaching the global target set under End TB strategic and SDG. The NSP goals and objectives for 2025 are in line with the end TB millstone for 2025. The 2018, WHO Global TB report were used as baseline for setting the targets for each year.



The draft NSP has been endorsed by the stakeholder's engagement in December 2019. The Approval from Ministry of Health and Population was obtained in the 2019.

2.1.1 The global and regional priorities

This NSP recognizes the GoM commitment to a number of regional and international commitments/Declarations to the fight against TB. These include:

1. The 2001 African Union Members Abuja Declaration for national governments to allocate a minimum of 15% of its national budget to the health sector.
2. The 2008 Ouagadougou Declaration on Primary Health Care and Health Systems in Africa which seeks to achieve better Health for Africa in the New Millennium.
3. The 2005 Paris Declaration on Aid Effectiveness, the Accra Agenda for Action and the Busan Partnership for Effective Development Cooperation which call for harmonization and alignment of aid in all sectors.
4. Maputo Plan of Action for the Operationalization of the Sexual and Reproductive Health and Rights (SRHR)
5. The 2012 Tunis Declaration on Value for Money, Sustainability and Accountability in Health aimed at increasing domestic funding through cooperation between Ministries of Health, Ministries of Finance, and technical and financial partners.

6. The 2012 African Union Roadmap on Shared Responsibility and Global Solidarity for AIDS, TB and Malaria in Africa which established the commitment of African leaders to strengthen country ownership to secure health security by investing national resources in order to reduce dependence on external financing.
7. The UN Sustainable Development Goals (SDGs).
8. The 2012 SADC Heads of State Declaration of TB in the Mining Sector.
9. The Moscow Declaration on TB
10. The Political Declaration of the UN High Level Meeting on Ending TB
11. The End TB Strategy

2.1.2 Guiding Principles

2.1.2.1 Country leadership and partner participation

The Government of Malawi provides the leadership in implementation of this document through the Ministry of Health and Population and other government ministries and departments. The National TB Control Program as a department within the Ministry shall provide the day to day guidance and leadership in the implementation of this strategic plan. Partners supporting the Government of Malawi shall abide to and cooperate with the GoM in implementation of this strategy through technical, financial, advocacy assistance, and such support as agreed with the GoM. The GoM appreciates the support provided by its partners in this sector and encourages collaboration between government ministries and departments and their partners in achieving the country's aspirations as spelt out in this and other overarching guiding documents recognized by the government.

The Technical working groups and country coordinating mechanism (CCM) are some of platforms that assist coordination at national level.

2.1.2.2 Equity and respect for Human Rights

This NSP seeks to ensure the delivery of needs based quality and comprehensive services to vulnerable and at-risk populations. It also seeks to ensure equity and a rights-based approach to the provision of services. Various means to address stigma at the community, district and national levels will be employed. This will include the engagement of former TB patients and PLHIV. Former patients have participated in the NSP development and will also continue to play a role in advocacy on behalf of TB and HIV clients.

The TB program continues to decentralize diagnosis and treatment sites as a way of ensuring geographic access to services, but also as a means of decreasing the financial burden of diagnosis, treatment and follow-up on clients and their families. Attention is channeled to increasing the awareness of TB and HIV, dispelling myths and misinformation among the general population and their rights to free, quality diagnosis and treatment.

2.1.2.3 Gender equality

The NTLP recognizes the importance of gender equality and special effort will be made to ensure availability of services to address special needs of women and men. Although relatively higher TB prevalence is registered among adult males than women according to the national TB Prevalence survey, more female TB patients are expected because of higher proportion of HIV in younger girls and women. The socioeconomic burden may hinder women disproportionately to seek health service for early diagnosis of TB. Despite GoM's free TB diagnosis and treatment policy, the cost associated with TB care is still too high for the poor. The opportunity cost and the burden to families is even higher when women are the affected in the family. The case finding strategies also seek to reduce the number of undetected and none notified TB cases in the community. Special emphasis will be given to TB/HIV co-infected men and women for early diagnosis and treatment for both susceptible and drug resistant TB.

2.1.2.4 Integration and collaboration with other programmes and areas of work

Integration of components of TB services within other services forms a large basis of the interventions. One of the major opportunities to further integrate service provision is with the HIV program and the various services offered through the HIV control program but is not limited to TB/HIV integration. TB case finding will be integrated with MCH and chronic illness clinics.

2.1.2.5 Capacity building

It is recognized that having a well-trained health work force with the capacity to deliver timely quality services is key to ensuring the success of the various strategies and interventions spelt out. A significant number of training activities aimed at equipping health care workers with the necessary skills and knowledge have been planned for. These capacity building activities are aimed at front line health workers and managers at the various levels to aid evidence-based decision making.

CHAPTER 3: VISION, MISSION AND GOALS

3.1 Vision

A TB and Leprosy free Malawi.

3.2 Mission

To ensure effective, equitable and accessible TB and Leprosy prevention, diagnosis, treatment and care services in Malawi.

3.3 Goals

- Reduction of tuberculosis related incidence by 50 % and mortality by 75% by the end of 2025 compared to the 2015.
  - o By end 2025, reduce TB incidence to 102/100,000.
  - o By the end of 2025, reduce TB related mortality of all TB patients to 18/100,000.
  - o Zero catastrophic costs due to TB among affected families (Reducing TB care costs less than 20% of annual household income)

- Elimination of Leprosy in all districts by 2025 (less than 1 case per 10,000 population)

3.4 Strategic and intermediate results

3.4.1 Improved patient care

By the end of 2025, improve patient centered care and prevention for TB

- Increase TB treatment coverage for drug susceptible TB to 90% from a baseline of 67% in 2018.
- Diagnose and treat 111,640 drug susceptible TB cases improve
- Diagnose and treat at least 10,050 children over the five-year period of this NSP
- Increase access to genotypic diagnostic methods by 50% between 2019 and 2025

- The number of Health facilities providing diagnosis and treatment for drug susceptible TB increased to 600
- 80% (153,330) of all household contacts (aged 5+ years) of PTB are screened for TB.
- 75% (98,360) of all eligible contacts (aged 5+ years) receive TPT.
- Over 75% (33,660) of under-five household contacts of PTB cases are screened for TB.
- 80% (21,840) of all under-five household contacts of PTB cases receive TPT
- By the end of 2025, increase the Treatment Success Rate (TSR) for new and relapse TB cases to >92% from a baseline of 86% in 2018.
- Diagnose and treat at least 1160 DR TB cases by the end of 2025.
- 85% of all previously treated TB patient have first line DST.
- All (100%) diagnosed DR-TB patients put on Second line Treatment.
- TSR of 80% for drug resistant TB achieved and maintained
- All (100%) districts providing DR-TB treatment initiation service including the new medicines.

Reduce grade 2 disability among new leprosy cases by 35% compared to the baseline (2018)

- "<3%_of notified leprosy cases with disability grade 2 and above

Reduce prevalence of leprosy by <1/100,000 by 2025

- 3400 leprosy cases diagnosed and treated

3.4.2 TB co-morbidities and Key populations

- 99% of notified TB patients have documented HIV result by the end of NSP.
- 99% of co-infected TB/HIV patients receive ART.
- 98% of PLHIV receive TB screening during each visit
- 15% of notified TB cases contributed through interventions targeting the key affected population.
- Joint planning, implementation and monitoring and evaluation for TB. HIV, Leprosy, NCDs and other conditions

- Coordination structures for TB, HIV, Leprosy and other conditions
- Joint supply chain planning, forecasting, quantification, procurement, and distribution

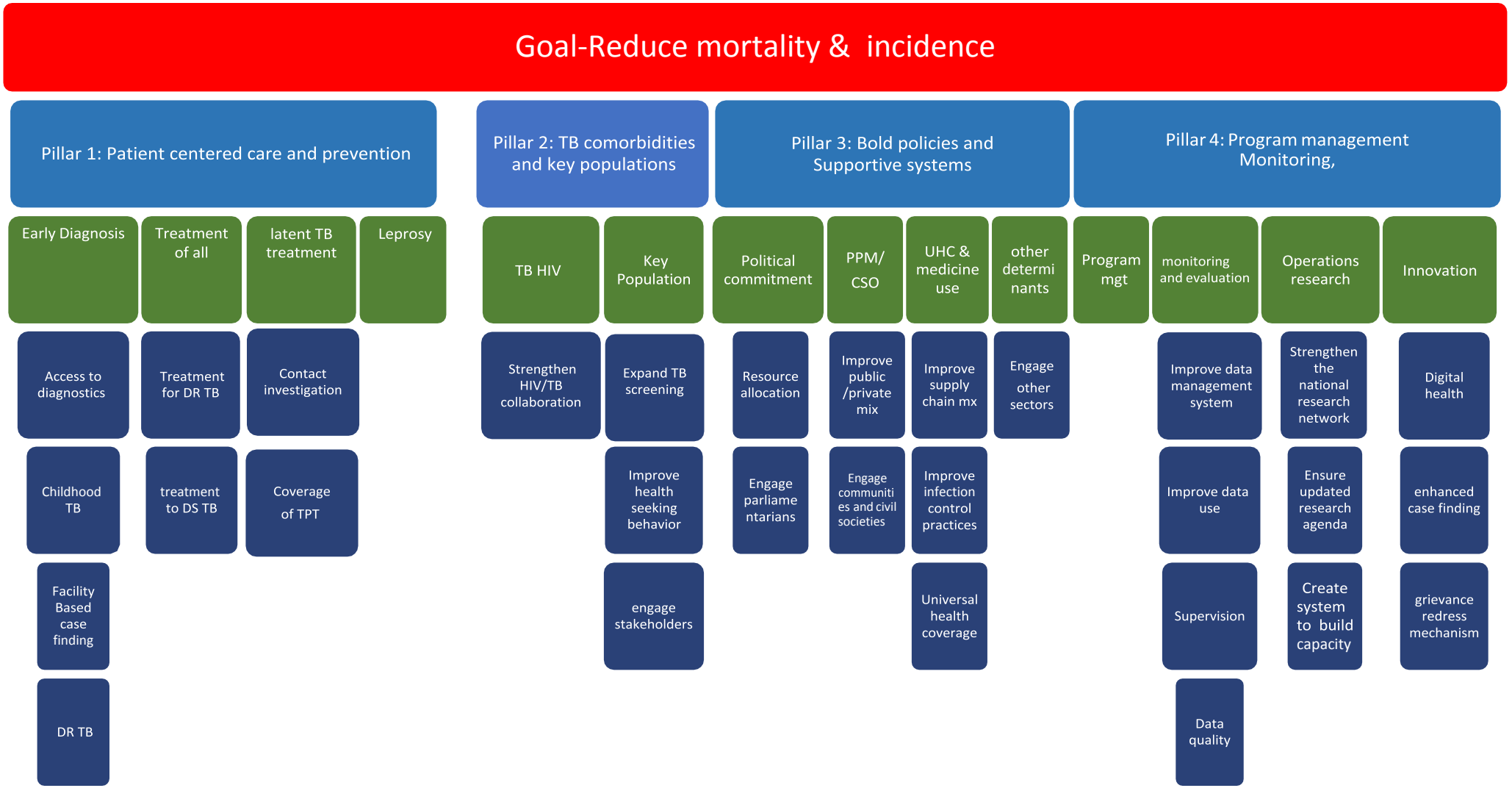
3.4.3 Improve supportive system and polices to end TB and leprosy

- The TB case notification through PPM increase to 30%.
- 15% of notified TB cases are achieved through community involvement systems.
- PPM coordination structures supported and sustained
- Community TB/leprosy systems set up, supported and sustained to participate in TB/leprosy control
- No medicines and commodities stock outs reported.
- All TB registration sites have functional TB IC committees and up-to-date TB IC plans in place.
- 80% of TB/leprosy patients targeted for economic, rehabilitative and/or nutritional support fully receive these services.

3.4.4 Program management, monitoring and evaluation, Research and innovation

- Increase use of operational researches for decision making to improve program performance
- 95% of health facilities have report data with good quality
- All (100%) zones and districts conduct quarterly program performance review meetings and receive quarterly supportive supervision.

3.5 Result framework



CHAPTER 4: PATIENT CENTERED CARE

4.1 Early diagnosis and detection

4.1.1 Improve access to TB diagnostics

The Ministry of Health and Population has in place a national strategic plan for diagnostics which provides broader guidance to all departments including the NTRL. TB laboratory plays a key role in TB diagnosis, prevention and control in Malawi. Smear microscopy (mainly fluorescent method), molecular techniques (LPA and Xpert MTB/RIF), culture (solid and liquid media) and TB LAM are available to diagnose both drug susceptible and drug resistant TB. The NTRL coordinates the overall TB diagnostic network, including the performance of EQA, provision of continuous technical assistance, implementation of the LMIS, and TB LIS.

With regards to integration of TB and HIV services, microscopy laboratories are available in about 51% of all facilities providing HIV care services. LED fluorescence microscopy for AFB examination has and is currently available in 266 high-volume facilities. Within facilities with TB microscopy laboratories, the turnaround time for AFB microscopy test is 1-2 days. Genotypic (Gene-Xpert) technology was introduced in Malawi in 2011 and currently there are 80 Gene-Xpert platforms of which 7 are placed in mobile TB diagnostic units, 73 machines are located in 62 health facilities. The Gene-Xpert coverage is limited to selected health facilities such as district hospitals, community hospitals and few private hospitals.

There are three regional public TB culture and DST laboratories in the country, including NTRL (Central region), Mzuzu Central (Northern region) and Zomba Central Hospital TB Laboratories (Southern region). The NTRL is also equipped with an automated LPA technology.

Malawi uses a national sample transportation system for all samples (including sputum for GeneXpert testing from all peripheral facilities) and a courier service for culture and DST samples (from districts to the regional culture laboratories). Results are transmitted back to facilities using the same system. There is need therefore to continue strengthening sample transportation from various facilities to diagnostic sites.

Priority Gaps

1. Limited access to the existing and new diagnostic technologies

About 45% of notified bacteriologically confirmed TB cases are diagnosed using genotypic methods. In health facilities without gene-based methods, sputum smear microscopy is performed as the first test.

Utilization rate of genotypic methods is just under 65% as of 2018. There has been steady increment in terms of utilization rate despite weak referral systems between peripheral facilities and testing sites, limited screening capacity at peripheral health facilities, long turnaround time for results, lack of standardized automatic result transmission mechanisms as well as malfunctioning of equipment due to power outages.

2. Limited TB microscopy coverage

Despite the fact that Malawi meets WHO's microscopy coverage target (1 to 50,000), only 50% of ART sites are able to perform TB microscopy, hence causing significant delays in TB diagnosis of PLHIV and increasing the possibility of missing TB patients across the care pathway.

3. Long turnaround Time

Samples are transported on 3 levels:

- District hospital to culture/ DST facility
- District (Facility to diagnostic facility)
- Community level to TB microscopy facility

The test results turnaround time for GeneXpert range from 4 to 7 days depending on the health facility's proximity to the testing sites. The long turnaround time observed is a function of the transportation time, the sample processing time and the time required to share results to between clinicians.

4. Low coverage of External Quality Assurance

The NTRL is enrolled in a proficiency testing program through different schemes namely the supranational laboratory based in Uganda, NHLS and CDC Atlanta.

The EQA coverage over the past three years was less than 75% for TB microscopy. The main reasons for the low participation were limited resources and insufficient feedback mechanisms. This requires further expansion to ensure 100% sites are enrolled in an EQA program. In addition, no proficiency testing scheme is currently in place for TB LAM.

5. Inadequate Infrastructure and Human Resource capacity

An assessment done by NTRL revealed significant infrastructure deficiencies in the majority of peripheral health facilities, including a lack of space for TB laboratory with minimum safety standards, inadequate back-up power, lack of local capacity for maintenance of laboratory equipment, absence of alternative respirator masks at testing laboratories in case of fit-test failure and insufficient sample storage equipment (refrigerators).

Human resource capacity for expansion of the TB microscopy services to the peripheral health facilities is currently inadequate especially in terms of numbers. In addition, there is need to build capacity and skills in staff especially on newer TB diagnostic approaches.

6. Limited use of radiology for TB diagnosis

Radiology is being used to make diagnosis of TB among sputum-negative patients and children. There is evidence of higher yield of TB in health facilities where chest X-ray is combined with sputum microscopy, than in those where X-ray investigations are not performed. Radiographers and clinicians prefer digital X-ray than analogue X-rays because they are less cumbersome, are viewed by many as easy to interpret and require less space for storage of films. The following are key factors for suboptimal use of the Radiology for diagnosis of TB.

- Lack of HR capacity to perform radiology related functions (image interpretation, archiving & machine malfunction trouble shooting)
- Inadequate support & supervision
- Inadequate infrastructure
- Limited coverage of viewing stations
- Lack of equipment
- Inadequate maintenance and servicing of radiology equipment

Strategic Intervention

4.1.1.1 Expand coverage of new TB diagnostics

This NSP supports the adoption and implementation of new technologies as well as scaling up other technologies currently in use. Coverage of TB diagnostics will be expanded by improving the capacity of genotypic, Lateral Flow-LAM, LPA and culture and DST services. In addition, the capacity of laboratory personnel working in TB service will be improved at each level through the implementation of regular training, mentorship and supervision on abovementioned TB diagnostic modalities. Expand and maintain gene-based diagnostic technologies

With due consideration of both case numbers and geographic distribution, the genotypic diagnostic coverage will be increased by 50% by 2025. Furthermore, GeneXpert MTB/RIF connectivity (GXALERT) will be expanded in line with the expansion plan. Minor refurbishment will be done base on assessment to diagnostic sites to fulfill the minimum requirement for testing platform. Additional GeneXpert platforms will be procured and installed and mechanisms for calibration and maintenance will be strengthened in order to work towards optimization of existing platforms. Integration with DBS specimen for HIV viral load testing will be guided based on patient volume. Genome sequencing technique will also be implemented in the lifetime of this strategic plan.

Expand the use of LF-LAM

TB LF-LAM urine test will be expanded in health facilities with a high number of HIV patients. The test is used as a complimentary diagnostic tool and reserved for PLHIV who are either very sick or have low CD4 counts. HCWs will be trained in the use of TB LF-LAM as per the developed expansion plan. TB LF-LAM testing kits and related supplies will be procured and installed, and a regulatory quality control system will be established.

Culture/DST, LPA including second line DST

The regional laboratories will be strengthened, and their access and utilization optimized through enrolment in proficiency test programs, better coordination and strengthened specimen referral networks. To build capacity and provide mentorship, a program with regular local and regional trainings will be established for culture

laboratory staff working at NTRL and the two regional laboratories. In addition, all patients with RR results will be subjected to culture and DST and patients on MDR-TB treatment will be subjected to culture for treatment monitoring. The culture sample referral mechanisms via courier system will be monitored and supported to maintain quality.

4.1.1.2 Expand quality assured TB microscopy

In line with the expansion of TB registration sites, TBmicroscopysites will be expanded to 600 facilities over the period of this NSP to meet the set target of 1:35,000. The quality and functioning of existing sites will be assessed and where required, minor renovations will be done to meet the minimum quality standards for TB microscopy laboratories. Procurement and distribution of TB microscopy reagents and of iLED fluorescence microscopy and related supplies will also be expanded, which will be coordinated by NTLP. Moreover, training of laboratory personnel and regular involvement of the health facilities in the national EQA scheme will be ensured.

All TB microscopy sites will be networked (hub for sample referrals will be established and/or strengthened) to facilitate communication between health facilities and to enable referral of specimens from sites without microscopy equipment. TB microscopy service will be expanded to 600 facilities over the NSP period and the target is set to meet a target of 1:35,000. This will be done in line with the expansion of TB registration sites. Minor renovations will be done to meet the minimum standards for TB microscopy laboratory. In line with expansion of TB diagnosis, procurement of equipment (LED microscopy and back up battery), reagents and related supplies, will be done during this NSP. Capacity building will be done for key health care providers. Regular Participation of health facilities in national EQA scheme will be ensured.

The district health office will be capacitated to provide annual maintenance for equipment (e.g microscopes) and conduct infrastructural upgrades on microscopy diagnostic sites to ensure adequate infection control and prevention measures. Quantification, procurement and distribution of LED microscopy and related supplies will be done and coordinated by the NTLP.

4.1.1.3 Quality Management System for Laboratory including EQA

4.1.1.3.1 Strengthen biosafety and infection Prevention in TB laboratories

This NSP aims to ensure infection prevention for TB laboratory workers through capacity building, provision of personal protective equipment (PPE), regular screening for TB and other related diseases, ensuring the proper waste management and documentation of those infected with TB. An operational plan will be developed to reinforce proper biosafety and infection control practices in health facilities and laboratories. Appropriate laboratory designs including adequate space, waiting areas and sputum collection booths will be ensured for each health facility, minor renovation will be considered to fit the medium standard for TB infection control. Provide biosafety cabinets, autoclaves and incinerators will be provided to strengthen the health waste management. Variable models of PPE (N95 masks) will be procured and distributed in case of fit test failures. Health care provider will be trained on biosafety requirements for TB laboratories. Annual safety audits with corrective actions is planned.

4.1.1.3.2 Improve and expand internal and External Laboratory Quality Assurance

The TB laboratory network will be equipped with adequate resources to conduct EQA of microscopy, GeneXpert MTB/RIF, culture and DST proficiency testing in all peripheral laboratories. More specifically, district laboratories will be capacitated to oversee the quality of the peripheral microscopy center. For instance, blinded rechecking and on- site evaluations will be conducted on a quarterly basis. PT will be prepared centrally and distributed to GeneXpert sites. There will be performance review mechanism for district and regional laboratories through quarter supportive supervision and review meeting at national and zone level.

4.1.1.3.3 Strengthen Laboratory Quality Management System (LQMS)

The implementation of the Laboratory Quality Management System (LQMS) will be supported towards accreditation and quality assurance measures will be strengthened. During this NSP period, 24 district hospitals will be enrolled in the SLMTA program. Based on the national roll-out plan for laboratory accreditation additional full-time experienced quality mentors will be recruited to support NTRL and RTRL in achieving accreditation. Staff from district Hospital will receive special training on SLMTA and SLIPTA followed by regular site level mentorship support.

Supplies such as computer, printer and stationary materials will be procured and provided to SLMTA mentors, auditors and staff in the participating laboratories.

4.1.1.4 Improve Human Resource capacity for Laboratory

The program will provide targeted mentorship to laboratory personnel with inadequate competence on key technical areas. This also includes recruiting additional laboratory personnel for NTRL and regional laboratories. The staff capacity building plan will be developed and implemented. To fill the laboratory personnel, need at peripheral facilities Assess staff competence as per national requirement.

4.1.1.5 Enhance management of laboratory commodities and equipment

Regular maintenance of the key laboratory equipment is crucial intervention to avoided unnecessary service interruption due to mal functioning of diagnostic equipment. This including service contract agreement for all lab equipment including biosafety cabinets, air conditional units, GeneXpert machines and microscopes. Lab staff will be trained on routine preventive maintenance for major diagnostic equipment. Under this NSP local capacity will be built to ensure the basic curative maintenance for TB microscopy and Biosafety cabinet in the network will be done by local capacity. This will be done by training local technicians on maintenance of various equipment, procuring the kits and other supplies needed for servicing of the equipment. For GeneXpert machines, Cepheid surcharge-based service level agreement will be maintained to ensure warranty for all platforms. This will be done in close collaboration with MOHP technical support Services unit. This mechanism shall be subject to review based on its perform. A retention mechanism will be designed to keep trained technicians in the system.

4.1.1.6 Improve sample Transportation and Turn Around Time

Cross-cutting challenges with regards to sample transportation and sample tracking persist at all levels. NTLP utilizes a bus service (AXA) to transport samples from district to NTRL. This service is not available in other districts across the country. In addition, sample transportation within districts is insufficient as the sample transportation services do not visit facilities frequently nor at times regularly. Against this backdrop, there is a need to expand and maximize the sample transportation loop and tracking systems in order to ensure better monitoring of the sample transportation cycle. These systems may include logbooks, expansion of the current

TB e-health platform among others. The frequency of collection of samples by courier systems will be increased and integrated with HIV and other programs to improve efficiencies. Triplicate logbooks will be used at referral laboratories.

4.1.1.7 Improve access to diagnostic technologies for other forms of TB (with focus among children)

Regular training will be provided to clinicians and nurses to improve their capacity, skills and confidence to interpret X-ray scans, PACS/DICOM management, sonography and FNA techniques. These will be complimented by onsite technical mentorship support. In high-volume facilities, digital X-ray machines will be procured and installed, and the number of viewing stations will be increased in order to improve diagnostic accuracy. With the aim to improve access to such diagnostic services, NTLP will collaborate with private health facilities and subsidize the cost of X-rays. Moreover, tele-radiography will be piloted to improve diagnostic quality. Furthermore, the feasibility of task shifting of procedures such as FNA from high- to mid-level HCWs will be explored. Minor renovation will be done where needed for X-ray and ultrasound to meet the minimum standard. Supplies for FNA services will be procured.

4.1.2 Childhood Tuberculosis

Childhood TB contributes about 9% of all new and relapse TB cases. About half of all childhood TB cases in 2018 were notified in Lilongwe, Blantyre and Mangochi. Some factors for the skewing of the distribution to these districts include the capacity to diagnose childhood TB in these districts. Lessons drawn from these districts in terms of capacity to diagnose childhood TB shall be explored and scaled to the rest of the districts.

TPT and contact investigation

According to the Malawi NTLP guidelines, TPT is provided to children aged 5 or younger who have contact with pulmonary TB patients and for which active TB has been ruled out. As children in this age group usually get infected by adults, guardians or members of the household, contact investigation is crucial and has been emphasized by the NTLP. More detailed information on TPT and contact investigation is provided in the section on prevention.

Priority gaps

Suboptimal contribution of childhood TB to case notification

Pediatric TB contributes 9% of all notified new and relapse TB cases per year, which lies considerably below the target of a 15% contribution of childhood TB of all cases stipulated in the 2015-2020 NSP. However, it is important to note that incidence has fallen from 193 in 2015 to 131 per 100,000 population in 2018 and case notifications were reduced by 7 % during the same period.

The pauci-bacillary nature of pediatric TB is challenging and involves that most pediatric TB cases are clinically diagnosed. The proportion of clinically diagnosed childhood TB cases has considerably declined between 2015 and 2019, from a contribution of 43% to 24%. This could be attributable to the low index of suspicion among clinicians and nurses and a lack of confidence on their part to make clinical TB diagnoses.

During the period covered by the 2015-2020 TB NSP, significant progress has been made in decentralizing microscopy, increasing genotypic coverage. In addition, the TB program has expanded the types of samples that can be examined on GeneXpert. During the same period, generalized symptom screening of all children attending selected health facilities has also been introduced. Furthermore, digital radiography has been institutionalized and expanded over the past 5 years.

Despite this progress, serious challenges persist in the area of childhood TB. Firstly, there is still limited integration with other programs operating in the pediatric space for instance IMCI and nutrition programs. Moreover, sample transportation within districts remains a challenge and the number of GeneXpert platforms remains inadequate. Furthermore, there is generally a lack of clinicians with adequate skills and qualifications in interpretation of X-rays scans. Lastly, 0.5% of contacts screened for TB are diagnosed with TB which is significantly below the expected target of 2%.

Suboptimal yield from Contact Investigation

Malawi's target is to screen 6300 contacts annually for TB, of which currently about 60% is achieved. In addition, about 60%of the eligible children are initiated on TPT, of which 90 % complete their TPT course. Contact investigation is a resource-intensive intervention including community HCWs homes for screening and follow-

up visits, and the enablers that go with this. The pauci-bacillary nature of pediatric TB means most diagnoses are clinical in nature, as such a high index of suspicion among clinicians and nurses is required to make a clinical diagnosis of tuberculosis especially when it is clinically diagnosed.

Strategic Interventions

4.1.2.1 Increase the proportion of child TB contacts identified and screened

Strengthening quality of contact investigation is a key activity in finding more TB cases among children. These include production, distribution and ensuring use of job aides and recording and reporting tools. Contact and reverse contact investigation for all Pulmonary TB index cases will be strengthened in all districts and primary health facilities by among others ensuring appropriate support. This support shall include mobility support by providing motorcycles or pushbikes and related logistical support to aid in contact investigation and other follow up activities related to TB in the districts.

4.1.2.2 Scale up use of new TB diagnostic technologies for all children

4.1.2.2.1 Genotypic diagnostic methods for all children and adolescents (0 – 19)

GeneXpert is a primary test for the diagnosis of tuberculosis among under five children. Health workers will be trained to improve use rapid diagnostic and other tests for diagnosis of TB among this group. On-site support shall be provided through mentorship and supportive supervisions. These include sputum induction, gastric aspiration, performing naso-pharyngeal swabs and fine needle aspiration. The diagnostic algorithm will be revised to include pediatric and adolescent.

4.1.2.2.2 Use of digital x-ray

Health care workers will be trained on chest radiography and ultrasound to assist diagnosis of Pulmonary and Extra Pulmonary TB in children. Deliberate efforts will be made to engage experts in radiology to mentor and support healthcare workers in all facilities where radiology is performed to diagnose TB.

4.1.2.2.3 Increase TB preventive treatment coverage for children

The NTLP anticipates active engagement of different cadres at each district and health facilities to carry out contact investigation to improve coverage of TPT. Health care workers will be trained and mentored to improve coverage of TB preventive therapy among children.

4.1.3 TB case finding in health care setting

The NTLP has implemented several cases finding interventions to increase the case notification rate, including triaging in health facilities, systematic screening of key populations and contact investigation. Standard Operating Procedures for systematic TB screening, including detailed instructions on the approach at district-, TB and HIV clinic- and health facility management level, have been defined.

Systematic TB screening for all OPD attendees has been implemented, including for PLHIV, children under five and contacts of pulmonary TB cases. Integration of TB screening to other service delivery area will be strengthened in the next 5 years

Priority gaps

- Sub optimal yield for TB screening in the health facilities
- Inadequate human resource for implementation of TB screening at health facilities
- Limited integration of TB screening into other service delivery points (MNCH, Wards, HIV and NCD clinics)
- Sub optimal intra-facility and inter-facility referral linkage

Strategic Interventions

4.1.3.1 Strengthen the systematic TB screening at OPDs in all hospitals, health centers and clinics

More emphasis will be given on systematically screening for all OPD attendees using TB symptom screening tools, irrespective of their presenting symptoms. Appropriate referral for presumptive TB patients for further investigation using microscopy, GeneXpert and/or chest X-ray imaging will be ensured within health facilities. This intervention will be implemented in all TB registration sites and private for profit,

private for non-profit health facilities. Health facilities in high TB burden districts will continue to be prioritized. The prioritization matrix will be revised based on the available data for differentiated responses to address TB with local context. In collaboration with CMED, the data recording tools will be revised to capture the TB screening information. Operational studies will be done on wide ranging areas in order to improve service delivery and patient outcomes.

4.1.3.2 Integrate TB screening in all service delivery points (NCDs, HIV, MNCH, in- patients/Wards)

All patients visiting any service delivery point will be offered TB screening services. Policies aimed at further integrating TB screening into general health services and special clinics, including for instance MNCH and NCD clinics, will be strengthened. Triaging based on TB signs and symptoms will be done and appropriate services provided to reduce transmission of TB within the health facility setting. Diagnosis and management of other respiratory diseases will be carried out to provide holistic, patient-centered care to patients with respiratory symptoms. This will be achieved by increasing HCWs' index of suspicion for TB and capacitating them to diagnose and treat TB across all service delivery points.

Regular TB screening in diabetic clinics, under five clinics, all in-patient wards, HIV clinic, and other vulnerable groups will be strengthened. Appropriate screening protocols will be developed and used to screen for TB among Children, PLHIV and other high-risk groups.

4.1.3.3 Strengthen inter and intra-facility patient referral and linkage to treatment

Appropriate referral mechanisms and linkages across the health service delivery system are crucial to improve the quality of TB care and treatment. Intra-facility linkages between the point of diagnosis (laboratory, X-ray unit, OPD, HIV clinic etc) and the treatment initiation point will be strengthened. In addition, the relevant recording and reporting tools will be updated to adequately capture patient details for improved tracking.

For inter-facility referrals, the referral system will be strengthened through promoting consistent use of a referral logbook for newly diagnosed patients who prefer to receive treatment at a different registration site. HCWs at the referring site will transmit important patient information to the receiving facility, which then captures the details in the facility records for subsequent patient management.

Regular monitoring of facilities will be established to ensure that all referred patients are adequately captured and reported.

4.1.4 Early detection of DR TB

The prevalence of DRTB in Malawi remains low despite projections that are higher than the national DRS results of 2014. Recent data indicate an increase in primary resistance as well as likelihood of extensively drug resistant TB due to migration especially to and from the southern part of Africa. The expansion of GeneXpert use for TB diagnosis in different high-risk populations for TB has been contributing to improved MDR-TB case detection. The country is exploring options of making the GeneXpert a primary test and this will be done in a stepwise manner considering all factors to make this possible. Appropriate mechanisms including revision of patient referral mechanisms and protocols in order to increase surveillance, diagnosis, treatment and reporting will be put in place in the current period.

Priority Gaps

Low Case detection for DR-TB and Low DST coverage for TB patients

- Case detection for DR-TB was at 57% in 2018. The low detection is attributed to the low DST coverage among all notified TB cases which was at 20%.
- Weak sample transportation system, limited coverage of courier services within district, low index of suspicion among health care workers in identifying and screening presumptive DR-TB are some factors that contribute to low detection of DR-TB.

Priority interventions

4.1.4.1 Improve DR-TB Case detection

The NTLP intends to improve DR-TB case detection among all notified TB cases and household and close contact of DR-TB cases by improving access to DST for at least Rifampicin. This will be achieved by ensuring prompt identification of DR-TB presumptive and screen for Drug resistance and enhancing the sample transportation system from peripheral site to GeneXpert site. All previously treated TB patients and RR patient will receive full DST. The capacity of health care workers and community volunteers will be improved through training and on job mentorship, provision

of various Job aides and SOPs. All care providers including Private for profit and nonprofit will be involved in identification and diagnosis of DR-TB presumptive.

Additional technical staff will be deployed to NTRL and Regional Culture laboratories to strengthen the human resource capacity to perform Culture and Full DST for all eligible.

4.1.4.2 Improve access to Second line DST

Enrolment to new medicines requires rapid test for Drug Susceptibility to select the most appropriate and effective regimen. The focus will be on strengthening the capacity of laboratory staff to conduct LPA and to perform tests using emerging technologies. Priority will also be given to the orientation of clinicians on the technologies to increase demand for the various tests and ensuring availability of reagents and related supplies to undergo culture, first- and second-line DST. This will be further strengthened through continuous technical capacity building for Regional and central culture laboratories, and technical support from SNRL. LPA will be the main methods to ensure second line DST for DR-TB.

4.1.5 Treatment of Drug Susceptible TB

The treatment success rate (TSR) for new and relapse cases remains high at 86 %. Despite this high average figure for Malawi, specific districts continue to record low treatment outcomes that bring down the national average. Furthermore, lower facilities within districts require more support to be able to provide quality treatment services that improve treatment outcomes for patients.

Key priority gaps

- **High Death Rate**

The high death rates at national level are a result of a combination of factors. For example, the high death rate at central and district Hospitals are attributable to late presentation of patients; delayed diagnosis; inadequate coverage of community TB interventions to raise awareness as well as diagnosis and care services. Additionally, presence of other advanced disease conditions which requires admission also contributed to the high death rates.

- **Inadequate DOT supporters**

TB treatment is initiated at designated TB registration site whereby health care workers provide information and counseling about TB treatment and adherence. However, the subsequent day to day treatment adherence monitoring, counseling, patient education about TB is provided by the TB treatment supporters. There is inadequate number of DOT supporters to perform these critical activities. This poses a risk for non-adherence to treatment which compromises the treatment outcomes.

Strategic Interventions

4.1.5.1 Ensure availability of first line anti TB medicines

Improve access to TB medicines for both adult and pediatric formulations through timely quantification and distribution. Quantification and forecasting for medicines will be done using the appropriate mechanisms and systems and regularly updated based on actual pipeline stock and enrollment.

4.1.5.2 Patient counselling and education.

Treatment adherence will be strengthened through DOT, patient counselling and education. These will be done during treatment initiation and course of treatment on potential side effects, pill burden, timing of medications, infection control, nutrition, treatment support at household and community level. To achieve this result, DOT supporters will be trained, and different job aids will be printed and distributed.

4.1.5.3 Improve treatment outcomes for Drug susceptible TB

Death audits will be conducted regularly in order to account for all TB related deaths. Deliberate efforts will be put in place to track patients who interrupt treatment. Surveillance of all patients on treatment to establish treatment failure will be done and appropriate actions taken quickly. Cohort analysis will be done to improve case management of tuberculosis.

4.1.6 Treatment for Drug Resistant TB

The NTLP has introduced the short-term regimen and new drugs also introduced (Bedaquiline and Delamanid) during 2018. Activities leading up to the introduction

of the STR include; developing an implementation plan with participation of NTLP and all stakeholder; updating of protocols and guidelines; capacity building of the staff (PMDT training); ongoing mentoring and supervision visits (on-the job training); and preparation of the DR-TB sites.

Nutritional support is provided to patients on quarterly basis. The nutritional package includes cooking oil, floor, beans, milk, Likuni phala, rice, and sugar. Patients on SLDs are supervised by health surveillance assistants (HSA) who work in the area where the patient resides.

Priority gaps

- **Sub-optimal treatment success rate for DR-TB**

The treatment success rate for DR-TB for the past 5 years has been low with the highest being recorded in 2018 at just under 60% which is lower than the intended target of 85%. Despite lowering death rates over the 5-year period, the death rates are still unacceptably high. The high death rates are attributed to severe adverse events (ADR) such as hypokalemia for patients on injectable based regimens. The incidence of the ADRs among MDR-TB patients may have contributed to non-adherence to treatment resulting in suboptimal treatment outcomes.

- **Inadequate clinical follow up and laboratory monitoring for DR-TB patients.**

NTLP requires monthly clinical review at district level. Efforts are underway to build capacity at the district level. This is an area that will be further strengthened in the life time of this plan. Zonal and district mentorship and support teams will be central in this support to district and facility levels.

- **Lack of isolation rooms**

Separation of patients by resistance is a challenge in most districts due to lack of purposely built isolation rooms. This poses risk of transmission of DR-TB to other patients, relatives and other care providers within the health facility setting. In 2018, out of 126 diagnosed RR-TB cases, 19 (15%) cases were not initiated on second line treatment.

- **Inadequate Active safety monitoring, management and referral linkages.**

There is limited capacity to perform a full range of laboratory tests at baseline and follow up at district hospitals. District hospitals have got limited capacity on availability of equipment, reagent and expertise to perform essential monitoring tests for DR-TB patient. These tests include Thyroid function test (TFT), Liver Function test (LFT), electrolyte, Electrocardiograph (ECG) and other ancillary tests. There is also limited capacity among health care workers to systematically identify, report and manage adverse events. With the foregoing in mind, it is expected that patients are referred from one facility to another. This may at times include transfer of patients to or closer to a referral facility with the necessary capacities. The NTLP has noted that the appropriate referral mechanisms require strengthening in order to provide quality care to the patients.

- **Non comprehensive patient support mechanism**

Patient support system is critical to improve the quality of patient care through enhancing treatment outcomes and promoting patient safety. Proper welfare system also contributes to reduction of catastrophic costs incurred by DR TB patients. Given that management of DR TB is mainly at district hospital, and patient need to travel long distances to seek service, the current patient support package (nutrition and transport) does not comprehensively address the patient's needs. This leads to patients to incur out of pocket (OOP) expenditures that makes them vulnerable to catastrophic costs.

There are high levels of stigma against DR TB generally. The NTLP seeks to advocate for a comprehensive multi sectoral approach to address the patients' needs holistically i.e. coordination between government departments, civil society, patient groups and communities.

Strategic interventions

4.1.6.1 Ensure quality treatment monitoring

This intervention will focus on ensuring that DR TB patients on treatment are monitored. All patients will be required to undergo the required laboratory monitoring tests including follow up culture as prescribed in the guideline. Active TB-drug Safety Monitoring and Management (aDSM) core package will be rolled out to all district hospitals. Priority will be given on site mentorship to improve

documentation related to aDSM and periodic causality assessment for serious adverse event in coordination with national PV center. Focus will be given to build the capacity of MDR-TB treatment center to conduct all necessary laboratory monitoring test including Full blood count, urea and electrolytes, liver function tests by ensuring availability of tests ad reagents. The NTLP intends to establish an aDSM database.

4.1.6.2 Improve patient support (nutritional and psychosocial)

The NTLP shall advocate for nutrition support and measures taken to facilitate transportation where need be. It should be noted that relevant stakeholders within and without the government especially district players shall be required to play a role in order to provide comprehensive patient support. Patients will also be visited at home by trained DOT supporter on regular basis following existing local structures.

4.1.6.3 Expansion of DR TB admission /isolation facilities

The NTLP plans to set up a Center of Excellence for management of DR TB in the country. The center shall conform to standards of such a facility in order to provide quality care for the patients as well as ensuring that transmission within the hospital setting is minimized or avoided.

4.1.6.4 Ensure all notified DR TB cases are started on second line treatment

All TB patients will have access to Genotypic DST and as such healthcare workers shall ensure that this service is provided regularly to improve coverage of DST. All DR-TB patients will be linked to treatment initiation facilities. Priority will be given to strengthen regular patient monitoring and patient referral linkage including cross border referral with border districts.

4.1.6.5 Strengthen DOT through treatment supporters /guardians

The NTLP together with relevant stakeholder including district councils shall ensure availability of enablers for DOT supporters to perform their roles.

4.1.6.6 Ensure availability of second line TB medicines for DRTB

Quantification and forecasting for medicines will be done using the appropriate mechanisms and systems and regularly updated based on actual pipeline stock and enrollment. The Central Medical Stores Trust shall continue to play its role in the supply chain management system.

4.1.6.7 Adoption of new medicines for management of Drug resistant TB

The NTLP acknowledges developments in production of new medicines and studies conducted on the same in order to generate evidence. Malawi shall continue to support evidence generation in this area. Decisions and speed of adoption of new medicines shall be based on country considerations while also ensuring that advances made in this area benefit the people who desperately need them.

4.2 Tuberculosis Preventive Therapy (TPT)

4.2.1 Contact investigation

Contact Investigation (CI) is one of the methods to identify new cases of active TB and point of entry for identification of Latent TB Infection WHO recommends Tuberculosis Preventive Therapy (TPT) for all contact regardless of age and HIV status of all household contacts of bacteriologically confirmed pulmonary TB cases in whom active TB has been ruled out (WHO, 2018). TB contact investigation in Malawi has been implemented based on the TB guidelines and the WHO adapted TB training modules by the National TB and Leprosy Control Program. The yield however has been consistently much lower than the target of 2%.

Despite the low yield above, relatively high rates of all children who initiate TPT successfully complete the preventive therapy as the table below shows.

Table 4: Pattern of Contact Investigation (2014-2018)

ITEM	2014	2015	2016	2017	2018
Number new Pulmonary TB cases (Index cases)	13,890	11,288	11,111	11,114	10,182
Registered index cases		8,118	7927	8,814	8,144
Estimated number of Household contacts (average family size= 4.5- 1 deducted)	48,615	28,413	27,745	30,849	28,504
Household contacts registered					21,638
Number screened for TB	NA	NA	13,337	19,807	19,757
Number presumptive TB cases		4,973	2,654	5,049	4,246
Estimated number of under five children who are household contacts of index cases	8,751	5,114	4,994	5,553	5,131
Estimated number of under five children eligible for IPT	7,876	4,603	4,495	4,998	4,618
Number started on IPT	2,770	1,947	2,303	3,068	2,641
Estimated coverage of IPT in under five children	35	42	51	61	57
Treatment completion (IPT)	85%	82%	74%	81%	90%

Priority Gaps

i. Low TB yield from contact investigation intervention (less than 1%).
ii. Low IPT coverage for eligible children (59%).
iii. Low adherence to SOP's by health workers evidenced by incorrect documentation.
iv. Limited coverage of contact investigation among close contacts-such as workplaces or schools
v. Limited coverage of contact investigation among household contact of HIV negative 5+ years

Interventions

4.2.1.1 Strengthen TB contact investigation

Contact investigation is meant as a guide for all levels of healthcare workers at all health facilities in Malawi on the specific processes that should be undertaken to ensure that all priority TB contacts are effectively and efficiently evaluated for TB and provided with appropriate follow-up care. The program aims for wide coverage TB screening among contact and further management.

4.2.1.1.1 Improve the coverage and quality of TB screening among household and close contacts

This entails training community level health workers, supervision/mentorship and use of appropriate SOPs and job aides. Communities shall be sensitized on contact screening and deliberate measures made to actively reach out to contacts by the health system. Institutions including schools and workplaces shall also be in these sensitizations.

4.2.2 Latent TB treatment

Tuberculosis preventive therapy(TPT) for people living with HIV

Malawi provides TPT HIV –positive clients in selected high burden districts and not throughout the country as per WHO international recommendations due to limited resources. All ART patients with a negative screening outcome for TB symptoms in these 5 districts are currently eligible for continuous IPT. IPT coverage range from 70 % to 82% in the districts in which IPT is being implemented (Department of HIV

AIDS, 2019). The NTLP proposes nationwide provision of TPT if the impact of this intervention is to be demonstrated.

Tuberculosis preventive therapy for under five children

The country has been providing isoniazid preventive therapy for eligible under five children for many years (contacts of pulmonary TB patients). Estimated coverage for isoniazid preventive therapy (IPT) among under five children has increased from 35% in 2014 to 57% in 2018. By 2018, IPT treatment completion rate was at 90%.

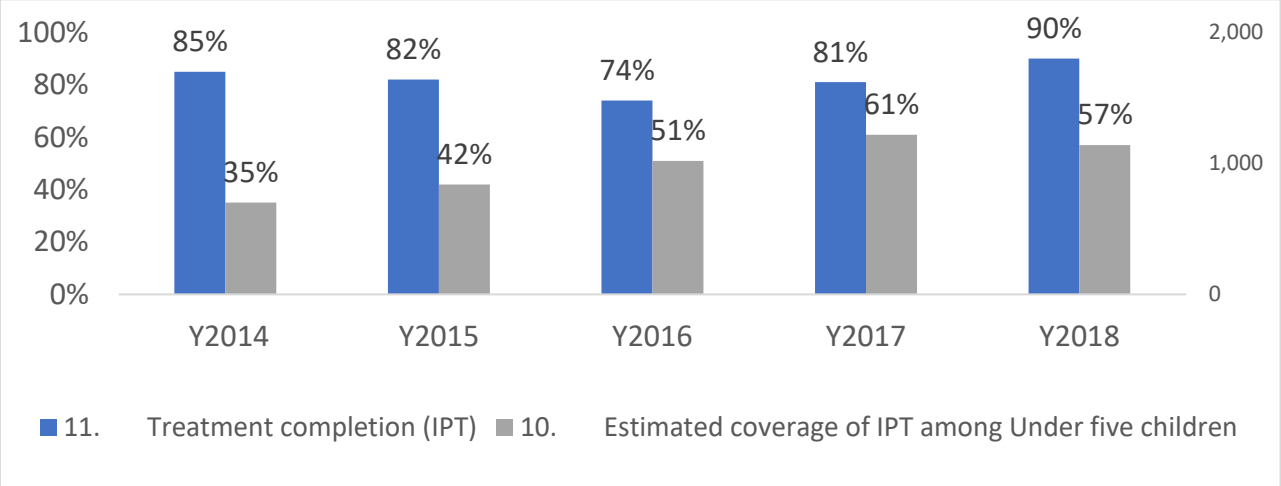


Figure 4: *Coverage of IPT and treatment completion (2014-2018)*

TB preventive therapy among other HIV negative individuals

Despite having a policy on TPT for children who under the age of 5 and PLHIV, Malawi has no policy for introduction of TPT among HIV negative individuals like adolescents/adults, health care workers, miners, immigrants from countries with high TB burden among others.

Gaps

i. Low coverage of HIV Testing Services(HTS) among presumptive TB cases.

Despite good coverage of HTS among confirmed TB patients, there is still a gap of HTS among presumptive TB cases. Majority of presumptive TB cases that have no HIV ascertainment are from active TB case finding services like mobile vans and community interventions.

ii. High death rate among TB-HIV co-infected patients.

The death rate among TB-HIV co-infected patients has consistently been high in the country. There are variations amongst districts, but some districts report very high death rates. MOH will explore causes of death among this population

iii. Limited number of TB registration sites

There is limited access for integrated TB-HIV services in the country. By the September 2019, there were 364 TB registration in the country, against over 700 ART sites.

iv. Suboptimal TB screening among PLHIV

Despite having 99% of PLHIV being screened for TB, only <1% are presumptive TB cases. This may be partly attributed to quality of TB screening by health care workers. Some of the presumptive TB cases may have been missed during the screening.

v. Low coverage of TPT among eligible PLHIV

TPT for eligible PLHIV is only provided in only 5 districts in Malawi out of 28 districts. Eligible PLHIV in the remaining 23 districts are left out of this life saving intervention presenting a huge gap if the country's aspirations in ending TB are to be realized.

vi. Low coverage of TPT among eligible under 5 children

Despite TPT for eligible under 5 children being implemented for several years in Malawi, just above half of the estimated eligible children have access to isoniazid preventive therap.
Priority interventions for treatment of latent TB infection

4.2.2.1 Improve coverage of TB Preventive Therapy among PLHIV

3HP will be the main regimen for TB preventive therapy among PLHIV. Health care workers will be trained, and availability of an interrupted supplies of commodities for TB preventive therapy will be ensured. A sentinel system will be established to monitor adverse events associated to TPT.

4.2.2.2 Improve coverage TPT among under five children who are household and close contacts of PTB patients

All under five children who have contact and close contact of Pulmonary TB patients will be targeted for TB preventive therapy. Active TB screening through house to house TB screening AND contact investigation using symptom and Chest X-ray will be an entry point for TPT intervention. Health care workers will be trained as part of comprehensive TB/HIV training to systematic call screen all household and Contact of PTB index cases. All necessary Screening tools will be made available in all health facilities with primary focus to high volume health facilities. Other option of TPT will be explored for eligible under five children

4.2.2.3 Improve coverage of TB prevention therapy among HIV negative individuals

Focus will be given to improve TPT coverage among HIV negative adolescents/adults who are household contacts of PTB cases, prisoners, health workers, immigrants from countries with a high TB burden. SOPs and job aids will be prepared to guide implementation. Health workers will also be trained as part of comprehensive TB/HIV training course. The M and E tool will be update and made available to health facilities to allow monitoring of TPT intervention.

4.2.2.4 Strengthen screening of TB for individuals who are eligible for TPT

The NTLP shall ensure thatTPT capacity of health workers to screen individuals for TB preventive therapy is strengthened. Regular supervision and mentorship will be conducted for targeted health facilities to ensure compliance to standard screening for TB.

CHAPTER 5: LEPROSY CONTROL

Leprosy is one of the chronic infectious diseases affecting the skin and peripheral nerves and usually presenting with skin lesions and nerve enlargement. It is caused by Mycobacterium leprae. The mode of transmission is uncertain but is believed to be spread by droplet inhalation or ingestion of infected fluid through sneezing or coughing. The disease mainly presents with hypopigmented skin lesions with loss of sensation, enlarged or tender peripheral nerves at the site of predilections and a positive slit skin smear. Diagnosis is mainly based on clinical sign and symptoms. It is classified as Pauci-bacillary (PB) and multi bacillary (MB). Among the communicable diseases, Leprosy remains a leading cause of permanent physical disabilities. Early detection and correct treatment are the most important interventions to prevent complications and disabilities. However, there are many negative traditional beliefs and practices among populations in relation to leprosy. It is considered to be a special public health problem because of its permanent disabilities and social consequences such as discrimination and stigma.

5.1 Leprosy situation in Malawi

Leprosy is endemic in all 29 districts in the country and affects all age groups. The disease is very rare in under- fives population. Malawi achieved the WHO leprosy elimination target of 1 case per 10,000 population in 1994. Since then, the prevalence rate for the disease has ranged between 0.3 to 0.7 in the last decade. In 2018, the country registered total of 532 leprosy cases representing 0.3 case per 10,000 population. However, there are six districts in which the elimination target of 1 case per 10,000 population was not achieved. These districts are Nkhotakota (2.9), Ntchisi (1.2), Mchinji (1.1), Nsanje (1.1), Balaka (1.0) Salima (1.0), Mangochi (1.0), Neno and Phalombe (1.0). In 2018 total of 532 leprosy cases registered and Put on treatment of which 90% had multibacillary indicating that patients presented late to health facilities. Men represented 61.5% to notified leprosy case in 2018 while children account for 2.6% of total leprosy case reported annually. Proportion of new leprosy cases with disability grade II was 6.6%%

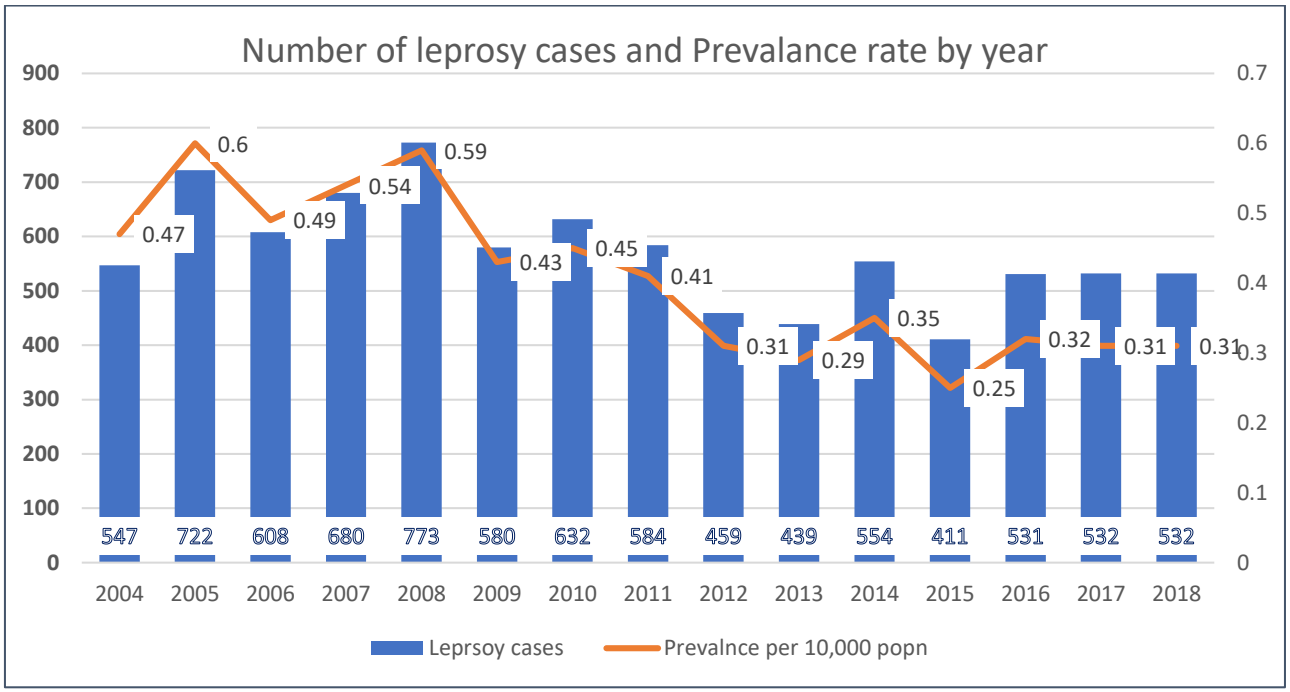


Figure 5: ***Updated leprosy burden and cases***

The presence of leprosy among children is an indication for on-going disease transmission in the community. In Malawi, Leprosy cases are diagnosed mainly through passive surveillance whereby cases are self-reported to health facilities with minimal or no promotion of community awareness by health workers.

Multi Drug Therapy (MDT regimens) have been the major factor in achieving this elimination target and maintaining it. Renewed commitments and efforts are needed to sustain leprosy elimination at national and district level. Improving knowledge and skills of health workers particularly those working in health centres, registration and recording of data, contact tracing, decentralization and integration of treatment to health centres and introduction of leprosy awareness days and community-based surveillance could help to improve early detection, treatment, case holding and prevention of disabilities and stigma.

Priority gaps

- Limited of community awareness on leprosy resulted in delay in diagnosis
- Limited health care workers capacity to diagnose the Leprosy cases resulted in delay in diagnoses which further
- High proportion of grant II disability among new leprosy cases
- High Stigma related to leprosy complimented with lack of rehabilitation services

Priority intervention

5.1.1. Improve programmatic management and coordination of leprosy control at all levels

A management structure will be established to provide central level strategic and implementation oversight. The existing TOR will be updated to accommodate for this structural change. Guide liens and SOPs will be developed and made available to care providers. Programmatic management and coordination of leprosy control will be integrated into TB program at all level.

5.1.2. Build the capacity of health care workers in detection and treatment of leprosy

Health workers will be trained to identify, manage and rehabilitate patients. Special training for clinician on surgical management of leprosy raised as result of disabilities and its complication. Equipment will be procured for patient management and support. MDT Drugs will be procured for 3400 leprosy cases over five years. To build the capacity of health care workers to manage the advance and complicated leprosy cases health care workers will be trained internationally recognized leprosy training center.

5.1.3. Strengthen the Monitoring and Evaluation and operational research for leprosy

Monitoring mechanism to improve surveillance and patient management will be strengthened. All recording and reporting tools will be printed and distributed to facilities. Health care worker will be trained on leprosy M and E as part of leprosy training. More cycle will be provided to nine leprosy priority districts. Regular supportive supervision and performance review meeting will be conducted in nine districts

5.1.4. Strengthen Advocacy, Communication and Social Mobilization (ACSM) for leprosy

Community awareness and sensitization campaigns will be conducted the minimize stigma. Leprosy specific orientation will also be provided to health surveillance assistants. Leprosy specific Audio visual and IEC materials will be developed

and made available in priority health facilities for dissemination using different channels (distribution of flyers, posters, airing of TV and radio spot messages).in collaboration with CSOs the world Leprosy day every will be commemorate with various community mobilization and awareness creation activities.

5.1.5. Improve access to disability prevention, stigma reduction and rehabilitation services

Focus will be given to strengthen the physical rehabilitation centers by provision of supplies used for physical rehabilitation service, support leprosy affected individual with disabilities by engaging in the income generation activities. Community volunteers will be trained to improve stigma.

CHAPTER 6: TB COMORBIDITIES AND KEY POPULATIONS

TB is associated with several conditions which make certain populations specifically vulnerable. These conditions and affected populations are increasingly becoming important globally and locally as they have far-reaching impact towards elimination of the disease

6.1 Key populations

Key populations are vulnerable, underserved or at risk of TB infection and disease. These include people with increased exposure to TB due to where they live or work, people with limited access to quality TB services, and people at greater risk due to biological or behavioral factors (refer to Table below). An individual's susceptibility to acquire TB infection and illness depends on a variety of factors, including living and housing conditions; contact with someone who has TB; income; nutrition; and pre-existing health conditions. Furthermore, the development and progression of TB is closely linked to several other risk factors such as diabetes and HIV which increase the likelihood of people becoming ill with TB. There are similar associations with silica dust, indoor smoke, tobacco smoking and alcohol use while most widespread risk factor is malnutrition or undernutrition.

In Malawi, children represent a unique key population which is disadvantaged by weak TB diagnostics services contributing only 9% of total notified TB cases per year. Key populations are not adequately reached with quality TB diagnostic and treatment services, neither by government nor by non-government sector such as NGOs, private practitioners and corporates.

NTLP has been implementing active TB screening among urban population, prisoners, miners and Ex-miners. The outcome of the screening is promising and shall be scaled up to other key populations elaborated in the following section. The current NSP acknowledges the significant actions required to address the key populations.

Table 6: Key populations for TB (STOP TB)

Category	Identified key populations in Malawi
People who have increased exposure of TB due to where they live	Household contacts including children, People who live in urban slums, Health care workers, community Health center workers, volunteers, Prisoners, Hospital Visitors, People working in congregate settings
People at an increased risk of TB because of their biological or behavioral factors that compromise immune function	People who are under nourished BMI <18.5K/M2, Patients with previous History of TB treatment, PLHIV, People with cancer/ undergoing immunosuppressive therapy, People who have diabetes, Elderly over 65 years
People who have limited access to quality health services	Refugees, Mobile and cross boarder populations, Children, Population living in hard to reach area, internally displaced people, Miners and Ex-miners

Defined key populations for Malawi

In the Malawian context the following have been prioritized as key populations. These groups have huge impact on efforts to control the TB burden in Malawi.

Health care workers: TB remains a significant occupational risk for health workers, the risk is particularly high in countries with a medium to high background TB burden and suboptimal infection control practices.

Prisoners: The conditions in many prisons fuel the spread of TB. Prison population are recognized as being at high risk due to the extreme overcrowding and limited availability of TB services. In Malawi there are more than 30 prisons with an estimated 13,929 prisoners in 2018 (73 prisoners per 100,000 national population). (Institute of Crime and Policy Research, 2019). Recent regular screening activities within the prisons in Malawi show as high as 527/100,000 population prevalence which is much higher than the general population. Screening among prison populations including warders is important in the context of the observed burden.

Miners and Ex miners: Mining, labour related migration and HIV are major drivers of TB in Southern Africa including Malawi. Leading risk factors include high prevalence of silicosis; lack of ventilation; crowded working and living conditions; high rates of HIV infection (Stuckler D, 2013) and the migratory nature of miners limiting their access to health services in different sovereign jurisdictions.

Migrants: Migrants are particularly vulnerable to TB as they migrate within or across international borders and work in overcrowded and poorly ventilated environments; are malnourished or use drugs; and at increased risk of HIV infection and becoming ill with TB. These populations often have poor access to health services, possibly because they are living in an area illegally, because of differences in language or ethnicity and/or lack of awareness of entitlement to services. [1]

The elderly: This population has a high rate of TB (>1,000/100,000) as a demographic group. Those 65 years and older are more vulnerable to TB due to diminishing immune function as a result of aging. In the ensuing period the country shall target this population for case notification and preventive therapy.

Urban Dwellers: The prevalence of TB is high among the urban population at 1,006/100,000. The NTLP has been targeting populations in cities with active case finding approaches and shall continue to do so in the ensuing years.

Malnutrition: Malnutrition and TB are strongly linked, with undernutrition reducing immune defenses against TB and encouraging the transition from latent to active disease. TB can lead to the impaired absorption of nutrients and micronutrients, which in turn leads to malnutrition and wasting. The country shall target those undergoing nutritional rehabilitation for TB screening and preventive therapy.

People living with HIV: HIV is the main driver of TB. Just under 50% of TB patients are HIV infected in Malawi. There is a 16 % death rate among EPTB patients, who are often HIV infected and have advanced HIV disease. In this period the country shall continue with screening of TB among HIV infected; scale up of new diagnostics and the scale up of TB preventive therapy. These will support the achievement of HIV related targets such as the 90 – 90 – 90 targets as well as help in reduction of mortality, incidence and the elimination of catastrophic costs.

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[1] Malawi: UNHCR Fact Sheet, April 2019; https://reliefweb.int/report/malawi/malawi-unhcr-fact-sheet-april-2019

Diabetes: Diabetes raises the risk of developing TB by 3.6 times. There are 70,000 registered diabetics in Malawi constituting a large potential reservoir of TB. In this period the country shall extend intensified case finding to these patients.

Children: NTLP reports indicate that less than 10% of all notified cases in Malawi are children. This shows under-detection of TB due to gaps in capacity to diagnose and treat children in almost all district hospitals except central hospitals.

Recent evidence indicate that men may be disproportionately affected by TB. This is in keeping with Malawi TB prevalence survey results of 2014 that indicated that men had higher prevalence than females.

Priority Gaps

i. **Limited access to TB Services among key population:** Unfriendly working hours at service delivery points, indirect cost and geographical factors and limited resources hinders access to TB services among the high-risk groups.
ii. **Limited TB awareness among key populations:** This hinders demand for TB services, fosters stigma and hinders compliance to treatment among key populations.
iii. **Inadequate services for Health Care workers with TB:** Health care workers with TB often lack occupational health services to support them. Where services are available, there are often issues of quality and confidentiality.
iv. **Limited participation of key stakeholder in addressing the need of key population:** Though a number of stakeholders and organizations are working to address other health problem of the key population, their participation is not optimized. There is a need to involve wider range of stakeholders in planning implementation and monitoring of intervention.
v. **Limited capacity to diagnose and treat TB in children:** only the central hospitals equipped with better technologies and skills are able to diagnose and treat children with TB. This means that health facilities at district and health center level are in need of capacity building in terms of equipment and human resource skills.

Key Population

6.1.1 Expand coverage of TB screening and diagnosis among key populations

The current policies and guidelines for key population will be updated. The existing list and size of key population will be reviewed. Based on size of the of population and geographic location, the program in close collaboration with relevant stakeholders and partners will address the key population with appropriate TB prevention and care services. All groups of key population will undergo regular TB screening using symptom, chest X-ray. The mobile TB diagnostic unit and health care workers will play key role in the implementation of period TB screening among these groups. Guidelines and algorithm will be updated for screening for different group of key populations and also define ACF modalities per key population and/or per setting. The following are interventions and specific activities to address TB among each key population group

6.1.1.1 TB among Miners

Comprehensive TB strategies must explicitly address the role of mining activities in the epidemic. Intervention such as Reducing silica dust, providing better housing, improving cross-border care, tracing contacts, and screening for HIV tackle TB among miners.

6.1.1.2 TB screening among Health care workers

All HCW are classified as key affected populations due to their higher risk of acquiring TB. Those who are symptomatic or/and with any signs of TB or chest X Ray abnormality will be offered an upfront rapid molecular testing upfront to rule in or rule out TB at the first instance and during periodic screening. Health care workers who are in contact with people having TB or clinical manifestation need to be offered TB testing and, if necessary, preventive therapy and appropriate infection control measures.

6.1.1.3 TB among Elderly (+65 years):

Special attention shall be paid to this population group which has the highest TB notification rate. Diagnosis in this population is difficult and frequently overlooked. Clinical features may be atypical, and older adults with pulmonary TB are more likely

to have non-specific symptoms. Regular TB screening will be implemented among this population and those with presumptive TB will be tested using geneXpert.

6.1.1.4 TB among Prisoners

Routine TB screening for every inmate at entrance, exit and as well as periodic TB screening using chest X-ray and geneXpert complimented with improved TB infection prevention intervention in all prison facilities are very crucial in prevention of further transmission of TB disease. There is need for implementation of a comprehensive package of TB services in all prison settings. Addressing TB in prisons will require significant collaboration among the health, correctional and judicial sectors devising innovative ways to prevent TB transmission.

6.1.1.5 Address TB among migrants and refugees

Health service provision must be sensitive and operate from a human-rights perspective, allowing people to access TB diagnosis and treatment regardless of immigration status. The program shall continue collaboration with Immigration and Labor authorities to ensure that appropriate services are provided for migrant populations and that people are not excluded socioeconomic opportunities based on their TB status. Health care workers will be sensitized to address the needs of migrants and ensure screening for HIV and TB including drug resistant TB.

6.1.1.6 Address TB among people with Non Communicable Diseases(NCDs)

The NTLP supports the integration of TB and NCDs including diabetes. Regular systematic screening will be introduced for people diagnosed with diabetes in high TB-burden settings especially cities. Health care workers will be capacitated to manage both NCDs (e.g. diabetes) and TB during TB treatment.

6.1.1.7 TB among undernourished populations

Systematic TB screening will be done for people with undernutrition. Health care workers responsible for managing malnourishment both at health facilities and community will be oriented on TB screening and management. In collaboration with the nutrition section within the Ministry, a national nutrition assessment tool will be revised to be used in screening among TB patients.

6.1.1.8 Strengthen the Active TB screening among urban poor

The urban poor are disproportionately affected by TB due to among others poor living conditions and suboptimal access to TB services. This population will be reached through mobile diagnostic unit equipped with X-ray and GeneXpert platform. Community sensitization and mobilization activities will be carried out to implement these activities.

6.1.1.9 Improve health care seeking behavior by improving awareness of TB among key populations

The NTLP recognizes the need to raise awareness among TB key populations to allow them participate effectively in the TB response. Working with the responsible department within the Ministry as well as the media, patient centered communication approaches will be developed and used to increase the awareness of TB among key populations. These will be done by developing and implementing targeted communication packages with use of appropriate media and technology such as digital messages, radio and TV, as well as theatre for development.

6.1.2 Improve engagement of key stakeholders

The National TB and Leprosy program collaborates with all relevant stakeholders in the provision of TB and leprosy prevention, treatment and care services in the country. These include but not limited to engagement in the planning, resource mobilization, implementation, monitoring, and evaluation. Some of the stakeholders are government ministries and agencies, development partners, NGOs, Civil Society Organisations, academia and the affected populations. This collaboration will be strengthened in the current strategy to benefit the intended populations.

6.1.3 Reduce risk of transmission in congregated settings / workplaces

The NTLP shall collaborate with the relevant stakeholders to improve TB infection control practices in different congregate settings where key populations have increased exposure. These include prisons, mines, factories, schools, refugee camps and such other institutions.

6.2 TB and HIV

Recognizing that TB is the most prevalent and deadliest opportunistic infection in PLHIV, Malawi has been working towards putting in place a robust system for TB screening and treatment among PLHIV as well as HIV screening and treatment among people suffering from TB. Despite HIV and TB being historically established as vertical programs, there has been collaboration between these two programs in the planning and delivery of services. Efforts have been directed at sensitization and education of the public about the likelihood and dangers of TB-HIV dual epidemic.

HIV co-infection rate was remains high at just under 50% (49%). Although the national trend indicates a declining trend in rate of co-infection, some districts show an increasing trend. ART uptake nationally has increased from 87% in 2013 to 99% in 2018. Over 90% of co-infected patients receive cotrimoxazole preventive therapy since 2013.

Intensified TB case finding (ICF) for HIV positive patients is carried out using a standard symptom checklist at every visit.

Priority gaps

i. **Suboptimal collaboration and coordination at all levels**
ii. **TBHIV co-infection remains high**
iii. **Suboptimal TB screening among PLHIV:** The yield of TB from PLHIV was less than 1%. This is attributed to limited quality of TB screening by Health care workers.
iv. **Suboptimal HIV screening among Presumptive**
v. **High rate of mortality among TB /HIV co-infected patients**
vi. **Suboptimal integration of TB/ HIV in community TB interventions Strategic Interventions**

6.2.1 Strengthen TB-HIV coordination and collaboration at all levels:

The TB and HIV programs will work towards improving collaboration and coordination at all levels. The TB/ HIV operational framework shall continue to be used to guide collaborative TB/ HIV activities. The national level TB / HIV working groups and committees will be supported and strengthened. Coordination will also be enhanced at sub national level through conduct of joint review meeting. At facility level the team will be supported to strengthen the multi-disciplinary team.

6.2.1.1 Strengthen TB/ HIV coordination and collaboration at national level:

TB collaborative activities including joint planning, joint program review, supportive supervision and capacity building exercises will be strengthened. Relevant TB/HIV policies and guidelines will be reviewed and updated as required.

6.2.1.2 Strengthen TB/HIV collaborative activities at district and facility level

Districts will be supported to conduct quarterly supervision and review activities. Facilities will be mentored to strengthen their TB/HIV multi-disciplinary teams

6.2.2 Improve quality and coverage of case finding and diagnosis for TB and HIV among PLHIV and TB

The NTLP and HIV programs shall strive to improve coverage of HIV testing among TB and presumptive TB clients. TB case finding effort will be intensified among PLHIV and other key populations. Access to TB diagnostics including rapid diagnostic techniques (e.g. geneXpert and LF-LAM) will also be expanded.

6.2.2.1 Provide HIV testing service to persons with presumptive and confirmed TB/ HIV

Capacity building among health care workers will be provided to strengthen HIV testing service among TB and presumptive TB clients.

6.2.2.2 Intensify TB/ HIV Screening among PLHIV in health facilities

TB screening will be strengthened through deploying and training of TB screening officers. Other key populations will also be targeted for this intervention including prisoners, miners among others.

6.2.2.3 Strengthening TB/HIV screening at community level

Community TB /HIV activities including screening and testing will be strengthened within the community health interventions in collaboration with the community health department of the Ministry.

6.2.2.4 Improve availability of rapid diagnostic tests for PLHIV

The rapid diagnostic TB tests for example GeneXpert, TB-LAM and Focused Assessment with ultrasound(FASH) will be made available. Health care workers will be trained, and site level support will be the key mechanism to improve quality of service.

6.2.3 Improve coverage of high-quality treatment to all TB/HIV co-infected people

The TB & Leprosy control program working hand in hand with the HIV department shall continue to work at improving coverage of ART and reduce mortality among TB/HIV co-infected clients. More collaborative activities between the two departments shall be explored inorder to provide quality TB/HIV services.

CHAPTER 7: BOLD POLICIES AND SUPPORTIVE ENVIRONMENT

7.1. Political Commitment

7.1.1. Resource mobilization for TB

The Ministry of Health & Population regularly conducts resource mapping exercises to appreciate the funding landscape for the health sector. These exercises assist in identifying gaps in funding as well as provide a basis for improving efficiencies in allocation to departments and disease control programs. From the latest mapping exercise, the amount of resources for TB control represents about 2% of total sector programmatic resources. Of those resources allocated to TB control, about 15% is provided by government while the rest is from external partners.

The Ministry working with other government ministries, departments and agencies as well as partners and civil society groups, from time to time propose to partners like Global Fund, World Bank and other financiers through submission of funding requests. This approach will continue to be used in the lifetime of this strategic document. The Ministry also will continue sourcing for support locally and internationally through corporate institutions, philanthropists and other such potential funders.

In order to ensure accountability for TB resources, the Ministry is working on developing and implementing the Multisector Accountability Framework (MAF) through engagement with the AU and SADC.

7.1.2. Engagement of political and traditional leaders at all levels

The Ministry has several fora to engage political leaders at different levels. The formulation of Parliamentary Caucus for TB which is a forum for parliamentarians seeks to put the TB agenda on top of the lawmaker's priority list. Through this forum, the Ministry of Health orients and updates the Members of the caucus on TB issues including the resource challenges. The role of political and traditional leaders at the district council level is critical in mobilizing resources for TB and health in general

7.2. Engagement of communities, CSOs and all public and private care providers

7.2.1. Private public mix

The NTLP is working with private institutions, practitioners and other congregated settings to improve public-public and public-private partnerships for TB control. The NTLP through the PPM TB DOTS initiatives fosters to improve tuberculosis (TB) control through expanding access to the directly observed treatment short course (DOTS) strategy.

The PPM includes private for profit, private nonprofit (CHAM), corporates (farms/ companies), retail pharmacies and medicine stores and informal care provider (including traditional healers), men and women in uniform, miners /ex-miners. Table 7.2-1 describes the current situation and the gaps that are existing in the implementation of PPM.

Table 7-1: Private public mix profile as of December 2018

Category of engagement	Total number of facilities	TB registration sites	TB microscopy/ diagnostic	Other engagement in TB services
Private for profit	221	20 (9.0%)	20 (9%)	Health education; HTS; Screening of NCDs;
Private nonprofit (CHAM)	171	94 (54.9%)	83 (48.5%)	TB screening, treatment and diagnosis and referral
Retail pharmacies and medicine stores	109	0	0	Referral of presumptive
Corporates / estates	8	2	2	Provision of wellness services; TB Education and awareness; Provision of nutritional support; HTS; Dental screening; Screening of hepatitis BB, Screening of NCDs like diabetes and HTN
Informal health care workers*	20,000	N/A	N/A	Referral of T B presumptive; IEC on TB

* Traditional healers and herbal medicine providers

One approach to this is 'Engaging All Care Providers', which evolved from the 'Public-Private Mix (PPM) DOTS' initiative. There are at least four objectives that are interlinked to the PPM DOTS initiative and include the following: 1) improving TB case detection; 2) Improving TB treatment monitoring and outcomes; 3) Enhancing access and equity of TB services; and 4) Reducing financial burden on patients accessing TB services.

To achieve these objectives, different interventions were put in place such as development of a strategic framework for implementation of PPM in Malawi, PPM guidelines and operational plan, piloting the engagement of traditional healers, pharmacies and medicine store (Informal Providers) in referral of TB presumptive; engagement of corporate companies in TB screening, scaling up of TB microscopy sites in the private for profit facilities including CHAM; signing of a Memorandum of Understanding with private health care providers and capacity building for health care workers from informal providers and finalization of a PPM guidelines.

Engagement of Informal Providers (IPs): A pilot was conducted to identify potential contribution of these informal providers -Traditional healers, Pharmacies and Medicine stores to increase TB case detection through identification and referral of TB presumptive.

Engaging corporate entities: A total of 1,987 industrial tobacco workers were screened for TB and 276 (13.8%) were identified as presumptive TB clients. 11 TB cases were detected through Gene X-pert platform and was 553/100,000 population.

Scaling up of diagnostic services (Microscopy and Gene Xpert) in private sector: An assessment of 221 private clinics across the country as conducted to determine the scaling up of laboratory services. A total of 80 of the private clinics were considered for scale up. Of these, 35 facilities were selected for scaling up TB diagnostic services.

Priority Gaps

i. Suboptimal engagement of private for-profit healthcare facilities in provision of TB care services.

The private sector is not fully engaged in TB services. From the mapped 221 private sector facilities in 2017, 35 (15.8%) were formally engaged in PPM initiative. In July 2019, 35 privates for profit facilities signed a Memorandum of Understanding so that

they start provision of TB services is formalized and the remaining PPM facilities will be required to do the same in due course. Therefore, there is need to accelerate the engagement of the private sector in the private sector to increase TB case detection. The previous NSP (2016-2020) targeted to reach 100 TB microscopy sites from private sector. By 2025 this NSP envisages to scale up to a total of 165 TB microscopy sites from the private sector. It is also envisaged that 35 PPM sites will be provided with GeneXpert platforms.

ii. Limited engagement of corporate companies in TB care and prevention services

The engagement of the corporate companies has been limited to tobacco sector hence there is need to extend the engagement to other corporate sectors such the formal and informal mining sector; roads and construction works; building contractors, textiles workers in congregate settings; cement whole sellers, cement back packers, cement industry; sugar cane cutters; beverage breweries

iii. Suboptimal involvement of informal care providers/medicine stores/ pharmacies

NTLP started engaging the informal care providers as a pilot since 2018 and this was implemented in 2 districts (Lilongwe and Mangochi). This limited coverage of engagement of IPs will be expanded to the remaining 27 districts across the country including community sputum collection volunteers.

iv. Inadequate capacity to diagnose and manage TB patient in private sector

From the PPM supportive reports, there is significant knowledge gaps in the clinical management of TB diseases in private facilities. This is mainly due to exclusion during local level planning, trainings and updating on new guidelines and treatment recommendations. In addition, there is high staff turnover or a disproportionately high amount of temporary staff (locum staff) in the private health sector that contribute to suboptimal capacity to manage TB clients.

v. Suboptimal linkage between service providers

The referral system between private and informal providers with the public health facilities and between private-to-private needs strengthening. Mechanisms to ensure

linkage and account for contribution of these providers shall be strengthened in this plan.

vi. Limited engagement of the uniformed services including military, prisons, immigration and police.

The NTLP has mainly engaged prisons and to an extent the military to screen for TB. Other uniformed services were not accessed with TB screening services especially Malawi Police Services and Malawi Immigration Department.

vii. Limited means of monitoring and evaluating informal providers under PPM initiatives

The NTLP monitoring and evaluation system is able to track formal providers in the private sector. However, there are no means of monitoring informal providers' contribution to the TB response. Surveillance data on the contribution towards access, diagnosis, treatment and care services shall be collected and reported.

viii. Minimal integration of health care services

Despite strong improvements in the previous NSP, integration of health care services still require strengthening apart from TB/HIV services. The NTLP expects that health care services will continue being integrated with other programs such as Malaria, NCDs, Hepatitis, HPV to cut catastrophic costs on patients and reduce delays in the referral processes within and between facilities.

Interventions

7.2.1.1. Scale up engagement of private and other healthcare providers in provision of TB services

Support will be provided to ensure that the services are provided within the catchment of the patient regardless of capacity to pay. Private and other providers shall be capacitated to diagnose and initiate TB treatment under agreements drawn by NTLP and the providers. Private laboratories will be engaged in TB diagnosis. NTLP will also provide the necessary equipment (eg microscopes and geneXpert) to selected facilities under an agreement with NTLP. Health care workers will be capacitated through trainings and on-site mentorship support.

7.2.1.2. Scale up engagement of corporate companies in TB care and prevention

Corporate companies will be engaged in TB prevention, screening, treatment and care services. On site mentorship, training, supportive supervisions, workshops and meetings shall be used to ensure corporate companies are engaged in TB control services.

7.2.1.3. Scale up involvement of informal care providers /medicine stores / pharmacies in TB care and prevention

Informal care providers will be mapped and engaged in TB case finding and referral. The focus will be identification of presumptive and referrals to diagnostic facilities. Appropriate monitoring mechanisms will be in place.

7.2.1.4. Strengthen the PPM secretariat to manage all the PPM initiatives

NTLP, with support from partners has established the PPM secretariat which coordinates all PPM initiatives in the country. NTLP has also supported the establishment of PPM steering committee which provides high level guidance and support to the PPM secretariat. Efforts shall be made under this NSP for the PPM secretariat to gain independence outside the MOHP and manage and coordinate all PPM activities in the country.

7.2.2. Engage communities and civil society in TB control

As of 2018, just under 70% of total estimated TB cases were notified and initiated on treatment. Evidence from other parts of the world show that [2]one third of people estimated to have TB are neither reached for diagnosis and treatment nor reported by the current health systems.

In order to reach underserved population and to detect more TB patients early in the course of their illness, a wider range of stakeholders need to be engaged in community-based activities. These include civil society organizations (CSOs), Community volunteers, media professionals, and other Government sectors that are actively involved in community-based development activities. These include those involved in primary health care, HIV and maternal and child health services.

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[2] MOH. Annual TB report 2018.

Community Sputum Collection Points (Enhanced TB case finding) aim at increasing community awareness, case detection and linking the detected TB cases to treatment centers. They are operated by 10 to 15 Community Volunteers who live together with the rest of the communities. They operate under an umbrella committee called "Village Heath Committee". Community volunteers help bridge gaps between health system and community. In addition, community volunteers contribute towards improved awareness and knowledge about TB and treatment adherence. A sputum collection point is expected to cover a catchment population of 2000-5000 population. The national TB control program with support from partners established more than 1500 community sputum collection points operated by more than 9,000 trained community volunteers. In 2018, total 758 TB cases were notified through community intervention which accounted for 4.8% of total notified TB cases in 2018

The national programme has been implementing house to house TB screening through 360 trained community volunteers in 180 high burden sites identified through prioritization matrix. As part of the prioritization, National TB Control Program prioritized 8 districts for the active case finding namely: Nsanje, Balaka, Mulanje, Chiradzulu, Mangochi, Mwanza, Blantyre and Lilongwe.

Table 7-2: TB screening results from house to house TB screening (Oct 2018 – June 2019)

District	Total screened	Total presumptive	TB cases	Yield
Blantyre	19408	2217	110	566.8
Chikwawa	9355	1568	62	662.7
Chiradzulu	10954	246	2	18.3
Lilongwe	10714	408	53	494.7
Mangochi	16522	776	44	266.3
Mulanje	14004	1020	30	214.2
Mwanza	7945	436	12	151.0
Nsanje	28317	1554	53	187.2
Grand Total	117219	8225	366	312.2

Key priority gaps

i. Inadequate inclusion of human rights and gender approaches in TB programming at community level

Access to health care services is a basic human right. Community members need to demand services including TB services. The 2018 TB annual report indicates that TB affects more men than females. However, there has been little emphasis on reporting on how women are affected as care givers, patients and community members. Furthermore, integration of legal frameworks which discourage discrimination, stigma and violations of health-related human rights were not clearly emphasized in the 2016-2020 NSP. This includes patient charter and international standards of TB care. The capability to address and provide legal support services is not properly articulated in the current legal framework. Therefore, this NSP strives to strengthen implementation of the legal provisions and health care provision at community level.

ii. Limited access to community TB services

The National TB Control Program (NTLP) reports that there are barriers to TB care for the underserved areas, especially in rural areas, resulting in delay in diagnosis and access to treatment. Noting the increase in the number of Community Sputum Collection Points (CSCPs) in rural communities, there is still a need to increase coverage and sustain the already existing ones. Currently 1500 CSCPs are functional against the required 3000 CSCP representing a 50 percent coverage. Gaps in capacity building to volunteers, inadequate enablers and transportation have been challenges for implementation of this intervention.

iii. Limited coverage of active case finding through house to house intervention

The introduction of Active TB case finding through house to house TB screening is one of the strategies put in place to close the gap in terms of TB case finding. The 2019 NTLP review noted that there are barriers to TB care for communities, especially in hard to reach areas. Implementation of house to house TB screening started in selected districts in the country towards the end of 2019 and the yield from this intervention is expected to improve over time with sustained efforts. The NTLP shall continue prioritizing of case finding interventions based on burden of TB. These shall take into consideration gender, age, geographical and socioeconomic factors among others.

iv. Minimal integration between HIV, TB and other health services at community level

The coverage of HIV ascertainment for presumptive referred from the CSCP is low as volunteers are not yet trained to offer provider-initiated HIV testing and counselling. The IMCI package of childhood illness and conditions does not include much of childhood TB, however the full integration of TB component has a potential to detect more TB presumptive among children in the community.

v. Inadequate coordination and engagement of CSOs

The national program has engaged several civil society organizations in TB control. However, more active engagement of the CSOs especially those already working in the HIV area is an opportunity for the programme. Engagement also is more at national level. There is also minimal level coordination among CSOs.

vi. Inadequate inclusion of TB information in conventional education curriculum

Primary and secondary school curriculum has for a long time not covered TB as a disease as opposed to other diseases and conditions like HIV/AIDS, Diarrhea and Malaria. This is a missed opportunity for the country in terms of providing relevant information on TB as children are agents of change and their involvement can promote more on message dissemination and practices preventive measures at school and to their homes. Therefore, need to scale up TB source book as one package and strategy to raise TB knowledge among Learners.

vii. Limited community awareness on TB

The national TB prevalence survey identified low health-seeking behavior in symptomatic individuals with or without cough with 55% of all individuals with any of the 4 symptoms (cough, fever, weight loss, and fatigue) seeking care. Of those with a cough for >= 2 weeks' duration, only 55% sought care left significant number of presumptive TB were seeking care neither in Public not private health facilities[6]. Reasons cited for not seeking care included lack of community awareness and lack of financial resource for transportation. Due to lack of community awareness, TB patients face stigma and discrimination which in turn also prevents other community members from accessing TB services.

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[3] National TB prevalence survey, Malawi

viii. Lack of patient centered communication approaches

Patients and other high-risk groups and key affected populations receive a series of packaged messages and information using different strategies and approaches on TB transmission, prevention and importance of early diagnosis to improve health seeking behavior. Specifically, there is an urgent need to develop patient centered messages on importance of treatment adherence and completion. The low incidence of TB in communities, the chronicity of the disease and the relatively low attention it has received in the media as compared to other diseases of public health interest contributes to low public awareness about the disease. Hence there is need to have a more targeted TB messages for TB patient through different channels.

Strategic Interventions

Community-based interventions have the potential to increase tuberculosis case detection and improve treatment outcomes. In the NSP, these are the key strategic interventions to address the above-mentioned priority gaps;

7.2.3. Expand and maintain community sputum collection points

The program will support further expansion of additional 2000 CSCPs while maintaining the existing 1500 CSCPs. This includes mapping of the site for expansion, capacity building, provision of enablers and other materials needed for effective operation of CSCPs.

7.2.3.1. Maintain and expand house to house TB screening in selected community with high TB burden

House-to-house volunteers are mainly involved in active case finding and they move door to door to increase community awareness, detect cases and linking the detected TB cases to treatment centers.

The NTLP will continue prioritization of high TB burden districts and health facilities for active TB case finding in order to achieve efficiencies. Volunteers will be capacitated and supervised by a catchment area Health Surveillance Assistant (HSAs) to ensure effective implementation.

7.2.3.2. Strengthen the TB/HIV and other health services integration at community level

A core challenge to TB control in communities is dealing with the dual epidemics of HIV and TB. Given the impact that HIV has on TB cases and vice versa, coordination between TB and HIV programs is vital. It is in documented that half of people living with HIV/AIDS develop tuberculosis, and tuberculosis has an adverse effect on HIV progression. This tuberculosis care and prevention should be priority concerns of HIV/AIDS programs, and HIV/AIDS prevention and care should be priority concerns of TB programs.

Interventions to tackle tuberculosis among HIV-infected people can occur in the home, community and hospital/clinic. Joint TB/HIV interventions seek to prevent HIV infection, prevent TB, provide care for PLWHA and provide care for people with TB. Much potential for overlap will occur, hence need for strong integration.

7.2.3.3. Strengthen CSOs partnership and coordination in TB prevention and care (faith based, community-based organization etc.)

CSOs are engaged in activities that range from community mobilization, Service delivery, and technical assistance to research and advocacy. This NSP give special focused in engaging wider range of stakeholders in community-based activities. This will be done by having great collaboration between CSOs and government to ensure integration of TB and HIV and enhance TB prevention and control. The Civil Society Organizations (CSOs) in Malawi are actively involved in community-based development particularly in Primary Health Care, Reproductive and Child Health, HIV/AIDS and Social Economic activities, but have so far not included TB control in their priorities and activities. Community-based TB activities represent a range of interventions that positively contribute to prevention, diagnosis, care, adherence to treatment and treatment outcomes of drug-sensitive, drug resistant, and HIV associated TB. These also include community mobilization activities, mainly drama performances, open days and advance publicity to promote effective communication and participation among community members to generate demand for TB prevention, diagnosis, treatment and care services.

7.2.3.4. Integrate TB prevention and care into schools and other entities

Awareness remains key in the fight against TB. Community awareness and children will help in the fight against this deadly disease. It is imperative that children know more about TB from their early ages especially during their elementary school. Children usually share whatever they learn to their peer and family members hence incorporating messages of TB prevention and care into school curricula and classroom learning can induce change among themselves and to the public. School children should be able to recognize TB symptoms and the importance of sputum examination so that they can encourage those at home who might have TB to get tested. Efforts aimed at addressing structural drivers to TB infection and progression in adolescence shall be made. These may include but not limited to HIV, early pregnancy, childbirth, diabetes, risky substance abuse, incarceration, and mental health conditions.

7.2.3.5. Expand TB services to Village clinics

The NTLP shall continue supporting integration of TB in Community Case Management (CCM) in which Health Surveillance Assistants (HSAs) are trained and deployed in hard to reach areas where access to health services is affected by distance and other geographical features. The HSAs will be trained to manage village clinics where they can screen TB, provide treatment adherence support, assess, classify and treat uncomplicated cases of malaria, pneumonia, and diarrhea and eye infection. They are expected to refer the presumptive TB to health facilities.

7.2.3.6. Improve on advocacy and community awareness in TB prevention and control (media house, printing IEC materials, drama group and others)

A wide engagement of media houses, political and local leaders will be engaged to improve community awareness and reduce stigma amongst people in the community.

7.2.3.7. Establish an innovative patient communication strategy

This element is very vital, and it promotes treatment adherence and desirable treatment outcomes. Patient centered communication approaches which elicit and understand the patient perspectives, concerns, ideas, expectations, needs, feelings and functioning will be developed and implemented.

7.3. Infection control and waste management

7.3.1. Improve infection control practice and health care waste management

Transmission of tuberculosis (TB) in health care facilities, household, community and other congregate settings is a major challenge to TB control and public health in Malawi. Health workers are a high-risk group because of frequent exposure to patients with potentially infectious TB disease. Coupled with the convergence of the TB/HIV epidemics, this cause for concern, prompts immediate scale up of infection control measures in health care settings. Adherence to TB Infection Prevention and Control (TB IPC) measures can greatly reduce HCWs risk of acquiring TB in health facility settings. Strong emphasis was put on TB infection control within the (2015 - 2020) NSP, the focus being on administrative, environmental and personnel protection measures. TB IC indicators like functional TB IC committees, availability of TB IC plans and availability of personal protection have improved from 2015 to 2018 (see graph below). Despite this achievement, more concerted efforts are required effort to improve these indicators.

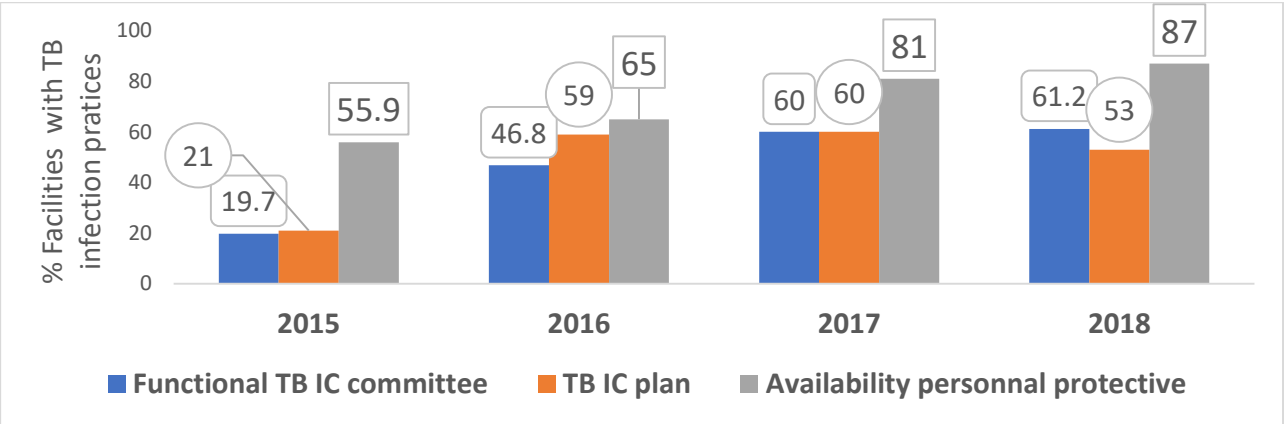


Figure 7-1: *Important TB IC indicator 2015-2018R*

Overcrowding of patients due to poor infrastructure has been a major challenge in many hospitals. Some few facilities have been renovated to improve the ventilation with support from partners during the previous NSP . Facilities that were renovated were Chikwawa, Machinga, Mangochi, Zomba. During the same period, some 36 facilities constructed the designated area (cough booths) for sputum collection across the country. TB transmission occurs in healthcare settings where infectious persons with undiagnosed or inadequately treated TB reside and move through crowded indoor spaces. As a way to reduce the concentration of infectious particles and

improve ventilation, in overcrowded facilities, 31 district and central hospitals were installed with Germicidal Ultraviolet systems. Where aerosol generation rates are high, upper room GUV air-mixing systems can add the benefit of 10 – 20 equivalent room air changes to spaces by inactivating organisms travelling through the upper room GUV field.

Health waste management is a major problem in Malawi health facilities both public and private. Environmental health reports indicate well over 80 percent of healthcare institutions have incinerators that do not meet the minimum standards or have literally none and, in such situation, incinerate health- care waste in open pits where burning is also not complete. The practice of open burning of such wastes is posing many threats to communities and the environment; air pollution being among such problems. The various TB preventive, treatment and care activities generate health care waste through several clinical activities including sputum testing or TB detection. These activities demand use of disposable needles, syringes, sputum cups and slides among medical equipment, which must be safely disposed to prevent infection. Management of Health-Care Waste (HCW) is thus a public health, workplace, safety, and environmental concern. Improper management of HCW may result into health and environmental hazards including: 1) Infectious hazards such as AIDS and respiratory cases; 2) Toxic hazards that include effects of radioactive substances; 3) Genotoxic hazards that include effects of cytotoxic drugs; and 4) Injury hazards from needle pricks and sharp objects. Sound health-care waste management system is therefore an obligation for the National TB Control Programme and shall therefore, best be done in accordance with recommended standards and procedures such as those of the WHO (2004).

Priority Gaps

i. Unavailability of functional TB IC Committees

Just over 60% of TB IC committees are available and functional. A good proportion of TB IC committees are not functional, and they do not actively engage in mainstreaming TB IC activities facility level.

ii. Unavailability of TB IC Plans

A proportion of almost 55% of health facilities have TB IC plans.

iii. Limited ventilation in facilities

Most patient waiting areas are crowded and have limited ventilation. In such overcrowded facilities, the possibility of nosocomial infections Is high.

iv. Limited availability of GUV platforms for infection prevention

A total of 1,229 GUV systems were installed in 31 facilities in the country. However, there is need for proper mechanism to engage partners for maintenance and proper disposal of remnants from the GUV that are installed in the 31 facilities across the country.

v. Unavailability of isolation rooms for DR-TB patients

There are very few facilities that have isolation rooms for DR-TB despite having a good proportion of the DR-TB patients that are on treatment.

vi. Limited knowledge on the use of Respirators

Despite the availability of respirator (N95) masks there is limited knowledge on the use of the masks by the health care workers across the country.

vii. Lack of updated TB IC guidelines and SOPs

There is need to review the Malawi TB IC guidelines and SOPs to reflect the 2019 WHO recommendations.

viii. Waste management for Pharmaceuticals and medical waste

Proper waste management systems and procedures are critical to ensure that expired and obsolete medicines are appropriately disposed. This must be done in an environmentally sustainable manner. Currently there are two pharmaceutical grade incinerators in the country against a national requirement of five incinerators (one for each region). Additionally, there are limited resources to carry expired commodities from facilities to the disposal site.

ix. Weak structures for HCW collection/segregation, storage, transportation, treatment and disposal

There are weak structures that constrain the management and disposal of wastes in the facilities. Some of the constraints noted in health facilities include: i) lack of planning or internal management procedures; ii) absence of viable data about HCW production and characteristics; iii) no monitoring system or staff member designated to monitor HCW management; iv) insufficiency of secure collection materials and protective equipment; v) mixing of HCW waste with household and office waste; and v) inefficient waste treatment and disposal. All these constraints need to be addressed in order to harness and strengthen the capacity for the facilities to ably collect, segregate, store, transport and properly dispose the wastes that are generated in the facilities.

x. Inadequate knowledge on waste management among Healthcare staff

There is evidence of limited knowledge among health workers on waste management.

This challenge is crosscutting in all health facilities. There is need to embrace measures fostered towards strengthening capacity of healthcare workers in the country.

xi. Lack of partner/private company engagement in waste care management

One of the major constraints noted in the Ministry Infection Control and Waste Management Plan (2016) assessment was that there is no private company or specialized companies involved in solid waste management in Malawi. This provides a limitation in management of HCW as the management skills and financial resources of the private sector are not tapped. It is thus important that any HCWM action plan should support private initiatives and develop a partnership between public and private sectors with civil society.

Strategic Interventions

7.3.1.1. Strengthen the IC committee at district and facility level

The NTLP will strengthen the implementation of TB IPC by ensuring the TB registration facilities have functional IPC committees in place. Targeted health care workers training is the main activity.

7.3.1.2. Scale up F.A.S.T strategy in high burden facilities

FAST is a refocused, intensified administrative approach to TB transmission control. FAST is an acronym for; Find cases Actively by cough surveillance and rapid molecular sputum testing, separate safely, and Treat effectively based on rapid drug susceptibility testing (DST). This approach assumes that most transmission occurs, not from known TB patients on effective treatment, but from persons not presumed to have TB. The key activities are training, supervision and hiring FAST promoters.

7.3.1.3. Reduce concentration infectious particles in health facilities, congregated setting and households

Environmental controls (ventilation systems including natural, mixed-mode, mechanical ventilation and recirculated air through HEPA filters) this is meant to dilute and remove contaminated air in a room thereby minimize the concentration of infectious droplet nuclei within facility. NTLP will ensure the transmission of TB in health care facilities is minimized. The key activities are renovation, procurement and installation of ventilation equipment including GUV.

7.3.1.4. Strengthen the respiratory protection at health facilities.

Personal protective masks (respirators) provide protestation to health workers when working with presumed or confirmed infectious TB patients. Personal protectives will be procured and distributed to health facilities.

7.3.1.5. Update TB IC guidelines and SOPS

TB IPC guideline and SOPs will be updated and distributed regularly

7.3.1.6. Improve HCW collection/segregation, storage, transportation, treatment and disposal

Steps in health-care waste management include: waste generation; segregation/ separation; collection; transportation, treatment and disposal. It is therefore recommended that appropriate HCW facilities (with accompanying equipment) be put in place to safely handle, treat and dispose waste in an environmentally friendly manner.

7.3.1.7. Strengthen Capacity Building and Advocacy on Community Involvement in HCWM

Capacity building and training is necessary to all health-care workers especially through service-training. It has also been widely practiced and suggested that awareness campaigns targeted to the public may facilitate reduction in HCW associated risks.
Health care workers will be trained to improve quality waste management in health facilities.

7.3.1.8. Create Public Private Partnerships

Investments in HCWM services through public private partnerships are being championed as a cost effective and efficient option for provision of various health services. The NTLP therefore sees it important to support private initiatives and develop a partnership between public and private sectors with civil society.

7.3.2. Improve TB supply chain management

The NTLP has overall responsibility of ensuring smooth supply and availability of essential TB commodities in all TB registration facilities, including anti-TB medicines (first line drugs and second line drugs), laboratory consumables/supplies and TB infection control items. The Program is also responsible for ensuring availability of critical diagnostic equipment such as X-Ray machines, Microscopes and GeneXpert machines in selected registration sites including related supplies.

The program creates an enabling and supportive environment to sustain optimal supply chain performance through provision of policy guidance and oversight, mobilization of financing and strengthening of the national capacity of health workers in managing in-country supply chain for TB commodities. The programme has maintained strong supply chain coordinating structures; a functional national coordinating mechanism for medicines and medical supplies (the Drugs Supply Management Technical Working Group (TWG)) under Health Technical Support Services (HTSS). The TWG meets on a quarterly basis to discuss stock status and coordinate the national supply chain. There is an internal PSM team within the NTCP which undertakes quantification, procurement and supply planning for TB

commodities. The NTLP PSM team has expertise to prepare long-term forecast and supply plans using Quan-TB. This is a quantification tool recommended by Global Drug Facility and endorsed by the Global fund, which is the main funder for procurement of TB medicines in Malawi. Two officials from the NTLP were trained for laboratory quantification tool for laboratory commodities. There has been full supply for First- and second-line anti-TB Medicines at national level in the past NSP. There was minimal stock out of anti-TB medicines in peripheral facilities. There was no funding gap during the implementation of the previous National Strategic Plan (NSP).

All health commodities of the NTLP are received and stored at the Central Medical Stores Trust (CMST) and distributed to the District Health Offices (DHOs) on quarterly basis through the regional stores of CMST. Through the technical guidance of NTLP anti-TB medicines and supplies are distributed regularly, through the pull-system distribution mechanism designed by NTLP. HIV/AIDS and Malaria commodities are distributed through parallel (non-CMST) channels and MOH is implementing a roadmap to integrate the parallel systems into CMST. Since June 2018 the DHOs started ordering medicines and key laboratory network items through Open LMIS platform- MOH-wide electronic Logistics Management Information System (LMIS) that is used for reporting and ordering of health commodities. Use of open LMIS reduced the need for on-site presence to monitor stock status and improved supply chain visibility by NTLP through central level monitoring of quantities ordered and stock status. The electronic approval of orders reduced the lead time for order processing from an average of seven days to one day

The NTLP procures WHO prequalified products through GDF. In -country Quality Assurance (QA) is coordinated by the Pharmacy, Medicines and Poisons Board (PMPB), a national regulatory authority mandated to provide oversight on quality assurance (QA). Every batch of TB medicine will be sampled for testing. PMPB is neither WHO prequalified, nor ISO certified to carry out tests on Global Fund supported products as per Global Fund policy and samples will be sent to regional laboratories. However, under the previous NSP there is a PMPB roadmap for ISO 17025 certification with support from Global Fund. After the product has been distributed; PMPB will withdraw samples from facilities for re-testing using a risk-based matrix through a phase 4/ Post marketing Surveillance System. There has not been a report of quality failure for anti-TB Medicines during implementation of the previous National Strategic Plan (NSP).

Key priority gaps

i. Limited capacity for supply chain management at district and facility level

Optimal performance of the supply chain relies on availability of well-trained personnel with capacity to coordinate the ordering and inventory management. Only 40 pharmacy personnel were trained on PSM in the past three years. Evidence from Drug Spot check has shown that facilities with trained staff manage their supply chain better compared to those sites with untrained personnel. Gaps in supply chain management have widened in the past two years due to changes in treatment guidelines. Key gaps have been noted in ordering procedures specifically late ordering and non-use of notified cases to determine quantities to order as per guidelines. This results in under/ over ordering leading to stock outs or overstocking. All these have been attributed to limited staff capacity and non-adherence to standard supply chain operating procedures including documentation.

ii. Suboptimal traceability of TB Commodities at District level and registration sites

Data from TB Drug spot-check shows that proper use of the Drug balance book and Drug ordering book is around 20%. There is inconsistent documentation of the medicines ordered, received and issued to patients that poses the challenge for traceability and accountability for commodities in registration sites

iii. Logistics Management Information System (LMIS) for TB laboratory commodities is not widely used

Logistics data is essential for making supply chain decisions on quantification (forecasting and supply planning) and procurement. The LMIS system of TB laboratory commodities is not widely used.

iv. Limited use of quantification tool for laboratory commodities

Accurate forecasting and supply planning are critical to ensure uninterrupted supply of commodities. It also ensures that there is no over-quantification and wastage through expiries. For Lab is a recently introduced quantification tool for the laboratory commodities and its full use is yet to be realized.

v. Inconsistent and none use of available data for ordering medicines at facility level

Number of patients at a facility (notified cases) and stock on hand are key data elements that ensure that accurate quantities of medicines are ordered. From routine order validation on Open LMIS, 30% of the orders do not correspond to the number of cases and stock on hand at registration sites which leads to over or under ordering.
vi. Inadequate use existing forums to discuss PSM issues: Coordination forums facilitate sharing of experiences, best practices and provide a platform for dissemination of latest guidelines and changes in supply chain management. There has been limited utilization of zonal and district forums to discuss PSM issues.

vii. Lack of local capacity for servicing of critical equipment

Uninterrupted diagnosis and TB detection rely on a well-maintained inventory of critical diagnostic equipment. However, during the last NSP period, there was reliance on international expertise because of lack of local capacity. This led to a long turnaround time for equipment repair and non-adherence to maintenance servicing schedule. Additionally, international providers were expensive which undermined value for money and sustainability.

Priority Interventions

7.3.2.1. Strengthen quantification, procurement and inventory management (warehousing, information systems and distribution)

This intervention will involve timely quantification, procurement, stock status review and pipeline monitoring of TB medicines and diagnostics. These processes will inform the establishment of a comprehensive system for ensuring availability of commodities and reducing expiries.

7.3.2.2. Quality assurance, patient safety and rational use of anti-TB medicines and diagnostics

This will involve procuring quality assured medicines from WHO prequalified manufacturers through GDF. For in -country quality assurance there will be collaboration with Pharmacy Medicines & Poisons Board (PMPB) for quality testing before distribution and withdrawals of samples after distribution for re-testing (Post

market surveillance). This NSP will promote rational use of medicines by ensuring that prescribing and dispensing of TB medicines follow stipulated treatment guidelines and that patients receive the correct doses at the right time. A pharmacovigilance system will be established and strengthened.

7.3.2.3. Build human resource capacity for supply chain management and coordination

This entails maintaining capacity of at all level for supply chain system. Different activities (training, supervision and review meetings) will be conducted to improve coordination at all level.

7.3.2.4. Strengthen management system for pharmaceutical and medical wastes

The capacity to classify and quantify and documentation of medical waste will be developed. Health workers will also be to manage waste disposal.

7.4. Social protection

In order to address the high economic burden faced by TB patients related to the direct and indirect costs of illness and health care several interventions are proposed to be implemented over the period of this plan. These interventions seek to address among others social consequences emanating from stigmatization and social isolation, interruption of studies, loss of employment, or divorce.

Key gaps

i. Loss of productivity at household level
ii. High indirect costs to access TB services
iii. Limited coverage of formal health facilities
iv. Availability of advanced TB diagnostic methods
v. Integration of TB services into other social development programs

Strategic interventions

The National TB Control Program shall work across government Ministries, Agencies and departments to leverage existing mechanisms targeting vulnerable populations to include TB key populations.

7.4.1. Expand coverage of social protection

Social protection should cover the needs associated with tuberculosis such as:

(a) schemes for compensating the financial burden associated with illness due to TB such as sickness insurance, disability pension, social welfare payments, other cash transfers, vouchers or food packages;

(b) legislation to protect people with tuberculosis from discrimination such as expulsion from workplaces, educational or health institutions, transport systems or housing; and

(c) instruments to protect and promote human rights, including addressing stigma and discrimination associated with TB, with special attention to gender, ethnicity, and protection of vulnerable groups. These instruments should include capacity building for affected communities to be able to express their needs and protect their rights, and to call to account those who impinge on human rights, as well as those who are responsible for protecting those rights.

Pursue *"health-in-all-policies"* approaches.

Actions on the determinants of ill health through "health-in-all-policies" approaches will immensely benefit tuberculosis care and prevention. Such actions include, for example:

(a) pursuing overarching poverty reduction strategies and expanding social protection;
(b) improving living and working conditions and reducing food insecurity;
(c) involving diverse stakeholders, including tuberculosis affected communities, in mapping the likely local social determinants of tuberculosis; and
(d) preventing direct risk factors for tuberculosis including smoking and harmful use of alcohol and drugs, and promoting healthy diets, as well as proper clinical care for medical conditions that increase the risk of tuberculosis, such as diabetes

7.4.2. Social Cash Transfer

The Social Cash Transfer (SCT), locally known as Ntukula Pakhomo, is implemented by the Ministry of Gender, Children, Disability, and Social Welfare (MoGCDSW).

The SCT is an unconditional cash transfer program targeted at households that are both ultra-poor and labour constrained. The SCT has the objective to reduce poverty and hunger among ultra-poor and labour constrained households; to increase school enrolment of children in the beneficiary households; and to improve the nutrition, economic, and general well-being of beneficiaries.

The SCT targets the bottom 10% of the ultra-poor and labor constrained households that are captured in the UBR. TB being a chronic disease is associated with high levels of infirmity and disability that affect economic productivity. Only a small proportion of TB patients are currently on this program. It is the Ministry of Health's desire to have increasing numbers of TB patients both (Drug Resistant and Drug Susceptible) enrolled on this program.

7.4.3. Public Works Programme

Public works programmes (PWP) is implemented by the Ministry of Local Government and Rural Development through the National Local Government Finance Committee (NLGFC). PWP are programmes that provide regular payments to individuals in exchange for work, with the objective of decreasing chronic or shock-induced poverty and providing social protection. The PWP targets the ultra-poor households that are not labour constrained and currently focuses on 11-25% of beneficiaries identified by the UBR (Thus excluding the 10% targeted under SCT). TB patients who have completed treatment and are declared fit to return to work should not be discriminated against but should be given equal opportunity to participate in development activities.

7.4.4. Nutrition support and School Feeding Program

The School Feeding Program is implemented by the Ministry of Education and is a response to studies that have shown the disastrous effects malnutrition has on the development of physical and mental capabilities of children. In recognition of the need to improve school enrolment and ensure that children are well nourished enough to pay attention in class, the provision of free school meals to Malawian students is a key part of the MNSSP II. School meals are provided mainly by the Government, NGOs, and the WFP. The goal of all school feeding activities is to improve child nutrition, increase children's' ability to concentrate in class, promote enrolment and regular attendance.

Provision of nutrition support to TB patients should be complimented by the School feeding initiative. Nutrition support may include provision of nutrients that can be mainly consumed by patients. The initiatives must be collaborated with other stakeholders for purposes of sustainability. This is assumed that this will be implemented in the new NSP

7.4.5. Savings and Loans Groups

Explore the establishment of Savings and Loans Groups amongst DOT supporters and TB survivors. Groups of these may be formed per assigned geographical area and provided the necessary orientation on the operations of Savings and Loans Groups. Initial capital may be obtained for example from allowances/incentives that target the DOT supporters.

7.4.6. Pro-poor Microfinance

Financial inclusion describes the delivery of banking services at an affordable cost to low income groups and the Government considers it to be an essential instrument for increasing agricultural productivity and production, expanding micro and small enterprises, creating employment, increasing household income, and smoothing consumption. TB patients may be considered for these loans given the impact of the disease on economic productivity and indirect costs on the family.

7.4.7. Fertilizer Input Subsidy Programme

The Fertilizer Input Subsidy Programme (FISP) is implemented by the Ministry of Agriculture. The FISP serves two main objectives, which are reducing poverty and ensuring the country's food security by fostering an increase in agricultural productivity levels. FISP supports resource poor farmers with inputs that include fertilizers (NPK and UREA); Seeds for cereal crops that include Maize, Rice and Sorghum that is drought resistant crop; Seed of legumes (Beans, Pigeon Peas, Soya, Cow Peas and Groundnuts), which are distributed to improve nutrition, soil fertility and as a cash crop.

TB and ex-TB patients suffer from food insecurity due to long duration of the illness that negatively affects agricultural productivity. Deliberate efforts targeting these patients should be made to provide them with inputs to assist these families back to agricultural productivity.

7.4.8. Decent and Affordable Housing Programme

The Decent and Affordable Housing (Cement and Malata) Subsidy Programme (DAHSP) is Malawi Government's programme which intends to provide subsidized cement, iron-sheets and other related building materials for the low-income households to build and improve their own houses.

The Ministry of Lands, Housing and Urban Development is implementing the DAHSP initiative whose objective includes facilitating construction and improvement of houses for the low-income households. Low-income households will manage to build and own decent houses through subsidized cement, iron-sheets and other construction materials under the DAHSP concept. The Ministry of Health through the NTLP intends to link the TB vulnerable populations who have poor accommodation

to this program. This will be done by collaborating with responsible ministries and departments to link Patients into social protection programs in the country, by conducting mainstreaming activities across government departments and agents, integration of services into existing health programs targeting key population through multi-sectorial collaboration and strategic partnership with other stakeholders

CHAPTER 8: PROGRAM MANAGEMENT, MONITORING, EVALUATION, RESEARCH AND INNOVATION

8.1. Program Management

The National TB control program provides overall leadership in the fight against TB and responsible for policy formulation and guidance of TB control services in Malawi. Currently, the NTLP structurally falls under the Directorate of Preventive Health Services in the MoHP. The program is led by program manager functioning as Deputy Director of Preventive Health Services in the MoHP and supported by one Deputy Program Manager and a team of dedicated officers responsible for TB/HIV, TB laboratory, medicines and commodities, care and treatment, operational research, community TB care, M&E and data management. Technical assistance to the program is also provided by stakeholders on short- and long-term arrangements in different areas of expertise.

The NTLP prepare the annual plan in coordination with the Directorate of Planning and Policy Development (DPPD). The planning process pass through a series of extensive consultations and prioritization with partners and stakeholders. The final plan is endorsed by Ministry of Finance and subsequently to by Parliament. The annual plans are guided by the National Strategic Plan which sets the direction that the program takes for a period of 5 years.

Policies and guidelines

Policy updates are developed in broad consultation with partners and stakeholders. The NTLP will expand consultation to reflect the program's commitment to broaden its reach in its efforts to strengthen the response to achieve goals and objectives set. Policy discussions are highly consultative and includes all stakeholders namely implementers, academia, civil society, faith-based organizations, patient representatives, partners and international and national bodies.

Partnership coordination

Partners working at national level on TB prevention and control will participate in different technical working groups (TWGs) and different fora based on their scope of interest, area of investment and expertise. This NSP acknowledge that CSOs and partners share valuable information, lessons, experiences and best practices for

NTLP to improve implementation. The NTLP will ensure engagement of district level CSOs, FBOs and community support groups to provide technical support for collective decisions. This NSP encourages new and existing partners to buy in the priority interventions for the common goal.

Key achievement

The NTLP has overall oversight on TB control implementation in the country.

- Up-to-date National TB treatment guidelines, manuals and tools for supervision are available
- Joint Quarterly TB/HIV supervision done consistently since 2015
- The NTLP conducted a regular program performance review both at national and zone level to improve program performance since 2016
- Data on TB notification, treatment outcomes and TB/HIV is available for many years.
- Mobilize resources for program management (drugs, supplies, supervision).
- No stock outs of anti-TB medicines reported during the previous NSP period
- Strong national level team to support implementation of activities

Priority gaps

i. Data storage not suitable for more analysis.
ii. Lack of transportation for district to conduct regular program monitoring and supervision
iii. Inadequate engagement of non-service providers such as line ministries
iv. Inadequate human resource at NTRL to perform in full capacity
v. High turnover of staffs at facility level

Priority Interventions

8.1.1. Improved stewardship and Program oversight

The NTLP represents Ministry of health and population on all matters related Ending Tuberculosis at regional and international forums. During the implementation of this NSP, members of staff at the NTLP will attend several strategic meetings and conferences at regional and international level.

The NTLP leads the development of annual operational planning for implementing TB interventions in line with NSP and the HSSP. NTLP work with District health Office in developing district specific operational plan and support the implementation TB interventions at district level and lower levels. During this NSP, the NTLP will develop and update existing guidelines, SOPs and tools as deemed necessary. Compliance to national TB guidelines will be followed up. The NTLP will work towards improved resource availability for ending TB in Malawi through working closely with development partners and other key stakeholders in mobilizing additional resources. NTLP also well come new partner who are willing to support NSP.

8.1.2. Improved coordination and partnership

NTLP will improve on coordination and partnership among different stakeholders by engaging them in the Strategic and annual planning meetings, Program reviews, and joint supportive supervision visits and review meeting. Coordination and partnership will be promoted to maximize efficiencies and reduce duplication of efforts. Technical knowledge will be shared among partners and stakeholders to improve technical efficiencies.

8.1.3. Improved leadership and program management at all levels

The NSP will assist to inform district level planning. District health plans are integrated and use the HSSP as an indicative plan. During the planning cycles, DTOs and zonal TB officers will actively participate and ensure NTLP strategic interventions as elaborated are incorporated into the district plan.

8.1.4. Improved capacity of health workers to improve TB programme performance

The NTLP strives to improve capacity of clinicians and program managers in clinical and program management skills. District and zonal TB officers will be trained on programmatic management of TB and drug resistant TB. Health workers will be trained on comprehensive TB and TB/HIV management.

8.2. Monitoring and evaluation

The national TB and Leprosy control program has a structured M& E system. The program M&E activities are guided by costed M&E plan. The costed M&E plan has

also outlined the human resource need, indicator reference sheet, target and source of information for indicators that are part of performance framework for the national programme. National program uses DHIS2 for data collection and data transmission to national level. Four TB modules (Notification, Treatment outcome, DR TB and TB HIV) are customized into DHIS 2. The reporting rate was at 90% by end of 2018 which has shown a substantial improvement since TB modules were customized into DHIS2. Reporting rate and timeliness are critical gaps in use of data from this platform

The program uses TB/HIV supervision to collect additional data. The TB HIV supervision helps the program to collect data for additional thematic areas of the program including contact investigation, community referral, laboratory related service uptake and case detection effort. The program has consistently carried out regular data quality assessment, zonal / national review meetings to assure data use at national / sub national level.

An epidemiological review was conducted to assess TB surveillance system according to WHO's standard benchmark. The epi review revealed an improvement in the surveillance system since the previous review. The epidemiological review has also generated key recommendations related to DHIS use, and other technical areas related to reporting of notification data, vital registration and others.

Key gaps

i. **Limited data use at all levels:** limited number of districts have conducted district review meeting in the past which is related to failure to ensure availability funds at district level. This has improved in the last 1 year; however, this improvement has not been satisfactory.
ii. **High turnover staffs:** There is a high turnover staffs and rotations which required regular capacity building exercise.
iii. **10 % facilities don't report data through DHIS 2 and limited use of DHIS 2 for decision making:** Reporting rate is a 90% on DHIS 2 which affect direct use of data from the DHIS 2.
iv. **Delay in implementation of electronic medical record for TB:** The program relies on paper-based data management system as a result of delayed implementation of EMR. This in turn has resulted in limiting use of real time data for program monitoring and limited use of disaggregated data.

Table 8-1: Summary of assessment of standard benchmark (WHO) TB surveillance system (Oct 2018)

Met	Partially met	Not met	Not applicable
B1.1 – Case definitions are consistent with WHO guidelines B1.2 – TB surveillance system is designed to capture a minimum set of variables for reported TB cases B1.3 – All scheduled periodic data submissions have been received and processed at the national level B1.6 – TB surveillance data are externally consistent B1.7 – Number of reported TB cases is internally consistent B2.1- – Surveillance data provide a direct measure of drug-resistant TB in new cases B2.2 – Surveillance data provide a direct measure of the prevalence of HIV infection in TB cases	B1.4 – Data in quarterly reports (or equivalent) are accurate, complete, and internally consistent (For paper-based systems only) 1.8 – All diagnosed cases of TB are reported B1.9 – Population has good access to health care	B1.10 – Vital registration system has high national coverage and quality B2.3 – Surveillance data for children reported with TB (defined as ages 0-14 years) are reliable and accurate AND all diagnosed childhood TB cases are reported	B1.5 (Electronic) – Data in national database are accurate, complete, internally consistent, and free of duplicates

Interventions

8.2.1. Improve data management system

Improvement in data management entails ensuring availability of all required M&E tools, standardized registers and SOPs at all level. Use of DHIS 2 platform optimally to transmit data from periphery to national level. In addition to that the program will ensure interoperability of all E health application the program. The program will ensure that HMIS focal persons and all personnel are capacitated at all level to have adequate skill in use of DHIS 2 at district level. Regular support will also be made available.

8.2.2. Improve data use at national and subnational level

Program use different platforms to improve data use at all levels. The following are key platforms that are used to ensure data use

8.2.2.1. Conduct regular review meetings at all level

The program conducts zonal and national review meetings regularly. Zonal review meetings are conducted quarterly while national meetings are conducted every 6 months. the zonal review meetings engage all districts and high-volume facilities within the respective zones. The program uses standardized template to ensure standardized approach to these review meetings. The district review meetings were conducted regularly and religiously.

8.2.2.2. Dashboard for data collected through DHIS 2

NTLP is working with CMED and WHO to customize DHIS 2 to help generate district, zonal and national level dashboard. The program has gathered all retrospective data into TB Historic data. This design of the dashboard is in progress and will be finalized by end of 2019

8.2.3. Improve quality of service through regular supervision and mentorship

The national program has been conducted regular TB HIV supportive supervision since 2015. The quality of supervision has improved through time. The program organized workshops to help supervisors improve their supervisory skills. The workshops were also aimed at improving quality of data collection through this supervision. A standard of care package was defined by a programme. Facilities were also assisted to follow up implementation of standard care package in their respective facilities.

The programme will continue implementation standard of care package. The tools will be regularly updated and improved.

8.2.4. Improve data quality through capacity building and regular data quality assessment

The program has conducted integrated TB/HIV training whereby recording and reporting is key component of the training. M&E specific training were also provided to TB focal persons. M&E team has regularly conducted data quality assessment to provide facility

tailored support. The data quality assessment has resulted in improving data quality over time. Majority of districts have concordance of 100%. There was very marginal underreporting when aggregated data was compared (0.3%)

8.3. Operations research

The NTLP realizes the critical role that research plays in generating information that facilitates evidence-based planning of the TB response. To this effect, the country has a research agenda that has recently been revised to take care of emerging issues in TB. Several studies have been conducted over the years and have contributed to interventions that have been implemented. The country will continue to monitor TB prevalence and incidence in general and in key populations by conducting regular surveys including Drug Resistance survey and client satisfaction survey.

Malawi has planned its second TB prevalence survey to be conducted in 2023 and this will measure TB burden and help to review prevalence and incidence over time. Surveys to monitor development and transmission of TB drug resistant strains will also be conducted regularly. Recently the National TB Control Program coordinated the review of the TB Research Strategy and identified research priorities that can aid effective planning of the national response and these are summarized in the Table 1 below and will be conducted during period of this NSP.

The program prioritizes, set and reviews areas for research on an annual basis. The priority is being given to research addressing programmatic strategic goals. The NTLP organizes annual TB research networking dissemination and best practice conferences in collaboration with stakeholders including research institutions and the academia.

The research component is in 2 components basically the scientific and operational researches. Operational research is an important tool for programmes performance improvement, development of competencies, motivation, both for the individual and the organization as well as to guide policy direction. The programme will continue to strengthen research to address operational issues including capacity building at different levels.

Table 8-2: Research priorities by thematic areas (NTLP)

Technical Area	Key Research Topics
Epidemiology	TB prevalence survey Prevalence of LTBI Spatial distribution of TB
Prevention	How best to reduce risk of transmission to HCWs and congregate settings Determine cost effectiveness of various TB control measures Tuberculosis Preventive Therapy: Coverage and outcomes of interventions in the next 5 years Barriers in uptake of Tuberculosis Preventive Treatment Integration with HIV
Diagnostics	An assessment of adopted Active Case Finding (ACF) algorithms among key populations Evaluation of community interventions related to improving access to TB diagnostics Evaluation of DST in Malawi among pulmonary TB cases
Treatment	Evaluating the effect of early TB and ART initiation on patient outcomes Investigating clinical management options of patients with TB/HIV co-infection and DR-TB Monitoring TB drug resistance emergence in children and adults receiving TB treatment Determining and monitoring side effects of susceptible TB and DR-TB regimens
Care and Support	Investigating models on how to integrate TB and HIV infections Assessing the extent and degree of stigma and discrimination Assessing the influence of gender in accessing TB and HIV/AIDS services Evaluating factors that influence TB screening amongst key populations

Priority gaps

i. Research related to coordination and collaboration challenges

Many stakeholders are commissioning studies without knowledge and approval of the NTLP leading to a failure by the NTLP to compile and update research work taking place in the country. It has also been noted that there is limited linkage with the academia.

ii. Limited support towards research activities

Stakeholders within the TB sector have not prioritized research work as evidenced by limited funding allocations in project activities.

iii. Limited platforms for sharing research findings

Even though there is provision for annual TB research networking dissemination conference, only 2 sessions have taken place in the past five years. This then calls for strengthening for coordination between the NTLP and stakeholders to prioritize research and dissemination platforms.

iv. Limited capacity in developing, implementing and analyzing research protocols

Experience has shown that even when there is a call for papers, very few institutions and individuals are forthcoming. Additionally, the submissions made show serious gaps in the way they are formulated and presented.

Key interventions

8.3.1. Popularizing the research agenda

The Research agenda was developed through an extensive consultation exercise, which incorporated detailed discussions with a variety of internal stakeholders including the Research Directorate of the Ministry of Health and the external stakeholders. The themes for the research agenda focus on burden of the disease, topics under prevention, topics under treatment, care and support and topics including operations research. The priority research agenda for 2021-2025 will be developed in consultation with stakeholders.

8.3.2. Build capacity to undertake Operational research

This NSP is paying attention to building capacity at institutional and individual level including key stakeholders within the TB sector in a bid to ensure evidence-based program management. The program aims to build the capacity health care provider and program officers on Operational research through short- and long-term training, mentorship in OR individual support of those trained on the job. Research fining will be disseminated in a local and an international forum including publication

8.3.3. Create a basket funding for research activities

This NSP envisages embracing activities that promote surveillance surveys and research activities which are critical to generating information. Therefore, there is need to allocate funds to conduct research activities, monitoring and dissemination

8.4. Innovations

Malawi has piloted and scaled up several innovations. These innovations have shown great potential to address bottlenecks in a range of program areas such as case detection, monitoring and evaluation, patient management and program management. The period 2021 – 2025 will see NTLP and its partners consolidating on the gains made through the wider deployment and refinement of these innovations.

8.4.1. Digital health

Malawi aspires to join the rest of the world in transforming health care delivery and strengthening care in health facilities through embracing innovative digital solutions falling under the common banner of digital health or e-health. A digital health intervention is a functionality of digital technology that is applied to achieve health objectives and is implemented within digital health applications and ICT systems, including communication channels such as instant messengers and traditional short messaging services.

Digital technologies provide concrete opportunities to tackle health system challenges, and thereby offer the potential to enhance the coverage and quality of health practices and services. Digital health interventions may be used, for example, to facilitate increased service uptake like in the pilot the NTLP has undertaken with sample tracking and patient management through the SATBHSSP supported initiative. Other examples are the HIV Electronic Management Record, TB EMR and the OPD EMR. The range of ways digital technologies can be used to support the needs of health systems is wide, and these technologies continue to evolve due to the inherently dynamic nature of the field.

The NTLP is promoting the digital health pathway fully aware that Digital health interventions should complement and enhance health system functions through mechanisms such as accelerated exchange of information but will not replace the fundamental components needed by health systems such as the health workforce,

financing, leadership and governance, and access to essential medicines.

The NTLP proposes the following digital health interventions to be implemented for the duration of the NSP:

Priority gaps

i. Limited availability and use of e-health for patient management and data use
ii. Poor internet connectivity
iii. Limited capacity to use existing ICT tools
iv. late data transmission
v. Incomplete data capture

8.4.1.1. Maintain and expand existing electronic application for patient management and data transfer

The program will strength the existing system by the time new NSP is operational. The EMR will be expanded further to all high-volume facilities. These incudes; Sputum sample tracking from community level, Gx alert, Laboratory Information Management System, Logistics Information Management System and Imaging Inventory storage and patient management systems.

8.4.1.2. Enhance use of existing platform for decision making and ensure interoperability

- Develop data use strategy from this system
- Implement guidance by QMD to ensure interoperability systems
- Building capacity of health workers to use these systems

8.4.1.3. Teleradiograph and other imaging modalities

The National Tuberculosis Control Program during the lifetime of the 2015 – 2020 National Strategic Plan made available 18 digital X-rays with an average of 5 viewing stations and Picture Archiving and Communication System. In the same time frame 20 Sonography machines have been made available.

Prioritized gaps

i. PACS activation and networking for all digital x-rays.
ii. Integration of PACS with other imaging modalities such as Ultrasonography, Computed Tomography and Magnetic Resonance Imaging.
iii. Integration with Electronic Patient Management Systems including lab and medicines-oriented health information
iv. Technical expertise to maintain and calibrate.
v. Not available in all facilities that should offer such services.
vi. Technical support and Mentoring
vii. Dedicated budget lines for review meetings and capacity building

The following key activities of this intervention

- Establish a system for tele-radiography
- Build capacity to manage the tele-radiography
- Expand the network to allow improved coverage

8.4.1.4. Tablet based audiometry

The Tuberculosis Control Program during the lifetime of the 2015 – 2020 National Strategic Plan increased the number of MDR – TB patients being enrolled on treatment from 59 in 2015 to 107 enrolled on treatment. This has hastened the need to perform audiometry. This was achieved by introducing tablet-based audiometry services and scaling up of such.

Gaps

i. Lack of audio-booths to adequately diagnosis hearing deficits as a result of MDR– TB treatment and other causes.
ii. Lack of capacity to interpret findings from audiometry.
iii. Lack of services to deal with auditory problems that arise from the use of such drugs as amikacin.

8.4.2. Grievance redress system

The NTLP is cognizant of the fact that in the course of implementing its activities,

issues around hospital workers-client interaction might arise. To deliberately deal with such issues in a systematic way, the NTLP has come up with a grievance redress mechanism whereby communities and individuals who believe that they are adversely affected by the initiatives undertaken may submit complaints to an independent office of the hospital ombudsman.

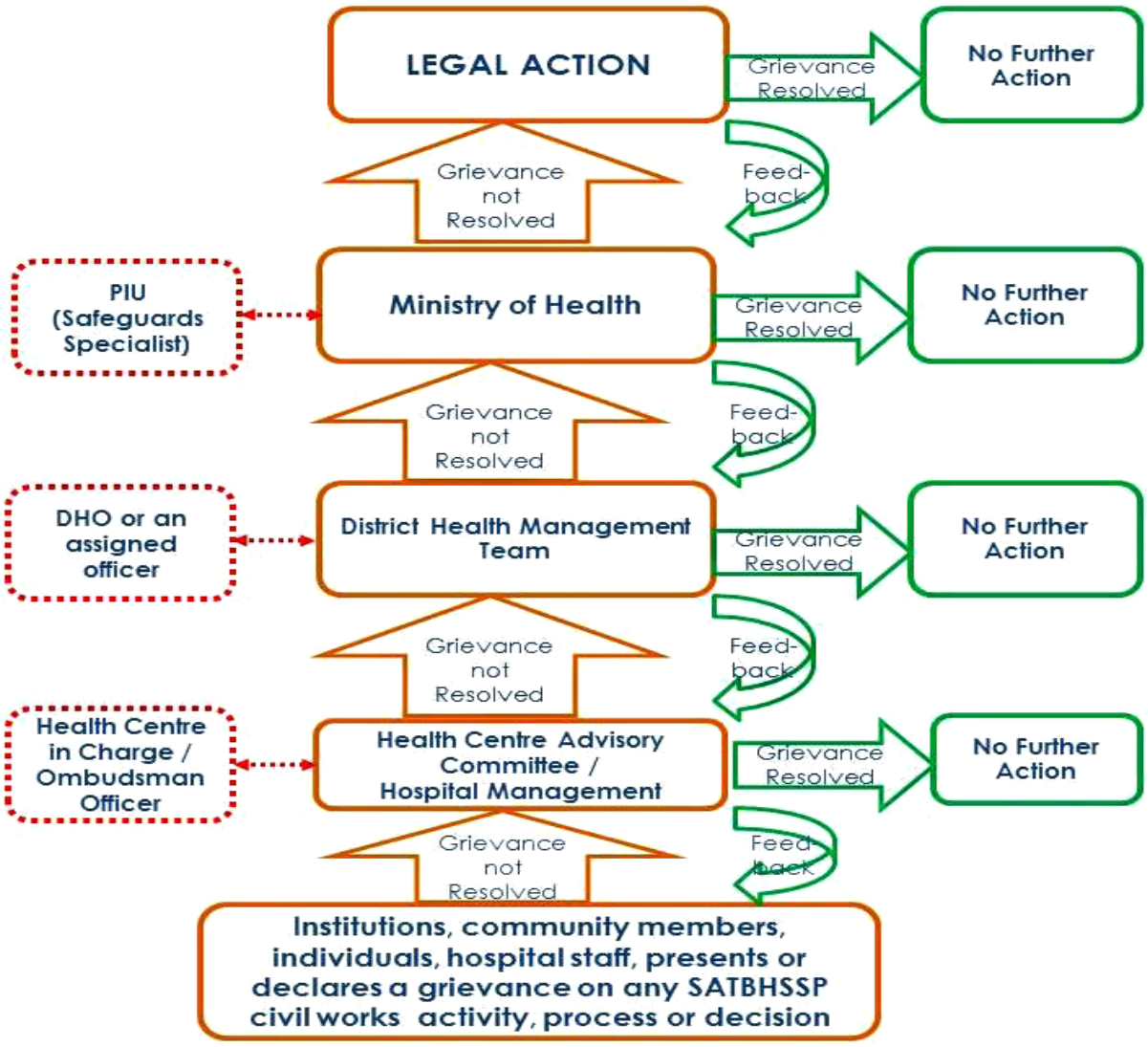


Figure 8: *Grievance redress mechanism*

Gaps in grievance redress

i. Not all ombudsmen are trained on the grievance redress system.
ii. Not yet in every facility across the country.
iii. Has not been fully disseminated to all relevant stakeholders.

Interventions /activities

8.4.3. Client satisfaction

In all its programming, the NTLP strives to achieve quality health caresystems through a continuous process of measurement and evaluation. This is achieved among others by measuring the gap between standards and actual practice. To this end, NTLP has been piloting the tracking of client satisfaction with the services offered to TB clients in health facilities across the 9 districts supported by the Southern Africa TB and Health Systems Support Project.

The satisfaction is measured using a standard questionnaire. This is done through exit interviews that are carried out by hospital ombudsman to patients about to graduate from their treatment. The Ombudsman was selected to manage this in a bid to bring independence in the findings as clinicians or nurses would have been biased in their interpretation of results as they are contact points with the patients.

Prioritized gaps

i. Not rolled out to all facilities.
ii. Not all ombudsmen are trained on how to administer the questionnaire.
iii. Not all ombudsmen are oriented on how to analyze the findings
iv. Has not been fully disseminated to all relevant stakeholders.

CHAPTER 9: TB NSP 2021-2025 BUDGET SUMMARY BY PILLAR AND RESULT AREA

Costing for TB and leprosy NSP 2021-25

Costing methodology and process

The TB and Leprosy National Strategic Plan(NSP) 2021-25 costing aims to calculate the cost of maintaining and scaling up TB and leprosy prevention and treatment interventions in Malawi. Estimating total resource needs of the TB and leprosy NSP supports domestic and external resource mobilization as well as transparent and accountable operationalization of the strategic plan.

The total cost of implementing this NSP was estimated using activity-based costing, a detailed costing method that is adequate for understanding programmatic costs and major cost drivers. This method breaks down processes into individual activities, which are necessary to deliver a service or to achieve a defined outcome. An activity is defined as a collection of resources combined to deliver a particular activity. Resource utilization measurement is performed separately for each activity, in order to obtain accurate and reliable cost estimates and detailed information about cost structures, which can be used to better cost control and improve decision-making and strategic planning.

The activity-based costing captures activities conducted at the national and subnational levels and adopted a health sector perspective, including costs entailed for government, NGOs, development partners, civil society and the private sector, but excluding patients' out-of-pocket costs. The NSP costing exercise was carried out for commodity procurement and programmatic support activities such as trainings, workshops, meetings, supervision visits, monitoring and evaluation, consultancies, equipment procurement and other capital investments. While existing cross-cutting health systems activities performed by MoHP were not included in the costing, incremental health systems implications of the scale-up of the TB and leprosy response were costed. These included amongst others medical equipment, infrastructure, HMIS, and leadership and governance.

NTLP held several participatory meetings with all the relevant stakeholders in the TB and leprosy landscape including national and international technical experts, health care providers, implementing and development partners as well as representatives

from both civil society and communities. This forum was used to define, validate and achieve consensus on detailed lists of programmatic and cross-cutting health systems activities and costing assumptions for each of the activities. Commodity quantifications for public sector procurement of each of the commodities needed for an effective TB and leprosy response were based on existing demographic data and epidemiological assumptions on the need for each commodity (e.g. the annual number of people requiring first-line anti-TB medicines). Consensus on assumptions was similarly reached through a stakeholder engagement process.

The NSP costing exercise drew from a number of sources to collect unit costs including NTLP, implementing and development partner program budgets, historical expenditures, proforma invoices, current guidelines and interviews with key informants, amongst others. All cost estimates used 2019 prices and excluded inflation. In accordance with government costs and approved harmonized development partner transport refund and daily subsistence allowance rates, a set of standardized costs was defined and applied for activity costs that differed between implementers. For example, a set of standard meeting, training and supervision/mentorship costs were applied, irrespective if they were government or development partner-implemented. A Microsoft Excel-based budgeting tool was developed to assist in deriving activity costs for each pillar. Collected unit costs were then applied to annual quantities and frequencies based on programmatic and intervention targets and goals included in the results framework.

Due consideration was given to achieve maximum value for money with selected interventions and activities. After developing the first version of the NSP budget, activity validation and integration meetings were held. The validation process ensured that the costing assumptions and calculations were consistent, logical and rigorous, and that the overall costs aligned with the prioritized interventions. Integration efforts were made to streamline and harmonize included activities and find efficiencies, with a particular focus being placed on the integration of trainings, meetings and supervisions/mentorships. For activities that could be harmonized, these were amalgamated into a single comprehensive activity to minimize time spent on these activities and reduce costs. For instance, comprehensive trainings on TB, TB/HIV, and leprosy prevention and management as well as on new TB diagnostics were established. In this way, the 5-year total cost of the activities included in the NSP could be reduced by approximately US$ 50 million.

Costing results

The total cost of implementing the TB and leprosy NSP is estimated at US$ 168.47 million over the 5 years. The annual cost is higher in the first year as compared to other years, with costs of US$ 39.05 million in 2021-22, and lowest in final year with US$30.43 million in 2025-26. The difference in annual costs is a consequence of front-loaded activities to allow the TB and leprosy response to be scaled up more rapidly so that outputs are realized sooner.

As detailed in Table 9-1 below, drugs and medical supplies assume the largest part of the cost (24.2% over the NSP period, US$ 40.7 million), followed by health information systems, monitoring and evaluation, and research (14.8%, US$ 24.97 million), and human resources (13.6%, US$ 22.85 million). Program management consists of 7.5% (US$ 12.65 million).

Table 9-1: Total cost of TB and leprosy NSP 2021-25 by cost category (in US$ million)

Cost category	2021	2022	2023	2024	2025	Total	% of Total
Program management	3.26	1.87	2.91	2.03	2.57	**12.65**	**7.5%**
Drugs and medical supplies	8.60	7.94	8.09	8.60	8.60	**40.67**	**24.2%**
Health Information Systems, M&E, and Research	5.32	7.02	4.26	4.17	4.21	**24.97**	**14.8%**
Human Resources	4.94	4.33	4.84	4.29	4.45	**22.85**	**13.6%**
Infrastructure	5.30	3.80	4.87	4.54	4.13	**22.64**	**13.4%**
Medical equipment	6.46	4.17	3.28	4.66	2.96	**21.53**	**12.8%**
Leadership & Governance	1.37	1.07	1.06	1.10	1.03	**5.63**	**3.3%**
Socio-Economic Determinants of Health	3.80	3.51	3.58	3.27	3.29	**17.44**	**10.4%**
Grand Total	**39.05**	**33.72**	**32.89**	**32.39**	**30.43**	**168.47**	**100%**

In addition to medicines for treatment of DS-TB and DR-TB, the cost category of drugs and medical supplies includes new TB diagnostics such as GeneXpert cartridges and LPA test kits as well as procurement and supply chain-related costs, thus explaining the substantial share of the total costs. In addition, the comparatively high costs for health information systems, monitoring and evaluation, and research are largely attributable to the inclusion of the TB prevalence survey and operational research

activities to be conducted over the NSP period as well as the planned maintenance and expansion of the TB EMR. With regards to human resources, it is important to note that healthcare worker salaries were not included in the costing; included costs comprised of training activities, professional services and incentives for community volunteers, amongst others. The cost category socio-economic determinants of health includes primarily behavior change communication efforts and treatment support to patients in the form of the procurement of food items and the provision of transport refunds to all DR-TB and a 10%-share of DS-TB patients.

Table 9-2 provides further detail of the estimated costs per NSP pillar and result. The improvement of **Patient-centered care** (Pillar 1) comprises about 42% (US$ 70.85 million) of the estimated total cost, followed by **Bold policies and Supportive Systems** (Pillar 3) at approximately 29% (US$ 48.96 million). **TB comorbidities and key populations** (Pillar 2) including TB/HIV prevention and management, and **Program management, monitoring & evaluation and research & innovation** (Pillar 4) account for about 18% (US$ 30.89 million) and 11% (US$ 17.77 million), respectively.

Table 9-2. Total cost of the TB and leprosy NSP 2021-25 by pillar and result area (in US$ million)

Pillar and result area		2021	2022	2023	2024	2025	Total	% of Total
Pillar 1	**Improved patient centered care**	16.50	12.61	13.57	15.28	12.89	**70.85**	**42.06%**
Result 1	Early diagnosis and detection	11.28	7.52	8.54	10.24	8.05	**45.61**	
Result 2	Treatment of all patients	4.43	4.28	4.14	4.16	4.01	**21.02**	
Result 3	TB preventive therapy	0.42	0.48	0.55	0.56	0.53	**2.55**	
Result 4	Reduction of grade II disabilities in leprosy patients	0.38	0.33	0.34	0.31	0.31	**1.67**	
Pillar 2	**TB comorbidities and key populations**	7.11	5.80	6.56	5.42	6.01	**30.89**	**18.33%**
Result 1	TB / HIV	2.79	2.79	3.12	3.10	3.10	**14.90**	
Result 2	Key population	4.32	3.01	3.43	2.32	2.91	**15.99**	
Pillar 3	**Bold policies and supportive systems**	12.07	10.39	10.47	9.49	9.31	**48.96**	**29.06%**
Result 1	Political commitment	0.01	0.00	0.01	0.00	0.00	**0.02**	
Result 2	Engagement of communities, CSOs and all public and private care providers	6.52	5.00	5.28	4.75	5.04	**26.60**	
Result 3	UHC policies, regulatory frameworks and rational use of medicine infection control	2.78	2.92	2.25	2.33	2.15	**12.42**	
Result 4	Social protection, poverty alleviation and actions and other determinants of TB	2.18	2.09	1.99	1.89	1.78	**9.92**	
Pillar 4	**Program management, Monitoring & Evaluation and Research & Innovation**	3.37	4.92	2.29	2.20	2.22	**17.77**	**10.55%**
Result 1	Program management	0.59	0.38	0.94	0.51	0.34	**2.76**	
Result 2	Monitoring & Evaluation	0.99	0.97	1.01	1.00	1.04	**5.01**	
Result 3	Operational Research	0.35	1.85	0.33	0.33	0.33	**3.18**	
Result 4	Innovation	2.04	2.10	0.95	0.88	0.85	**6.82**	
Grand Total		**39.05**	**33.72**	**32.89**	**32.39**	**30.43**	**168.47**	**100%**

A review of costs at the intervention level reveals that approximately 80% of the estimated 5-year cost of the NSP is driven by 10 interventions (Table 9-3). Improving access to TB diagnostics is the largest driver of costs in the NSP with the share of about 22% of total cost. This again highlights the substantial costs involved in enhancing patient access to both new TB diagnostic modalities, including PLHIV and other TB key populations. Furthermore, the closer look at intervention level reveals engaging communities and civil society in TB control is one of the mainstays of the TB response going forward, as reflected in the 10% share of this intervention of the total NSP costs.

Table 9-3: Resources required by 10 interventions with highest costs (in US$ million)

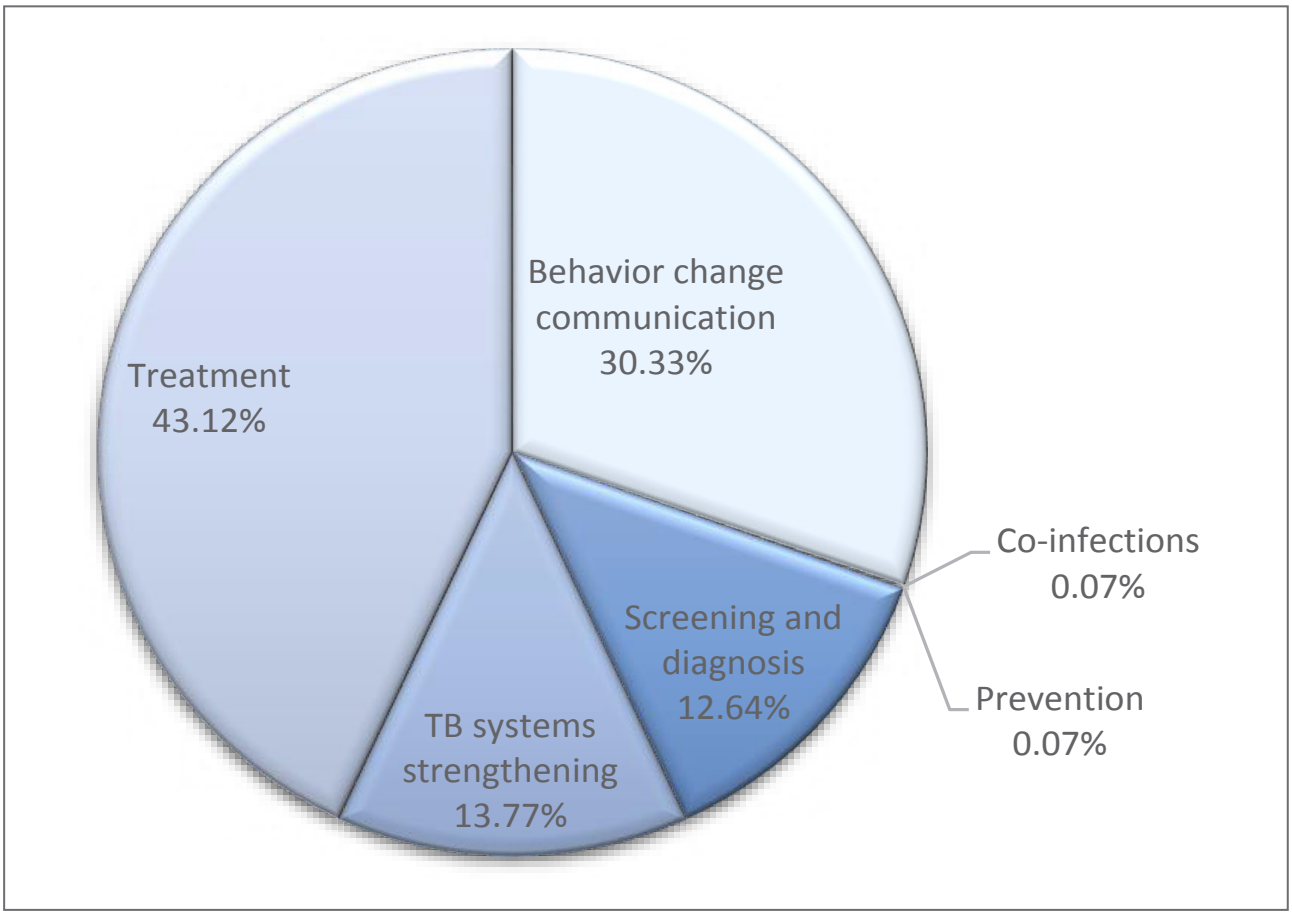
Pillar and intervention		Total	% of Total
Pillar 1	**Improved patient centered care**		
Result Area 1	**Early diagnosis and detection**		
Intervention 1	Improve access to TB diagnostics	38.42	22.18%
Result Area 2	**Treatment of all patients**		
Intervention 1	Treatment of DS-TB	10.36	6.15%
Intervention 2	Treatment of DR-TB	10.65	6.32%
Pillar 2	**TB comorbidities and key populations**		
Result Area 1	**TB / HIV**		
Intervention 1	Strengthen TB-HIV coordination and collaboration	6.41	3.81%
Intervention 3	Improve quality and coverage of case finding and diagnosis for TB and HIV among PLHIV and TB	8.46	5.02%
Result Area 2	**Key population**		
Intervention 1	Expand coverage of TB screening and diagnosis among TB key populations	13.51	8.02%
Pillar 3	**Bold policies and supportive systems**		
Result Area 2	**Engagement of communities, CSOs and all public and private care providers**		
Intervention 1	Improve Private-Public-Partnership	9.56	5.67%
Intervention 2	Engage communities and civil society in TB control	17.04	10.12%
Result Area 3	**UHC policies, regulatory frameworks and rational use of medicine infection control**		
Intervention 1	Improve infection control practices and health care waste management	11.87	7.05%
Result Area 4	**Social protection, poverty alleviation and actions and other determinants of TB**		
Intervention 8	Provision of nutrition support	7.47	4.44%

Financing of the TB and Leprosy NSP 2021-25

The annual MoHP Resource Mapping exercise provides the opportunity to compare the estimated costs of the TB and Leprosy NSP 2021-25 to the indicative funding envelope for the Malawian TB and Leprosy response as currently budgeted by the Government of Malawi, development partners, non governmental organizations, CHAM, and other stakeholders. Resource mapping data increases visibility on past and planned investments across districts, disease programs, interventions, activities and cost categories, thus providing a consolidated overview of the health sector budget at macro level.

The comparison of the TB and Leprosy NSP 2021-25 resource needs to Resource Mapping data aims to identify, quantify funding gaps in the TB and leprosy response, as well as to highlight inefficiencies in budgets that could be mitigated through improvements in aid coordination, and budgeting and planning processes of NTLP. The sixth round of Malawi's health sector Resource Mapping collected budget and expenditure data for the 5-year period ending December 2020. Data was collected and categorized both on a programmatic and a cost category and cost item basis. For the calendar year 2020, an amount of US$ 9.1 million was budgeted for TB by the Government of Malawi and partners. The Figure 9-1 shows the breakdown of funding for 2020 budgeted for TB from all funding sources by Resource Mapping programmatic function namely; prevention, screening and diagnosis, treatment, co-infections (including TB/HIV prevention and management), behavior change communication and TB systems strengthening. Almost three quarters (73.45%) of available funding are allocated for treatment and behavior change communication in 2020, followed by funding for TB systems strengthening (13.77%) and screening and diagnostic activities. Only 0.07% respectively are allocated to prevention and co-infections. For leprosy, US$ 289,500 were budgeted for 2020 by both the government of Malawi and development partners.

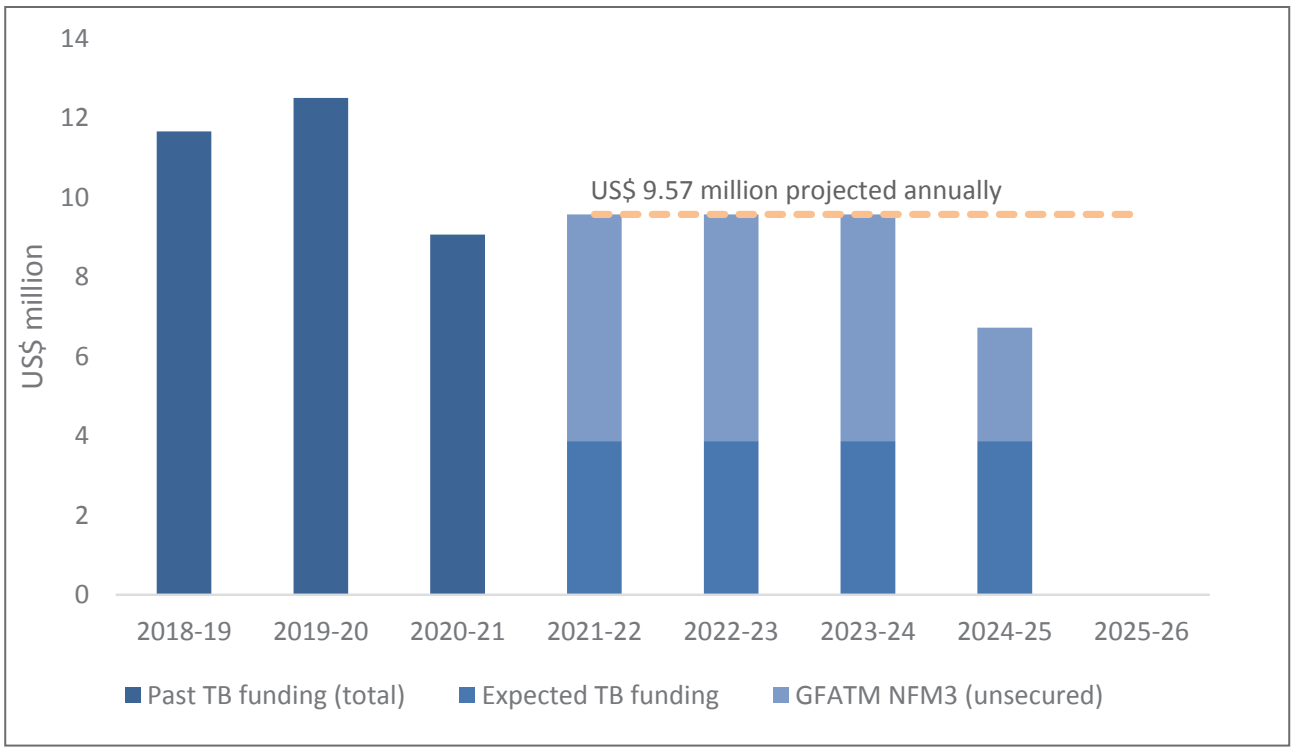
Figure 9-1: Funding for TB budgeted for 2020 by Resource Mapping programmatic function



Source: ***MoHP, Resource Mapping Round 6, 2020***

Due to limitations in data collection in Resource Mapping Round 6, budgets are currently only available up to December 2020 as mentioned above. To estimate the financial gap for the NSP, it was therefore necessary to make assumptions on the funding available for TB and leprosy through 2025. Based on historical budget data from government and major donors, there is no clear evidence suggesting that resources will increase or decrease over the period between 2021 and 2025. Therefore, it was conservatively assumed for the funding envelope for TB to remain constant at US$ 9.57 million per year over the coming 5 years, as illustrated in Figure 9-2. The same conservative assumption of funding to remain constant at the 2020 level (US$ 289,500) was made for leprosy.

Figure 9-2: Historical and projected TB funding in Malawi



To estimate the financial gap, it was first necessary to map each activity included in the NSP against the programmatic functions included in the Resource Mapping exercise. After aggregating the activity costs in the NSP by Resource Mapping Round 6 programmatic function, the subsequent financial gap against the total cost for TB activities of US$ 166.8 million (US$ 168.5 million minus US$ 1.67 million for leprosy activities) over the 5-year period is presented in Table 9-4. The total financial gap for the 5-year period 2021-25 amounts to approximately US$ 119 million. TB systems strengthening and screening and diagnosis exhibit the largest funding gaps over the NSP period of US$ 58.4 million and US$ 40.9 million, respectively, followed by treatment with a gap of US$ 9.1 million.

Table 9-4: Financial gap for TB against total resources projected over 2021-25 (in US$ million)

Resource mapping programmatic function	Resources needed 2021-25	Resources available 2021-25	Financial gap 2021-25
Behavior Change Communication	7.78	14.04	6.27
Beyond EHP	2.86	0.00	-2.86
Co-Infections	6.68	0.03	-6.65
Prevention	7.43	0.03	-7.39
Screening and Diagnosis	46.92	6.08	-40.85
TB Systems Strengthening	64.58	6.24	-58.35
Treatment	30.54	21.24	-9.12
Grand Total	**166.80**	**47.84**	**-118.95**

Against the total projected resource envelope of US$ 1.45 million between 2021-25, the financial gap for leprosy for the 5-year period totals US$ 225,200, with the annual financial gaps ranging between US$ 90,200 and US$ 18,800 (Table 9-5).

Table 9-5: Financial gap for leprosy against total resources projected over 2021-25 (in US$ thousand)

Leprosy	2021	2022-23	2023	2024-25	2025-26	Total 2021-25
Resources available 2021-25	289.5	289.5	289.5	289.5	289.5	**1,447.5**
Resources needed 2021-25	379.7	332	340.4	321.2	308.3	**1,672.7**
Total financial gap	**-90.2**	**-42.5**	**-50.9**	**-22.7**	**-18.8**	**-225.2**

Costing limitations

There are several limitations of the costing and the financial gap analysis of the TB and Leprosy NSP. The costing exercise aimed to strike a balance between operating cost efficiency and feasibility, with the integration of trainings, meetings, supervisions/ mentorships serving as an example. However, the cost savings that could thus be achieved are contingent upon the successful implementation of this program management structure. Furthermore, the financial gap analysis assumed a consistent distribution of resources across the different Resource Mapping programmatic functions based on the 2020 projections. While the total financial gap would remain unchanged, the respective financial gaps per programmatic function would change based on an altered resource distribution. In addition, the funding projections are based on budgets rather than actual expenditures, and the budget forecasts are thus characterized by a high level of uncertainty.

	Baseline (2018)	2021	2022	2023	2024	2025	Source
Key impact /outcome indicators							
TB Incidence	131	119	111	105	103	102	
TB mortality including HIV	30	30	28	24	21	18	
Case notification rate (new and relapse TB cases)	88	123	114	104	96	87	
Treatment coverage (Case detection rate)	67	70%	77%	80%	85%	90%	
Number new and relapse TB cases	15,858	24,319	23,192	21,770	20,764	19,520	
Case notification rate (bacteriological confirmed TB cases)	40	55	51	47	43	39	
Treatment success rate (New and Relapse TB cases)	86	89	89	90	92	92	
Drug resistant TB cases detected	126	232	236	235	224	210	
1. Improved patient centered care							
Result 1.1 early diagnosis and detection							
IR1.1 Improved access TB diagnostics							
Number TB microscopy centers	375	450	500	600	600	600	
Number of functional GeneXpert facilities including mobile diagnostic units)	79 (2019)	100	110	120	120	120	
Number of TB microscopy facilities that participate in the EQA during the period	275	450	500	600	600	600	
Percentage of laboratories showing adequate performance in external quality assurance for smear microscopy among the total number of	>90%	90	90	90	90	90	

laboratories that undertake smear microscopy during the reporting period							
Percentage of new and relapse TB patients tested using WHO recommended rapid tests at the time of diagnosis	NA	50	55	60	60	60	
Number of laboratories with 2 stars through SLPTA/SLAMTA	5	8	12	16	20	24	
IR1.1.2 Childhood TB							
Childhood TB diagnosis and treatment	1391	**2,432**	**2,551**	**2,395**	**2,492**	**2,733**	
Percentage Notified children among all notified cases	9	10	11	11	12	14	
Treatment success rate among children	88	89	90	90	90	92	
IR1.1.3. Facility based case finding							
% OPD clients screened for TB-(10+ years)	NA	45	50	55	60	65	
% Presumptive TB cases identified at OPD (10 +year)	1	3	4	4	4	4	
yield among presumptive TB cases in OPDs	5	5	6	7	7	7	
IR1.1.4 Improved DR TB detection							
Number of MDR TB treatment initiating sites providing treatment including new drugs	6	26	26	26	26	26	
Number of TB cases with Rifampicin-resistant (RR-TB) and/or MDR-TB notified	126	232	236	235	224	210	
Number of cases with RR-TB and/or MDR-TB that began second-line treatment	107	232	236	235	224	210	

Percentage of TB patients with DST result for at least Rifampicin among the total number of notified (new and retreatment/previously treated) cases in the same year	20	40	45	45	50	55	
Result 1.2 Treatment of all patients							
IR1.2.1 Treatment of DR TB							
Treatment success rate DR TB patients	58	63	65	70	75	80	
IR 1.2.2 treatment to DS TB							
Treatment success rate new relapse TB cases	86	89	89	90	92	92	
Treatment success rate among TB/ HIV coinfected patients	84	85	85	87	88	89	
Result 1.3 Latent TB treatment							
1.3.1 Strengthen contact investigation							
Percent HH contacts of Pulmonary TB cases who were screened for TB		65%	70%	75%	80%	80%	
Yield among screened of household contacts	0.40%	1%	1%	1%	1%	1%	
1.3.2 Improve coverage of TB preventive therapy among eligible groups							
TB preventive therapy coverage among children who are HH contacts of pulmonary TB	59%	65%	70%	75%	75%	75%	
TB preventive therapy coverage household contacts of pulmonary TB cases aged 5+ years (HIV -)	NA	50%	60%	70%	70%	70%	
Treatment completion rate for TB preventive therapy (under five children)	90%	90	90	90	90	90	

Result 1.4 Leprosy							
Number of leprosy cases Notified		650	650	700	700	700	
Proportion of new leprosy case with disability grade II	7%	5%	5%	4%	4%	3%	
Treatment completion rate for Leprosy		85%	87%	90%	90%	90%	
Number of Leprosy patient need rehabilitation service		70	70	70	70	70	
2. TB comorbidities and key populations							
Result 2.1 improve quality TB/HIV service							
Percentage of people living with HIV in care (including PMTCT) who are screened for TB in HIV care or treatment settings	98%	98%	98%	98%	98%	98%	
Percentage of people living with HIV newly enrolled in HIV care started on TB preventive therapy							
% newly registered TB patients who have HIV test result	99	99	99	99	99	99	
Percentage of HIV-positive new and relapse TB patients on ART during TB treatment	99	99	99	99	99	99	
Result 2.2 key populations							
% notified TB cases contributed by key / vulnerable population	10	15	15	15	15	15	
3.0 Bold Polices and supporting environment							
Result 3.2 Engagement of communities civil society organizations and all public and private care providers							
IR 3.2.1 Improve Private Public Partnership							
% Contributed by Private facilities (private for profit)	<1	5	5	5	5	7	TB unit register
% contribution by private facilities (CHAM)	18	20	22	22	25	25	

IR3.2.2. Engage communities and Civil societies in TB prevention and control							
% Contribution of Community referrals of all notified TB cases	13%	15	15	15	15	15	
Result 3.3 Universal health coverage policies and regulatory framework and rationale use of medicine and infection control							
IR 3.3.1 Improve supply chain management							
Percentage of reporting units reporting no stock-outs of anti-TB drugs on the last day of the last quarter of the year(Adult RHZE)		98	98	99	99	99	
IR 3.3.2 Improve infection control practice and health care waste management at all levels							
# health facilities with TB IC plan	180	220	250	300	350	400	
# health facilities with TB IC committees	212	220	250	300	350	400	
IR 3.3.3 Universal health coverage							
# TB registration sites	370	450	500	600	600	600	
Result 3.4 Social protection and social determinants of TB							
% TB patients who are targeted for Economic /nutritional support receive service	<20%	80	80	80	80	80	
Pillar 4. Program management Monitoring, evaluation Research and Innovation							
Result 4.1 Program management							
Updated guideline		2	2	2	2	2	
Result 4.2. Monitoring and evaluation							
% health facilities with 95% accuracy (concordance in selected indicators)	>90%	95	95	98	98	98	
# review meetings at national level		2	2	2	2	2	

Result 4.3 Operations research							
Number of OR conducted		10	10	10	10	10	
Result 4.4 improved coverage of Innovation							

Treatment coverage should be assessed based on prevailing incidence estimate of TB (WHO)

REFERENCES

Department of HIV AIDS . (2019). *Integrated HIV Program Report October-December 2018.*

Institute of Crime and Policy Research. (2019, December 05). *https://www.prisonstudies.org/country/malawi.*

MDHS. (2015-16). Malawi Demogrpahic Health Survey. MOH. (2017). Health Sector Strategic plan HSSP II.

National Statistical office. (2019). Malawi Population and Housing Sensus. National tuberculosis Control Program. (2019). 2018 NTLP Annual report.

National Tuberculosis Control Programme. (2013-2014). *National TB prevalence survey.* Lilongwe.

Oterro, L., Pimpin, L., & Fukunanga, R. (Oct 2019). *Tuberculosis National Epidemiological Review and DHIS2 Assessment.* Lilongwe.

STOP TB. (n.d.). Global Plan to End TB.

STOP TB Partnership. (Sept 2017). Data for action for TB among key population.

Stuckler D, S. S. (2013). Dying for gold: the effects of mineral mining on HIV, tuberculosis, silicosis, and occupational diseases in southern Africa. *Int J Health Serv, 43:639–49.*

The World Bank in Malawi. (2019, October). Country overview.

WHO. (2018). Latent tuberculosis infection; Updated and consolidated guidelines for programmatic management.

WHO, Global TB report. (2019). Global TB report.

World Health Organization. (2019). *REPORT OF THE JOINT REVIEW OF THE HIV, TB AND VIRAL HEPATITIS PROGRAMMES IN MALAWI.* Lilongwe.