



Report of the End-Term Review of the National Tuberculosis, Leprosy and Lung Health Strategic Plan, 2019-2023



24 March – 08 April 2022

TABLE OF CONTENTS

Contents

TABLE OF CONTENTS	2
ACKNOWLEDGEMENTS	4
ABBREVIATIONS & ACRONYMS	5
EXECUTIVE SUMMARY	8
1.BACKGROUND	11
1.1 Country Profile	11
1.1.1 Geography	11
1.1.2 Demography	11
1.1.3 Administration and Governance	11
1.2 Health Service Delivery	12
1.2.1 Health Profile	12
1.2.2 Health Structure	12
1.2.3 National Health Policy and Financing.....	12
1.3 National Tuberculosis, Leprosy and Lung Health Response and Control in Kenya.....	13
1.3.1 Coordination and Service Delivery for TB, Leprosy and Lung Health services.....	13
1.3.2 Epidemiology of Tuberculosis.....	13
1.3.3 Drivers of TB epidemic in Kenya.....	16
1.3.4 Epidemiology of leprosy in Kenya	16
1.3.5 Epidemiology of Lung Health in Kenya.....	17
2. END OF TERM REVIEW OF THE NATIONAL STRATEGIC PLAN FOR TUBERCULOSIS, LEPROSY AND LUNG HEALTH, 2019-2023	18
2.1 Rationale	18
2.2 Review Objectives.....	18
2.3 Methodology and Materials	18
2.3.1 Preparatory phase and process.....	18
2.3.2 Thematic areas of focus.....	19
2.3.3 Field activities	19
2.3.4 Thematic compilation of field findings.....	19
3. FINDINGS & RECOMMENDATIONS OF THE END TERM REVIEW OF THE NATIONAL STRATEGIC PLAN 2019-2023	20
3.1 PROGRAMME MANAGEMENT AND GOVERNANCE, INTER-PROGRAMME AND MULTISECTORAL ENGAGEMENT	20
3.1.1 . Governance and Program Management	20

3.1.2 Inter-Programme Coordination, Partnerships and Multisectoral Engagement.....	22
3.2 HEALTH FINANCING AND SOCIAL PROTECTION.....	25
3.2.1 Health Financing for the National Strategic Plan for TB, Leprosy and Lung Health ¹¹	25
3.2.2 Social Protection.....	26
3.3 PUBLIC PRIVATE MIX (PPM).....	27
3.4 TUBERCULOSIS DIAGNOSIS AND CASE FINDING IN KENYA.....	28
3.4.1 TB DIAGNOSTIC LABORATORY SERVICES AND NETWORK IN KENYA.....	28
3.4.2 SCREENING AND OTHER CASE FINDING STRATEGIES.....	33
3.5 TB PREVENTION, CARE AND TREATMENT.....	36
3.5.1 TB PREVENTIVE THERAPY AND INFECTION PREVENTION & CONTROL.....	36
3.5.2 TB CARE AND TREATMENT.....	39
3.5.3 PROGRAMMATIC MANAGEMENT OF DRUG RESISTANT TB (PMDT).....	41
3.5.4 CHILDHOOD & ADOLESCENT TB.....	43
3.6 TB IN VULNERABLE POPULATIONS AND CO-MORBIDITIES, INCLUDING HIV.....	48
3.6.1 TB and HIV.....	48
3.6.2 TB and DM collaboration.....	52
3.6.3 TB IN VULNERABLE POPULATIONS.....	50
3.6.4 NUTRITION.....	53
3.7 LEPROSY.....	54
3.8 LUNG HEALTH AND POST-TB CARE.....	55
3.9 SUPPLY CHAIN MANAGEMENT AND ADSM.....	56
4.0 EQUITY, ETHICS, HUMAN RIGHTS, GENDER & SOCIAL PROTECTION.....	59
5.0 COMMUNITY SYSTEM STRENGTHENING AND ACCE.....	61
6.0 MONITORING, EVALUATION, RESEARCH AND VITAL REGISTRATION SYSTEMS.....	63
7. ANNEXES.....	i
Annexe 1: Local reviewers team members.....	i
Annex 2: List of external review members.....	iii
Annex 3: List of Key Informant Interview Organizations.....	iv
Annex 4: List of counties and facilities visited during the review.....	v
Annex 5: Roadmap towards the End of term review of the NSP 2019-2023.....	vii
Annex 6: Agenda of the End of Term program review for Kenya, 2022.....	viii
.....	viii
8. References.....	ix

ACKNOWLEDGEMENTS

The review team would like to thank the Ministry of Health for entrusting them to participate and provide the technical expertise in this important national exercise. The team appreciates the leadership and support provided by the Office of the Chief Administrative Secretary of Health, the Director General of Health, Department of Preventive and Promotive Health, Directorate of Strategic Health Programs and the Division of the National Tuberculosis, Leprosy and Lung Disease Program. Special recognition goes to the national steering taskforce and the secretariat that played a fundamental role to successfully steer the planning and coordination of the review exercise.

The review team would also like to appreciate the inputs and insights from senior managers, representatives and respective respondents from various state departments within the Ministry of Health, Ministry of Education, Ministry of Labor, Social Security and Services, The National Treasury, Ministry of Interior and Coordination, and other sectors. The team would also like to recognize the county governments for their support and role in providing insightful information on implementation of the strategic interventions at the service delivery level.

Finally, the review team would like to thank the World Health Organization (WHO) for coordinating the identification of technical experts from different organizations and institutions across the globe. In particular, the team acknowledges the support from the office of the WHO Country Representative and the country office staff; and the contribution by technical experts from the United States Agency for International Development (USAID), STOP TB Partnership, Global Fund to fight AIDS, Tuberculosis and Malaria (GF-ATM), US Centers for Disease Control and Prevention (CDC), Bill and Melinda Gates Foundation (BMGF), the Foundation for New Innovative Diagnostics (FIND), KNCV, International Organization for Migration (IOM) and UNICEF.

ABBREVIATIONS & ACRONYMS

ACCE	Advocacy communication and community engagement
ACF	Active case finding
ADR	Adverse drug reactions
ADSM	Active TB drug-safety monitoring and management
AI	Artificial intelligence
AIDS	Acquired immune deficiency syndrome
ART	Antiretroviral therapy
CAD	Computer aided design
CASCOS	County AIDS & STI coordinators
CBO	Community based organizations
CCC	Comprehensive care clinic
CDC	US Centres for Disease Control and Prevention
CHA	Community health assistants
CHMT	County health management team
CHV	Community health volunteers
CLHIV	Children living with HIV
CO	Clinical officers
COE	Committee of experts
COPD	Chronic obstructive pulmonary disease
CQI	Continuous quality improvement
CSO	Civil society organization
CSR	Corporate social responsibility
CSS	Community system strengthening
CTLC	County TB & leprosy coordinator
CXR	Chest X-Ray
DFID	UK Department for International Development
DHIS	District health information system
DM	Diabetes mellitus
DNTLD	Division of National Tuberculosis, Leprosy and Lung Disease Program
DOT	Directly observed therapy
DR TB	Drug resistant TB
DST	Drug susceptibility testing
DS TB	Drug sensitive TB
EMR	Electronic medical record
EPTB	Extrapulmonary tuberculosis
ETR	End term review
FAO	Food and Agriculture Agency
FBO	Faith based organization
FDC	Fixed dose combination
FEFO	First expiry first out
FLD	First line drugs
GAM	Global AIDS monitoring
GDP	Gross domestic product
GF	Global fund
GOK	Government of Kenya
HCW	Healthcare worker

HIS/HMIS	Health information system / Health management information system
HIV	Human Immunodeficiency Virus
HR	Human resources
HRG	Human rights & gender
ICC	Interagency coordinating committee
IEC	Information education & communication
IMCI	Integrated Management of Childhood Illnesses
INH	Isoniazid
IOM	International Organization for Migration
IPC	Infection prevention & control
IPT	Isoniazid preventive therapy
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya medical supplies authority
KENPHIA	Kenya Population-based HIV Impact Assessment
KES	Kenya shillings
KHIS	Kenya health information system
KII	Key informant interview
LF-LAM	Lateral flow urine lipoarabinomannan assay
LIMS/LMIS	Laboratory management information system
LPA	Line probe assay
LTFU	Lost to follow up
MB	Multibacillary
MDR	Multidrug resistant
MDT	Multidisciplinary team
ME	Monitoring and evaluation
MGIT	Mycobacteria growth indicator tube
MOH	Ministry of Health
MOI	Ministry of Interior
mWRD	Molecular WHO-recommended diagnostics
NASCOP	National AIDS & STI control program
NHIF	National Health Insurance Fund
NPHL	National public health laboratory
NSP	National Strategic Plan
DNTLD-P	National TB, Leprosy and Lung Disease Program
NTRL	National TB reference laboratory
OJT	On job training
PEF	Peak expiratory flow
PLWHIV	People Living With HIV
PMDT	Programmatic Management of DR TB
PPB	Pharmacy and Poisons Board
PPM	Public Private Mix
PSM	Procurement and supply chain management
PTB	Pulmonary TB
PV	Pharmacovigilance
RH	Rifampicin and Isoniazid
RR	Rifampicin Resistant
SDG	Sustainable development goals
SCTLC	Sub-County TB & Leprosy Coordinator

SLD	Second line drug susceptibility testing
TIBU	Treatment Information from Basic Program
TWG	Technical Working Group
UHC	Universal Health Coverage
UNAIDS	United Nations Program on HIV/AIDS
WHO	World Health Organization
XDR	Extensively Drug Resistant TB

EXECUTIVE SUMMARY

The National Strategic Plan (NSP) for Tuberculosis, Leprosy and Lung Diseases 2019 – 2023 represented an evolution in the Government of Kenya (GOK)'s response to these scourges. It reflected a patient-centred approach to planning and evidence-based prioritization of resource allocation to close the gaps along the patient pathway to quality care. The activities included in the NSP addressed systemic and root causes of the gaps along the patient pathway, with complementary roles of county and central governments, departments across the Ministry of Health, partners and other sectors. The NSP 2019-2023 presented the full aspiration of the country, including outcome and impact targets that aligned with international goals, and the full portfolio of activities needed to reach these goals.

An end of term review (ETR) of the NSP was conducted between 24 March and 08 April 2022, led by the WHO in conjunction with MOH-DNTLD-P, county governments and other key partners and stakeholders. The review objectives were to assess progress made towards reaching the NSP's goals and targets including delivery of strategic interventions, as well as to document achievements, bottlenecks, lessons learned and make recommendations to sustain the gains made. The ETR was preceded by an epidemiological review, which assessed country's surveillance system against WHO standards and benchmarks for TB surveillance systems. It evaluated the extent to which the TB surveillance system in Kenya measures the TB disease burden and mortality and looked at the trends to ascertain the TB epidemiological profile and the interventions to address TB disease. The country's surveillance system aligns with the recommended WHO case definitions and uses two electronic systems called TIBU (case-based) and Kenya Health Information System 2 (KHIS-2). Vital registration coverage for community and health facility mortality data was at 40%, with plans to adoption of the ICD11 which has Artificial Intelligence in determining the causes of death. Kenya fully met six benchmarks, four were partially met and had challenges in meeting three.

Kenya remains among the list of countries with the highest of TB and TB/HIV burden countries globally¹. There has however been a progressive decline in TB incidence since 2006 the highest documented with 243,000 TB patients to 139,000 in 2020². According to the WHO Global TB Report 2021, Kenya is among the nine high TB burden countries that reached the End TB Strategy milestone for 2020 with a 32% reduction in TB incidence compared to 2015, against a target of 20%. Further, the country also achieved a 44% reduction in the number of TB deaths compared to 2015, against a target of 35%³. Furthermore, during the lifespan of the current NSP, Kenya has transitioned out of the global list of 30 countries with the highest burden of MDR/TB. Despite these significant achievements, the country's treatment coverage gap remains wide at nearly 50% of unreached people with the estimated TB treatment coverage declining from a peak of 63% in 2018 to 52% in 2020 according to the WHO Global Report 2021².

Notably, there has been a gradual decline in TB notifications between 2018 and 2020. There was a 10% decline between 2018 and 2019, and a further decline of 15% between 2019 and 2020. Adversely, the decline observed in 2020 was due to the COVID-19 pandemic and the accompanying public health measures. In 2021 there was 6.7% increase notifications compared to 2020. Further, the Kenya population-based HIV impact assessment (KENPHIA) survey conducted in 2018, estimated the burden of HIV among adults in Kenya to be 4.9% and 0.7% among children translating to approximately 1.3 million living with HIV in Kenya, with the prevalence noted to be twice as high among women at 6.6%, compared to men at 3.1%. Only 51% of people estimated to have HIV-positive TB were notified in 2020, pointing to the need to improve case detection. Coverage of HIV testing for notified TB cases and initiation of ART among HIV-positive TB patients were 99% and 97% respectively in 2021. High death rates during TB treatment were reported among people living with HIV (PLWHIV) averaging 11% nationally, compared with 4% among people without HIV.

Kenya is in the global post-elimination phase for leprosy, having attained the WHO elimination target of less than 1 case per 10,000 people in 1989. Despite this status, new leprosy cases continue being reported in the recent years, mostly from known endemic counties which account for more than 60% of the total cases notified in the country. Notably, asthma, chronic obstructive pulmonary disease (COPD) and lung cancer are among lung health conditions of public health concern. Although there is limited data on the burden of lung health in Kenya in general, the country relies on global estimates as well as local studies and research. According to existing literature, the reported prevalence of asthma

ranged from 3% to 28.6%, with this variation reflecting the highest estimate found amongst the subset of patients with allergic conditions in clinical settings⁴.

Kenya has a well-structured National Tuberculosis, Leprosy and Lung Disease Program (DNTLD-P), whose staff establishment is largely government funded. The DNTLD-P has staff for key technical areas at national level and is complemented by development and technical partners. At county level, the County TB and Leprosy Coordinators (CTLC's) oversee TB and leprosy activities. However, there is limited attention to leprosy and lung diseases sub-programs at all levels. The program has experienced frequent leadership changes and rapid staff turnover during the NSP period which have negatively affected stewardship of the program. The program has good collaboration with implementing partners and with some of the key departments in the Ministry of Health (MOH). However, there is inadequate systematic engagement with some relevant MOH departments, including the National Public Health Laboratories (NPHL), the division housing the National TB Reference Laboratory (NTRL). There is also need for improved collaboration with key sectors outside of MOH. The scope of stakeholders involved in strategic planning and policy dialogue should be broadened to also include stakeholders (both government and non-government) involved in socio-behavioral aspects of the TB response. The private sector engagement and performance against the NSP goals was largely sub-optimal, although there are significant efforts to implement its PPM Action Plan 2021-2023. Government funding for TB largely goes to procurement, with minimal allocation for other key programmatic activities. Lung health and leprosy are particularly affected by the shortage of dedicated resources. There is a perception especially at the county level that the TB program is a donor-funded activity and thus does not require county-level domestic financing. Although the TB program provides a special insurance cover for MDR TB patients, there is need for stronger advocacy for the inclusion of TB, leprosy and lung health in the Universal Health Coverage (UHC) health benefit package and National Health Insurance Fund (NHIF). There are also national social protection programs that offer safety nets for vulnerable populations, but there is need to ensure explicit inclusion of eligible TB patients in existing social protection schemes.

The NSP prioritized approaches to improve TB case finding through facility-based screening, strengthening the laboratory network, strengthening public-private collaboration and community-based interventions and outreaches. At the time of the ETR, a total of 236,329 TB notifications had been reported against a target of 597,000 for the period 2019-2023. Detection of TB in children aged less than 15 years remains low with a treatment coverage of 45% in 2021, accounted for 9.6% of all DS-TB patients notified during the same period and 2-4% of DR TB between 2019 and 2021. The country has two main public TB reference laboratories, NTRL in Nairobi, and KEMRI-Kisian in Western region, with additional regional first and second line -probe assay (LPA) laboratories in Malindi, Kitale and Machakos. The diagnostic network comprises of 226 gene xpert machines and 3,159 smear microscopy sites. There are 285 documented private laboratories in Kenya including 37 that have GeneXpert machines, five LPA and two culture and DST services. This network serves approximately 10,000 public and private health facilities. In addition, the country introduced 38 Truenat molecular assays, four interferon release gamma assays (IGRA) and urine lateral-flow lipoarabinomannan (LF-LAM). At the time of the review, there had been prolonged disruption of testing services due to frequent, erratic supply of GeneXpert cartridges, which resulted in use microscopy. While the correct high-risk groups were being prioritized for culture and DST, second-line DST coverage among MDR RR TB patients was low at 47%. The proportion of people with presumptive TB tested for TB increased from 40% to 51% against a target of 80%, those with a genexpert test at diagnosis stood at 41% against a target of 90%. The treatment success rate for new and relapse patients for the 2019 cohort was 86%, 74% for people with RR/MDR TB for the 2018 cohort².

The review also documented the early adoption of WHO recommended treatment regimens for TB preventive therapy (TPT) with rifapentine based regimen including the expansion of eligible populations beyond under-five contacts and PLWHIV. High coverage was noted among PLHIV in care in counties that were well served with commodities and where training and sensitization of all relevant staff were completed. Similarly, the oral longer-term treatment regimens and newer medicines had been introduced successfully. However, the WHO-recommended shorter all oral regimens for MDR TB and 4-months regimen for drug susceptible strains had not been introduced. Child-friendly formulations for first line drugs were in use, while second-line medicines were reported to have been recently procured. Universal nutritional assessment for among most TB patients was implemented, with high levels of malnutrition noted to be prevalent in both children and adults

with TB and leprosy. Wide-spread long standing stock-out of nutritional support and therapeutic feeds was reported. There were laudable efforts to integration TB case finding, diagnosis, treatment and prevention within prison services, however, these were yet to be extended to vulnerable populations as envisioned in the NSP. Capacity building and targeted interventions on equity, human rights and gender, media and educational campaigns, and an active national network of people affected by TB and CSOs are in place. However, there is need to cost and fund community rights and gender activities in the plans at both national and county levels and include relevant indicators and targets in the M&E framework. The review noted significant efforts to strengthen community system and interventions towards TB response and control. Nonetheless, the proportion of people with TB referred to health facilities by CHVs and informal service providers marginally rose from 10% to 12%. This is possibly due to under-reporting, with limited documentation of community contributions as there were no data on the proportion of people with symptoms of TB from the community that seek appropriate care from health facilities. There is need for better coordination and resourcing of community TB activities, and to streamline and synergize community TB activities with other community health activities within the broader MOH.

The DNTLD-P has robust and real-time case-based TB surveillance system at the national and sub-national levels, that collates information from paper-based patient records and patient register at the facilities. In addition, a newer module, T-BU Lite, an android-based app version of TIBU designed for use by frontline HCWs and community health workers, as a point of care platform is currently being piloted in 13 counties, with plans for scale up. The review also established limited capacity for data utilization for decision making at the sub-national level, with operational research not fully optimized as envisioned in the NSP.

1.BACKGROUND

1.1 Country Profile

1.1.1 Geography

Kenya, one of the countries in Eastern Africa bordered by Ethiopia to the North, Somalia to the North East, Tanzania to the South, Uganda to the West, the Indian Ocean to the East and South Sudan to the North West. It has a total area of approximately 582,646 square kilometers (225,000 square miles) and is divided into 47 administrative counties.

Kenya's climate is primarily tropical, with a diverse range of weather patterns because of its location on the equator. Temperatures vary depending on location; generally, they are warm at low- to mid-altitude and very hot at high altitudes. Arid and Semi-Arid Lands (ASALs) spread across 29 counties, located primarily in the northern, eastern, and southern parts of the country. The central and western highlands are characterized by temperate and forested hilly climate and are the most productive agriculturally and, consequently, most densely populated areas. The urban population accounts for 27% of the total population, with an urbanization rate of 4.23%.



Figure 1: Map of Kenya and the neighboring countries
Source: Government of Kenya

1.1.2 Demography

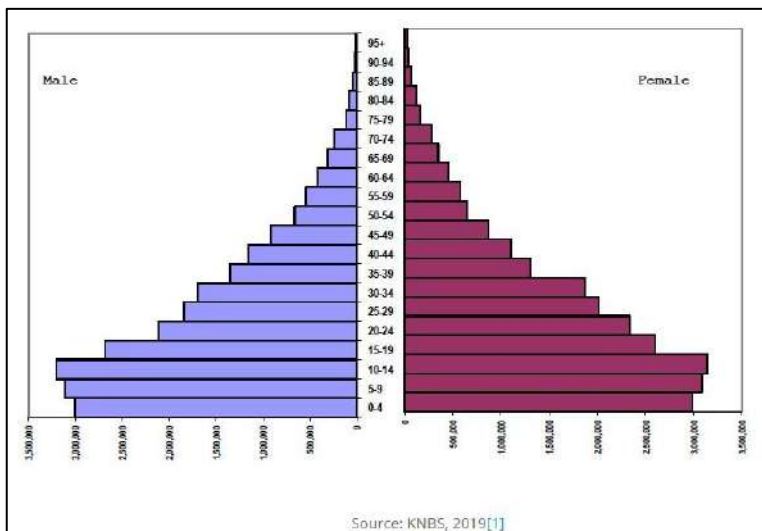


Figure 2: Population pyramid of Kenya in 2019
Source: Kenya National Bureau of statistics, Census Report 2019

According to the 2019 National Population and Housing Census, Kenya's population was estimated at 49.6 million people, translating to an average national population density of 82 persons per square kilometer. It is projected that the population will increase to approximately 52 million by 2023 at an annual growth rate of 2.2%. with a projected annual growth rate of 2.2%. The population's median age is 20 years (male: 19.9 years and female: 20.2 years). People aged between 0-14 years account for 39.03% of the population, 15-24 years for 19.61%, 25-54 years for 34.27%, 55-64 years for 4%, and 65 years and over for 3.08%, as shown in figure 2 below. In 2018, the birth rate was 22.6 births/1,000, a death rate of 6.7 deaths/1,000, and a life expectancy of 64.6 years.

1.1.3 Administration and Governance

Kenya is a presidential democratic republic in which elected officials represent the people and the president as the head of state and government. The government consists of ministries headed by Cabinet Secretaries and run by Principal Secretaries. Kenya promulgated a new constitution in 2010, which administratively divided the country into two arms of governments: The National Government and 47 County

Governments as shown on fig. 1. The county governments are further divided into 300 sub-counties and further into wards. Under devolution, the national government retained policy development and regulatory functions to monitor and evaluate its implementation and provision of technical assistance to the counties. The functions transferred to county governments include direct service delivery and management of human resources. The appointed and elected county governments manage local government functions and jurisdictions.

1.2 Health Service Delivery

1.2.1 Health Profile

Considerable gains have been made in overall health in the recent past. Kenya has observed a steady decline in the under-five mortality rate from ~100 per 1000 live births in 2000 to 42 per 1000 in 2020. The infant mortality rate has declined from 60 per 1000 live births in 2000 to 31 per 1000 in 2020¹, while maternal mortality declined from 488 in 2013 to 362 per 100,000 live births during the same period². Human Immunodeficiency Virus (HIV), lower respiratory tract infections (LRTIs), and diarrhea are the top three documented causes that accounted for 95% of premature mortality in Kenya between 2012 and 2017.

1.2.2 Health Structure

Kenya adopted a new constitution in 2010, with a devolved system of governance under which delivery of health services is assigned to county governments while the national government is responsible for development of national policies, legislations, capacity building for counties and management of national referral health facilities. Health services are delivered through a six-tiered organizational structure that develops from Community health Units to National Referral Hospitals in all 47 administrative counties.

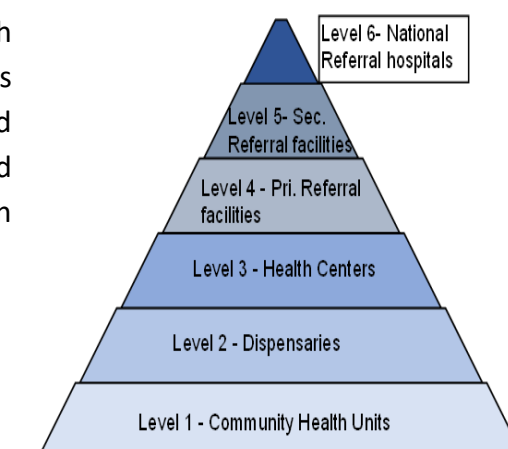


Figure 3: Levels of service delivery in Kenya

1.2.3 National Health Policy and Financing

The Kenya's Health Policy 2014-2030 and the Kenya Health Sector Strategic Plan 2018-2023 have been developed and anchored in line with the WHO health system building blocks, the Constitution of Kenya 2010 and Kenya Vision 2030, the country's economic blueprint, which seeks to improve Kenyans' livelihoods by providing an efficient and high-quality health care system with the best standard of care. Consistent with the SDG commitments, Kenya launched universal health coverage (UHC) in 2020, with an overall goal of ensuring access to preventive, promotive, and curative health services, with a deliberate shift in focus from curative to preventive health care. This is the context in which disease specific strategic orientations, such as ending the TB epidemic by 2030, are derived.

The government of Kenya has been allocating about 7% of its national budget towards healthcare services. The total government health expenditure increased from KES 104.5 billion (USD 1.2 billion) in 2014/15 to KES 230.4 billion (USD 2.3 billion) in 2018/2019. In 2018/2019, the Directorate of Preventive and Promotive Health was allocated 4.5% of the total national health budget, KES 5 billion (USD 50.5 million), with 16% of this apportioned TB. The national government disburses funds to all 47 counties through the Division of Revenue Bill (DORB) in the form of equitable share, conditional grants, and grants from development partners. The counties then develop their annual budgets and appropriations bills using the laid down procedures and planning cycles. It is from the annual budgets that counties finance the health sector. County governments also generate own-source revenue (OSR) as stipulated by Article 209(3) of the Constitution of Kenya (2010).

1.3 National Tuberculosis, Leprosy and Lung Health Response and Control in Kenya

1.3.1 Coordination and Service Delivery for TB, Leprosy and Lung Health services

The Division of National Tuberculosis, Leprosy and Lung Disease Program (DNTLD-P) is domiciled in the Directorate of Preventive and Promotive Programs in the Ministry of Health. It is mandated to provide technical leadership and develop national policies and standards in response, monitoring and evaluation as well as overall coordination of TB, leprosy and lung disease interventions and activities. There are two levels of organizational and coordination structures: the national level, headed by the DNTLD-P Manager, and the county level, led by county TB and leprosy coordinators (CTLCs) in all 47 counties. At the national level, technical coordinators oversee different technical areas. These include: care and treatment, active case finding, laboratory services, TB/HIV, nutrition, infection prevention and control, public-private mix (PPM), community system strengthening, ACCE, childhood and adolescent TB, programmatic management of drug resistant TB (PMDT), commodity supply chain management, aDSM & pharmacovigilance, monitoring and evaluation and research, social protection, policy and planning and finance.

At the sub-national level, the County and Sub-County TB and Leprosy coordinators (CTLCs and SCTLCS) are responsible for overseeing and coordinating TB, leprosy and lung health services at county and sub-county levels respectively. Technical and implementing partners, community-based organizations (CBOs), faith-based organizations (FBOs), civil society organizations (CSOs), and patient groups support TB activities at both the national and sub-national levels.

1.3.2 Epidemiology of Tuberculosis

According to the WHO global list for high burden countries for TB, HIV associated TB and drug resistant TB (DR TB) 2021-2025 published in 2021, Kenya remains among the 30 high burden countries for TB and HIV associated TB as shown in figure 4 below. These are countries that together contribute approximately 90% of the estimated global TB burden. Kenya was transitioned out of the list of 30 countries with the highest burden of DR TB, however it remains a public health threat and thus, is a priority area of focus for the country.

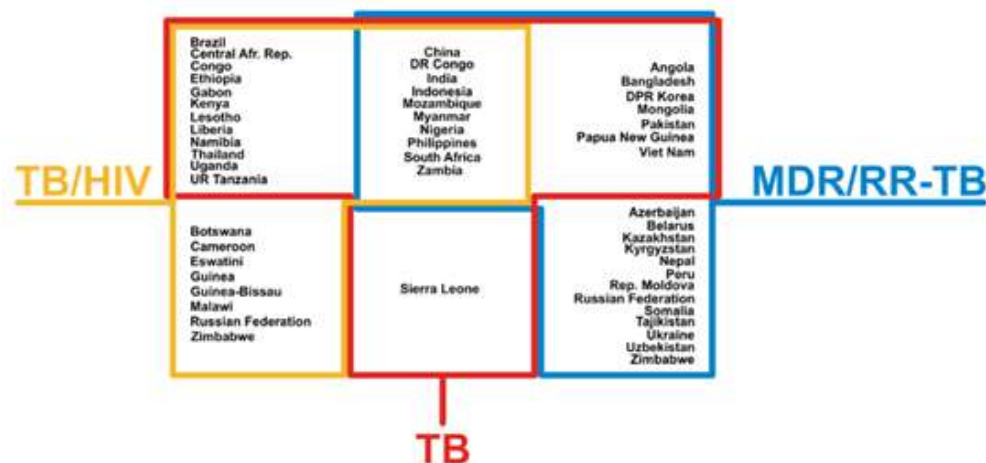


Figure 4: WHO Global list of high burden countries for TB, HIV associated TB and Drug Resistant TB
Source: WHO, 2021

1.3.2.1 TB Incidence and treatment coverage

Over the past years, there was an observed increase in TB incidence of 144,000 TB patients in 2000, with the highest number of 243,000 TB patients recorded in 2006, following which there was an observed decline, to 139,000 in 2020 as shown in *figure 5* below ². According to the WHO Global TB Report, 2021 Kenya was one of the high TB burden countries that achieved WHO's End TB Strategy milestone for 2020 with a

32% reduction in TB incidence compared to 2015, against a target of 20%. Further, the country also achieved a 44% reduction in the number of TB deaths compared to 2015, against a target of 35%³.

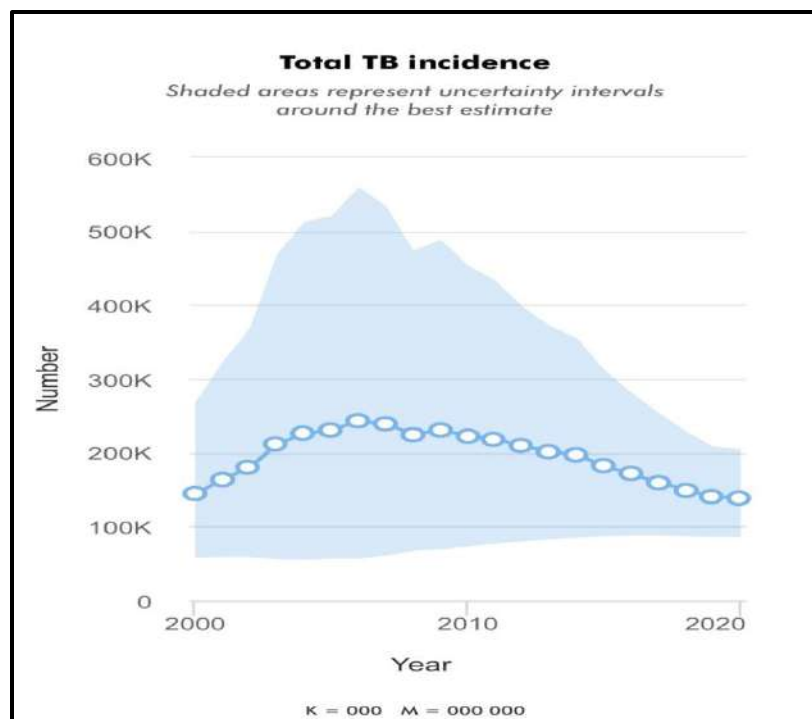


Figure 5 Incidence of TB cases between 2000 and 2020
Source: WHO Global report, 2021

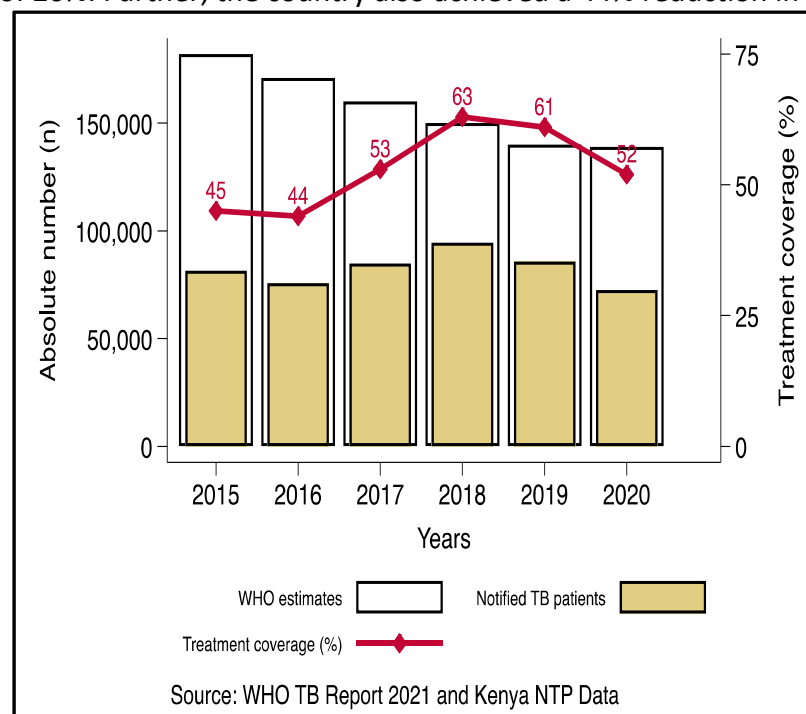


Figure 6 Treatment coverage 2015 -2020

Despite these significant achievements, the country's treatment coverage gap remains wide at nearly 50% of unreachable people with TB in 2020. Notably, there has been a downward trend with the estimated TB treatment coverage declining from a peak of 63% in 2018 to 52% in 2020 according to the WHO Global Report 2021, and as shown in *Figure 6* above. Similarly, TB notifications show a declining trend from 94,550 in 2018 to 72,663 in 2020 (*Figure 7*). *Figure 8* shows proportional change in notifications by year between 2015 and 2021. The increase in 2021 could reflect a recovery of TB services following disruption brought about by the COVID pandemic. The number of children with TB notified in the country is also seen to declining, from 10.1% in 2018 to 7.8% in 2020 as shown in *figure 9* below.

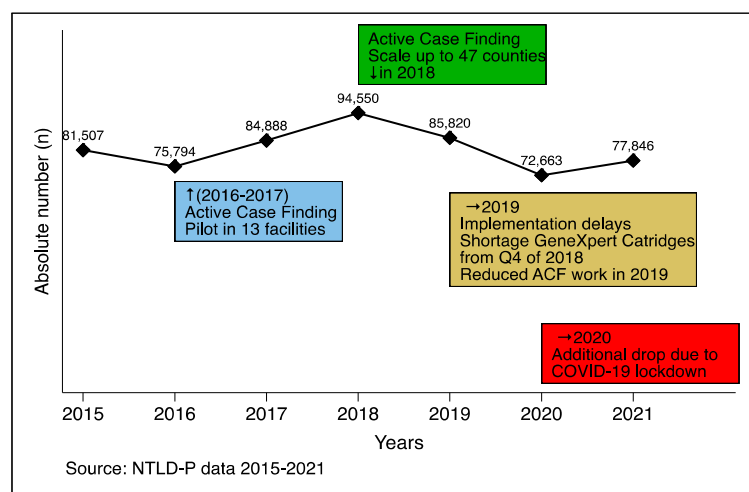


Figure 7: Case notification trend for TB between 2015 and 2021

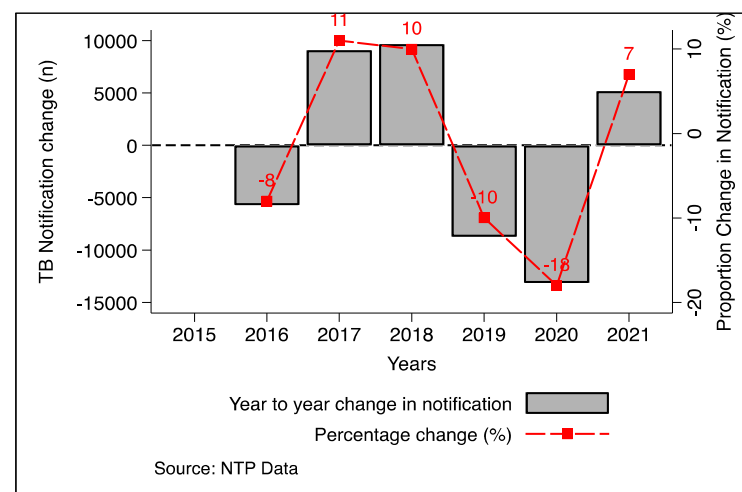


Figure 8: Percentage change in TB notification between 2015 and 2021



Figure 9: Trend of TB patients notified between 2009 and 2020

Source: Data from DNTLD-P, MoH

Drug resistant TB remains a significant public health scourge in Kenya as demonstrated by the increase in the number of DR TB patients notified over the years as shown in Figure 8 below.

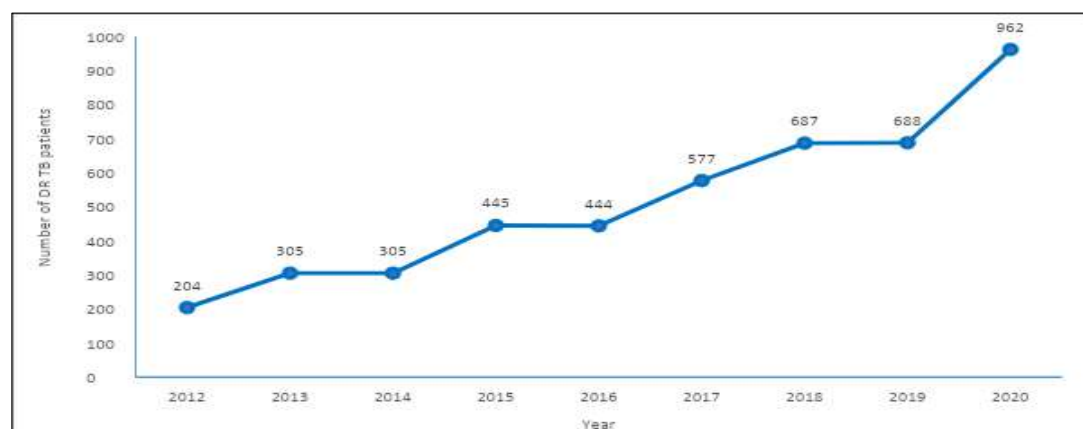


Figure 10: Trend of DR TB patients notified in Kenya between 2012 and 2020

Source: Data from DNTLD-P, MoH

In 2018, the first national TB patient cost survey estimated that up to 27% of households affected by TB incurred catastrophic costs, and when considering drug resistant TB, 86% of patients and their families incurred catastrophic costs while seeking TB care. Another finding of note was that 45% of people with drug-susceptible TB and 54% of people with drug-resistant TB diagnosed in 2020 were undernourished at the time of diagnosis.

The 2021 Report on Epidemiological review of TB provides additional details on the TB landscape in Kenya.

1.3.3 Drivers of TB epidemic in Kenya

Undernutrition, HIV, alcohol use disorders, smoking and diabetes mellitus are the key drivers and social determinants of tuberculosis in Kenya, according to WHO Global Report 2020 ³. Kenya is listed among the top 30 high burden TB/HIV countries globally, with WHO estimating that approximately 35,000 people falling ill with TB and HIV and, 12,000 people succumbing to the co-infection in 2020 ³. Further, the Kenya population-based HIV impact assessment (KENPHIA) survey conducted in 2018, estimated the burden of HIV among adults in Kenya to be 4.9% and 0.7% among children. This translates to approximately 1.3 million living with HIV in Kenya, with the prevalence noted to be twice as high among women at 6.6%, compared to men at 3.1%. The global HIV 90-90-90 target: i.e 90% of PLWHIV know their status, 90% of PLWHIV who know their status are initiated on life-saving HAART and, 90% of people on HIV treatment are virally suppressed; is documented to be 79.4%, 95.7% and 88.4% respectively in Kenya ⁵. The [Food and Agriculture Agency](#) (FAO) estimates that 24.8% of Kenyans were undernourished in 2018, with the prevalence of those experiencing moderate or severe food insecurity estimated to be 68.5% in 2020. Similarly, the number of children with wasting and stunting was estimated to be at 4.2% and 19.4% respectively in 2020 ⁶. In addition, according to the latest related WHO reports, 11% of the Kenyan population are [heavy episodic alcohol consumers](#) ⁷ and [11% smoke tobacco](#) ⁸. The International Diabetes Federation projected the number of people with DM will increase from 190,000 in 2000, to 821,500 in 2021, and further to 1,965,000 in 2045. The current burden is estimated to be 460 diabetics per 10,000 population, with 4% of Kenyans between 20-79 diagnosed with DM while two-thirds of whom are unaware of their condition, a concern given that diabetes is a key risk factor for TB ⁹. In addition, the COVID-19 pandemic will likely have an additional impact on the social determinants such as poverty, undernutrition, alcohol consumption and housing, and the current conflict in Ukraine will also have a negative impact on food security, further compounding the TB situation.

1.3.4 Epidemiology of leprosy in Kenya

Kenya is in the post-elimination phase for leprosy, having achieved the WHO elimination target of less than 1 case per 10,000 people in 1989. Despite this status, there has been an increasing trend of new leprosy cases being detected and reported in the recent years, mostly from known leprosy endemic counties. Notably, leprosy is being reported among both children and adults, with children accounting for 6% of all the new cases. The leprosy endemic in the Coast, Western and parts of Nyanza regions account for more than 60% of the total cases notified in the country, although sporadic cases have also been reported in non-endemic counties. Multi-bacillary leprosy, the infectious and severe form of the disease, accounts for 90% of the cases reported in Kenya. In 2020, more than half of the 89 notified leprosy patients had some level of disability at diagnosis, with 29% of these having disability grade one, and 22% with disability grade two, suggesting late diagnosis, leading to an increase in transmission, as well as disease severity. Out of the 164 cases reported in 2019, 53% were released from treatment, 10% were declared to be lost to follow-up, 2% died, 4% transferred out, and 31% were yet to complete treatment.

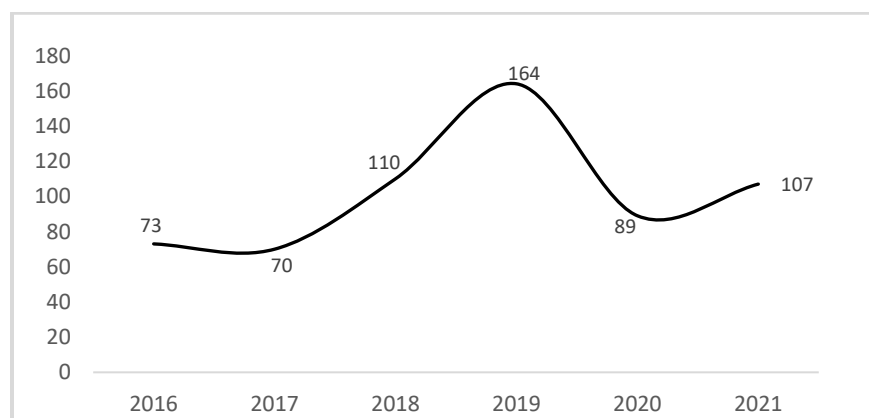


Figure 11: Trend of Leprosy Cases notified in Kenya between 2016 and 2020

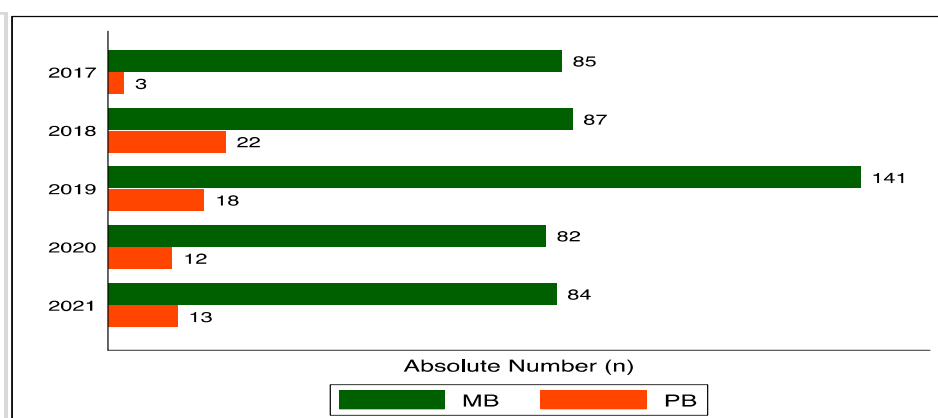


Figure 12: Types of leprosy

1.3.5 Epidemiology of Lung Health in Kenya

In Kenya, asthma, chronic obstructive pulmonary disease (COPD) and lung cancer are among lung health conditions of public health concern. Although there is limited data on the burden of lung health in Kenya in general, the country relies on global estimates as well as local studies and research. According to existing literature, the reported prevalence of asthma ranged from 3% to 28.6%, with this variation reflecting the highest estimate found amongst the subset of patients with allergic conditions in clinical settings⁴. Similarly, existing data found cancer to be the third leading cause of death after infectious and cardiovascular diseases. In 2020, the new cases of cancer were estimated at 42,116, with an estimate of 27,092 deaths. Lung cancer is ranked 14th among the cancers with an incidence of 794 new cases, and 12th in mortality with 729 deaths, translating to a high fatality rate of 92% ¹⁰.

2. END OF TERM REVIEW OF THE NATIONAL STRATEGIC PLAN FOR TUBERCULOSIS, LEPROSY AND LUNG HEALTH, 2019-2023

2.1 Rationale

The country planned to evaluate the implementation of interventions and strategies in the National Strategic Plan for Tuberculosis, Leprosy and Lung Health 2019-2023 (here henceforth referred to as the NSP). The aim was to take stock of program outcomes, document achievements, lessons learnt and bottlenecks towards the attainment of the overall goal in addressing TB epidemic. Implementation of the NSP took place amidst a global COVID-19 pandemic which threatened to reverse the progress towards ending TB in Kenya. The review recommendations are expected to inform the successor NSP.

2.2 Review Objectives

Two overall objectives were specified:

1. To assess progress made towards reaching the NSP's goals and targets, including delivery of strategic interventions and access to quality TB care services.
2. To document achievements, bottlenecks, lessons learned and recommendations to sustain the gains made

Specific objectives included:

- 1) To assess progress made towards the implementation of strategies and initiatives geared towards finding the missing people with TB
- 2) To assess diagnostic services coverage and networking for both first and second-line DST as well as quality assurance
- 3) To evaluate the responsiveness of the people-centered approach in finding the missing people with TB and provision of quality care along the care cascade in Kenya
- 4) To assess the supply chain management system for TB and leprosy commodities in Kenya
- 5) To assess mechanisms of multi-sectoral engagement with stakeholders and sectors in tuberculosis control
- 6) To determine the responsiveness of service delivery models and human rights and gender coverage for populations at risk of TB

2.3 Methodology and Materials

The review of the NSP had three main components:

- desk review of relevant literature on health and TB, and an epidemiological review of TB, leprosy and lung disease;
- field visits and key informant interviews; and
- consolidation and dissemination of review findings

2.3.1 Preparatory phase and process

The preparation for the review involved the following processes:

- Establishment of an in-country task force comprised of DNTLD-P officers and other key stakeholders, supported by a secretariat, who provided logistical planning for the review process
- Development of the concept note and a detailed road map
- Definition of the review objectives, thematic areas, review approach and dates
- Collation of relevant national policies, strategic and operational guidelines and documents
- Identification of local and external technical reviewers, with WHO leading the identification of external reviewers
- Epidemiological review of TB and leprosy, including assessment of the performance of the program's surveillance system against global standards and benchmarks for TB
- Development, review, and digitization of data collection tools
- Identification and mapping of key informants and respondents from: various departments across relevant ministries and sectors, county governments, state and non-state agencies, regulatory bodies, partners, civil society organizations, among others

- Purposive sampling of facilities and review sites for field visits

2.3.2 Thematic areas of focus

- Program management, coordination and governance
- Health financing (universal health coverage (UHC))
- Partnerships and multi-sectoral engagement
- TB case finding strategies: including active case finding (ACF) and other strategic initiatives
- TB laboratory network and services
- TB treatment and care
- TB in vulnerable populations and co-morbidities, including TB&HIV
- Childhood and adolescent TB
- Programmatic management of drug resistant TB
- Commodities and supply chain management, including active drug safety monitoring (aDSM)
- Community systems and programming for TB
- Advocacy, communication, and social mobilization
- TB prevention and infection prevention
- Monitoring and evaluation, strategic information, and research
- Public-private mix
- Leprosy
- Lung health
- Human rights and gender, nutrition, and social protection

2.3.3 Field activities

The review took place between 24th March and 8th April 2022 and adopted a hybrid (remote and in-person participation) approach to allow for participation of technical experts who were not able to travel due to the COVID-19 pandemic. At national level, the review targeted policy and decision makers at MOH and other ministries representing other sectors relevant to TB control, including ministries responsible for education, transport, social protection, devolution and immigration services. The National Parliamentary Caucus on TB was also engaged. Additionally, technical partners and stakeholders, including civil society and professional bodies were also interviewed.

At implementation level, purposive sampling was used to identify twelve counties that would represent varying disease patterns and burden; Within each county, all county referral hospitals, sub-county hospitals, and where available, at least one faith-based health facility, a private facility (including private laboratory and/or chemist) and a prison facility were selected. In addition, in special circumstances, a county/facility was selected to meet specific objectives of identified thematic areas.

Field teams comprising external reviewers and local technical experts from DNTLD-P and technical/implementing partners (12-15 people per team) conducted field visits, interviews, and focused group discussions with the County Health Management Teams (CHMT), county and sub-county TB and leprosy coordinators (CTLCS and SCTLCS), health workers, community health Volunteers (CHVs), TB champions and patients.

2.3.4 Thematic compilation of field findings

Field findings were shared with the overall review team in a one-day debrief meeting, which also served as a dissemination/feedback forum for county and facility representatives. Subsequently, the review team synthesized the information and built consensus across the thematic areas which was used to debrief the WHO country representative, senior MOH officials, and other stakeholders.

3. FINDINGS & RECOMMENDATIONS OF THE END TERM REVIEW OF THE NATIONAL STRATEGIC PLAN 2019-2023

3.1 PROGRAMME MANAGEMENT AND GOVERNANCE, INTER-PROGRAMME AND MULTISECTORAL ENGAGEMENT

The NSP under review had significant focus on strengthening program management capacity as well as engagement of other programs and sectors. Some of the key interventions to foster engagement include those targeting selected key populations (for planning, implementation, monitoring and evaluation of TB services), workplace initiatives (workplace TB services and employment protection policies), Ministry of Labour and Social Protection (labour protection laws and TB workplace policies), multisectoral engagement (political commitment), county governments (county strategic planning and establishment of multisectoral fora), other government departments (access to agricultural subsidies, housing allocation and other social benefits), human rights and gender institutions, and across sectors and with other ministries for food security (Agriculture and Social Protection, National Treasury, Ministry of Labour and Social Protection, Ministry of Devolution, Ministry of Agriculture, Livestock, Fisheries and Irrigation, NHIF, WFP, DFID, USAID, World Bank, WHO, UNICEF).

3.1.1 . Governance and Program Management

3.1.1.1 The Division of National Tuberculosis, Leprosy and Lung Disease Programme (DNTLD-P)

The Division of National Tuberculosis, Leprosy and Lung Disease Programme (DNTLD-P) falls under Strategic Public Health Programmes in the Directorate of Preventive and Promotive Health within the MOH. It is headed by a programme manager who is assigned by the Ministry’s Principal Secretary. This position is not by appointment, and it is at the discretion of the Principal Secretary to re-assign individuals to this position at any time. There is a well-structured and established national TB programme. The organogram of the DNTLD-P (generated based on discussions with the DNTLD-P programme manager and staff) is presented in Figure 8 below.

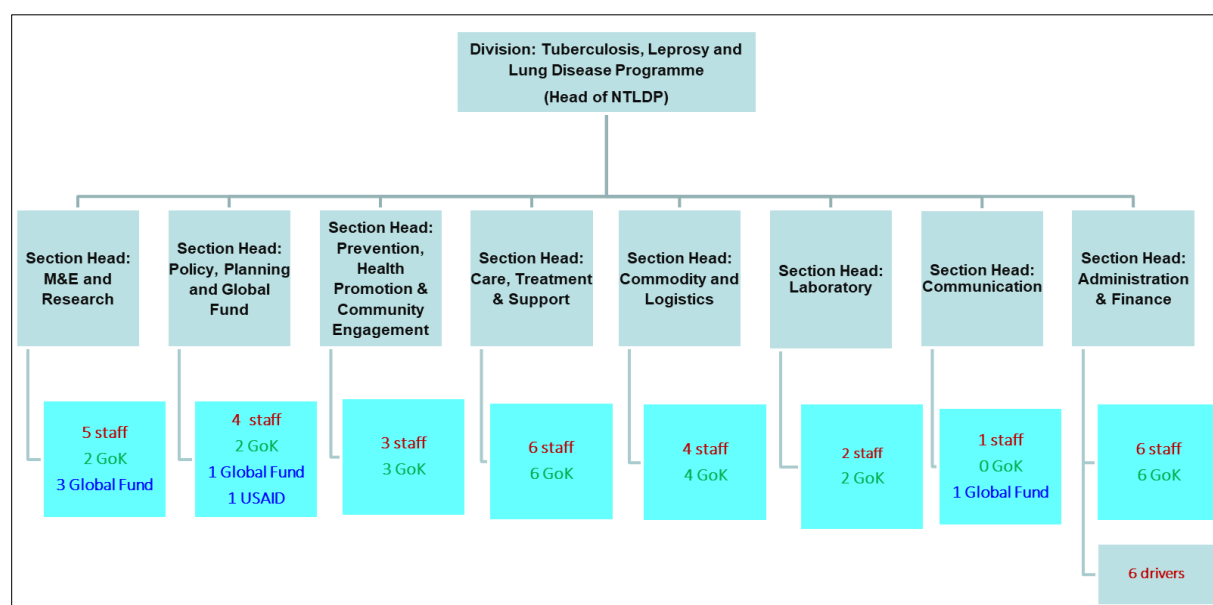


Figure 12 DNTLD-P organogram and staffing generated from key informants

The reviewers were not able to obtain a formal staff establishment or a documented organogram for the DNTLD-P, and the current structure has no provision for a deputy/assistant manager. Job descriptions for the program manager, section heads and most of the staff were not available for review. Only GF-supported positions had job descriptions available for review. The section heads are appointed by the Program Manager. The current program manager has been in the role since February 2022, with the previous program managers having served for the following periods: March 2021 - February 2022 (12 months), June 2019 - February 2021(21 months), and July 2017 - June 2019 (24

months). At the time of review, there was an envisaged restructuring of the Strategic Health Programs. At county level, the County Tuberculosis, Leprosy and Lung Disease Coordinators (CTLC) coordinate the programs activities.

3.1.1.2 National TB Reference Laboratory (NTRL)

The National TB Reference Laboratory (NTRL) is under the Division of National Public Health Laboratories (NPHL) within MOH-Department of Laboratory Services. The laboratory is a member of International Laboratory Accreditation Commission (ILAC) and is ISO 15189/2012 accredited. Its mandate includes oversight of national TB diagnostic network(s), conducting periodic and routine surveillance for TB and TB drug resistance, coordination of TB sample referral, testing and feedback, technical leadership in development or/and review of TB laboratory diagnostic guidelines and training materials. In addition, it oversees quality assurance, specialized testing for TB, technology verification or/and validation of new TB testing technologies, serve as a gatekeeper for product listing, registration and licensing, specimen repository/archiving of biological materials generated during testing, and conducting epidemiological and operational research.

At the time of the review, the country was in the process of updating the NPHLS plan, although there was limited engagement of the DNTLD-P in this process. Except during surveys, there is no structured platform for coordination between the NTRL and the DNTLD-P, with no systematic approach to coordinate the national TB diagnostic network. The Global Fund (GF) is the primary funding source for NTRL diagnostic services combined with support from other donors. At the time of the review, Global Fund support for NTRL staff was expected to end in June 2022 and there was a process underway to transition NTRL staff from Global Fund to GOK.

3.1.1.3 Key findings, progress and achievements

- There is a well-structured and established national TB programme which has maintained continuity despite significant leadership changes during the strategic plan period, and despite the challenges presented by the COVID-19 pandemic.
- There is good technical capacity to address the different TB programme areas at national level. There are also clear TB programme structures at county and sub-county levels, and good communication between TB programme staff at national and county levels.
- The national strategic plan is used as an important reference document by all partners and stakeholders.
- There are specific initiatives to address the needs of selected TB vulnerable populations (cross-border patients, refugees, and migrants), in partnership with some local organisations (e.g., UNHCR, Kenya Red Cross Society)
- There is good partnership and engagement with the private sector for TB services.

3.1.1.4 Main challenges and areas for improvement

- There have been frequent leadership changes affecting the programme during the strategic plan period, with rapid staff turnover resulting in inadequate programme stewardship, delays/ stalling in activity implementation and loss of institutional capacity.
- There is a significant funding gap for implementing the NSP, with reliance on Global Fund support for staffing for some key programme functions, including the laboratory network. Anecdotally, the funding gap for TB has increased due to COVID-19. Laboratory services, lung disease and leprosy interventions are particularly affected by the funding constraints.
- There are uncertainties regarding the implications of the envisaged restructuring exercises on the placement of the TB programme in the Ministry of Health, and how this will affect the structures and functionality of the DNTLD-P.
- A formalized DNTLD-P organogram was not available, with position descriptions for most key positions also not immediately available.
- There is inadequate coordination, collaboration, and joint planning with other relevant programmes in the Ministry of Health.
- While leprosy and lung health are prominent in the strategic plan, there is limited attention to these sub-programmes, due to lack of funding and inadequate institutional capacity.
- There is inadequate stewardship and suboptimal coordination between the DNTLD-P and the Division of National Public Health Laboratories within MOH Department of Laboratory Services, with no structured platform for ongoing engagement to optimise the functionality of the national TB diagnostic network.

3.1.1.5 Key Recommendations

- Senior MOH management should facilitate greater stability in programme leadership (within the context of the Public Service rules) to enable a more coherent and consistent approach to programme management, strengthen programme ownership and facilitate establishment and maintenance of linkages and networks with other sectors and programmes for multisectoral engagement and inter-programme collaboration.
- Kenya remains one of the high TB burden countries, and MOH restructuring processes should be carefully considered to further strengthen the programme at national and sub-national levels and avoid negating the good progress that Kenya has made towards ending TB.
- Update/Formalize and communicate DNTLD-P's organogram, with clear terms of reference for the respective programme positions.
- Strengthen collaboration with other programmes and sectors particularly for social protection, NCDs, substance use disorders, and vulnerable populations.
- Strengthen the lung health and leprosy sub-programmes through advocacy for resource mobilisation, collaboration with other programmes and partners, including the private sector and clear job descriptions and roles for DNTLD-P staff for these sub-programmes.
- MOH leadership should accelerate the transition of key NTRL staff from donor funding to GOK funding to avoid disruption of services.
- Senior MOH leadership should create a structured platform for engagement and coordination between the DNTLD-P and the NPHL, with clarification of the roles and responsibilities and joint planning and ongoing guidance from MOH leadership. This platform could also be used to harmonize strategic and operational planning and resourcing of the TB diagnostic network.

3.1.2 Inter-Programme Coordination, Partnerships and Multisectoral Engagement

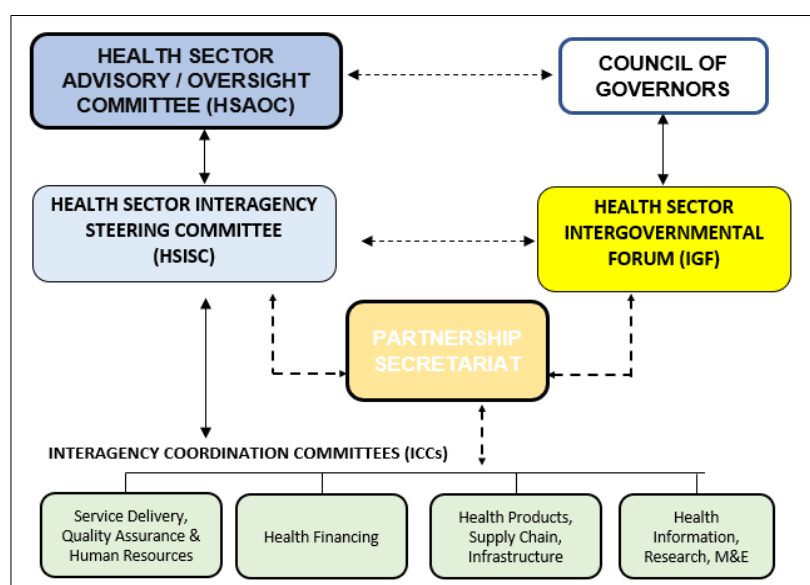


Figure 13: Kenya Health Sector Partnership Structure 2019

Source: Ministry of Health

The Kenya Health Sector Partnership Structures (2019) guide the coordination of health services with partners and across sectors in Kenya. The TB, Leprosy and Lung Health Technical Working Group (formerly ICC, and also referred to as the TB Health Sector Working committee) is one of the TWGs of the Service Delivery, Quality Assurance & Human Resources ICC and meets quarterly. The working group is chaired by the Head of Department of Strategic National Public Health Programs (and co-chaired by the Head of the DNTLD-P). Membership includes MOH, National Treasury, county governments, Council of Governors, technical partners, local and international NGOs, human rights groups, NASCOP, faith-based institutions, professional bodies, research teaching and referral institutions, and pharmaceutical sector. Key responsibilities include coordination of implementation, technical assistance and support for priority actions; joint monitoring, review and reporting and holding all partners jointly accountable for achieving results.

Additional coordinating platforms in place or under development include:

- Kenya Coordinating Mechanism (KCM) for Global Fund
- National multisectoral accountability framework for TB (MAF-TB)
- Coordination with the counties that is handled by the Council of Governors

DNTLD-P develops a joint annual workplan, a process which includes DNTLD-P, the Ministry of Education, NASCOP, MNCH, and other key development and implementing partners. The workplan is then shared with all stakeholders and implemented collaboratively. Review of participation in the most recent joint workplan development forum showed limited representation from other MoH departments and non-health sectors. Good collaboration on TB/HIV and increasing collaboration on TB/Diabetes policy work and capacity building was noted. There is a supportive private sector, willing to scale up new innovations and approaches to complement the MOH.

All programmes in the Ministry of Health are required to have costed strategic plans. The current NSP for TB, leprosy and lung disease covers the period January 2019 - December 2023. Other related NSPs are the Health Sector Strategic Plan (HSSP) (July 2018 – June 2023), the Kenya AIDS Strategic Framework (2020/21- 2024/25) and the Kenya Malaria Strategy (2019-2023). Despite the non-alignment of the periods covered by the TB and health sector strategic plans, there were efforts to align some of the indicators in the TB M&E plan with the indicators in the HSSP. Multi-sectoral engagement at national level, there have been efforts to introduce workplace policies and initiatives for TB in some of the government sectors (e.g., Ministry of Labour, Ministry of Interior). There is also an engaged TB parliamentary caucus in place, with a very good understanding of the country's TB situation and an interest to elevate TB advocacy to the highest offices in government.

3.1.2.1 Key findings, progress and achievements

- There is very good TB programme coordination between national and county, subcounty and facility levels, and TB services are largely aligned to the national policies.
- There is a Technical Working Group for TB, leprosy and lung health in place chaired by the Head of Department of Strategic National Public Health Programmes, with a clear description of the responsibilities.
- There are various Committees of Experts (COEs) to facilitate technical level engagement with relevant programmes and partners and other MoH departments.
- There is good coordination and collaboration on TB/HIV and increasing collaboration on TB/diabetes policy work and capacity building.
- There is a willing and supportive private sector, which can complement the MOH in the provision of TB and lung health services, including introduction and scale-up of new innovations and approaches.
- There have been efforts to introduce workplace policies and initiatives for TB in some of the government sectors
- At the county level, there is some collaboration with key stakeholders including prisons, non-government organisations (NGO), faith-based organisations (FBOs), private hospitals, retail pharmacies, communities, and civil society representatives in the provision and notification of TB services.
- There is an engaged TB parliamentary caucus in place, with a very good understanding of the country's TB situation and an interest to elevate advocacy on TB issues to the highest offices in government.
- The programme has initiated the development of a national multisectoral accountability framework for TB

3.1.2.2 Main challenges and areas for improvement

- There is a varied level of engagement of different stakeholders, particularly those outside the mainstream TB technical partners at national and county level. Some key government sectors and stakeholders were not engaged in the development and implementation of the current NSP, and there are no focal persons in key government offices.
- Other key government offices and relevant UN agencies are not represented in the TB TWG, and there is inconsistent participation from MoH senior management in the TWG meetings. There is also limited and inconsistent participation of other relevant MOH offices and departments in the COEs.
- There is limited awareness among key stakeholders of the existence of multisectoral collaboration platforms for health issues outside the Ministry of Health (except for HIV/AIDS and COVID-19). The TB response is perceived to be too focused on biomedical interventions at the expense of socio-behavioural aspects of the response.
- There is suboptimal strategic leadership and technical coordination across relevant MOH programmes and government ministries and external stakeholders, for inter-programme and intersectoral collaboration and coordination at all levels. Joint planning and implementation of activities with other key programmes (e.g., mental health, substance use disorders, nutrition, etc) is limited.
- There are perceptions among stakeholders that some of the partner resources are not well aligned with key government priorities particularly at county level, with a need for strengthened and transparent joint planning with different partners and to leverage flexible financing and support.
- At county level, there is inadequate multisectoral engagement, with limited engagement of key ministries and sectors, including those outlined in the strategic plan.
- There is no clear assignment of responsibility and accountability for actions to address TB and its determinants, particularly beyond the health sector.

3.1.2.3 Key Recommendations

- Organize inclusive policy dialogue with key partners and stakeholders at national and county levels as part of the development of the next strategic plan. The process should include provision for orientation of ‘new’ stakeholders and should allow adequate time for the participating stakeholders to consult with their respective constituencies.
- Formalize the TB TWG membership and terms of reference, with official nomination of members by the respective organizations. The TWG should preferably continue to be chaired by levels above the TB programme to help foster accountability and leadership for the TB response, as well as for the MOH hierarchy to provide the necessary direction and stewardship. Similar TWG’s should also be considered at county level.
- Optimize private sector engagement, including the corporate sector through value proposition (instead of CSR), involvement in planning, and customized communication channels for private sector engagement. The private sector could also support with validation and registration of new diagnostics.
- As part of the NSP development process and leveraging the parliamentary TB caucus, conduct inclusive comprehensive stakeholder mapping and engagement, to inform the finalization of the Multisectoral Accountability Framework for TB aligned to the next NSP.
- Strengthen intersectoral collaboration for lung health, including addressing tobacco smoking and air pollution, among others.

3.2 HEALTH FINANCING AND SOCIAL PROTECTION

Kenya has overarching legal and policy provisions geared towards supporting the financing of the health sector. These are: Kenya Vision 2030, Kenya Health Policy 2014-2030, The Constitution of Kenya, 2010, Kenya Health Financing Strategy 2020–2030, Kenya Universal Coverage Policy 2020 -2030, Kenya National Hospital Insurance Fund (NHIF) Act, Health Act, 2017 and Harmonized Health Benefit Package, 2021. The 2017 Health Act provides legislation to establish a unified health system, to coordinate the interrelationship between the national government and county government health systems, to provide for regulation of healthcare services and service providers, health products and health technologies and for connected purposes. Development partners including DFID, PEPFAR AND NON PEPFAR USG, WHO and others play a critical role in providing complementary resources for health.

The resources mobilised for health in Kenya are managed by different institutional units (financing agents), who make decisions about where the funds will be allocated. The main agents are: government units (national MOH, county health departments, and government non-health departments), households, non-profit making organizations, the National Hospital Insurance Fund (NHIF), private commercial corporations and health facilities (select community based health insurance schemes).

3.2.1 Health Financing for the National Strategic Plan for TB, Leprosy and Lung Health¹¹

The NSP for TB, leprosy and lung disease was costed using an input-based costing (IBC) approach and estimated to require KES 29.8 billion for implementation. A 50% shortfall was anticipated and was to be filled progressively through resource mobilization strategies.

3.2.1.1 Key findings, progress and achievements

Domestic resource mobilization: Presently, the government allocates KES 260 million to the Ministry of Health for procurement of first line anti TB medicines. An additional KES 480 million as counterpart financing for procurement, as part of fulfilment of co-financing commitments for Global Fund grant terms. Notably, there is minimal allocation of resources by the government for programmatic activities. At the county level, there is a perception that the TB program is a donor-funded activity and thus does not require county-level domestic financing. There is a perception at the county level that the TB program is a donor-funded activity and thus does not require county-level domestic financing. There has been some advocacy efforts by CSOs and the Stop TB Partnership-Kenya, to ensure more county-level government funding for programmatic activities as well as preventive and promotive aspects of the TB response.

UHC health benefit package and NHIF: Kenya has a UHC benefits package in place, however TB, leprosy and lung health care services were not part of it. The main reasons given for the non-inclusion of the conditions in the UHC benefits package was that the services are already provided free of charge by government and partners. Notably, some TB patients may benefit from the UHC package if they meet other eligibility criteria such as being indigent, vulnerable or orphaned. The TB program, through Global Fund grant resources and NHIF mechanism, extends a special insurance cover for MDR TB patients. However, it is likely that many of these patients would be eligible for the UHC benefits based on other criteria. There is also there is no clear policy on how TB services should be purchased under national health insurance (e.g., capitation, fee-for-service, etc) to maximize TB outcomes. All children under five years of age are eligible to access health care at no cost.

Contracting: Important elements of the TB response that are donor supported, namely, active case finding and private health service providers' engagement are currently being implemented at least in part by non-state organizations i.e FBOs and NGOs through contractual agreements. There is very limited capacity at the DNTLD-P to take over the contracting of such organizations, even if the necessary domestic financing was in place. Although the donor financing and contracting will remain for considerable time, it will also take many years to establish the necessary contract management skills within the MoH and DNTLD-P. Thus, the country should initiate gradual establishment of such contract management capacity within government, covering the entire procurement cycle.

3.2.2 Social Protection

The country has social protection programmes that offer safety nets for vulnerable populations, including the elderly, orphans, and people with disabilities. The social protection programmes are led by the Ministry of Labour and Social Protection, which guides the development of related policies. People with TB are captured under different safety nets if they meet other criteria. Some of the mechanisms that bring social protection to vulnerable populations and are likely to include people with TB include the universal health coverage (UHC), social assistance (conditional cash transfer for indigent/ poor households) and social insurance as part of NHIF, whose national coverage is still very low (17%).

3.2.2.1 Main challenges and areas for improvement

- The DNTLD-P has a significant funding gap and is largely remains donor funded, with the government funding 38% of the budget for TB services
- While a significant number of strategic plan interventions are implemented by FBO's and NGOs, there is insufficient capacity to use government funds to contract non-government TB implementers.
- TB, leprosy, and lung diseases are not included in the UHC benefit package, and there is no clear policy on how TB services should be purchased under national health insurance (e.g., capitation, fee-for-service, etc) in order to maximize TB outcomes
- At around 20%, national insurance coverage is low, with low coverage (17%) of NHIF benefits. A plan is in place to increase this to UHC under the NHIF Act, with GOK covering premiums for the poor¹².
- At the time of the review, it was not clear whether TB and leprosy patients qualify or fulfil the vulnerability criteria in the National Social Protection Policy for them to access social support. People with TB are captured under different safety nets if they meet other criteria.

3.2.2.2 Key Recommendations

- Advocate for increased domestic funding and continued donor funding for TB to build on the progress that the country has made towards ending TB and considering the impact of the COVID-19 pandemic on TB services. As part of this advocacy, the DNTLD-P should be represented and actively participate in intersectoral coordination committees for health financing at national and county levels.
- Build capacity for DNTLD-P staff and CTLCs on government and county budgeting and planning processes to ensure adequate reflection of TB, leprosy, and lung health services in county implementation plans. In addition, include civil society.
- Develop a strategy to transition from donor support to domestic financing systems, with definition of the expected roles of national and county-level funding for TB, leprosy, and lung health services (including human resource for health, programmatic activities such as training and programme monitoring).
- Advocate for inclusion of TB, leprosy, and lung health services as part of UHC benefit package covered under NHIF. Possible reasons to be considered for prioritizing inclusion of TB in the benefit package include:
 - Providing a pathway for gradual absorption of at least the clinical costs of TB services into an important domestic funding stream;
 - Improving access to services and the reach of the programme to both public and, notably, private providers who are contracted under NHIF (though note that private provider accreditation to NHIF has previously been a barrier);
 - Improving the visibility of TB as a core service that remains a national health priority. If the inclusion of TB in the benefit package may result in too great of an impact on the beneficiaries' premiums, an alternative funding source could be a fiscal transfer from Treasury (or MOH) to NHIF.
- Initiate discussions on the purchasing approach(es) under NHIF that would best support improved TB outcomes in the country.
- Initiate the process to establish capacity for contracting of TB services to non-government entities, using government funding.
- Conduct/update comprehensive costing of TB services, including prevention, to inform the design the next UHC benefit package.
- Pursue the explicit inclusion of TB patients in existing social protection schemes.

3.3 PUBLIC PRIVATE MIX (PPM)

Public Private Mix (PPM) is included under pillar two of the NSP (2019-2023); Bold Policies and Supportive Systems. The NSP sought to address priority gaps that include:

- Suboptimal engagement of private sector care providers (less than half of the counties are actively engaging in PPM activities, and within these counties not all private providers have been reached);
- Limited engagement of corporate and workplaces that provide health services through wellness clinics;
- Inadequate capacity to diagnose and manage TB patient in private sector and low case notification from the private sector including underreporting of bacteriologically confirmed cases.

The goal of the NSP (2019-2023) for PPM was to increase participation of the private sector through strategic interventions that strengthen coordination and stewardship, scale up innovative PPM models of care and strengthen engagement that will lead to increased notification of TB and quality of care. They included: Implementation of the multi-sectoral engagement framework, engagement of the corporate sector, including workplace TB services, Improving the quality of diagnosis and management of TB in the private sector, Improving case notification from the private sector and reduced out-of-pocket health expenditure due to TB.

3.3.1 Performance against the NSP targets

Table 1 Performance indicators for public private mix against the NSP targets

Outcome Indicator	Baseline	Target (2023)	Achievement (2021)
Proportion of private sector providers engaged to provide comprehensive TB services	12% (2017)	30%	25.3%
Contributions of the private sector in TB case finding	18% (2018)	25%	20.1%
Number of counties engaging the informal health sector providers in TB care and prevention	7 (2017)	47	23
Proportion of the engaged private sector providers recording and reporting TB cases through an e-system	No data	100%	12%
Ensure treatment success of at least 90% of all DS TB patients managed by private providers	N/A	≥ 90%	85.6%
Ensure treatment success of at least 80% of MDR TB patients managed by private providers	N/A	≥ 80%	74.7%
Reduce deaths among HIV-infected TB patients managed by private providers to 5% or lower	N/A	≤ 5%	11%

3.3.1.2 Key findings, progress and achievements

- NTLP has a well-established PPM unit at the central level that is led by a PPM coordinator and supported by a COE that oversee, coordinate and provides guidance towards implementation of PPM activities in Kenya.
- The current PPM Action Plan (2021-2023) incorporates a revised approach of the pediatric model, that integrates in all paediatric services in the subsequent models, a laboratory model has been re-named the diagnostic model and now includes the imaging centers/clinics, the corporate model has been re-named the workplace model, to include all the workplaces (both formal and informal ranging from large corporates to small scale workplaces) and Chemists and Pharmacists and Informal Service Providers.
- Inclusion of some private facilities in capacity building (training, mentorship, CMEs), data review meetings, and support supervisions and inclusion in the technical assistance missions
- Support to private facilities with TB medicines, GeneXpert machines, commodities, supplies, and R&R tools

- Private providers utilize the sub-county sample referral network (riders) and treatment network with public facilities.
- All visited private facilities are reporting to the National level.
- Proportion of bacteriologically confirmed PTB in the private sector has remained constant between 45-48% vs 49-59% National average.
- Private sector partners (i.e., AMREF, RESOK, Centre for Health Solutions, KCCB-Komesha TB, TALAKU, PS Kenya, MALTESER, TB ARC II) and professional bodies are part of the County TB planning processes.
- Standard R&R tools i.e., Patient cards, registers, referral forms are available, while some private facilities have EMR systems that captures TB data.

3.3.1.3 Main challenges and areas requiring improvement

- Suboptimal engagement of the private providers across all PPM models
- PPM activities majorly partner led with lack of formal mechanism for coordination of PPM activities at the county level: Notably, there were no focal persons, no PPM TWG/Committee, no MOUs between counties and private providers
- Human resource related challenges which includes: limited number of staff to provide TB services in most private facilities, high staff turnover leading to skill loss, Low suspicion index and limited capacity to diagnose TB, as well as unwillingness/lack of motivation/Hesitancy to provide TB services.
- Lack of diagnostic capacity in most private facilities evidenced by few GeneXpert machines despite the private facilities accounting for about 50% of all health facilities, stock out of GeneXpert Cartridges and user costs for GeneXpert, X-ray services and other tests in the private sector limit access
- Incomplete recording and reporting, parallel paper based and EMR in some facilities, and lack of TB screening module in some EMR
- Inadequate linkage of the private sector/facilities with community TB strategies and interventions

3.3.1.4 Key Recommendations

- More meaningful involvement and engagement of the private sector in policy and guideline formulation, coordination platforms and TB service delivery at all levels. Ensure program guidelines and SOPs are disseminated to all facilities including the private sector
- Establish a coordination mechanism for PPM activities and identify a PPM focal person at the county and sub-county level. In addition, engage regulatory bodies and associations in PPM activities at all levels
- Support private facilities by engaging donor implementing partners to support human resource capacity i.e., Lab personnel, TB clinician, TB nurse, CHVs to support TB service provision in high volume private facilities and sample transportation/IPC
- Consider incentives for providing TB services i.e., training, recognition, and payment for performance
- Scale-up and roll-out of t-bu lite and develop dashboards with PPM focus to ensure monitoring and increase accountability
- Allow the private sector to charge a defined small fee for providing TB services

3.4 TUBERCULOSIS DIAGNOSIS AND CASE FINDING IN KENYA

3.4.1 TB DIAGNOSTIC LABORATORY SERVICES AND NETWORK IN KENYA

For improved access to diagnostics the NSP represents the operationalization of a new national policy that recommends that all confirmed TB patients receive DST. The NSP proposes progressive achievement through increasing GeneXpert equipment placement across the country, the optimum number 450 - 500 as provided for GeneXpert Network Optimization Report, in addition to improvements in GeneXpert utilization rates which stood at 47% in 2017. Importantly, the NSP has noted the limited role CXR has played in TB diagnosis due to its limited availability (currently available only in Level 4 health facilities and private institutions) and that patients bear its cost.

The strategic interventions laid out by the NSP towards accelerating appropriate diagnosis through robust laboratory services include:

1. Use GeneXpert MTB/RIF as initial TB diagnostic test for all adults and children being investigated for TB
2. Increase the number of counties with a TB sample referral system, with TAT as a key performance indicator
3. Rapid adoption of new WHO recommended diagnostic tools and approaches
4. Universal access for 1st and 2nd line DST for all Rifampicin resistant TB patients
5. Use of a broader/more sensitive TB screening criteria, including adoption of digital CXR
6. Development and roll-out for quality assurance system for all diagnostic tests
7. Appropriate human resource with regular training and adequate mentoring, monitoring and supervision
8. Establishment of a framework for engaging private laboratories in TB diagnosis

3.4.1.1 Key findings, achievements and progress

- The laboratory component is included in National TB, Leprosy and Lung Health strategic plan with implementation coordinated by the NTRL and DNTLD-P. In addition, there is a functional technical working group of laboratory and diagnostic services
- In the life of the NSP, the country revised the national screening and diagnostic algorithm that incorporates, the chest x-ray as a screening tool, in addition to GeneXpert MTB/RIF test being the test for TB diagnosis for all presumptive TB patients.
- The diagnostic network comprises of the latest WHO recommended TB diagnostic technologies and tools which is oversighted by NTRL & DNTLD-P;
 - Genexpert machines increased from 189 machines to 226 machines, introduced Genexpert Ultra, 34 Trunat machines, 4 IGRA machines and LF LAM
 - Expand the use of Xpert Ultra and MTB/RIF on all paediatric specimens including stool
 - Introduced digital CXR AI reading using CAD4TB software for screening for TB
- There is a functional integrated sample referral system (SRS) and national guidelines and standard operating procedures available to guide the counties towards implementation.
- A service level agreement is in place with Cepheid for maintenance and calibration of GeneXpert instruments across the TB laboratory network in the country
- EQA for Xpert MTB/RIF proficiency testing panels and microscopy are prepared annually at the NTRL and disseminated across the microscopy laboratory network.
- The laboratory request forms, registers and report template are standardized and widely in use. Laboratory data are maintained using an electronic laboratory information system.
- Health care workers and laboratory scientists demonstrated understanding and capacity in TB surveillance and laboratory and diagnostic standard operating procedures and guidelines

3.4.1.2 Overview of Laboratory system and network

The Kenya National Tuberculosis Laboratory Diagnostic Network is under the Division of National Public Health Laboratories and the Department of Laboratory services. The laboratory works closely with the Directorate of Disease Control and Prevention. The National TB Reference Laboratory (NTRL) in the network, reports directly to the head of the National Public Health Laboratories and works in close collaboration with the head of the National TB Program (NTP). The NTRL has oversight for TB diagnostic services throughout Kenya at county and sub-county levels. Coordination within the diagnostic network is facilitated through linkages between the counties and sub-counties.

The national laboratory system and network in Kenya comprises of two government-owned culture laboratories: the National TB Reference Laboratory (NTRL) and Kisumu culture laboratory-KEMRI; three regional decentralized 1st and 2nd DST LPA laboratories (Malindi Sub-County hospital, Kitale County Referral Hospital, and Machakos

County Hospital), 226 gene xpert machines and 3,159 smear microscopy sites. There are 285 documented private laboratories in Kenya including 37 that have GeneXpert machines, five LPA and two culture and DST services. This network serves approximately 10,000 public and private health facilities. In addition, the country introduced 38 Truenat molecular assays, four interferon release gamma assays (IGRA) and urine lateral-flow lipoarabinomannan (LF-LAM).

National Tuberculosis Reference Laboratory (NTRL)

The NTRL mandate is to oversee TB and multi-drug resistant TB (MDR TB) surveillance, coordination and oversight of the external quality assurance (EQA) programs throughout the country. It also supports with the preparation of proficiency testing panels for Xpert MTB/RIF and Xpert MTB/RIF Ultra, and acid-fast bacilli (AFB) smear microscopy. The NTRL also supports mentorship and verification of novel TB diagnostic tools, national scale-up and decentralization of verified TB assays, develops policy, and coordinates resource mobilization. An electronic laboratory information management system (LIMS) is available for routine monthly, quarterly, and biannual reporting of data to the NTP.

NTRL is well equipped, with one BSL-III, one large BSL-II and three BS-II laboratories for molecular diagnostics. Besides from Acid-fast bacilli (AFB) smear microscopy using Ziehl-Neelsen and fluorescence staining, they perform mycobacterial cultures using solid Lowenstein-Jensen (LJ) and liquid Mycobacterial Growth Indicator Tubes (MGIT) for 1st and 2nd line DST and Line Probe Assay (LPA). The NTRL attained ISO 15189:2012 accreditation in 2018 and has a quality management system established. The laboratory is supported by the Uganda Supranational Laboratory (SRL) through supervisory and technical assistance visits annually and routinely participates in culture and DST EQA programs bi-annually. The laboratory maintains exceptional performance of 100%.

Human resource capacity at NTRL

The NTRL is staffed with 13 laboratory scientists, 11 of whom are supported by GF, with the other two supported by GoK. The NTRL reports that an additional 18 laboratory scientists would be required to meet the current demands of the program. The review established, that the GF contract staffs' contract will ending in June 2022, with indications that the GF guidance to MoH to transition contract staff into government HR financing mechanisms. At this writing, the status of this remained unclear.

Financing for NTRL services

The Global Fund (GF) is the primary funding source for NTRL diagnostic services. Combined with support from other donors, 80% of the operating budget is donor supported, with the government of Kenya (GOK) providing the remaining 20%. For budget year 2022-2023, the government of Kenya allocated Ksh. 80,208,000 and will be channeled to support commodities for mycobacterial culture and LPA, as well as an procurement of an additional MGIT 960 machine. Additional funding sources include the Clinton Health Access Initiative (CHAI), the United States Agency for International Development (USAID), Centre for Health Solution (TB ARCH II) and the US Centers for Disease Control and Prevention (CDC). Overall, the NTRL and NTP reports current funding levels do not adequately meet the needs to fully support the required TB diagnostic services throughout the country.

Performance and Trends of workload at NTRL

A steady increase in the culture workload since 2019 was observed as shown in *figure 14*. Overall, Lowenstein Jensen contamination rates were slightly above the national target at 5% in 2020, with slight improvement in 2021 of 4.4%. The trend was also noted in MGIT contamination rates, with 11.5% observed in 2020 and 9% in 2021 against a target of 10%. Specimen rejection rates in 2021 was 1.3% which was well under the national target of 3%. As part of the ISO15189 management standard, the NTRL routinely assesses customer satisfaction through surveys. Scores for all categories were above 70% except for TAT of results recording 55% in 2019 and 68% in 2021. Regarding Test request forms, documentation was largely complete, except that diagnostic assays performed by the submitting facility prior to submission to NTRL were not captured.

Turnaround time of results

The NTP has established the following targets for turnaround time of results:

- Positive and negative LJ cultures: 65 days
- Positive and negative liquid cultures: 45 days
- AFB smear microscopy: 24-48 hours
- Phenotypic drug susceptibility testing: 14 days from time of culture positivity
- Molecular line probe assay: 3.5 days (AFB smear positives only)
- Gene xpert: 2-5 days

Data captured for this quality indicator is aggregated. During the site visit, data were available for 2020, but were not captured for 2021 or 2022. The NTRL scores this indicator in broad categories, there is need for disaggregation to monitor turnaround time of results. This should be monitored for each phase of the diagnostic cascade; specimen collection to receipt in the laboratory, receipt of specimen through finalization of the report, release of the report through receipt by submitting facility.

GeneXpert services in Kenya

The country currently has 226 platforms, out of which, 193 are in public facilities and 34 which are in the private and research institutions. Facilities that participate in the Xpert MTB/RIF PT program are 193, with the PT panels prepared by the NTRL and are provided to all government and private facilities. GeneXpert training and refresher training occurs biannually. Kenya has been very proactive in its use of the GeneXpert platform to support multiple programs. This includes testing for TB, HIV viral load and early infant diagnosis, and SARS CoV2. Currently, GeneXpert has an online reporting system that has been digitized. In most facilities, SOP were available for specimen collection, packaging and transportation, AFB & GeneXpert testing.

Microscopy services

AFB sputum smear microscopy is primarily used to monitor patient response to TB therapy. There are 469 FM and 2690 ZN Microscopes in Kenya, spread across facilities. While GeneXpert is the primary initial diagnostic throughout the country, AFB smear microscopy tests are occasionally used when there are shortages of GeneXpert cartridges, or in facilities where access to GeneXpert may be limited. Microscopy training is provided biannually with the support of the county trainers and the diagnostic team, with oversight from NTRL.

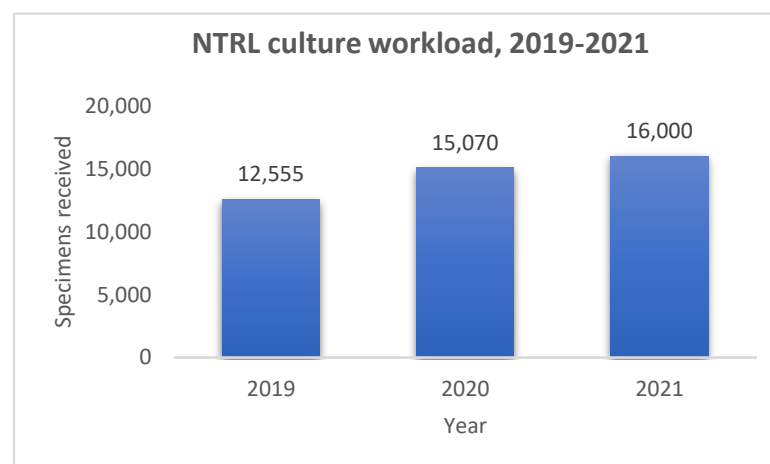


Figure 14 Trends of culture workload at NTRL, between 2019 and 2021
Source: NTRL

Sample transport and referral systems

An integrated sample referral system (SRS) with national guidelines for operations have been established within the diagnostic network. The network also includes private facilities, and is supported by GoK, counties, USAID (TB ARC) and GF. Currently, 32% of the facilities in the country have a functional SRS for transport of TB specimens. Dissemination of the guidelines has only been done to ~50% of the counties. Nonetheless, some counties have developed their own integrated SRS e.g., Murang'a, Kisumu. DNTLD-P has developed a template to evaluate SRS's efficiency and to assist in identifying bottlenecks, though this is yet to be implemented.

Laboratory Supply chain and Commodity management

Persistent stock outs have been a serious barrier to providing uninterrupted TB diagnostic services. GeneXpert commodities are currently requested through 2 channels: online GXLIMS and KHIS (Lab registers). There are plans to harmonize this process.

DST commodities for the decentralized labs are supplied through NTRL.

Main challenges remain bottlenecks within the procurement cycle and poor forecasting processes. The DNTLD-P needs to be able to track available commodity levels, as is currently possible for GeneXpert (lab commodity dashboard in place.) Another challenge relates to commodities outside of KEMSA's procurement scope e.g., new DST molecules, ATCC organisms for QC and PT production commodities.

Service and maintenance of equipment

Biannual service maintenance of the GeneXpert platforms is supported and facilitated by DNTLD-P with a service level agreement in place between CEPHEID, the Principal recipient and the national procuring agency. Notably, a total of 193 gene xpert sites participate in the Xpert MTB/RIF Panel testing program. The PT panels are prepared by NTRL and provided to both government and private facilities with report submission done online. There are CAPA mechanisms available.

DNTLD-P/NTRL are currently piloting CQI activities for 20 lower level GeneXpert sites. Counties routinely perform blinded rechecking of AFB smears, with 1,803 of 2,555 (80%) microscopy facilities were enrolled at the time of the review. Microscopy EQA panels are produced by NTRL and provided to 47 counties, with most facilities participating being those from the government facilities. Microscopy EQA results reporting has been digitized, however 180 sub-county medical lab coordinators lack the required hardware (laptops or tablets) to facilitate reporting.

Laboratory Reporting systems

With regards to laboratory reporting, currently GeneXpert has an online system where reports have been digitized. AFB microscopy is in the process to have all results be submitted through a USSD system which is in the process of development so that it will be linked to the current NTP case-based data collection tool. All this data will then be directed to the main ministry of Health reporting system-KHIS.

3.4.1.3 Main challenges and areas of improvement

- Inadequate stewardship and suboptimal coordination between DNTLD-P and NPHL, with no structured platform for ongoing engagement to optimize the functionality of the national TB diagnostic network. The country was also in the process of updating NPHL's NSP, but there was limited engagement of DNTLD-P in this process.
- Operations at the NTRL laboratory is highly financed by the partners, with an impending risk of significant disruption of TB laboratory services if the envisaged transition of 11 out of 13 NTRL staff from Global Fund to GOK is not completed in timely
- The capacity to continue using GeneXpert as the first diagnostic test for TB is threatened countrywide due to erratic supply and, in some instances prolonged stock outs of genexpert consumables at the Xpert testing facilities in all counties
- Inventory & commodity gaps at the NTRL, with the BSL-III lab found to be non-functional for the preceding 2-3 months
- Sub-optimal coverage of the integrated sample referral system marked with inexistence of SRS guidelines and awareness in some counties. In addition, there was irregular availability of the standard materials used for sample triple packaging and transportation at the county

- Laboratory operations at the culture and LPA laboratory services both at the central and regional laboratories have stalled due to operational challenges: commodity stock outs, human capacity challenges, sub-optimal technical support as well as biosafety/infrastructural concerns
 - At the time of the visit, the NTRL BSL-III was inoperable (note: the site reported the BSL-III not functioning for the past 2-3 months). These safety concerns have been documented, however the site reports limited funding to address the repairs
 - Regional laboratories are yet to be accredited although plans are underway
 - There are several faulty microscopes and safety hoods in some health facilities, that require servicing and maintenance
- Sub-optimal engagement and coverage of the private and research laboratories in diagnostic network activities such as sample referral system, capacity building, technical support, monitoring and evaluation and EQA program
- Results and feedback for the EQA activities are not shared systematically with all the laboratories assessed
- Staff shortage was observed at NTRL and most counties visited, this issue was exacerbated by a high staff turnover in additional counties
- No existing MoU or agreement that defines the collaboration between the NTP/NTRL regarding the provision of TB services (however the PPM framework provide guidance on engaging the private sector)

3.4.1.4 Key recommendations

- Strengthen coordination, planning and collaboration between NPHL, NTRL and DNTLD-P to streamline strategic and technical plans, for joint implementation of surveillance and laboratory related interventions and activities.
- Assess the human resource needs and capacity at national and county levels, to adequately quantify the gap and develop an elaborate plan for mobilization of resources for recruitment of additional staff and to foster staff retention. Urgently, fast track the transitioning of contract staff to MoH.
- Strengthen supply chain and commodity management, including forecasting and procurement system for the all laboratory commodities for NTRL and GeneXpert to ensure uninterrupted service and address/prevent downtime of all TB Diagnostic networks
 - Fast-track FBS registrations at KEMSA to facilitate procurement of commodities that are not procured through KEMSA and are unavailable in-country.
 - Harmonization of the forecasting, quantification and ordering process of the commodities in the TB diagnostic network all through the system i.e. NTRL, DNTLD-P, KEMSA, the counties and facilities. Expansion of the GeneXpert cartridge dashboard to include other commodities could be a place to start.
- Accelerate the expansion of mWRDs, including Trunat, LFLAM and other new tools; including adoption of TB whole Genome Sequencing as a testing platform to improve access to TB testing and strengthen surveillance
- Mobilize and secure financial resources particularly, from domestic sources to ensure allocation of resources to support full decentralization of TB culture and phenotypic DST, SRS operationalization and servicing and maintenance of equipment and machines for optimal performance
- Build capacity of HCWs and laboratory staff through mentorship and competency training, to sustain efforts, as well as roll-out of the QMS activities to the sub-counties and ensure regular TA/mentorship to ensure all facilities are enrolled in the program.
- The NTP/NTRL to operationalize the guiding framework of engagement and collaboration for partnership between the MoH and the private sector; as facilitated by the PPM action to ensure availability of diagnosis and screening services

3.4.2 SCREENING AND OTHER CASE FINDING STRATEGIES

The current NSP has set ambitious targets for TB case notification of finding 597,000 people with TB during the implementation period. It lays out four main approaches to improve TB case finding: One, improving community-based interventions and outreach, two, improving

facility-based screening, strengthening the laboratory network and strengthening public-private collaboration. Community-based screening among key populations by means of targeted TB outreaches in suspected areas of focalized transmission, high-risk populations and congregate settings has been prioritized by the NSP. For facility-based TB case finding, the current NSP recommends symptom screening of all individuals presenting to any service delivery point (SDP). Any individual found to have respiratory symptoms should be triaged for appropriate diagnostic testing and management of any other respiratory diseases.

Performance against the NSP targets

Table 2 Performance indicators for case finding efforts against NSP targets

Indicator	Baseline	Target	Achievements (2021)
Proportion of people with TB referred by Community Health Volunteers and Informal Service Providers	10%	25%	12%
Proportion of the people with symptoms of TB from the community that seek appropriate care from health facilities	-	80%	Unclear
Proportion of notified TB cases that receive a rapid diagnostic test (GeneXpert MTB/RIF) at the time of diagnosis	47%	90%	42%* (65%-70%) [£]
Proportion of presumptive TB (with respiratory symptoms) patients tested for TB	40%	80%	51%**
Total TB Notifications 2019-2023	NA	597,000	236,329 [∅] .
*Current machine utilization was estimated at 41% from the lab team presentation £ ACF team data ** reported in TIBU ∅ As at end of 2021. With two years remaining in the NSP, the gap is 360,671. Even allowing a 20% increase in notification in each of the next two years, there will be a gap of 170,000 cases in 2023.			

3.4.2.1 Key findings, progress and achievements

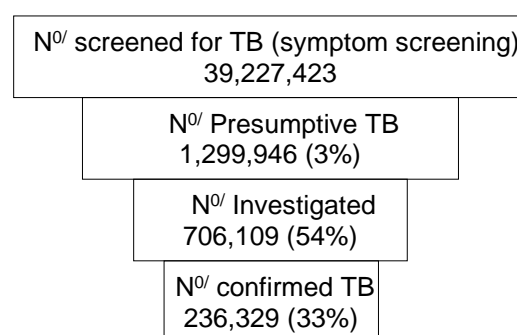
- We observed widespread implementation of verbal symptom screening at OPD, CCC and other points in most health facilities. The staff had a general understanding of the process in the ACF cascade
- Global Fund provides funding to the non-state principal recipient, AMREF, for country-wide implementation of various ACF activities: contact investigation, loss-to-follow-up tracing and community outreaches. USAID also supports some ACF activities through implementing partners and project funding such as TB REACH.
- Community based ACF is provided by a wide range of implementation partners, often through CHVs. There are also long-standing engagements with private and FBO providers to improve TB case detection through referral and in some cases treatment support.
- Various models of sample networking were in place in all sampled counties and were either donor supported, or facility supported. This network provides transport for both HIV viral load and EID as well as TB testing transport. In many GeneXpert testing sites, referred samples represented 30-40% of cartridges used underlying the importance of the sample network.
- Testing using GeneXpert is the mainstay of TB diagnosis and the diagnostic algorithm for children above age 10 and adults were available and visible in most but not all facilities
- All counties demonstrated shortages of GeneXpert cartridges for several months (2021-2022) affecting testing of people with presumptive TB.
- AFB microscopy continues to be used for follow-up evaluations and is still used when GeneXpert testing is not available accounting for around one third of bacteriologically positive (Bac+) diagnoses.

- CXR was being used to increase the numbers of people with TB diagnosed clinically. This is critical for populations like children and PLHIV, and needs to be further strengthened, but some concerns have been raised with the quality of clinical diagnosis.
- There were several good examples of bi-directional TB/COVID screening that helped improve TB case detection in some counties during the pandemic.
- Presumptive TB registers and other ACF tools were available and in use with some facilities demonstrating evidence of use of data at the facility-level TB through performance monitoring charts. Although limited in coverage, where available, EMRs included TB screening questions and were being used, while in others a TB screening stamp was available.
- Long established engagements with PPM for referral and testing contribute up to 18% of national notifications and are documented in the PPM section.

3.4.2.2 Main challenges and areas of improvement

- The quality of screening in health facilities appears deficient. Figure 15 below shows that out of the people screened at OPD, very few of them end up being tested for, a missed opportunity. This ‘leakages’ are due to the multiple-step screening process, whereby a clinician must certify a presumptive TB case identified in the community before they can be tested. While this may reduce the workload in the laboratory, and artificially increase the yield of GeneXpert testing, it results in missed opportunities to find persons with TB.
- Only 20 of the 47 (43%) counties have an established TB sample referral system.
- Many TB cases diagnosed with microscopy (smear-positive TB) did not have specimens submitted for testing with GeneXpert RIF, missing an opportunity for early detection of DR TB.
- The current strategy mainly focuses on facilities, there is a need to broaden case finding to reach the communities in order to reach the targets of finding
- Data quality on TB screening cascade at health facilities visited is insufficient to inform evidence-based decisions about which interventions need to be prioritized.
- Cost and availability of chest x-ray were the main barriers for use of CXR to screen for TB where available.

Figure 15 Case finding cascade between 2019 and 2021
Source: MoH, (TIBU)



3.4.2.3 Key Recommendations

- Increase the numbers of people with presumptive TB who are identified and tested with mWRD test. There must be acceptance that increased testing with a decreased yield will be necessary to maximize case detection
- Within the health care facilities, there are several entry points (e.g. M&CH, Nutrition, Chronic Care Clinics) that could also prioritize screening and testing for the patients
- Empower well-trained CHAs and CHVs to identify people who need testing, collect sputum, make referrals, and follow up to ensure adherence to clinic visits and any required testing

- Document the outcomes of all screening processes, especially community based ACF, to decide if they are worth continuing or expanding
- Wider use of digital CXR with AI/CAD, whose efficiency is documented. CXR can reduce the number of people who need expensive GeneXpert testing

3.5 TB PREVENTION, CARE AND TREATMENT

3.5.1 TB PREVENTIVE THERAPY AND INFECTION PREVENTION & CONTROL

The programmatic management of TPT (PMTPT) is a key component of the End TB strategy by 2035 in Kenya. Kenya has implemented TB preventive therapy program since early 2000 with scale -up efforts with isoniazid preventive therapy (IPT) for TB prevention both among contacts <5 years and PLWHIV commencing in 2015.

Strategic interventions prioritized in the NSP targeting TPT include: -

- 1) Sustain proportion of PLHIV initiated on TPT by maintaining high service coverage. In addition, a comprehensive framework for TPT that includes use of WHO recommended shorter TPT regimen with regular monitoring and outcome evaluation will be developed and implemented.
- 2) DNTLD-P will develop and cascade county targets for child contact management and TB prevention therapy.
- 3) The counties and their implementing partners will use the community health systems to provide public education and create demand.
- 4) They will implement active contact screening and preventive therapy through engagement with and support for community and primary health care providers.
- 5) In addition, the DNTLD-P will introduce and scale up shorter and safer regimens to treat TB infection in child contacts.
- 6) Child contacts of patients with drug resistant TB will be routinely evaluated according to existing policy guidelines for treatment of disease and prevention of transmission.

Performance against the NSP targets

Table 4 Performance indicators for case finding against NSP targets

Outcome Indicator	Baseline	Target (2023)	Status 2021
Proportion of PLHIVs initiated on TB Preventive therapy	65%	90%	80%
Proportion of eligible children under 5 years who are contacts of people with TB, who are put on TB preventive therapy	39%	90%	45%

3.5.1.1 Key findings, achievements and progress

Kenya had committed to provide TPT to nearly 900,000 individuals by 2023. Although these TPT targets are yet to be achieved, the country has successfully expanded coverage of TPT to additional eligible populations as shown in the box 4 below. PLHIV enrollment has increased to about 80%, which is among the highest in the world. On the other hand, despite progress, TPT uptake among contacts of TB patients remains low (45%).

Expanded target populations for TPT	
•	People Living with HIV
•	All household contacts of a person with Bacteriologically confirmed pulmonary TB patients (children, adolescents and adults)
•	Prisoners and Prison staff
•	Health care workers and support staff working in health care settings
•	Others population at risk.
○	Patients on immunosuppressant's.
○	Patients on dialysis
○	Patients preparing for an organ or haematological transplant
○	Patients with silicosis

Figure 16 Target populations for TB preventive therapy in Kenya; Source: MoH

TPT scaleup started in Kenya in 2016 using a 6-month Isoniazid regimen (6H) and gradually covered all the 47 counties. The target population during this period remained PLHIV and children who were <5 year of age. The National guidelines on the programmatic management of TB preventive therapy 2020 and draft Anti-Retroviral guidelines 2022 recommend use of 3HP for adolescents and adults ages 15 years and above (HIV positive and HIV negative), use of INH for children and adolescents less than 15 years (HIV positive), pregnant women and those who are intolerant or not eligible to receive 3HP and finally use of 3RH for children below 15 years who are HIV negative. The country started implementation of shorter rifapentine containing weekly regimen of 3HP in phases. Phase one targeted 11 counties and the implementation largely started in January 2022. 3HP is planned to be scaled up to 12 more counties by April 2022. High coverage of TPT noted among PLHIV in care in counties that were well served with commodities and where training and sensitization of all relevant staff were completed. In general, the review observed TPT completion rates of between 75% to 80%, which were even higher at about 90% with the shorter 3HP regimen. General awareness about the importance of TPT exists both among health care workers and community volunteers, including knowledge about the latest national TPT guidelines at the county level. TPT uptake variable is also found to be variable among HCWs across different counties. In 2021 a total of 1618 HCWs received TPT in the 11 initial countries that received 3HP under the IMPACT 4TB project.

TPT scaleup started in Kenya in 2016 using a 6-month Isoniazid regimen (6H) and gradually covered all the 47 counties. The target population during this period remained PLHIV and children who were <5 year of age. The National guidelines on the programmatic management of TB preventive therapy 2020 and draft Anti-Retroviral guidelines 2022 recommend use of 3HP for adolescents and adults ages 15 years and above (HIV positive and HIV negative), use of INH for children and adolescents less than 15 years (HIV positive),

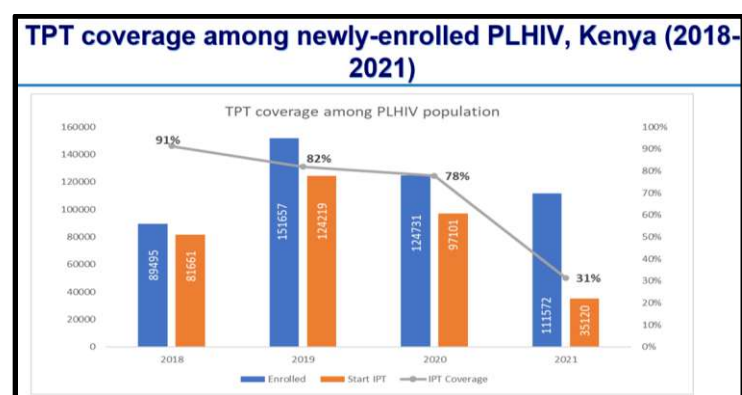


Figure 17 TPT coverage among newly enrolled PLWHIV, in Kenya, 2018 and 2021

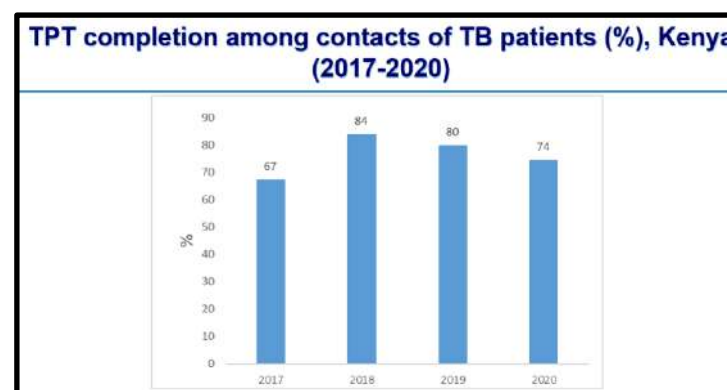


Figure 18 TPT completion among contacts of TB patients, Kenya, 2017-2020

Infection Prevention and Control (IPC)

High-quality health care service delivery, a safe working environment and safety for health care workers (HCWs) are key in all health facilities. The review team assessed TB Infection prevention and control under three controls of administrative, environmental control and personal protection. COVID-19 pandemic further emphasized the importance of effective airborne infection control measures, particularly in health

care settings. During this period measures such as hand washing stations were made available for patients and HCWs outside service delivery points (Entry gate, OPD & CCC)

Administrative control:

- Almost all health facilities visited had an IPC focal person for review and implementation of infection control measures.
- National IPC policy and guidelines were available but HCWs were not trained on these guidelines.
- Facility infection control plans exist in most facilities; however they focus on hospital infection control measures and not airborne infection control. Some facilities also had outdated work plans.
- IPC risk assessments were not done in all facilities visited and where it was, airborne infection control component was neglected
- Implementation of IPC practices was found sub-optimal with low or no focus on triage for early identification of TB symptomatic and fast tracking for separation of such clients from others in the waiting area. This was particularly pronounced in overcrowded OPD waiting areas at high-volume sites where clients with respiratory symptoms (coughers) mingled with other patients. In some facilities CHVs are entrusted with conducting triage for TB symptoms in waiting areas and facilitate fast tracking.
- IEC material to educate patients about cough etiquettes and importance of use of facemask not seen at strategic locations.
- Isolation wards to admit TB patients who need care not available in most counties. TB patients are admitted along with other patients having no TB.

Environmental control:

- Waiting areas are generally well ventilated and open, but also congested in high volume facilities.
- Windows and doors in consultation rooms, particularly in the CCCs and TB clinics were open allowing good ventilation.
- Display informing clients with TB symptoms regards expected actions not seen at entrance or waiting areas of health facilities.

Personal Protection:

- There was a supply of surgical masks for health care workers and also supply of N95 respirators for those involved in care for MDR TB patients.
- Systematic TB screening of health workers is implemented to variable extent noted in few but not done in the majority of counties.

3.5.1.2 Key challenges and areas of improvement

- TB prevention is considered a priority at the national level with target sets at the national strategic plans, this however, wasn't a priority in some county within their strategic framework
- TPT is largely not available in 24/47 counties: 10 counties use 6H for PLHIV, 11 have started implementation of 3HP among the expanded target population
- Significant funding gaps exist that hinder the implementation of activities that would accelerate scale up such as capacity building among HCWs, procurement of TPT commodities and chest X-ray for screening and tests for TB infection
- Non-assuring availability/security of TPT commodities to due erratic supply has caused long-standing disruptions in TPT scale up. This also resulted in incomplete TPT completion among many PLHIV started on treatment
- Uptake of TPT following the contact evaluation is generally very low (20-25%). Hesitancy among the index patients to enroll children and older family members for evaluation and TPT, with gaps in disclosure counselling and support for travel to complete the evaluation.
- Systematic documentation and review of the ADRs linked to TPT is lacking
- TPT is yet to be offered to clinical risk populations such as individuals on dialysis, preparing for organ or hematological transplant and receiving anti-TNF treatment
- TPT provision through private providers is limited and capacity building/training of private providers particularly individual providers lacking

3.5.1.3 Key recommendations

- Ensure commodity security, rational distribution, develop patient packs and provision of child friendly formulations to ensure acceleration in scale up TPT to all the 47 counties in Kenya as well as, completion of TPT for those initiated
- Systematically engage and strengthen collaboration to create synergy with implementing partners in addressing gaps for TPT expansion such human resource, building capacity and streamlining supply chain management
- Strengthen contact tracing, screening and TPT initiation, including drawing strategies drawn from CAP-TB project (consider travel support for contacts referred for evaluation by health care worker)
- Strengthen aDSM and pharmacovigilance reporting and reviews for TPT
- Integrate TPT into PPM interventions including provision of training and commodity support
- Mobilize resource allocation and investments into testing for TB infection including new skin tests recently recommended by WHO and subsidize X-ray investigation
- IPC focal persons at health facilities to ensure IPC training is offered to all staff including continued on-job training, CMEs and ensure compliance with national guidelines.
- Strengthen IPC risk assessment by providing SOPs and tools, and adapt facility work plans based on assessment
- Advocate and support counties to implement the isolation policy: establish isolation facilities for TB patients in line with the isolation policy

3.5.2 TB CARE AND TREATMENT

The current NSP envisioned strengthening the quality of care, optimizing cure rates among bacteriologically confirmed patients, other favorable experiences among patients initiated on treatment, and reducing case fatality ratio and addressing underlying causes of mortality during TB care. It focused on putting in place strategies that address the loss of patients within the health system; from those visiting health facilities but missed at diagnosis, lost between diagnosis and treatment initiation, and those initiated on treatment but not completing treatment.

Performance against the NSP targets

Table 5 Performance indicators of care and treatment against NSP targets

Outcome Indicator	Baseline	Target (2023)	Achieved 2021
Treatment success rate (TSR) for all DS-TB cases	81%	90%	84%
Cure rate among bacteriologically confirmed TB patients	69%	90%	85%
Case fatality ratio (all forms)	6%	<5%	<5%
% of people with TB who are detected but are not notified or started on treatment (initial LTFU)	21%	0%	Data not available

The review found that the NSP and TB guidelines are aligned with the normative guidance from WHO on the current best practices in controlling TB. Finding people with TB is highly prioritized and emphasized in all policy guidance and implementation activities by the DNTLD-P and its partners as mentioned above.

3.5.2.1 Key findings, progress and achievements

- The review found that the NSP and TB guidelines are aligned with the normative guidance from WHO on the current best practices in controlling TB. Finding people with TB is highly prioritized and emphasized in all policy guidance and implementation activities by the DNTLD-P and its partners as mentioned above.

- The Programme has an established formidable and all-inclusive committee of experts (COE) that reviews and supports guideline development.
- Most facilities have dedicated TB focal point persons to coordinate TB interventions and to provide guidance. In a number of facilities TB and HIV services are integrated into one stop shop.
- Mortality audits were observed to be conducted in level 4 and 5 health facilities. This is one best practice that needs to be scaled up in all facilities.
- DS-TB patients are linked to care and started on treatment within 24 to 48 hours of TB diagnosis. Monthly sputum monitoring is well documented in most of the patient files.
- HIV testing and linkage to ART was at 99% and 97% respectively.
- A patient-centered approach is incorporated into the care of drug sensitive TB patients, demonstrated through re-alignment of the differentiated service model implemented during the COVID-19 peaks, whereby the CHWs delivered drugs to patients at home, based on patient preference.

3.5.2.2 Main challenges and areas of improvement

- To a large extent, all patients are managed the same way with no attempt to distinguish care for patients according to their circumstances e.g. there is no evidence of extensive counselling services, mental health care or personalized DOT plan.
- Another gap was that generally, patient clinical details on history and physical examination findings were hardly documented despite there being a provision in the patient files.
- Further, at lower levels of the care, there was low technical capacity in the holistic management of patients, leading to failure to recognize comorbid conditions and factors predisposing to mortality.
- There was also no structured system for referral or linkage of patients with other comorbid conditions for evaluation and specialized care
- Passive implementation of the initiative of multidisciplinary involvement in the management of TB patients
- Passive case finding approaches are leading to missed cases of TB and delayed diagnosis, both impacting negatively on treatment outcomes

Unfavourable Treatment Outcomes

Deaths, loss to follow up and patients whose outcomes are not evaluated remain the greatest determinants of the failure to achieve the 90% treatment success target. (Figure BG) Mortality is showing an upward tick and is higher in the age groups starting age 35 and highest in the age group of 65+. (Figure TY). This may be linked to an earlier observation that there may be lack of a comprehensive evaluation of patients for other comorbid conditions, including NCDs, commonly found among older people.

3.5.2.3 Key recommendations

- Mobilize county governments support and involvement in the provision of primary health care providers and strengthen community health workforce, in the identifying TB patients, providing care and where need be in mortality audits
- Involvement of senior clinicians in the management of patients to promote a more patient-centered treatment approach
- Inclusion of a clinical focus during supportive supervision, to evaluate and promote patient-centered care
- Invest in building capacity of all frontline HCWs, through CMEs, OJT and mentorship to provide patient-centered care and targeted areas of care
- Comprehensive screening for and appropriate management of comorbidities among at-risk DS-TB patients
- Counties to implement quality improvement strategies to e.g., develop a referral directory to assist with tracking referred patients, innovative approaches to reduce LTFU and deaths among TB/HIV co-infected patients
- Consideration to be made for enhancement of telemedicine to promote access to specialist especially given the limited number of specialists across the country and challenges faced by poor severely ill in accessing referral services

3.5.3 PROGRAMMATIC MANAGEMENT OF DRUG RESISTANT TB (PMDT)

The current NSP envisioned and prioritized the following strategic interventions for PMDT:

- 1) Ensuring Universal Drug Susceptibility testing for all TB patients using Xpert and other molecular technologies to increase detection of all drug-resistant TB and link them to appropriate treatment
- 2) Optimizing the coverage and quality of treatment and care for all patients put on treatment for drug-resistant using internationally recommended treatment combinations, including the introduction of injectable-free and new medicines delivered through effective patient-friendly models.
- 3) Providing for admission and isolation facilities at county levels to cater for patients requiring inpatient care, and
- 4) Sustaining social protection and support for patients while on treatment through the provision of cash transfers based on minimum wage, NHIF enrolments to cover additional outpatient and inpatient costs.

Performance against the NSP targets

Table 6 Performance indicators for care and treatment against NSP targets

Outcome Indicator	Baseline	Target	Achieved 2021
Proportion of notified TB patients who receive DST	47%	95%	63%
Proportion of DR TB cases detected	21%	80%	69%
Proportion of eligible DR TB Cases initiated on new molecules	13%	90%	100%
Proportion of DR TB Patients' households incurring catastrophic costs	86%	43%	No data

3.5.3.1 Key findings, progress and key achievements

Drug Resistant TB Surveillance

- The review documented the new WHO 2021 Global listing of High TB burden countries that has declassified Kenya as a high MDR/TB burden country
- The last drug resistance survey was conducted in the country in 2015, 7 years previously and had shown MDR TB prevalence of 0.7% among new cases and 2.1% among previously treated cases
- There was an observed increase in DR TB case notification of 40% in 2021 compared to 2020, despite the COVID 19 pandemic, a period other programmatic intervention area documented a decline
- Notwithstanding, the increasing DR TB treatment coverage, DR TB case detection rate remained below target
- DRTB screening and testing is being routinely done among high risk populations as per national guidelines
- Presumptive DRTB clients are routinely screened using molecular technology and culture and DST as recommended
- There was evidence of above average contact listing, tracing and Xpert testing at the time of diagnosing index cases (however, there was very little documentary evidence of repeat testing three months after the baseline test as recommended in the national guidelines)
- On average, patients take between 6-12 months from the time of presenting with TB symptoms to time MDR TB diagnosis is made.
- There is overreliance on laboratory diagnosis of DR TB among children resulting in 100% bacteriologically confirmed childhood DR TB cases

Models of Care and Patient Support

- DOT is generally in practice; either facility based or community-based models; 72% of DR TB patients on treatment were on community-based DOT, with practically every DR TB patient is attached to a DOT worker. CHVs were actively implementing contact listing and screening, and defaulter tracing.
- A standard patient support package that includes a monthly stipend of KES 6,000 for the patient, as well as for DOT worker, for the duration of treatment is available
- Enrollment of DR TB patients on health insurance (NHIF) that allows patients to access other specialized care and services such as X-ray and ECG services and hospital admission.
- Waiver of costs for monthly follow-up laboratory tests exists. There was verifiable access to specialist services (including psychiatrist and psychologists' services), although utilization of psychosocial support was only moderate.
- Nutrition assessment is done on all DR TB patients, and when available, nutritional supplements and therapeutic feeds are provided.
- Patient knowledge of their condition and perception regarding quality of care and access to support services was above average and universally positive. The concept of "my personal doctor" was highly evident from each beneficiary

Clinical Management and Monitoring

- National policy guidelines and algorithms in use for diagnosis and treatment are aligned to current international recommendations; All oral longer-term treatment regimens with new drug have been introduced successfully, including those using new molecules
- Roadmap towards implementation of all STR under operational research was in place
- All TB treatment sites visited also offer DR TB services when a new patient is identified, with only 4 admission isolation facilities in the 47 counties
- National DR TB guidelines version 2020 and SOPs are available and in use, however, this was not the case in private facilities;
- MDR TB treatment sites take about 3 days to initiate treatment while sites without existing MDR TB patients take approximately 14-28 days. Delays in getting medicines was the commonest cause of the delay of up to 2 weeks in peripheral sites.
- Logbooks (patient record booklets) were available, and there was a multidisciplinary approach to DR TB care. Monthly reviews by SCTL and clinical review teams were taking place, as were quarterly review meetings at county level. There is an integrated DR TB/HIV approach with good quality of care;
- Baseline laboratory investigations are being done through donor support but there is a significant gap on follow-up tests.
- ADR monitoring is undertaken for DRTB clients but documentation is not systematic and complete. In particular, reporting to the Pharmacy and Poisons Board (PPB) is suboptimal

Treatment outcomes

There has been significant improvement in DR TB outcomes during the lifetime of the NSP. The treatment success rate for MDR/RR cases stands at 77% against a target of 80%. Death rate is high at 13% and lost to follow-up is at 5.4%. Factors associated with mortality include severe acute malnutrition, late presentation and advanced HIV disease. Mortality audits have conducted but not in all sites, and these data are not reported through TIBU as there are no formal tools.

PMDT: Pediatric DRTB Performance

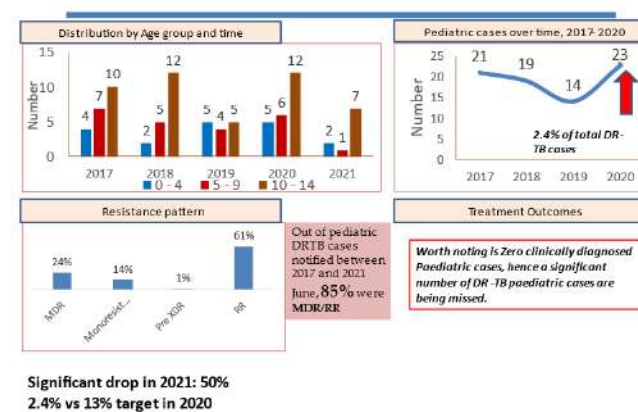


Figure 19 Drug resistant TB diagnosis and treatment profile for children in Kenya, Source DNTLD-P

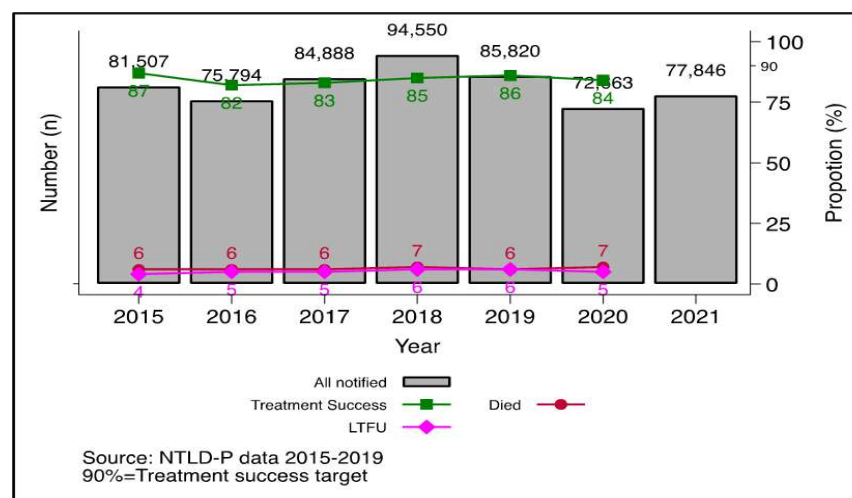


Figure 20 Treatment outcome of drug resistant TB patients in Kenya, between 2015 and 2020

3.5.3.2 Main Challenges and areas requiring improvement

There has been prolonged lack of access to Xpert testing services in most of the facilities visited in the country, mostly ascribed to widespread interrupted supplies of Xpert cartridges

- There is a notably longer than average turnaround time (TAT) 3 weeks for LPA and up to 3 months for MGIT. Second-line DST coverage among MDR RR TB patients is also very low; Similarly, there is a verifiable long TAT between DR TB diagnosis and treatment initiation of between 2 to 4 weeks
- The WHO-recommended shorter duration (9-12 months) all oral shorter duration treatment for MDR TB has not yet been introduced in the country
- Not all facilities documented a multi-disciplinary team clinical review teams or meetings for DR TB clients. There is no documented evidence of ADR reporting beyond the patients file or TIBU in some of the facilities
- Gaps in ECG and visual monitoring were observed with peripheral neuropathy assessed through symptomatic screening. Monthly follow-up cultures, LPA and SL-DST are not being consistently documented in the registers/ patient logbook
- New definitions for Pre-XDR and XDR TB are not yet known or applied in the country
- There was unavailability of child-friendly formulations for treatment of DR TB in children
- There was very little evidence of repeat testing for contacts of DR TB patients at three months after the baseline test as recommended in the national guidelines
- There is no national policy position on preventive therapy for DR TB, consequently, this intervention is not in operation in the country
- Baseline and follow up ECG testing is not being routinely conducted in almost all the facilities visited because of stock outs of ECG paper and having very few available in each county (only one per county)

3.5.3.3 Key Recommendations

Summary of key recommendations for PMDT	Responsible
Case finding	
Conduct follow up drug resistance survey to determine the actual burden of MDR-TB and revise targets for the next NSP	NTLP/NTRL/IPs
Implement Next generation sequencing for the next DRS to improve precision at affordable costs	NTLP/NTRL/IPs

Scale up sentinel sites for DR-TB surveillance with lessons learnt from 10 counties that recently piloted sentinel surveillance systems for drug resistant TB.	NTLP/NTRL/IPs
Strengthen contact tracing and follow up to identify more childhood TB cases	NTLP/lps
Clinically diagnosed pediatric TB cases are missed. They need to be notified as presumptive DR TB cases.	NTLP/lps
Expand coverage with molecular testing services through procurement of additional GeneXpert and other emerging molecular testing equipment and platforms; and scaling up further sample referral systems to areas without the equipment on site	NTLP/Donor funding agencies
Introduce the MTB/XDR cartridge into the diagnostic network to improve TAT for second line DST results for confirmed MTB cases	NTLP/NTRL
Clinical management	
Expedite roll out of all oral shorter regimen	NTLP/KEMSA
Reduce time to treatment initiation by reducing the delays in getting drugs from KEMSA <ul style="list-style-type: none"> Consider decentralization of drugs from KEMSA to some referral or high-volume facilities 	NTLP/KEMSA
Institutionalize death audits in the DR-TB sites: Include them in the Monthly clinical review meetings	NTLP/County
Expand admission/Isolation facilities for DR-TB patients and prioritize counties with high DR-TB burden	NTLP/County
Monitoring Adverse events (ADSM)	
Procure visual monitoring tools to assist with early detection of visual impairment	NTLP/County
Increase ECG machines to one per subcounty and prioritize high volume sites	NTLP/County
Consider strategizing reporting of ADRs -could be done by Clinicians or together with Pharmacists to PPB.	NTLP/PPB
Monitoring and Evaluation	
Conduct weekly review of registers/logbooks on documentation of culture and DST results and include in the mentoring and supportive supervision plan.	Subcounty coordinator
Sensitize the DRTB focal persons on the new WHO changes on the definitions of pre-XDR and XDR TB and consider sending a memo highlighting the changes on page 175 of the guidelines	NTLP
Each pediatric age group needs to have their treatment outcomes evaluated separately. This is important in knowing which age group has challenges in care and have measures to improve outcomes	NTLP
Develop a quarterly reporting template for mortality audits	NTLP
Review the current deaths audits to inform the variables to be prioritized for the reporting template to NTLP	
Capacity building	
Conduct advanced DRTB and ADSM training for doctors, clinical officers, TB coordinators, nurses and pharmacists	NTLP
NTP to implement a standardized DRTB site start-up package for facilities where a new DRTB case is identified: Contains the minimum package of care for DRTB patients and how to go about managing DRTB patients.	NTLP

Potential areas for Technical Assistance from partners

- Conduct follow up Drug Resistance Survey to determine the actual burden of MDR-TB and inform target setting in new NSP
- Implementation of Next generation sequencing and adoption of the MTB/XDR cartridge technology to speed up time to accessing results of second line DST among confirmed MTB patients.
- aDSM Implementation
- Paediatric case finding
- Conduct follow up Patient Cost Survey

3.5.4 CHILDHOOD & ADOLESCENT TB

Childhood TB is included as a targeted population in the NSP, recognizing that TB case detection gap is highest among children and young adolescents below 15 years. The current NSP envisioned and prioritized the following strategic interventions:

1. 90% of child contacts under 5 access TPT with county targets; provision of education and creation of demand; active contact screening and TPT; Introduce and scale up shorter TPT regimens
2. Increase the proportion of children with TB who are detected: including update of training materials, job aids; county targets
3. Training, mentorship and supervision: identification of TB symptoms, evaluation, diagnosis, management; centres of excellence
4. Diagnosis: screening at OPD, MCH; capacitation on sample collection; access to GeneXpert; clinical diagnosis and WHO recommended diagnostics
5. Strengthened collaboration with RMNCH services, HIV programs, education institutions private sector, professional bodies, training institutions, CBOs, NGOs; screening in all entry points (OPD, nutrition, HIV, adolescent health, ANC, EPI in public and private facilities; school health programmes, pre-service training and community interventions
6. Increase paediatric TB TSR to 90%: child-friendly formulations of DS and DR TB; patient-centred approach
7. Implementation research to optimize the impact of childhood TB interventions: new service deliverer options e.g. contact management, collaboration with RMNCH, sample collection

Performance against the NSP targets

Table 7 Performance indicators for childhood and adolescents TB against NSP targets

Outcome Indicator	Baseline	Target 2023	Achieved 2021
% of children with TB who are detected	35%	70%	45%
Paediatric TB treatment success rate	85%	90%	88%
% of children <5 years contacts with bacteriologically confirmed cases on TPT	13%	90%	45%

In 2020, the estimated TB incidence in Kenya for children under 15 years was 16,600 (8,900 for 0-4 years and 7,700 for 5-14 years). The estimated treatment coverage (previously referred to as case detection rate) was 52.2% for children under 5 years (4,646 notifications in this age group), 36.9% for ages 5-14 years (2,845 notifications) and 45.1% overall (based on the incidence estimates for 2020 and notifications for 2021). The estimated number of eligible child contacts aged under 5 years was 17,560 in 2020.³ The country has a high HIV prevalence and high rates of malnutrition in children and among TB patients.

3.5.4.1 Key findings, progress and achievements

DNTLD-P has a childhood TB focal person, supported by a functional Committee of Experts with good representation of stakeholders. They include: the DNTLP, NASCOP, Division of child and adolescent health, Division of nutrition, Ministry of Education, the paediatric association, academia, private sector practitioners, CSO and patient advocates, development and implementing partners.

³ <https://www.who.int/teams/global-tuberculosis-programme/data>

Case detection of paediatric TB

TB screening was routinely implemented at entry points, including paediatric and general outpatient departments (OPD), MCH and HIV clinics. Nonetheless, overall case detection remains low with 45% treatment coverage, with childhood TB contributing only 9.6% of all DS-TB in 2021 and 2-4% of DR TB between 2019-2021. Capacity building has been conducted on sample collection (nasopharyngeal and gastric aspirate), clinical diagnosis and chest radiography (CXR) interpretation. Use of stool as a specimen for gene-xpert testing is being piloted in 10 counties, although with a low yield.

Low index of suspicion was observed as in the case presented in Box 1, from a level 3 facility which illustrates a missed opportunity to recognize presumptive TB children during routine childcare. There was also low HCW confidence in making a clinical diagnosis of TB in children, with high reliance on bacteriological confirmation, which is infrequently obtained. In addition, lack of a practical decision algorithm to support diagnosis and treatment remains a key gap. Capacity building has been conducted on

A case of missed opportunity to detect TB in a child

A 1 year and 9 months old girl with a weight of 8kg (Z-3) presented to the facility. Her weight had not been plotted on the growth curve since the age of 6 months, with the available weights written alongside the curve. The last known weight was 8.7kg at 9 months. Her mother had brought her to the health center because of fever and lethargy and tested positive for malaria. There was no known history of TB contact and HIV exposure. The healthcare worker had prescribed treatment for malaria and paid no attention to the growth curve and possible underlying causes of weight loss and severe malnutrition.

sample collection (nasopharyngeal and gastric aspirate), clinical diagnosis and CXR interpretation. However, access to CXR is limited as it is only available in higher level facilities, and even though its free for children <5 years, the high transport expenses are a barrier to access. LF-LAM for children living with HIV is also unavailable after the completion of pilot implementation. GeneXpert stool testing for children was piloted in 10 counties (SOS processing method), however, the yield was lower than expected. The proportion of extrapulmonary TB (EPTB) in children between 5 and 9 years is relatively high at 29%, likely due to classification of intrathoracic lymph node TB (the most common form of intrathoracic TB disease in young children) as EPTB. This has been revised to PTB in the 2022 WHO guidelines. Figure BF2 shows most children under 5 years are clinically diagnosed.

Contact investigation and TPT

Active contact investigation is routinized in most facilities, with a few counties expanding beyond household contacts observing a good yield. The most recent integrated guideline for TB expands the age group eligible for TPT to include adolescents, with the introduction of 3RH for HIV-negative contacts aged less than 15 yrs. Further, strong linkage between community and facility supporting contact investigation through community health volunteers (CHVs) was noted.

However, the review documented reports on stock-outs of RH FDC for continuation phase treatment and TPT due to late arrival of stocks, possibly due to limited recording of the additional utilization for TPT. Similarly, stock-outs of INH were noted, with limited caregiver and community awareness on and demand for TPT.

Clinical management

The treatment success rate among children was high at 88% for the 2020 cohort. Notably, use of child-friendly formulations of first line drugs (FLD) that is RHZ, RH and E was observed, however, their supply was found to be irregular. Child-friendly second-line formulations were recently procured nationally and awaiting distribution. There is routine nutritional assessment at higher level facilities, with high rates of malnutrition were observed as follows: among <5yrs 39% had severe malnutrition and 14% had moderate malnutrition; among 5-9 years, 16% had severe malnutrition while 6% had moderate malnutrition. There was erratic supply of nutrition commodities. HIV testing in children and adolescents with TB was 95% with 95% of TB/HIV co-infected patients initiated on ART, a testament to successful integration of TB/HIV services. However, treatment success rate is lower among children and adolescents with TB/HIV, with higher mortality compared to those

who are HIV-negative. Mortality is also relatively high in HIV-negative children aged <5 yrs and in children with DR TB aged between 5 and 14 years. Mortality audits are needed to better understand the underlying causes of this high mortality.

Training, mentorship and implementation research

A 2-day training curriculum based on the integrated guidelines is in place and has been cascaded nominally to all counties, with further roll-out of the trainings planned at county and sub-county level. Additional modules in development include adolescent TB and school health. However, on-the-job mentorship activities to support and strengthen implementation are limited. A number of implementation research projects have been conducted or are underway e.g., CaP-TB project, TB REACH 7 project. A gap remains in the utilization of routine programme data for operational research projects by local researchers. Key strategic gaps towards national, regional and global targets were the remaining low case detection in children and young adolescents for both DS- and DR TB; important gaps in the capacity to make a decision to start treatment for paediatric TB; limited availability of commodities for the management of child and adolescent TB (child-friendly formulations, nutritional supplements); addressing adolescents as a key age group with high risk of TB and specific behavioral risks and associated needs and limited community awareness and demand for child and adolescent TB services.

Opportunities identified during the review included:

- Adoption of new WHO recommendations and guidance (2022 guidelines and operational handbook), as follows:
 - Expand the use of Xpert Ultra and MTB/RIF on all paediatric specimens including stool
 - Treatment decision algorithms for the diagnosis of PTB children under 10 years
 - Shortening treatment for children and adolescents with non-severe TB to 4 months (2HRZE/2HR) and alternative treatment regimen (6HRZEto) for TB meningitis; In addition, use of BDQ and DLM as part of all oral regimens in children with MDR/RR-TB
- Strengthen multisectoral collaboration and private sector engagement to increase screening and diagnosis in children and adolescents
- Involvement of paediatricians and other experts at county level to drive childhood TB communities of practice

3.5.4.2 Key Recommendations

- Strengthen active contact investigation approaches with increased use of digital CXR, especially in facilities with low yield
- Training of all HCWs, followed by regular on-job mentoring and clinical supportive supervision at all levels
- Consider adopting the integrated treatment decision algorithms from the 2022 WHO operational handbook (as proposed above)
- Strengthen quantification and forecasting, for paediatric medicines FDC for treatment and TPT
- Include adolescents as targeted population in the new NSP, covering establishment of adolescent-friendly TB and TB/HIV services
- Enhance awareness and demand for child and adolescent TB services
- Explore differentiated models of care for children and adolescents in areas with access barriers (e.g., long distances, harsh climate, low income, limited transport)

3.6 TB IN VULNERABLE POPULATIONS AND CO-MORBIDITIES, INCLUDING HIV

3.6.1 TB and HIV

Strategic interventions prioritized in the NSP targeting TB/HIV include:

- 1) Strengthening integrated community TB/HIV case finding
- 2) Strengthening TB case detection among PLHIV in care within the health system
- 3) Reducing mortality among HIV positive TB patients
- 4) Sustaining proportion of PLHIV initiated on TPT
- 5) Strengthening TB/HIV coordination bodies
- 6) Scale up TB/DM collaborative management

Performance against the NSP targets

Table 8 Performance indicators for TB and HIV against NSP targets

Outcome Indicator	Baseline	Target (2023)	Status 2021
Proportion of registered TB patients (all forms) with documented HIV status	97%	100%	97%
Proportion of HIV - positive TB patients started on ART	95%	100%	97%
Treatment success rate among HIV positive TB cases	79%	85%	79%*
Proportion of PLHIV initiated on TB Preventive Therapy	65%	90%	80%**

* 2020 Cohort

** PEPFAR data for all PLHIV currently on ART

Whilst there is indication that the NSP targets for TB/HIV might be within reach, some challenges were still noted which need to be addressed in order to optimize the TB/HIV response. Only 51% of people estimated to have HIV-positive TB were notified in 2020, pointing to the need to improve case detection. High death rates during TB treatment were reported among people with HIV – averaging 11% nationally (and as high as 30% in some counties), compared with 4% among people without HIV. Cross-cutting challenges were noted, including stockouts of TB and HIV commodities as well as limited HR capacity to conduct supportive supervision, and monitoring and evaluation of quality TB/HIV service delivery. There are no targets for other comorbidities within the monitoring and evaluation framework and reviewers found that implementation of collaborative activities for other comorbidities was limited.

3.6.1.1 Key findings, progress and key achievements

Strengthening TB case detection of HIV-associated TB within the health system

As at 2021, data indicated that the country has made gains in the TB/HIV response with targets almost attained across all the areas, including for TB screening among people with HIV. It was noted that policies, tools and job aids for TB and HIV, including the latest Integrated guidelines, were largely in place. HIV testing rates have remained high in TB patients at 97% as compared with all people with HIV who know their status at 96%. The TB screening rate among people attending HIV care is also high at more than 90%. However, the yield is on the decline, with latest reported data showing 2% yield at the national level, which could be a result of limited sensitivity of symptomatic screening among PLWHIV, improper documentation of elicited TB-related symptoms, poor quality of delivery of symptom screening, or stigma affecting the accuracy of patient responses to symptomatic screening. Screening is prompted by the EMR system and is a required data entry field. Where there is no EMR system, paper-based ICF cards are used to document TB screening status. Additionally, MOH 257, the HIV clinical encounter forms, also have a field for indicating TB screening status.

Widespread stock-out of GeneXpert cartridges is likely to have a negative impact on diagnostic confirmation among PLHIV with presumptive TB for whom a more sensitive diagnostic tool is critical.

Reducing mortality among HIV positive TB patients

Coverage of antiretroviral therapy among people with HIV/TB has slightly increased from baseline to 97% as compared with 86% of all PLHIV. TB/HIV cases presented with advanced HIV disease, resulting in a higher case fatality ratio at 11% compared to 4.5% among HIV negative patients. In addition, 76% of those who died had moderate or severe malnutrition. The patient centered model of integrated care with one clinician reviewing the patient for both TB and HIV was the most common model. However, in large referral facilities as well as private sector, TB and HIV services are delivered separately and on different days. The review found some evidence of engagement of community forums to improve uptake and demand of TB/HIV services in a number of counties through CHVs, chief's barazas, community ART clubs (CAGS), schools and colleges. However, it was noted that this element could be further scaled up, in coordination with NASCOP and the CASCOs using the untapped army of CHVs to encourage earlier presentation.

Sustaining proportion of PLHIV initiated on TPT

While the 80% target of TPT initiation among all PLHIV currently on ART has been surpassed, completion rate was 69% in Q4 21, UNAIDS. Further, data show a notable reduction in TPT coverage among people *newly* on ART from 91% in 2020 to 31% in 2021. A nationwide stock out of TPT regimens was observed during the review could contribute to this, as well as failure of initiation among PLHIV eligible for TPT.

Strengthening TB/HIV coordination bodies

TB/HIV coordinating bodies were mostly in place and meeting for joint data review, technical support and coordinated supportive supervision. However, functionality was varied, with lack of resources (human and financial) cited as barriers to effective coordination. These were also largely, supported by partners.

3.6.1.2 Main challenges and areas of improvement

- Symptom screening has been demonstrated to have lower sensitivity among people receiving ART
- Sub-optimal testing using mWRDs (due to stockouts of Xpert cartridges, outages of GeneXpert power supplies), the absence of national policy on LF-LAM and limited access to CXR for screening will likely result in suboptimal case detection rates and higher mortality among this most at-risk population.
- High case fatality ratios were observed in TB/HIV coinfecting patients, with advanced disease and with under-nutrition were noted as key drivers for the high mortality rates. Stockouts of HIV test kits, CRAG test, viral load tests, CD4 tests, fluconazole, and nutrition supplements were reported.
- TPT completion rates were found to be low at 69% in Q4-2021, whereas stockouts were preventing initiation of TPT on other eligible PLHIV.
- Reduced capacity for supportive supervision, and monitoring of TB/HIV collaborative activities due to overlapping roles of some the TB coordinators doubling up also as the main TB clinician
- High patient costs were reported in facilities where patients had to attend separate clinics for TB and HIV, with this level identified as a barrier to access and adherence
- Whilst HIV services have mostly upgraded to an EMR, the TB services data recording system is paper-based posing a challenge in patient follow-up, recording and reporting and data quality.
- Reporting on TPT coverage by Kenya to UNAIDS GAM on TPT has found higher numbers initiated on TPT reported to PEPFAR than reported to UNAIDS, reflecting an underestimation of TPT coverage nationally

- The policy of LF-LAM has not yet been adapted, uptake of which will also increase case detection and reduce mortality among this population.

3.6.1.3 Key Recommendations TB/HIV

- Increase TB case detection rates among PLHIV through:
 - Scale up and seek to subsidize costs to access to digital CXR, including for periodic screening for PLHIV that is aligned with routine HIV checkups
 - Expand access to mWRDs for rapid TB diagnosis among PLHIV (including through the use of high through-put platforms such as Roche Abbott, and by the uptake of policy on use of stool, blood and urine as specimens for mWRD diagnostic testing)
 - Adopt and scale up latest recommendations on lateral flow urine lipoarabinomannan assay (LFLAM)
 - Ensure systematic HIV testing of TB contacts and incorporate TB screening within targeted community HIV testing
 - Optimize use of mWRD, consider using high throughput platforms (Roche Abbott) and purchase of more point of care mWRDs to expand coverage to harder to reach areas.
- Establish a quality improvement framework and subsequent institutionalization of CQI to improve quality delivery of TB screening among PLHIV adults and children, diagnosis, and treatment and TB preventive treatment initiation and completion, including in private facilities.
- Incorporate TB screening services within targeted community HIV testing and provide TPT to those eligible. In addition, scale up one stop shop TB/HIV delivery models (one patient, one clinician), including in level 5, referral hospitals
- Expand network of CHVs and CAGs for service delivery and for stigma reduction to enhance TB screening and uptake of TB preventive treatment among PLHIV
- Increase and sustain capacity at the county, sub-county and facility to deliver the package of care on: TB/HIV & advanced HIV disease, undernutrition among TB patients, commodity management and data management
- Lobby for inclusion of prioritized TB comorbidities and essential commodities such as nutrition support within NHIF coverage essential package
- Strengthen TB/HIV collaborative mechanisms at all levels and improve joint planning, implementation and data review at all levels including in the following areas: Funding, Policy guidance formulation, Human resource capacity, Monitoring and evaluation, joint supervision and mentoring, CQI, PSM, PSM, design models of service delivery and PPM and community engagement

3.6.2 TB IN VULNERABLE POPULATIONS

Table 9 Vulnerable populations and interventions

Key populations	Interventions
PLHIV	Collaborative TB/HIV activities (covered in 3.6.1 above)
Undernourished	Assessment, counselling and co-management of undernutrition and TB
People with diabetes	Collaborative TB/DM activities
Prisoners	ACF, TPT and other services as appropriate
Healthcare workers	ACF, TPT and other services as appropriate
People who misuse alcohol and PWID	Integrated TB/HIV screening and care among PWID (both institution and outreach (MAT)
Men 25-34 years	Small scale ACF among Matatu screening matatus etc.
Mobile populations and pastoralists	ACF and outreach
Refugees, migrants, cross-border populations	ACF and outreach

People with cancer/undergoing immunosuppressive therapy	
People who live in urban slums	
Elderly over 65 years	
Homeless/street families, MSM	
People in congregate settings/factories/plantations/boarding schools	

The NSP envisioned to increase case detection and improved treatment outcomes among vulnerable populations.

1. Engagement of key populations in planning, implementation, monitoring and evaluation of TB care.
2. Prioritize systematic screening of key populations based on contribution to burden.
3. Service integration into existing health programs targeting key populations
4. Implementation of primary prevention in high-risk occupations

These vulnerable populations and the targeted interventions are shown in below:

3.6.2.1 Key findings and achievements

The targeted interventions for the above-mentioned vulnerable populations was covered under different sections of the NSP. The review evaluated the performance of the program for people living with HIV, and people with diabetes, the undernourished (all three addressed under a separate reporting areas), prisoners and healthcare workers. The Integrated guidelines for tuberculosis, leprosy and lung disease clearly lay out approaches, protocols and tools for supporting activities to address TB among vulnerable populations, both in terms of finding and addressing TB among the populations, as well as in finding and addressing vulnerabilities among people with TB. Screening for vulnerabilities among TB patients for conditions that can affect treatment such as mental health, drug and alcohol use disorders, and smoking was also evident. Data are also collected in the TB recording tools on drug and alcohol use, diabetes, and on age and sex. The review also found that targets set out in the NSP M&E framework relate only to HIV and undernutrition, as they might be the driving factors behind the TB epidemic in Kenya and thus a reflection of the DNTLD-P's prioritization.

Varied levels of service integration for the different populations was observed, depending on infrastructure, capacity, or maturity of integrated service delivery (TB/HIV vs TB/DM) programming. Active TB case finding was noted during the review on a more routine basis among people with HIV, people with diabetes, as well as prisoners. TB screening was also noted in people who inject drugs, matatu drivers, mobile populations, police cell entrants, on a smaller scale basis. Routine health care workers surveillance was also observed in some counties visited. Primary prevention was noted among HCWs who are usually screened for TB annually and are eligible for TPT.

3.6.2.1.1 TB Care in prisons settings

Regular active case finding with symptom screening is being conducted in most prisons, on entry and thereafter at varying frequency, depending on the prison. Similar 'leakage' challenges as described in the ACF section, were also identified. Healthcare is accorded to prisoners for free and covered by NHIF, with people with TB or HIV receiving a double ration of food and nutrition supplements.

The latest policies and data tools were largely in place, with some prisons documenting outcomes for all prisoners who had been released or transferred. There was linkage and follow-up for those released prior to treatment completion at the community level through linkage assistants supported by implementing partners. The review team noted variable progress in implementation of TPT services in prisons. While some prisons received TPT commodities, trained staff and offered TPT to all eligible inmates (except children) others are awaiting formal communications from the prison authorities before starting inmates on TPT. All prisons have had roof turbine vents installed to improve air circulation for TB/COVID-19 IPC, with quarantine facilities provided for inmates with TB and DR TB. However, ventilation and lighting in the TB isolation cells observed was deemed inadequate. Linkage to ART services as noted to be high among HIV positive prisoner, although

screening for viral hepatitis is not yet in place as recommended as part of the comprehensive package. In some prisons, inmates are enrolled into a vocational skills training programmes and linked to a stable job or income generating activity on discharge.

3.6.2.1.2 TB, DM and other comorbidities

The review found that collaborative activities for TB and diabetes are still very much at early stages. The integrated guidelines on tuberculosis, leprosy and lung disease clearly outline interventions and tools to address TB and diabetes, as well as other key comorbidities and health-related risk factors such as mental health disorders, alcohol and drug use disorders and smoking. Job aids for TB and diabetes screening have also been developed and recording and reporting tools capture data on TB screening among people with diabetes, and diabetes screening among TB patients, .The patient treatment card also captures data on comorbidities or risk factors such as mental health disorders, alcohol and drug use disorders and smoking.

TB screening among people with diabetes was noted as part of facility-based ACF, symptom screening for diabetes is also being implemented among TB patients, but not systematically. The same was observed for other comorbidities and risk factors. Co-management of TB and diabetes as well as mental health are implemented through referral due to staff capacity and availability of commodities. Diabetes is increasing in people with HIV, so there may be potential synergies for building on TB/HIV collaboration to lobby for inclusion of diabetes to be included within the essential package of services and for strengthened implementation.

3.6.3.2 Key challenges and areas of improvement

- Sub-optimal engagement of some key populations in planning, implementation, monitoring and evaluation of TB care was limited, (except for TB patients with HIV and DM). In addition, no activities towards creating demand for TB services among key populations were noted.
- Coordinating platforms for TB/DM activities were not observed at any level
- Supplies for diabetes testing and treatment come at an extra cost to the patient and this is a considerable barrier to scale-up.
- Screening of health care workers was found to be sub-optimal among HCWs; while in lower-level facilities, N-95 masks were not available for HCWs, while others did not know how to fit their masks
- HIV testing kit shortage was noted in some prisons, while in others HIV testing services were not routinely offered.
- Health facilities in prisons were found understaffed, poorly equipped or under-capacitated to meet the health needs of this population, including screening for TB, HIV and hepatitis
- Stock outs of essential commodities such as TB, HIV testing kits and TPT were reported in most counties.
- Hesitancy to taking up TPT was noted among healthcare workers in several counties due to fears of side-effects.

3.6.3.3 Key Recommendations

- DNTLD-P to systematically coordinate with other sectors, UN agencies and non-governmental stakeholders supporting vulnerable populations efforts in the country e.g. IOM/UNHCR/NASCO for cross border populations
- Capacity building of counties and sub-counties on mapping and prioritization of key populations based on local epidemiology and identification and working alongside key stakeholders and partners in supporting activities, setting targets, and monitoring the implementation
- Including key stakeholders and people with lived experience (ex-prisoners, Healthcare worker Union representative) in CoEs to finetune approaches for vulnerable populations.
- Strengthen routine health care workers surveillance at all levels
- DNTLD-P and counties to coordinate with NASCOP, Mol and partners to assure consistent availability and equitable access to a comprehensive package of quality care for screening, prevention and care for TB, HIV, viral hepatitis and other comorbidities for prisoners.
 - Assess and build capacity as appropriate for prisons (staff, training, supervision, supplies, etc)

- Provide access to digital chest X-ray for systematic screening on entry, exit and periodically with related sensitization among inmates and prison staff
- Scale up TB preventive treatment for all eligible (and address stockout issues)
- Assess and address issues of size, ventilation and lighting of cells (inc. quarantine cells)
- Inclusion of targets for key populations in next M&E Frameworks to track implementation of interventions and outcomes
- Develop a plan for strategic national scale-up of recommendations for TB and each of the prioritized comorbidities as identified in the integrated guidelines, to include capacity building of healthcare workers, equipping, supply and health education
- Build capacity and harmonize TB, HIV and NCD recording and reporting platforms and digital information systems and tools, including for capture of data from partners and private practitioners to facilitate patient follow-up and data analysis
- Establish coordinating platforms for TB and comorbidities at all levels for joint programming

3.6.4 NUTRITION

In Kenya, malnutrition is a major risk factor and key co-morbidity among TB patients with 49% of patients notified with TB and 56% with DR TB patients, suffering from under nutrition in 2021 according to the MoH Annual TB report. The current NSP proposes to reduce the impact that malnutrition has on the treatment outcomes of TB patients through the following strategic interventions: Strengthening collaborations and partnerships across sectors and with relevant ministries, ensuring universal nutritional assessment for all TB patients, optimization of nutritional management for all eligible TB patients, strengthening systems surrounding nutrition commodity forecasting, quantification and supply chain management and service integration through bidirectional screening for TB within nutrition and diabetes clinics.

Performance against the NSP targets

Table 9 Performance indicators for nutrition interventions against NSP targets

Outcome Indicator	Baseline	Target	Achieved 2021
Proportion of TB patients who are evaluated for nutritional support	82%	100%	96.7%
Proportion of eligible malnourished TB patients who have accessed appropriate nutrition support	40%	95%	24.7%
Mortality among malnourished TB patients	13%	5%	6.6%

3.6.4.1 Key findings, progress and achievements

- The review noted that nutritional assessment was being done for all TB patients. In some facilities TB and Nutrition services are well integrated and in others, referral systems to the nutrition clinic for undernutrition management were also available.
- Functional anthropometric equipment(s) were available at TB points of service. Vitamin A and pyridoxine were readily available to all TB patients.
- Some counties had County Nutrition Technical Forums (CNTFs) in place, these provide technical guidance on nutrition interventions and practices
- Vitamin A and pyridoxine were readily available to all TB patients

3.6.4.2 Main Challenges and areas of improvement

- Prolonged stock outs of therapeutic feeds and erratic supply of some nutrition commodities for care and management of malnourished TB patients
 - Nutrition interventions found to be underfunded with no evidence of budgetary allocation

Capacity gap among HCWs on nutrition management in TB. Notably, sub optimal nutrition staffing levels and high staff turnover in a number of health facilities

- Nutritionists are unable to reconcile their records (MOH 407A &B) with TIBU, due to limited access to the platform. Data on nutrition in TB is therefore sub-optimal
- TB screening was unavailable at the nutrition service points, attributable to lack of TB screening training among nutritionists.

3.6.4.3 Key recommendations

- Advocacy at national and county levels to have funding for nutrition commodities and strengthen supply chain management to ensure steady supplies
- Multi-sectoral approach and collaboration (Inter and Intra) to address the determinants/risk factors of malnutrition as well as linking program to food security avenues and social security for malnourished TB patients
- Build capacity of HCWs on nutrition assessment, screening for TB (among nutrition staff) and optimal care and management of malnutrition in TB
- Improvement of linkage of nutrition registers and TIBU numbers on TB patients managed for malnutrition.

3.7 LEPROSY

Strategic interventions prioritized in the NSP towards leprosy control included:

- 1) Strengthening the political commitment on leprosy, promoting partnership of state and non-state actor and budget allocation at national and county levels.
- 2) Active case finding through creation of community awareness, household contact screening and HCW training to promote early case detection.
- 3) Strengthening surveillance systems through revision of data capture tools and including leprosy in supervision checklists.
- 4) Promote disability prevention and management to improve quality of life among leprosy patients

Performance against the NSP targets

Table 8 Performance indicators for Leprosy against NSP targets

Indicator	Baseline	Target	Achievements (as at 2021)
Proportion of New Leprosy Cases with Grade 2 Disability (G2D)	25%	<10%	14%
Proportion of children among new leprosy cases	6%	3%	2.6%

3.7.1 Key findings and general observation

Leprosy control is jointly implemented with TB control by the DNTLD-P at national, county and sub-county levels. This also includes supportive supervision. There is a focal person responsible for oversight of leprosy issues at DNTLD-P. Old versions of R & R tools available at facility level. Leprosy data is reported to DNTLD-P through *TIBU*.

Leprosy control was included in most county and subcounty strategic as well as annual work plans. Leprosy services were available in designated health facilities, with clinical review and ordering of drugs done by the SCTLCS.

Although there has been a steady increase in leprosy new case detection (NCD), with 6 additional counties that did not report new cases in 2019 doing so in 2020, leprosy NCD was noted to be low across most counties. This is attributable to knowledge gaps across all levels, lack of funding for leprosy control activities especially at county level and lack of IEC materials.

Despite the decline in proportion of new leprosy cases with G2D to 14%, this is still high, indicating delayed detection of new cases. While the NSP target was achieved, detection of new cases among children signifies on-going community transmission of leprosy. The proportion with

multibacillary leprosy in the endemic counties reviewed has been consistently >95%, a testament of the high burden of leprosy in the community. 52% of leprosy cases reported in 2019 were released from treatment implying that there is room for improvement in case-holding across the counties. A high proportion (48%) of cases enrolled on treatment in 2019 had unfavorable treatment outcomes. Overall, strategies and structures to support early case finding (active screening at HF and community level, contact investigation, management and rehabilitation for people affected by leprosy who have disability) are inadequate at all levels.

3.7.2 Key recommendations

- Additional key leprosy indicators (MB and PB completion rates, % of women among new cases detected) should be included in the NSP priority targets to mainstream gender and quality of care in leprosy services.
- Strategies promoting NCD e.g., cluster approach to new case finding, household contact tracing, community engagement and stigma reduction should be implemented.
- A clear funding line dedicated to leprosy interventions should be developed at national and county levels.

3.8 LUNG HEALTH AND POST-TB CARE

The integration of lung health in TB programming is novel and essential. At the national level, a focal person has been assigned for lung health, which is key in driving the programme. The approach to lung health includes a focus on asthma, interstitial lung disease, COPD, bronchiectasis and lung cancer.

3.8.1 Key findings, progress and achievements

- Lung health services are mainly offered at level 4 and 5 health facilities, where lung health equipment such as nebulization machines, oxygen concentrators, PEF meters and pulse oximeters are available.
- DNTLD-P has a strong partnership with the Respiratory Society of Kenya (ReSOK), and has placed a number of spirometers in facilities, although overall coverage and availability of equipment relative to lung health conditions remains low.
- DNTLD-P has developed and distributed integrated guidelines on TB and lung health, which are closely aligned to the Global Initiative for Asthma (GINA) guidelines.

3.8.2 Main Challenges and areas requiring improvement

- However, a lung health training curriculum is yet to be developed, and the knowledge and skillset for managing lung health conditions is suboptimal.
- While under the current NSP the DNTLD-P aims to ensure that all DSTB patients completing TB care are followed up for a period of six months, while those completing DR TB care for two years, it was generally observed that follow up of patients was not documented.
- Lung health services are largely not linked to TB clinics.
- There are no recording and reporting tools for lung health post TB, thus no data on the status of lung health in the country
- Medications and consumables for lung health are in short supply, especially in the public facilities, and some are not included in the essential drug list.

3.8.3 Key recommendations

- DNTLD-P to mobilize resources to support lung health interventions, and support advocacy for inclusion of lung health in the National and County strategies and budgets
- Develop a training curriculum and build capacity on lung diseases.
- SCTLCS to provide supportive supervision and mentorship on diagnosis and management of lung health conditions
- TLD-P to urgently stabilize the supply of essential commodities and consider adopting WHO's Package of Essential Non-communicable (PEN) disease interventions for provision of lung health services at the primary care level
- DNTLD-P to urgently put in monitoring and evaluation mechanisms for tracking the coverage of lung health services, post TB lung inclusive.

- DNTLD-P and counties to develop a lung health scale up and decentralization plans

3.9 SUPPLY CHAIN MANAGEMENT AND ADSM

Supply of essential equipment and commodities to support diagnosis and treatment at health facilities is critical in achieving the EndTB targets that Kenya has committed to. The strategic interventions laid out by the NSP towards ensuring uninterrupted supply of anti-TB medicines and commodities include: -

- 1) Regular pharmaceutical supply chain audits envisaged to reduce proportion of TB treatment sites reporting stock outs of key commodities, reduce level of expiries at treatment sites; increase reporting rate through DHIS2 and increase order fill rate for TB medicines.
- 2) Strengthening DHIS2 to include LMIS indicators
- 3) Strengthening forecasting and quantification through HCW training
- 4) Active Drug Safety Monitoring

Performance against the NSP targets

Table 9 Performance indicators for supply chain and management against NSP targets

Indicator	Baseline	Target	Achievements (as at 2021)
Priority intervention 1: Strengthen supply for TB commodities			
Strengthen supervision/supply chain audits to prevent stock outs and expiries	<ul style="list-style-type: none"> • 70% expiries rate • 80% stock out rate • 20% data quality and reliability audits. 	<ul style="list-style-type: none"> • 0% expiries rate • 0% stock outs rate • 100% data quality and reliability audits. 	<ul style="list-style-type: none"> • 40% expiries in facilities • 25% stock outs rate** • 30% data quality and reliability audits.
Counties and sub counties to increase reporting rate through DHIS2 and increase order fill rate	45% reporting rate.	100% Reporting rate	98% reporting rate
Strengthen DHIS to include LMIS data for TB commodities	40% uptake rate in the systems.	100% uptake rate [^]	75% cumulative rate [£]
Strengthen coverage of the supply chain by enhancing maximum molecules and commodities available to the patient.	50 % order fill rate	100% order fill rate	80% cumulative order fill rate [§]
Strengthen forecasting & quantification (F&Q)	<ul style="list-style-type: none"> • 100% F&Q annual and annual review workshops. • 0% NOMT workshops on quarterly basis. 	<ul style="list-style-type: none"> • 100% F&Q annual and annual review workshops. • 100% NOMT workshops on quarterly basis. 	<ul style="list-style-type: none"> • 50% F&Q annual and review workshops. • 0% NOMT workshops on quarterly basis.
Priority intervention 2: Strengthen active drug safety monitoring and management (aDSM)			
Train Health care workers on aDSM for patients on second line treatment		<ul style="list-style-type: none"> • COE counties all SC and County pharmacists • Non-COE counties Referral hospital pharmacists 	<ul style="list-style-type: none"> • COE counties - 11 County pharmacists sensitized • Non-COE counties - 0
Reporting of ADR in PPB	<10%	100%	< 5%
Link TIBU & County allocation tool with PPB platform	0%	100%	Not done
Development of the ADSM and related tools.	0% done	100% developed tools.	100% developed ADSM and related tools.

**paediatrics, culture lab and nutrition commodities. (NB: these commodities have a short shelf life)

[^] for all the key programmatic commodities

[£] because lab commodities uptake is about 5% and Nutrition have not been included

\$ for therapeutic commodities, diagnostic and nutritional supplementation.
 NOMT - National Order Monthly Team
 COE-Centre of Excellence

Overall, PSM parameters have improved. Functional commodities and PV sectional management structures exist, with roles as described in *Figure 21* below.

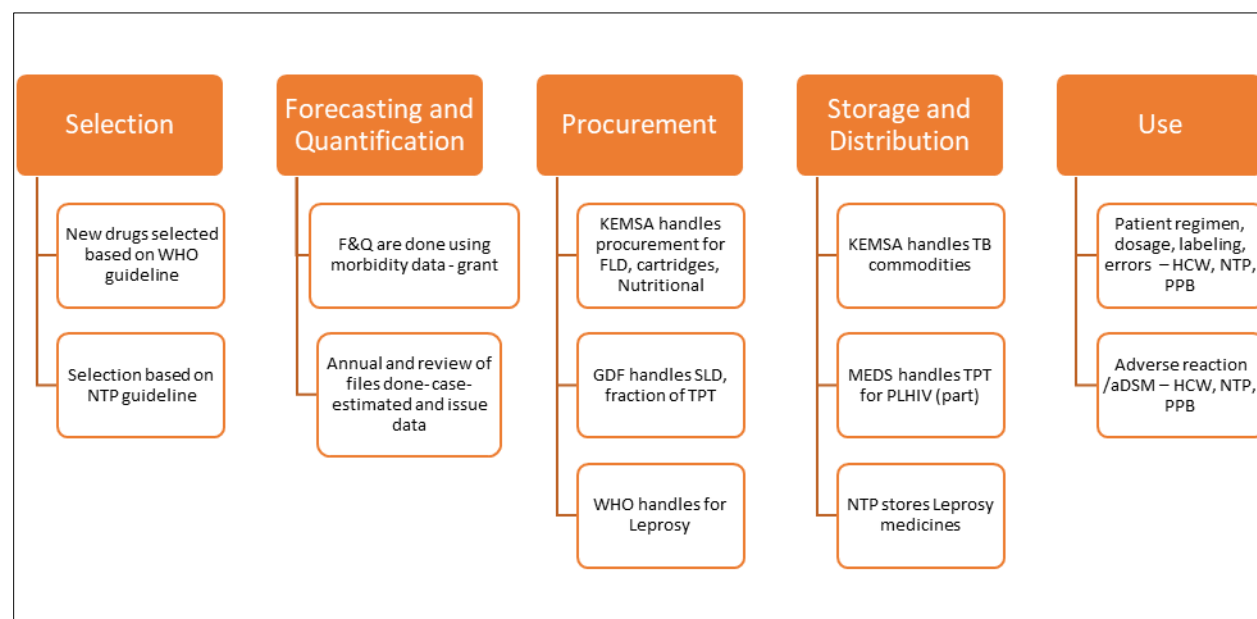


Figure 21 Functional commodities and pharmacovigilance management structure; source DNTLD-P, MoH

3.9.1 Key findings, progress and achievements

TB medicines

- There is government commitment to continue funding procurement of TB medicines. 70 % of budget for procurement of first line TB medicines (FLDs) is covered by the Government of Kenya.
- The national level health products and technology directorate has one TB focal officer that act as liaison officer to facilitate TB PSM related activities with MOH
- Functional commodities and pharmacovigilance management structures exist: Monthly National Order Management Team (NOMT), Commodity Security Management (CSM), procurement and aDSM committee meetings are held monthly.
- Regular forecasting and quantification have improved commodity security and reduced wastage.
- uninterrupted supply of second line TB medicines, adult FLD (patients packs) and leprosy medicines
- The country has in-country capacity for quality control (QC) and quality assurance (QA) through PPB QC laboratory and two WHO prequalified laboratories.
 - Post marketing Surveillance (PMS) is being conducted. The last PMS was conducted in 2019 and the next one is planned for 2022.
 - No TB medicines failed quality control testing in the past 12 months.
- TB medicines are registered by the pharmacy and Poisons Board (PPB) with exception of the new molecules and repurposed medicines. The Kenya Essential Medicines List, 2019 has been updated to include new and repurposed medicines.
- A functional web-based TB allocation tool for TB commodities in place, rolled out to all 47 counties and used for ordering, reporting and rationalization/allocation and projection of monthly TB orders.

- linkage of TB order management and reporting system (TB allocation tool) to KHIS (DHIS2) has improved LMIS data visibility for supply chain decision making.
- The key PSM monitoring parameters have improved. Some are above average – reporting rate - 98%, expiry percentage is lower, order fill rate is high (80%)
- Good storage and distribution practices are followed at KEMSA warehouses. Good distribution lead time (FLD<1month; SLD- 1 to 2 weeks).
- Sub county stores use the pull system (KHIS & TB allocation system) to order for supply of TB medicines.
- Development of guidelines and tools- PPB guideline on pharmaceutical waste management, aDSM road map and improved reporting and requesting tools
- COVID 19 commodities have been added to TB tools, the updated TB/ COVID 19 commodities tools were piloted in 5 counties under GF support.

Pharmacovigilance (PV) and PSM

- There is existence of a functional pharmacovigilance system under the coordination of PPB. Electronic adverse drug reaction reporting system is in place and most facilities have access to electronic PV forms though reporting is low.
- An aDSM implementation roadmap have been developed. The aDSM tool and auxiliary tools are in place to support aDSM activities and have been approved for use.
- 7 aDSM related tools for Medicines Therapeutic Monitoring (MTM) clinics were developed namely: Therapeutic Drug Monitoring Tool (TDM), Drugs Utilization Review Tool (DUR), Facility Causality Assessment tool (CA), Pharmaceutical care plan tool (PCP), Bioequivalence Testing tool (BET), Extemporaneous compounding Tool (ECT), Pharmacotherapeutics and substance abuse detox Tool(PSAD)
- aDSM monthly meeting are held and progress is well documented
- There are on-going efforts to strengthen capacity of health care workers to manage aDSM. Only 11 county Pharmacist of the Centres of Excellence (COEs) for TB participated and were sensitized. One operational research on aDSM was conducted in 2021

Laboratory, nutrition and leprosy commodities

Laboratory commodities are distributed alongside other TB commodities. The lab PSM personnel participate in the monthly commodities security meetings as well as F&Q meetings. Nevertheless, there has been erratic supply and severe shortages of GeneXpert cartridges and other lab commodities countrywide, due to inadequate funding but also poor F&Q and an early warning system: no tools for F&Q of lab commodities with underutilization of the *GxLIMS* system. Stock visibility at KEMSA warehouse is also opaque-the TB LIMS is not linked to KEMSA Warehouse Management System. There has been prolonged stockout of nutrition commodities. These are not included in the F&Q tools currently available and lack visibility in the pipeline order management tool. Supply has been a challenge due to high freight costs. There has been a stable supply of Leprosy medicines. Quantification and supply is managed by WHO with involvement of DNTLD-P. Ordering is needs-based and sent to the health facility where patient is being managed. However, periodic stockouts observed due to logistics constraints occasioned by the COVID19 pandemic. Distribution is outside of the TB system, and currently relies on USAID TB ARC.

3.9.2 Main challenges and areas requiring improvement

- Delays and challenges with procurement and supply chain due to the ongoing restructuring at KEMSA resulting in supply disruptions due to delayed approvals along the approval chain
- Capacity gaps among the new national PSM team and other stakeholders on TB medicines quantification and early warning system (QuanTB)
- Gaps in forecasting and quantification has resulted in excess stocks for some medicines with the risk of potential expiries, while for other medicines, resulting in risk in stock outs

- Inadequate funds to support activities to optimize TB supply chain systems such as: supportive supervisions or mentoring, conducting supply chain audit, aiding stock movement, distribution/ redistribution and disposal of expired medicines. This also includes operationalization of aDSM roadmap
- TB LMIS tools not linked to KEMSA Warehouse Management System, this makes effective commodity allocation and management difficult, this can potential lead to expiries
- Sub-optimal uptake of ancillary medicines at health facility level resulting in 60% of procured ancillary medicines expired
- Knowledge gaps observed among HCWs including pharmacy personnel on pharmacovigilance and commodity management leading to gaps in ADR reporting, documentation and inadequate FEFO practice.
- Sub optimal storage conditions at facility level – no thermometers, no temperature charts, space constraint, ventilation issues
- Lack SOPs, job aids for commodity management including dosing chart for patient pack constitution and TPT Daily Activity Register not available in some facilities.
- Delays in processing of import permit leading to delayed port clearance especially for second line TB medicines due to challenges with human resource at the respective directorate
- Minimal reporting of ADR to the PPB as TIBU system is not linked to PPB electronic PV system, so adverse events reported in TIBU are not reflected in the country’s data captured in the PPB reporting system

3.9.3 Key Recommendations

- Build capacity at the national level and other stakeholders on the use of Quan TB tool and sustain funding for forecasting and quantification bi-annual
- Streamline early initiation of procurement processes and expedite shipment so as to address bottlenecks to timely supply and distribution of commodities in the supply chain
- Mobilize resources to build capacity among HCWs and pharmacists on Pharmacovigilance/aDSM, supply chain and stocks management, supply chain audits, reverse logistics for unused commodities and disposal of expired medicines
- Align adoption of policy guidance of clinical/programmatic guidelines to commodities stocks so as to avert stock outs; as well proper sensitization on change of regimen to also ensure improved uptake of available stocks excessive wastage/expiries
- Resource mobilization for procurement of lab commodities, with linkage between KEMSA warehouse management system and TB LMIS for both to show real time stock data
- Streamline an integrated approach for distribution of leprosy, nutrition, laboratory and TB commodities to optimize existing support and resources
- Expedite the linkage of TIBU platform to PPB PV electronic system for a national overview on the burden on all TB related ADRs for decision making and prompt action
- Develop/adopt forecasting and quantification tools for laboratory commodities and build capacity of the national and county staff on forecasting and supply planning for laboratory commodities

4.0 EQUITY, ETHICS, HUMAN RIGHTS, GENDER & SOCIAL PROTECTION

To ensure a human rights and gender-based approach to TB management and care, this NSP proposed the following strategic interventions:

- 1) Sensitization of lawmakers, law enforcement agents and HCW on a rights-based approach in the management, treatment, care, and support of TB patients.
- 2) Removal of the legal, human rights and gender barriers to access of TB, leprosy and lung diseases services.
- 3) Monitoring and reforming laws, regulations and policies relating to TB, leprosy lung diseases.

- 4) Formation of intersectoral partnerships between the Ministry of Health (DNTLD-P) and other departments within government to embed TB, leprosy and lung diseases concerns.

While there were no formal targets, the review noted significant efforts towards the strategic interventions. These include establishing partnerships between DNTLD-P, Networks of TB-affected communities and civil society, which provide a channel for accountability and collaboration, capacity building of TB champions in 10 counties on human rights and gender (HRG).

4.1.1 Key findings, progress and achievements

The National TB Program has done initial assessments of the legal, policy, and gender gaps related to TB and Key populations. Though not to scale, these initial assessments informed the various chapters of the current TB strategy and the previous one. Incorporating human rights and gender in the National Strategic Plan as well as the development of an isolation policy have been documented as milestones.

There are established partnerships between the National TB Programme, Networks of TB affected communities and civil society. This has provided a good channel for accountability and collaboration. Media & educational campaigns done through Global Fund funding, CFCS grant on matters human rights and gender in partnership with the National TB programme. In addition, there have been GF-funded media and educational campaigns and an active national network of people affected by TB and CSOs. Program data is also segregated by age and gender, and there is a focal person focusing on HRG issues at DNTLD-P. The support for the Stop TB Challenge Facility has helped move forward some of the recommendations, including setting up an active National network of TB champions.

4.1.2 Main challenges and areas requiring improvement

- The absence of a costed operational framework for gender and human rights activities has slowed down the pace of implementation as well as made it difficult to assess the progress made.
- Many county TB coordinators did not have strategic plans that addressed human rights and gender issues, with many using World TB day as their only avenue of reaching out to the public on matters of TB, human rights, and gender.
- General lack of knowledge on HRG at all levels of implementation
- Minimal measurement, monitoring or remedies of and for TB stigma and discrimination
- Delays in accessing social protection packages (NHIF, monthly allowances) which is only available for DR TB clients excluding DSTB and Post TB clients
- TB services have not factored in People Living with Disability, especially those with hearing impairment
- Prison set up do not have isolation facilities and if they have they do not meet the minimum required standards as set out the Isolation policy
- 43 counties do not have isolation centres as envisioned by the TB Isolation Policy, with those with isolation facilities not meeting the minimum required standards as set out the Isolation policy
- Majority of facilities lacked a visibly displayed TB patient charter and those with, it is not translated into local language and made to be age appropriate and disability friendly

4.1.3 Key recommendations

- Strengthen coordination and structures for TB related human rights reporting at the national and county levels
- Development of a costed community rights and gender operational plan at national and county levels.
- Development of an M&E framework for HRG, with set output targets and indicators for HRG and social protection activities to systematically implement and monitor the strategic interventions in the NSP.
- Need for technical support from UN agencies and development partners on TB HRG issues particularly in operationalization of policies and assessments.

- Funding TB HRG interventions and enhance Community led monitoring interventions of service quality and to enhance peer support and community mobilization
- Improve multi-sectoral collaboration and accountability between the National TB program, TB Actors and other sectors at the National and County level
- Need for tailored services and programming for key and vulnerable populations depending on county context
- Sensitization of all stakeholders at all levels on TB equity, ethics and HRG issues pertinent to their sector, including public awareness on their rights and responsibilities including patient chapter
- Engage technical support from UN agencies and development partners on TB HRG issues particularly in operationalization of policies and assessments
- Need to operationalize policies launched at the National level, including the TB Isolation policy and ensure social support for MDR TB patients is availed to all

5.0 COMMUNITY SYSTEM STRENGTHENING AND ACCE

The *Kenya Community Health Policy 2020-2030* place people at the center of health care services. Based on the principles of Primary Health Care, the policy recognizes the role communities play in advocating and participating in their own health and the need for external and internal partner support. The community is recognized as a level of health service delivery (Tier 1) in the Kenya Health Policy (Figure TGB).

Proposed interventions captured in the NSP include:

- 1) Innovative patient centered communication methods
- 2) Building political support and establishing collaboration at all levels to help mobilize domestic resources
- 3) Empowering community actors, stakeholders and TB champions to inform, educate and support patients, patient families and communities through a coordinated engagement framework.
- 4) Community based systematic screening for KPs
- 5) Improving community- based access to TB prevention through Infrastructure support and enhanced referral mechanism

Performance against the NSP targets

Table 10 Performance indicators for community system strengthening against NSP targets

Indicator	Baseline	Target	Achievements (as at 2021)
Proportion of the people with symptoms of TB from the community that seek appropriate care from health facilities	40%	80%	**
Proportion of people with TB referred by CHVs and informal service providers	10%	25%	12%
**Measured through a referral proxy (# referred/ # reached and received a service at the community level). Data to be availed through AMREF.			

5.1.1 Key findings, progress and achievements

Reported coverage of community TB health services is high (100% of Basic Management Units in 2019)⁴ although there are variations from country to county, with only 12 out of 47 counties having made specific budgetary allocation towards community health.⁵

Significant investment by Global Fund (>5M USD) and other donors has been made towards community systems strengthening and ACCE, with the community component of the current GF grant focusing on sustaining community TB service delivery and mending existing gaps, including the sub-optimal linkages between community systems and health facilities, and improve CHVs contribution to notified TB cases. Despite these investments, the 2019 Global WHO TB report indicates that communities contribute 10% of notified TB cases, below the NSP target of 25%, which is corroborated by DNTLD-P's data as shown in Figure 22 below.

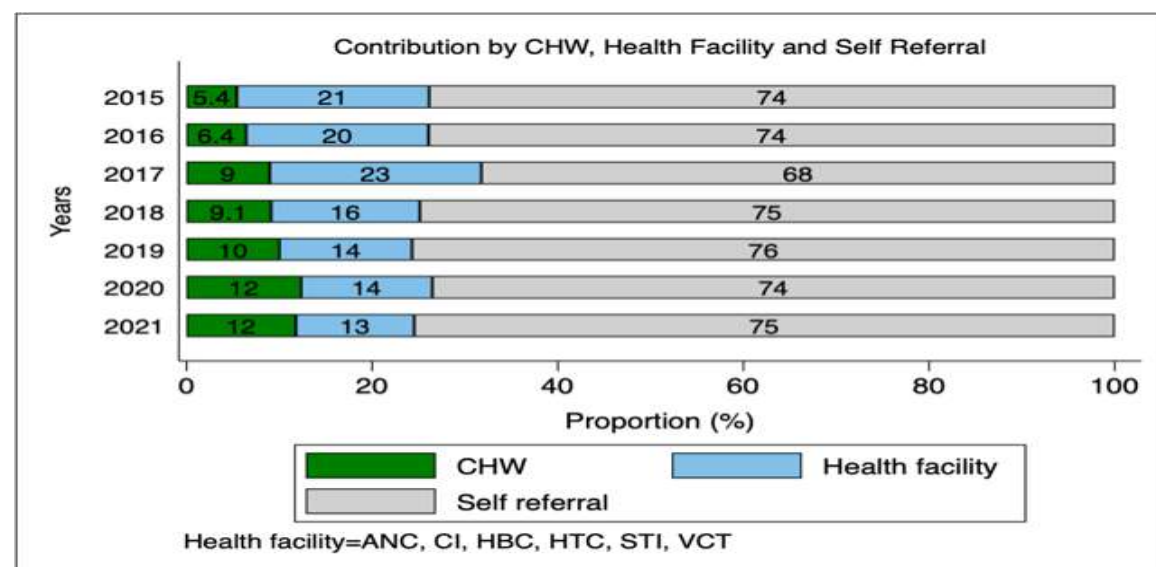


Figure 22 Contribution of TB cases by the community interventions notified in Kenya 2015-2021; Source DNTLD-P, MoH

Possible explanations point to under-reporting of community contributions, limited capacity at the community and facility level to document community contributions, and/or a parallel reporting system of contributions captured by AMREF (the main non-state GF recipient) not making its way to the NTLN surveillance system.

Community system strengthening (CSS) is well supported by IPs, with activities geared towards engagement of CHVs for household contact screening and active case finding through the Kenya Innovation Challenge-TB Fund, with their involvement in data review to improve documentation and reporting of community TB activities. There has also been targeted TB screening outreaches, with community-led monitoring for TB being piloted in three sub-counties in different counties.

The main gap has been unstructured coordination, limited policies/ guidelines to support integration of TB and comorbidities, lack of an integrated M & E framework and sub-optimal linkages with health facilities. This is partly due to community TB care being heavily donor and partner driven, which also negatively impacts sustainability. e.g., a community stakeholders database sits at AMREF and not DNTLD-P. This is in spite there being a CSS TWG that coordinates community stakeholders and CSOs (hosted by AMREF), as well as an interagency coordinating committee (ICC) TWG. This lack of coordination could also be contributing to knowledge gaps among CHVs, as organizations could be training the same person(s) multiple times. At MoH level, the Division of Community Health has been leading efforts to develop an overall M & E framework for ALL community health activities. There needs to be better liaison and engagement between this division and DNTLD-P, to leverage other non-TB supported CHVs and ensure they are also engaging in TB-related activities during their household visits.

⁴ Global tuberculosis report 2020. Geneva: World Health Organization; 2020. License: CC BY-NC-SA 3.0 IGO <https://apps.who.int/iris/bitstream/handle/10665/336069/9789240013131-eng.pdf> (accessed 11 August 2021)

⁵ GF Funding request 2020-2022

Kenya has a diverse range of civil society actors engaged in community TB advocacy and resource mobilization. Boosted by the existence of a focal person at DNTLD-P, activities targeting ACCE include engagement with the parliamentary TB Caucus and Parliamentary Health Committee to CSOs to advocate for political commitment on selected TB issues such as budget allocation and disbursements. However, there is insufficient funds allocated for community TB and ACCE activities despite being included in the county work plans. There are draft SBCC strategy and community engagement/ACCE guidelines.

5.1.2 Key recommendations

- Develop a costed advocacy, communication and resource mobilization plan as part of the next NSP
- Set up mechanisms to adequately track and report community contribution to the TB response at national and county levels, with review and revision of community-related indicators.
- Finalize and disseminate key strategic and programmatic documents e.g., SBCC strategy, ACCE guidelines
- Establish differentiated models for outreach to vulnerable populations for TB services, coupled with awareness programs for stigma reduction
- Introduce/support locally appropriate community-led gender sensitive interventions to reach/sensitize communities

6.0 MONITORING, EVALUATION, RESEARCH AND VITAL REGISTRATION SYSTEMS

The priority strategic interventions identified to address MER gaps in the NSP include:

- 1) Upgrade and integration of *TIBU* with other EMR systems
- 2) Adoption of unique patient identifier for improved surveillance
- 3) Strengthening notification of people identified with TB by the private sector
- 4) Strengthening of monitoring and evaluation systems through development, review, printing and uninterrupted supply of data capture tools, algorithms, job aids with training on HCWs on use.
- 5) Implementation of the data quality improvement framework through strengthening of county-based data quality audits.
- 6) Building capacity for data utilization for decision making
- 7) Strengthen vital registration systems to address inadequate TB mortality data in the national vital registration system.
- 8) Engage in surveys and operational research to identify and address program implementation gaps.

Performance against the NSP targets

Table 11 Performance indicators for community system strengthening against NSP targets

Indicator	Baseline	Target	Achievements
Proportion of people with TB who are detected, but are not notified or started on treatment (initial loss to follow up)	21%	0%	Unavailable*
* No inventory study in the lifetime of the NSP			

6.1.1 Key findings, progress and achievement

A. Monitoring & Evaluation

Upgrade and integration of TIBU system with other EMR systems

The Kenya Public Health Act (Cap 242) mandates reporting of priority diseases, including TB. Monthly aggregate reporting is done through KHIS2, with near-universal reporting from public and faith-based organizations.

TIBU, the DNTLD-P case-based surveillance system is available for use by CTLCs and SCTLs, with the latter completing the case information from paper-based patient records and *TB 4* register at the facility during supervision visits. *T-bu Lite*, an android-based app version of *TIBU* designed for frontline HCW use as a point of care case capture platform is currently being piloted in 13 counties, with plans for scale up. *TIBU* is integrated with KHIS2, pushing data therein quarterly. Currently, there is a lag in data entry from the paper registers to *TIBU*, resulting in data discrepancies between KHIS and *TIBU*. EMR systems implementation is varied countrywide. Some EMR systems observed were not capturing TB screening information.

There is also a gap as *TIBU* is not interoperable with the commodity and logistics supply management systems, contributing to inefficiencies in data management.

Monitoring and evaluation systems

The DNTLD-P has a functioning M&E Technical Working Group, with a formal M&E plan tracking the achievement of key indicators set in the NSP. Most of the facilities visited have at least one TB focal person, which was inadequate for the high-volume facilities. Paper-based tools for recording and reporting (R&R) were available, and the TB clinic staff were well versed in their use, with systematic follow up of patients on treatment until their treatment outcome is determined. Consistent registration/notification of patients using *TIBU* was noted, although limited IT infrastructure curtails its use. However, these tools were numerous, resulting in increased workload and consequently data quality issues. National and county supervision visits were done regularly, including in private health facilities. SCTLs conduct support supervision visits to high volume facilities at least monthly and quarterly to low volume facilities. Stock-out of IEC materials for patient education on TB care & control was noted. In some facilities, the old registers are still in use.

Building capacity for data utilization for decision making

In many facilities, monthly summaries for TB indicators were displayed as charts on the TB clinics' wall

WHO data dashboards are still being developed and hence there is partial monitoring of key TB indicators. There was limited involvement of sub county and health facility health records information officers in validation and reporting of TB Data flow processes to the subcounty, due to limited capacity in analysis, use and communication.

Data quality improvement mechanisms

There was good data concordance between TB4, patient cards and *TIBU*. However, incomplete recording of some of the R&R tools were observed in many facilities, particularly the TB screening and presumptive TB tools outside of the TB clinic. This was attributed to lack of training on use and sensitization on importance of documentation in these units.

These supervisory visits are largely donor dependent and tended to be only funded for clinical aspects while laboratory and commodities are not supported to do routine supervisions for TB at county level.

IPs must be commended for supporting onsite data verification/data quality audits frequently. The integration of programme performance review with other health performance review/in-charges meetings in some counties is a notable achievement and which is resulting in better understanding of the programme by the county authorities.

Unique patient identifier for improved surveillance

The MOH has approved the framework for unique identifiers within the health sector, though legal challenges have stalled implementation of the unique *Huduma* number.

Surveys and operational research

At the national level, only 3 of the 19 planned ORs were carried out. In the counties visited, no OR on TB had been conducted in the last 3 years, due to lack of funds and capacity.

B. Vital registration systems

The overall coverage of civil registration of about 40% of the health facilities results in the underestimation of the death occurring at health facility. There is no death certification at the community level. Death certification dropped from 38% to 35% during COVID19 as the bodies were buried quickly and death registration was slowed by remote working of registration officers. Finally, there is low capacity to ascertain causes of death among health care workers. The country must be commended for the adoption of the ICD-11, which has Artificial Intelligence, in determining the causes of death. The ICD-11 is being developed and hosted in KHIS2, with MoH set to train 220 health care workers on this by end of April 2022.

6.1.2 Key recommendations

- Fast-track interoperability of TIBU with key EMRs e.g., *Kenya EMR*, the main HIV EMR system
- Prioritize the inventory survey to track performance against the indicator as outlined in the M&E framework/NSP.
- DNTLD-P to consider reducing the variables documented in various registers, and facilities task shifting register completion to non-clinicians to reduce their workload.
- Scale-up of *T-bu Lite* to allow primary point of care data capture.
- Timely and informed quantification, printing and distribution of TB reporting tools, ensuring that current versions of recording tools are supplied to facilities.
- Collaborate and outsource TB capacity building, including data use and conduct of OR, to training institutions and organizations with a good track record on the training of health workers.
- Expand ICD-11 to health facilities with realistic targets which need to be tracked and reported.

6.1.3 OPPORTUNITIES FOR OPERATIONAL RESEARCH

TB Care and treatment

The DNTLD-P to conduct an in-depth study to understand the drivers and causes of the decreasing trend in treatment success and increasing trend in deaths when segregated by age and equally look at the causes of death in PLHIV despite the high ART uptake

Programmatic management of drug resistant TB

- DR TB treatment outcomes in different contexts and factors affecting these outcomes
- Quality of care audits
- Feasibility of video DOT for DR TB in different contexts in Kenya
- Role of clinical decision support systems/artificial intelligence in addressing quality of DR TB care
- Incidence/prevalence of DR TB adverse effects and operational barriers/enablers to effective ADSM in the country.
- Reasons for late presentation to DR TB diagnosis.

Vulnerable populations

- Monitor additional yield of chest X-ray among prisoners
- Assess the effectiveness of interventions/projects to address TB in key vulnerable populations
- Scale up mortality audits, monitor timing of TB/HIV deaths and share lessons learnt

TB preventive therapy and Infection Prevention & Control

- Explore expected number of household/close contacts per bacteriologically confirmed TB patients
- Rates of TB infection among different target populations, such as contacts > 5 years of age, health care workers to inform national policy and identify need for testing for TB infection
- Ways to optimize access to chest X-ray for assessment of eligibility for TPT among contacts > 5 years of age, health care workers and other target populations
- How to enhance acceptance of contact evaluation by index TB patients including best practices such as disclosure counselling
- Ways to enhance referral to health facility for evaluation of eligibility for TPT following index patient home visits for contact evaluation.
- Review of quality of TB screening and identification of presumptive TB patients among PLHIV and contacts of TB patients
- Review quality of facility risk assessment for Airborne infection control
- Explore factors influencing successful completion of TPT, including 3RH, 3HP and 6H among different target populations
- Review and understand the proportions and at what point of time clients completed TPT develop TB disease

Equity, Ethics, Human Rights, Gender & Social Protection

- TB Stigma Index Survey
- TB Catastrophic Cost Survey
- Assessment of NHIF Coverage among TB patients
- County level mapping of Key vulnerable and underserved populations
- County surveys on gender and cultural norms affecting access to services

Community system strengthening and ACCE

- Differentiated screening and patient support models (different target groups in different counties versus a one size fits all model)
- Imonitor App currently being piloted by AMREF (systems for capturing community data) to be part of TIBU or TIBU light for documenting community efforts to the TB response
- Operations research on the CHVs Facility based referral system (Is this the best way to capture community contributions or support TB services?)
- Outcomes/impacts of community-based training & advocacy

Supply Chain Management and aDSM

- Pharmacovigilance and adverse drug safety monitoring practices and reporting
- Impact of adverse events on quality of care

Public-private mix

- Incentives and enablers for uptake and sustainability of TB services by private health providers
- Cost effectiveness of different PPM models implemented in Kenya
- Impact of different PPM models on diagnostic delays and equity in access of TB services in Kenya

Drug Resistant TB

- DRTB treatment outcomes in different contexts and factors affecting these outcomes
- Quality of care audits
- Feasibility of video DOTS for DR TB in different contexts in Kenya
- Role of clinical decision support systems/artificial intelligence in addressing quality of DRTB care
- Incidence/prevalence of DR TB adverse effects and operational barriers/enablers to effective ADSM in the country
- Reasons for late presentation to DR-TB diagnosis

7. ANNEXES

Annexe 1: Local reviewers team members

Carol Asin	MOH-DNTLD-P	David Kimosop	MOH-DNTLD-P	Margaret Mburu	CDC	Joel Kangangi	Senior TB Expert
Aiban Ronoh	MOH-DNTLD-P	George Oballa	MOH-DNTLD-P	Ernest Makokha	CDC	Daniel Kibuga	Senior TB Expert
Silas Kamuren	MOH-DNTLD-P	Moses Kigen	MOH-DNTLD-P	Judy Mwaluko	CDC	Samuel Misoi	Senior TB Expert
Jacqueline Kisia	MOH-DNTLD-P	Mary Wambura	MOH-DNTLD-P	Herman Weyenga	CDC	Amos Kutwa	Senior TB Expert
Lydia Kamau	MOH-DNTLD-P	Stephen Macharia	MOH-DNTLD-P	Abraham Katana	CDC	Ego Agere	Senior TB Expert
Sam Githui	MOH-DNTLD-P	Rhoda Pola	MOH-DNTLD-P	Kimberly McCarthy	CDC	Joshua Limo	PS Kenya
Dickson Kirathe	MOH-DNTLD-P	Dorothy Mibei	MOH-DNTLD-P	Julius Oliech	CDC	Evaline Kibuchi	STOP TB-Kenya
Fiona Muhiri	MOH-DNTLD-P	Adano Godana	MOH-DNTLD-P	Margaret Mburu	CDC	Oduor Otieno	DPHK
Rosemary Muroria	MOH-DNTLD-P	Godana Mamo	MOH-DNTLD-P	Ernest Makokha	CDC	John Burton	UNHCR
Joyce Kiarie	MOH-DNTLD-P	Ambrose Juma	MOH-NASCOP	Judy Mwaluko	CDC	Teresa Simuyu	USAID
Simeon Ndemo	MOH-DNTLD-P	Dorothy Mwangae	MOH-NASCOP	Stephen Wanjala	CHS TB ARC II	Diana Kemunto	USAID
Abdille Nur Farah	MOH-DNTLD-P	Nellie Mukiri	MOH-NTRL	Anne Masese	CHS TB ARC II	Edmon Obat	USAID
Jacqueline Limo	MOH-DNTLD-P	Beatrice Kinaiya	MOH-NTRL	Rose Wandia	CHS TB ARC II	Immaculate Kathure	USAID
John M. Mutisya	MOH-DNTLD-P	Jack Irungu	MOH-DDSR	Dennis Oira	CHS TB ARC II	Philip Owiti	USAID
Timothy Kandie	MOH-DNTLD-P	Athanas Omonyi	MoH	Simon Wachira	CHS TB ARC II	Maurice Maina	USAID
Lilian Kerubo	MOH-DNTLD-P	Christine Wambugu	MoH-Child Health	Lorraine Mugambi	CHS TB ARC II	Eunice Omesa	WHO
Silas Kamuren	MOH-DNTLD-P	John Wanyungu	MOH- DCH	Patrick Angala	CHS TB ARC II		
Jeremiah Okari	MOH-DNTLD-P	Rosemary Muroria	MOH-Nutrition	Brenda Mungai	CHS TB ARC II		
Omar Abdullahi	MOH-DNTLD-P	Dorothy Adongo	Bungoma County	Wandia Ikua	CHS TB ARC II		
Martin Githiomi	MOH-DNTLD-P	Saumu Wayuwa	Mombasa County	Kennedy Muimi	CHS TB ARC II		
Sora Jatani	MOH-DNTLD-P	David Mureithi	Laikipia County	Wanjiru Githieya	CHS TB ARC II		
Boru Okotu	MOH-DNTLD-P	Timothy Malika	Kisumu County	Dan Rono	CHS Tegemeza		
Catherine Githinji	MOH-DNTLD-P	Emmy Annoh	Vihiga County	Virginia Karanja	CIHEB		
Elvis Muriithi	MOH-DNTLD-P	Polly Kiende	Tharaka-N County	Phillip Nyakwana	CSO/KCM		
Wesley Tomno	MOH-DNTLD-P	Peter Kimuu	National Treasury	Felix Mboya	EGPAF		

Mercy Nyangaresi	MOH-DNTLD-P	Bernard Langat	AMREF	Michael Macharia	KCCB		
Alice Tebes	MOH-DNTLD-P	Benson Ulo	AMREF	Maerro Lutta	KCCB		
Nduta Waweru	MOH-DNTLD-P	Edward Omondi	AMREF	Samson MUGA	KCCB		
Wendy Nkirote	MOH-DNTLD-P	Richard Kiplimo	AMREF	Virginia Karanja	CIHEB		
Drusilla Nyaboke	MOH-DNTLD-P	Joan Thiga	AMREF	Phillip Nyakwana	CSO		
Nicholas Ezati	MOH-DNTLD-P	John Mungai	AMREF	Allan Maleche	KELIN		
Evans Kituzi	MOH-DNTLD-P	Anne Munene	AMREF	Evans Amukoye	KEMRI		
Mutua Josphat	MOH-DNTLD-P	Titus Kiptai	AMREF	Jane Ong'ang'o	KEMRI		
Mary Nyaga	MOH-DNTLD-P	Christine Mwamsidu	AMREF	Albert Okumu	KEMRI-CDC		
Julius Mwololo	MOH-DNTLD-P	Philip Kimani	CHAI	Robina Momanyi	MTRH		
Felix Mbetera	MOH-DNTLD-P	Najma Salim	CHAI	Anne Njoroge	KNH		

Annex 2: List of external review members

Fausta Masha	WHO- Lead reviewer	James Malar	Stop TB Partnership
Annabel Baddeley	WHO	Stephen Anguva	Stop TB Partnership
Michel Gasana	WHO	Stephen John	Stop TB Partnership
Avinash Kanchar	WHO	Maria Ochigbo	Stop TB Partnership
Nkateko Mkhondo	WHO	Jacob Creswell	Stop TB Partnership
Francis Mhimbira	WHO	Chiji Osakwe	Stop TB Partnership
Debrah Vambe	WHO	Victoria James	Stop TB Partnership
Wilfred Nkhoma	WHO	Kruger Kaswaswa	Stop TB Partnership
Sabine Verkuijl	WHO	Enos Masini	Stop TB Partnership
Patrick Lungu	WHO	Refiloe Matji	Stop TB Partnership
Nomthandizo Lukhele	WHO	Sode Matiku	Stop TB Partnership
Brendan Kwesiga	WHO	Monde Muyoyeta	Stop TB Partnership
Hillary Kipruto	WHO	Beatrice Kirubi	Stop TB Partnership
Farai Mavhunga	WHO	Salama Mwatawala	Stop TB partnership
Brendan Kwesiga	WHO	William Wells	USAID
Simon Walusimbi	WHO	Peter Kerndt	USAID
Lana Syed	WHO	Cleophas D'auvergne	USAID
Christian Gunnerberg	WHO	Alex J Durena	USAID
Sarah Rylance	WHO	William Wells	USAID
Yves Barogui	WHO	Jamie Tonsing	Global Fund
Marek Lalli	WHO	Guy Stallworthy	BMG
Ernesto Jaramillo	WHO	Sam Acellam	FIND
Allan Maleche	Stop TB Partnership	Degu Dare	KNCV

Annex 3: List of Key Informant Interview Organizations

Ministry of Health	Other sectors & organizations
Chief Administrative Secretary	Kenya Legal & Ethical Issues Network on HIV and AIDS (KELIN)
Head, Directorate of Preventive & Promotive Health	WACI Health
Head, Strategic Public Health Programs	Lean on Me (Host TB Women)
Head, Division of Universal Health Care	
Representative, Division of Financing and Planning	
Rep, Division of NCDs	
Rep, National AIDS Control Council	
Rep, National AIDS & STI's Control Program	
Rep, Division of Childhood & Adolescent Health	
Rep, Pharmacy & Poisons Board	
Rep, Division of Health Informatics	
Rep, Kenya Medical Supplies Authority	
Rep, Division of Nutrition	
Head, National Public Health Laboratories	
Head, National TB Reference Lab	
Head, Occupational Safety & Health	
Head & Section Heads, National TB, Leprosy & Lung Disease Program (DNTLD-P)	
Partners	
US Centers for Disease Control and Prevention (CDC)	
United States Agency for International Development (USAID)	
AMREF Health Africa	
Elizabeth Glasier Pediatric AIDS Foundation (EGPAF)	
Kenya Conference of Catholic Bishops (KCCB)	
Stop TB Partnership	
Red Cross	
Clinton Health Access Initiative	
Center For Health Solutions (CHS)	
World Health Organization (WHO)- Kenya	
Multi-sectoral Engagement	
Christian Health Association of Kenya (CHAK)	
Ministry of Education	
Department of Correctional Services	
Ministry of Social Protection	
Parliamentary Caucus	
Kenya Health Federation	
Respiratory Society of Kenya (RESOK)	
Kenya Association of Private Hospitals (KAPH)	

Annex 4: List of counties and facilities visited during the review

<p>Busia</p> <p>Busia County Referral Hospital</p> <p>Amukura Health Centre</p> <p>Teso Sub-county Hospital</p> <p>Malaba Dispensary</p> <p>Holy Family Mission Hospital, Nangina</p> <p>Tanaka Nursing Home</p> <p>Khunyangu SC Hospital</p> <p>Busia GK Prisons Dispensary</p>	<p>Samburu</p> <p>Samburu Referral Hospital</p> <p>Archers' Post Subcounty Hospital</p> <p>Nile Medical Clinic</p> <p>Maralal Catholic Hospital</p> <p>Kisima Clinic</p> <p>Seketet Clinic</p> <p>Baragoi Sub County Hospital</p> <p>Wamba Catholic Hospital</p> <p>Maralal GK prison</p>	<p>Machakos</p> <p>Machakos Level 5 hospital</p> <p>Kathiani Level 4 Hospital</p> <p>Kalama Level 4 Hospital</p> <p>Shalom Hospital</p> <p>Masinga Level 4 Hospital</p> <p>Muusini dispensary</p> <p>Bishop Kioko Mission Hospital</p> <p>DASPharm Chemist</p> <p>Yatta Prison</p>	<p>Kitui</p> <p>Kitui County referral Hospital</p> <p>Mutomu Mission Hospital</p> <p>Blue Turtle Clinic</p> <p>Alliance Laboratory</p> <p>Mwingi Sub County Hospital</p> <p>Mwingi Medicare Hospital</p> <p>Kwa Vonza Dispensary</p> <p>Yatta Health Center</p> <p>GK Prison Kitui</p>
<p>Kericho</p> <p>Kericho County Referral hospital</p> <p>Litein AIC Mission hospital</p> <p>Londiani Sub County hospital</p> <p>Fort Ternan Health centre</p> <p>Sosiot Health centre</p> <p>Kapsoit Dispensary</p> <p>Unilever Central hospital</p> <p>Kericho GK Prison Health Centre</p>	<p>Taita Taveta</p> <p>Moi County Referral Hospital</p> <p>St Joseph's Shelter of Hope Hospital</p> <p>Wesu Subcounty Hospital</p> <p>Wundanyi Prison</p> <p>Bura Health Dispensary</p> <p>Taveta Sub County Hospital</p> <p>Kitobo Dispensary</p> <p>Manyani Prison Dispensary</p>	<p>Siaya</p> <p>Siaya CRH</p> <p>Ramula HC</p> <p>Ndere Chemist</p> <p>Got Agulu HC</p> <p>Mama Anne Odede (private)</p> <p>Ambira SCH</p> <p>Sikalame Dispensary</p> <p>Mbaga Mission HC</p> <p>Siaya GK Prison dispensary</p>	<p>Meru</p> <p>Meru Teaching and Referral Hospital</p> <p>Consolata Mission Hospital</p> <p>Mitunguu Medical services</p> <p>Genesis Laboratory</p> <p>Mitunguu Health centre</p> <p>Nyambene Sub County Hospital</p> <p>Mikinduri Sub County Hospital</p> <p>St. John's of God (Tigania hospital)</p> <p>Meru GK Prison</p> <p>Kangeta Prison Dispensary</p>
<p>Kiambu</p> <p>Thika level 5 hospital</p> <p>St Mulumba Hospital</p> <p>Gachororo health center</p> <p>Ruiru level 4 hospital</p> <p>Kiambu level 5 hospital store</p> <p>Amner dispensary</p> <p>Mercylight Private Hospital</p>	<p>Kajiado</p> <p>Kajiado Country Referral Hospital</p> <p>AIC Dispensary</p> <p>Magadi Hospital</p> <p>Oltepesi Dispensary</p> <p>Ongata Rongai Sub-County Hospital</p> <p>Clepa Chemist</p> <p>Oloitoktok Sub-Country Hospital</p>		

Sacred Heart hospital
Wangige level 4 hospital
Kiambu GK Prison

Kimana Health Centre
Kitengela Sub-County Hospital
GK Prison Kitengela

Kitui

Kitui County referral Hospital

Mutomo Mission Hospital

Blue Turtle Clinic
Alliance Laboratory
Mwingi Sub County Hospital
Mwingi Medicare Hospital
Kwa Vonza Dispensary
Yatta Health Center
GK Prison Kitui

Kirinyaga

Kerugoya County Referral
Hospital
Baricho Chemist/medical
laboratory
ACK Mt Kenya Hospital
Kianyaga SCH
Gatugura Dispensary
Kagio Hospital
Kangaru Dispensary
Kutus HC Dispensary
Thiba Health Center
Mwea Mission Hospital
Mwea Medical centre
Mwea GK Prison

Nairobi

Mama Lucy Kibaki Hospital
Mukuru MM Health Center
St. Mary`s Mission Hospital
Mutuini county HC
Kibera DO Health Center
St Joseph Edarb HC
Eastleigh Health Centre
Coptic Hospital
Getrudes Children Hospital
Baraka HC


Kenyatta National hospital

Nairobi Metropolitan Services
Nairobi Remand Prison

Annex 5: Roadmap towards the End of term review of the NSP 2019-2023

End- Term review for the National Strategic Plans for Tuberculosis, Leprosy and Lung Disease 2019-2023																								
NSP ETR Roadmap	Resources / Requirement(s)	Responsible Person	Frequency/Due date	Tracker (indicate when task was completed)	2021/2022												2022						Comments	
					Oct	Nov	Dec	Jan	Feb	March	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar		Apr
PHASE 1: PLANNING PHASE																								
Nomination of a secretariat	Zoom meetings	HoP	Done																					
Nomination of task force members	Zoom meetings	HoP	Done																					
Communication to secretariat and task force members	Official Letters, Memos	HoP/Dr Carol	Done																					
Secretariat meetings	Zoom meetings	Dr. Carol/Alban Rono	Weekly/Wednesdays																					
Taskforce meetings	Zoom meetings	HoP	Fortnightly																					
Concept Note development (Updated version)	Zoom meetings	Dr. Omesa/Alban	30th Nov 2021																					
Country request to WHO CD/AFRO for technical support	Official Letters/Memos	HoP/WCO	30 November 2021																					
Identification of a Local Consultant	Concept Note / Memos / Terms of Reference	Dr Lorraine	15th Dec 2021																					
Identification of an External Lead Reviewer	Concept Note / Memos / Terms of Reference / SoW	Dr Omesa / WHO AFRO	15th Dec 2021																					
Identification and engagement the external reviewers	Letters, memos	WHO AFRO	10 January 2022																					
Budget and resource mapping	Concept note, roadmap	Silas Kamuren (Lead)/Alban/Dr Macharia/Dr Omesa/Dr Lorraine/Phillip Kimani/Dr Muga/Drusilla	31st Dec 2021																					
Resource mobilization	Concept note, road map, funding request letters	HoP / Alban	Continuous																					
Communication with the MoH HQ	Memo, concept note	HoP / Alban	10 January 2022																					
Communication to County Governments and technical partners and stakeholders	Memo, concept note	HoP / Alban	17 January 2022																					
Sharing of NSP, national policy documents, reports	–	Secretariat	–																					
Identification and engagement of in-country/local reviewers	–	Secretariat	31st December 2022																					
Notification to the reviewers	Letters, memos	HoP / Alban	10th January 2022																					
Tools development onsite workshop 1 (for data collection)	DSA	Alban/Lins	17th to 21st January 2022																					
Consent/Ethical clearance	–	–	–																					
Identification and endorsement of counties and facilities	Zoom meetings	Secretariat/Task force	31st December 2021																					
Notify identified counties and facilities	Letters, memos	HoP / Alban	17th January 2022																					
Develop Agendas for the End Term Review including fieldwork (Discuss on logistics)	Concept Note / Budget	Drusilla / Dr Omesa / Alban	10th January 2022																					
Team composition/pairing with external reviewers	–	Secretariat/Review Lead	31st January 2022																					
Sharing of data collection tools with external reviewers	–	Alban / Dr Omesa	31st December 2021																					
Logistical planning (Transport, stationery, DSA, meeting links, digitization of tools)	Procurement/printing/digitization of tools	Secretariat	Continuous																					
PHASE 2: FIELD WORK PHASE (28th March- 8th April 2022)																								
Arrival of the lead consultant	Travel logistics	WHO	21st March 2022																					
Ground planning: Consultant meeting with NTP/secretariat	Meeting logistics	Alban / Dr. Omesa	22nd March 2022																					
Arrival of external consultants	Travel logistics	WHO	24th March 2022																					
Courtesy call of the consultants to the DG, PS and the WHO WR	Ground logistics	–	–																					
Stakeholders meeting: status of TB response in Kenya & review objectives	–	Dr. Waqo/Alban/Dr. Omesa	25th March 2022																					
Arrival of participants and stakeholders at KSG Briefing meeting with all field teams	–	–	–																					
Uploading of the digitized field tools	–	–	–																					
Overview of objectives and expectations of field work	–	–	–																					
Logistics briefing	–	External reviewer/ Local consultant	26th March 2022																					
Depart to the field	Travel logistics	Team leads	27th March 2022																					
Field work	Travel logistics	Team leads	28th March- 1st April 2022																					
Report writing in the field	–	Team leads	2nd April 2022																					
Travel from field to Nairobi	–	Team leads	3rd April 2022																					
Debriefing from the teams- Field team sharing	KSG	External reviewer/ Local consultant/Dr. Waqo	4th and 5th April 2022																					
Thematic group presentations	KSG	External reviewer/ Local consultant/Dr. Waqo	6th April 2022																					
Departure of county teams	–	–	7th April 2022																					
WR and MOH debrief	–	External reviewer/ Local consultant/Dr. Waqo	7th April 2022																					
Partners and stakeholders debrief	KSG	External reviewer/ Local consultant/Dr. Waqo	8th April 2022																					
Departure - External reviewers	–	–	9th April 2022																					
PHASE 3: REPORT WRITING & DISSEMINATION PHASE (APR - JUN 2022)																								
Consolidation and submission of final field and thematic reports by thematic lead reviewers	–	Field & Thematic leads	22nd April 2022																					
Consolidation of field and thematic review findings & recommendations	–	Local review lead/external reviewer	6th May 2022																					
Sharing of draft report with external and local reviewers (for inputs)	–	External Lead reviewer	13th May 2022																					
Incorporation of reviews and comments	–	External Lead reviewer	20th May 2022																					
Submission of final report to WHO	–	External Lead reviewer	1st June 2022																					
Dissemination of Final Review report to MoH	Zoom meeting	WHO	3rd June 2022																					

Annex 6: Agenda of the End of Term program review for Kenya, 2022

<p style="text-align: center;">REPUBLIC OF KENYA</p>  <p style="text-align: center;">MINISTRY OF HEALTH</p> <p style="text-align: center;">National Tuberculosis, Leprosy and Lung disease program End-Term program review Agenda: 24th March – 9th April 2022 Log in details: https://us02web.zoom.us/j/86376610410</p>				
Day	Date	Activity	Responsible	Venue
Mon	21st March 2022	Arrival of external lead and Epi reviewers	WHO	Nairobi
Tue	22nd March 2022	Briefing with review secretariat & task force	WHO/NTP	Afya annexe
Wed	23rd March 2022	Pre-WORLD TB DAY		
Thur	24th March 2022	WORLD TB DAY		
Friday	25th March 2022	Courtesy call - MoH (PS, CAS & DG) Courtesy call WR, WCO Arrivals		
Sat	26th March 2022	Pre-review briefing meeting with all TB review stakeholders	NTP, External review lead and local consultant	Tamarind Hotel
Sun	27th March 2022	Preparation for field departure	Team leads	County
Mon - Friday	28th March-1st April 2022	Field work	Team leads	County
Sat	2nd April 2022	Report writing in the field - Facility reports - Region reports and presentations	External and local team leads	
Sun	3rd April 2022	All day- travel to Nairobi		
Mon	4th April 2022	Debriefing from the teams- Field team sharing	External and local team leads	Crowne Plaza
Tue	5th April 2022	Thematic summaries compilation	External reviewers & local thematic leads	
Wed	6th April 2022	Thematic presentations	External reviewers	
Thu	7th April 2022	Technical debriefing to stakeholders	External lead reviewer	
Friday	8th April 2022	Briefing: CS, CAS, PS and strategic partners	MoH	MoH
Saturday	9th April 2022	Departure	All	

8. References

1. World Health Organization. WHO global lists of high burden countries for tuberculosis (TB), TB/HIV and multidrug/rifampicin-resistant TB (MDR/RR-TB), 2021–2025: background document. Published online 2021.
2. World Health Organization. Global tuberculosis report 2021: supplementary material. Published online 2022.
3. World Health Organization. Global tuberculosis report 2021: supplementary material. Published online 2022.
4. Nturibi E, Mecha J, Kamau E. Epidemiology and Risk Factors for Asthma in Kenya. *J Kenya Assoc Physicians Sept.* 2018;1(2).
5. National AIDS and STI Control Programme (NASCOP). Preliminary KENPHIA 2018 report. Published online 2020.
6. UNICEF. The state of food security and nutrition in the world 2021. Published online 2021.
7. World Health Organization. *Global Status Report on Alcohol and Health 2018*. World Health Organization; 2019.
8. World Health Organization. *WHO Global Report on Trends in Prevalence of Tobacco Smoking 2000-2025*. World Health Organization; 2018.
9. Sun H, Saeedi P, Karuranga S, et al. IDF Diabetes Atlas: Global, regional and country-level diabetes prevalence estimates for 2021 and projections for 2045. *Diabetes Res Clin Pract.* 2022;183:109119.
10. Sung H, Ferlay J, Siegel RL, et al. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin.* 2021;71(3):209-249.
11. Muigua K. Ensuring Healthy Lives and Well-being for All Kenyans. Published online 2030.
12. Barasa E, Rogo K, Mwaura N, Chuma J. Kenya National Hospital Insurance Fund Reforms: implications and lessons for universal health coverage. *Health Syst Reform.* 2018;4(4):346-361.