REPUBLIC OF KENYA



MINISTRY OF HEALTH

PATIENT PACK

NATIONAL STRATEGIC PLAN FOR TUBERCULOSIS, LEPROSY AND LUNG HEALTH

2019 - 2023



NATIONAL TUBERCULOSIS, LEPROSY AND LUNG DISEASE PROGRAM

Theme:

Prioritised action to reach all people with TB, Leprosy and Lung Diseases in Kenya **REPUBLIC OF KENYA**



NATIONAL STRATEGIC PLAN

FOR TUBERCULOSIS, LEPROSY AND LUNG HEALTH

2019 - 2023



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>> ACRONYMS

ACF	active case finding	CHEW	community
ACSM	advocacy, communication and social mobilization	CHS -	Centre for H
ADR	adverse drug reaction	Kenya	Kenya
aDSM	active TB drug safety monitoring	CHV	community
	and management	CHW	community
AFB	acid-fast bacilli	CI	confidence
AFRO	African Regional Office (of the World Health Organization)	CIDP	county inte plan
AIDS	acquired immunodeficiency	COC	Clinical Offic
	syndrome	CoE	centre of e>
AMR	antimicrobial resistance	СоК	Constituion
ART	antiretroviral therapy	COPD	chronic obs
BC	bacteriologically confirmed		disease
BCC	behaviour change communication	CPD	continuous
BCG	Bacille Calmette-Guerin	CDT	actrime
BMI	body mass index		COLITITIOXAZO
BOLD	burden of lung disease	CQI	continuous
BSC	biosafety cabinet	CR	cure rate
CAD	computer-aided detection	CRH	county refe
СВНІ	community based health	CSO	civil society
	insurance	CSR	corporate s
СВО	community based organization	CTBC	community
CDC	Centres for Disease Control and Prevention	CTLC	county tube coordinator
CDR	case detection rate	CU	community
CFR	case fatality ratio	CU	Central Uni
СНС	community health committee	CV	community
CHE	current health expenditure	CXR	chest x-ray

CHEW	community health extension worker
CHS - Kenya	Centre for Health Solutions - Kenya
CHV	community health volunteer
CHW	community health worker
CI	confidence interval
CIDP	county integrated development plan
сос	Clinical Officers Council
CoE	centre of excellence
СоК	Constituion of Kenya
COPD	chronic obstructive pulmonary disease
CPD	continuous professional development
СРТ	cotrimoxazole preventive therapy
CQI	continuous quality improvement
CR	cure rate
CRH	county referral hospital
CSO	civil society organization
CSR	corporate social responsibility
СТВС	community tuberculosis care
CTLC	county tuberculosis and leprosy coordinator
CU	community unit
CU	Central Unit
CV	community volunteer
CXR	chest x-rav

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DALY	disability-adjusted life year	GD
DALYs	disablity adjusted life years	GF
DHIS2	District Health Information System 2	GL
DM	diabetes mellitus	GN
DOT	Directly Observed Treatment	Go
DOTS	Directly Observed Treatment Short-Course	HB HC
DQA	data quality assessment	нс
DRS	drug resistance survey	HIS
DRTB	drug-resistant tuberculosis	
DST	drug susceptibilty testing	HIV
DSTB	drug-susceptible tuberculosis	НМ
ECHO	extension of community health outcomes	HR
EHF	eye-hand-foot	HS
EMR	electronic medical record	HT
EQA	external quality assessment	IBC
ETR	electronic TB registry	ICI
FBC	full blood count	
FBO	faith based organization	
FDC	fixed dose combination	ICF
FELTP	Field Epidemiology and Laboratory Training Program- Kenya	ICI
FIND	Foundation for Innovative New Diagnostics	IEC
FLD	first line anti-TB medicine	IM
FM	flourescence microscopy	IN
FMS	free maternity services policy	101
FY	financial year	
GDF	Global Drug Facility	IPC
		ISE

GDP	gross domestic product
GF	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GLC	Green Light Committee
GNI	gross national income
GoK	Government of Kenya
HBC	high-burden country
НС	health centre
HCW	health care worker
HISP	Health Insurance Subsidy Programme
HIV	human immunodeficiency virus
HMIS	health management information system
HRH	human resources for health
HSSF	Health Sector Services Fund
HTC	HIV testing and counseling
IBC	input based costing
ICD 10	International Classification of Diseases 10th Revision
ICER	incremental cost effectiveness ratio
ICF	intensified case finding
ICT	information, communication and technology
IEC	information, education and communication
IMAM	integrated management of acute malnutrition
INH	isoniazid
IOM	International Organization for Migration
IPC	infection prevention and control
ISP	informal service provider

ISTC	International Standards on Tuberculosis Care
ІТ	information technology
JICA	Japan International Cooperation Agency
KAD	Kenya Association of Dermatologists
KAP	knowledge, attitude and practices
KAPTLD	Kenya Association for the Prevention of of Tuberculosis and Lung Diseases
KELIN	Kenya Legal & Ethical Issues Network on HIV and AIDS
KEMRI	Kenya Medical Research Institute
KEMSA	Kenya Medical Supplies Authority
KES	Kenya Shillings
КНР	Kenya Health Policy
KHSSP	Kenya Health Sector Strategic and Investment Plan
KMA	Kenya Medical Association
KMLTTB	Kenya Medical Laboratory Technicians and Technologists Board
KNDI	Kenya Nutritionists and Dieticians Institute
KP	key population
KPA	Kenya Pediatric Association
L5H	level 5 hospital
LAM	lipoarabinomannan
LMIS	laboratory management information system
LPA	line probe assay
M&E	monitoring and evaluation
МСН	mother and child health
MCH	mother and child health clinic

MDG	Millenium Development Goal
MDRTB	multidrug resistant tuberculosis
MDT	Multidrug Therapy
MES	Managed Equipment Services project
MNCH	maternal, neonatal and child health
МОН	Ministry of Health
MOPC	medical outpatient clinic
MPDB	Medical Practitioners and Dentists Board
MSF	Medecins Sans Frontieres
MSM	men who have sex with men
МТВ	Mycobacterium tuberculosis
MTEF	medium term expenditure framework
MTP	medium term plan
MTR	mid-term review
NACC	National AIDS Control Council
NASCOP	National AIDS and STI Control Program
NCDs	non-communicable disases
NCK	Nursing Council of Kenya
NGO	non-governmental organization
NHIF	National Hospital Insurance Fund
NHLS	National Health Laboratory Services (South Africa)
NPISH	non-profit institutions serving households
NSPP	National Social Protection Policy
NTLD-P	National Tuberculosis, Leprosy and Lung Disease Program
NTSA	National Transport and Safety Authority

TLO	on the job training	SCMLT	sub - county medical laboratory
OOP	out-of-pocket payment	SCTLC	sub - county tuberculosis and
PAL	practical approach to lung health	50120	leprosy coordinator
PBG	performance based grant	SDG	Sustainable Development Goal
PCR	polymerase chain reaction	SDP	service delivery point
РНС	primary health care	SHA	System of Health Accounts
РНОТС	Public Health Officers and Technicians Council	SLD	second line anti-TB medicine
PLHIV	people living with HIV	SLMTA	Strengthening Laboratory Management Toward
PMDT	programmatic management of drug-resistant tuberculosis	SOP	standard operating proceedures
POC	point of care	SORK	Society of Radiographers of
PPB	Pharmacy and Poisons Board		Kenya
PPE	personal protective equipment	SRL	Supranational Reference Laboratory
PPM	public-public and public-private mix	STI	sexually transmitted infections
PPR	policy planning and research	ТА	technical assistance
PSK	Pharmaceutical Society of Kenya	TAT	turnaround time
PSM	procurement and supply	ТВ	tuberculosis
	management	TB ARC	Tuberculosis Accelerated
PT	proficiency testing	TRICC	
PWID	people who inject drugs	Three	Coordinating Committee
QAS	quality assurance system	THE	total health expenditure
QC	quality control	TIBU	treatment information from basic
QMRL	Queensland Mycobacterium Reference Laboratory		unit program
QMS	quality management system		training of trainers
R	rifampicin		tuberculosis preventive therapy
RCC	Regional Coordinating Committee	ISR	treatment success rate
RPB	Radiation Protcetion Board	TST	tuberculin skin test
RRTB	rifampicin resistant TB	TWG	technical working group
SACCO	savings and credit cooperative	UHC	universal health coverage
		UHC-EBP	UHC essential benefits package

UNAIDS	Joint United Nations Programme	USD	US Dollar
		WB	World Bank
UNICEF	Children's Emergency Fund	WRD	WHO - recommended rapid diagnostic
UPI	unique patient identifier	XDRTB	extensively drug-resistant TB
USAID	United States Agency for	7N	Ziehl Neelsen
	International Development	ZIN	Zient-neelsen



The vision of the National Strategic Plan (NSP) for Tuberculosis (TB), Leprosy and Lung health 2019-2023 is a Kenya free from TB and Leprosy and reduced burden of Lung Diseases. Kenya joined the rest of world in in September 2018 for the United Nations (UN) High Level meeting on TB in New York, where His Excellency President Uhuru Kenyatta committed to the country to ending TB by the year 2030, in line with Kenya Vision 2030 and Sustainable Development Goal (SDG) 3.

The development of this NSP has been realized through the many country level dialogues meetings that brought together various stakeholders including the national and county governments, bilateral and multilateral development partners, Non-Governmental Organizations (NGOs), Civil Society Organizations (CSOs) and key affected population representatives, among others.

This NSP is an evidence-based document whose development has been weighted on the review of various epidemiological data, the previous NSP (years 2015 to 2018), the National TB Prevalence Survey 2016 report, the Patients Cost Survey report and the Patient Pathway, among others. This NSP is fully costed and prioritised, based on the anticipated funding. It also captures a patient-centred approach on prevention, diagnosis, treatment and care.

TB has been singled out as one of the indicators for the Universal Health Coverage (UHC). Therefore, this NSP is in line with the Big Four Agenda, in which Kenya has adopted UHC as one of the priorities by His Excellency the President, with an aspiration that by 2022, all citizens will be able to access essential health services for their wellbeing including TB through a single unified benefit package without the risk of financial catastrophe. This NSP recognizes that all human beings have equal rights regardless of their nationality, ethnic origin, sex, race, religion, or any other status and are built around core human rights principles, as enshrined in the Constitution of Kenya (2010).

I thank all those who contributed to the development process of this NSP. Kenyans should be reminded of the commitments made, and the timely need for action to scale up research, funding, human rights and accountability to end TB. I therefore also call upon all the stakeholders and development partners to support the implementation of this NSP so that we can realize our set goals and targets, as we gear towards the elimination of TB and Leprosy, and in reduction of Lung Diseases.

Sicily K. Kariuki (Mrs.), EGH Cabinet Secretary, Ministry of Health

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>> WORD FROM CHIEF ADMINISTRATIVE SECRETARY



The National Strategic Plan for National Tuberculosis (TB) Leprosy and Lung health 2019 -2023 (NSP) has dual objectives of sustaining close collaboration with development and implementing partners by enlisting and nurturing new local and international partnerships. As part of this NSP, the county governments has developed County NSP framework to guide in domestic resource mobilization, this is part of strategy to cushion the country as donor support reduces in health sector.

This NSP recognises the huge funding gaps that face TB, Leprosy and lung Diseases prevention, treatment and care. The 2019-2023 NSP endeavours to address Domestic resources Mobilization and prudent utilization of the available resources for maximum output in achieving the set goals and targets in ending TB by 2035 according to the End TB strategy and for post elimination of leprosy and reduction lung diseases in the country. The NSP is based on setting the priority for the country and maximizing on available resources through a model called the incremental cost effectiveness ratio (ICER) against which the costing of the NSP is based.

The financial and other resources made available by the National and County governments for the health sector have been impressive. However, there is need to increase funding if achieving the set goals and targets in this NSP are to be realised through innovative and new approaches used for resource mobilization in partnership and collaboration from all sectors, both public and private.

A multi-sectoral approach will thus ensure that we leverage resources, expertise, knowledge and reach to reduce the burden on (TB) in Kenya. Working beyond the health sector will address the complex challenges that the NTLD-P has faced in its efforts to end the diseases in Kenya. The various partners have various roles in TB control. The education sector, transport sector, the community just to mention a few will be involved in the efforts towards fighting TB.

UHC is among the president's Big 4 Agenda. The TB patients have been known to face catastrophic costs due to high costs they meet while seeking treatment and care. Pillar 3 of the NSP and the End TB strategy targets zero families facing catastrophic costs due to TB. As such, UHC will be implemented to ensure that this target is met.

Lastly, I wish to appreciate the tremendous contribution of both development and implementing partners in TB, Leprosy and lung diseases prevention, treatment and control. The government is committed to the full realization of this NSP and will ensure that the NSP is fully funded.

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Dr. Rashid Abdi Aman, BPharm., PhD Health, Chief Administrative Secretary

WORD FROM THE PRINCIPAL SECRETARY



The Government has made significant progress towards achieving the objectives set to end Tuberculosis (TB) in Kenya. To sustain the developmental gains so far in TB prevention, diagnosis and treatment, we need to mobilize and sustain adequate financial and human resources over the next five years through the National Tuberculosis Leprosy and Lung Disease – Program (NTLD-P) National Strategic Plan (NSP) 2019 – 2023.

In Kenya, funding for TB is mainly from the Government which has increased over the years, United States of America through USAID and CDC, and the Global Fund for AIDS, TB and Malaria (GFATM). Nevertheless, Kenya has attained middle-income status thus the decline of partner support which might further reduce investments for prevention, diagnosis, and treatment of TB. This strategy is cognisant of the dwindling funds and there is a need to step up our efforts and commitments to mobilize both domestic and donor resources to attain our set targets.

The NTLD-P extensively explored key interventions that will address the priority gaps as outlined in the NSP 2019 – 2023 which was costed using the input-based costing (IBC) approach. The estimated resource requirements towards the full implementation of the strategy is KES 29.8 billion. The funding needs will, therefore, be addressed through Domestic Resource Mobilization, Engagement and strengthening of the private sector through the Public-Private Partnership (PPP), Linkage of eligible TB patients to existing social protection programs, Intense Advocacy, Capacity building of community-based health insurance schemes (CBHIs), provision of incentives and mobilization of donor funds.

The Government remains fully committed to the full implementation of the NSP 2019 – 2023. I, therefore, call upon all stakeholders to stay the course and continue working harder towards the realization of the goals set forth in this NSP.

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Ms Susan N. Mochache, CBS Principal Secretary, Ministry of Health

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The 2019-2023 NSP covers Tuberculosis (TB), Leprosy and other Lung Diseases. Globally, TB cases have been on the rise. According to 2018 global TB report, 10 million people developed TB disease in 2017, of which 10% were children under 15 years. In 2017, 1.3 million deaths were reported among the HIV negative, and an additional 300,000 deaths among the HIV positive.

In Kenya, TB is among the top ten leading causes of death. According to the National TB Prevalence Survey report 2016, the burden of TB in Kenya was 426 cases per 100,000 population. This is more than previously reported. TB case notifications increased by more than 10% over the years. In 2018, half of all estimated TB cases were missed. Among them, twothirds of the children with TB were not diagnosed; and 80 % of people with drug-resistant TB were missed.

Globally, new infection of Leprosy has been on the decline. The Global Leprosy Strategy 2016–2020, "Accelerating towards a leprosy-free world", was adopted by most countries where leprosy is endemic. Kenya is a low endemic country for Leprosy and has achieved national elimination status for several years. However, there are still six high burden counties that accounted for 73% of notified cases. The majority of these cases were multi-bacillary and included children under 15 years, signifying continuing recent community-based transmission of the disease. The NSP reflects a focus on earlier identification of people with Leprosy and quality care.

Chronic Obstructive Pulmonary Diseases (COPD) is currently the fourth leading cause of death in the world, but projected to be the third leading cause of death by 2020. More than 3 million people died of COPD in 2012 accounting for 6% of the deaths globally. COPD represents a public health challenge that is both preventable and treatable. It is projected that there will be an increase in the burden of COPD in future due to exposure to the risk factors.

Among the respiratory diseases, lower respiratory infections, drug susceptible TB, drug susceptible HIV/AIDS-TB, and COPD account for a considerable burden of morbidity and mortality in all age groups in Kenya.

I wish to congratulate NTLD-P for developing the NSP 2019-2023 for TB, Leprosy and Lung Health, which is a patient-centred and evidencebased document. This NSP has 3 pillars to address the challenges of TB, Leprosy and COPD prevention, diagnosis, treatment, and care.

Dr. Jackson Kioko, OGW, Director of Medical Services Ministry of Health



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ACKNOWLEDGEMENTS

The National Strategic Plan 2019-2023 for Tuberculosis, Leprosy and Lung Health represents the milestone in leadership and commitment of Ministry of health in ending TB, Leprosy and in reducing the burden of other lung diseases in Kenya. I wish to take this opportunity to thank our President, the top leadership of the Ministry of Health, development partners and other key stakeholders for their immense support and contribution towards the realization of this NSP 2019-2023.

I wish to also thank and appreciate the members of the Secretariat led by Dr Newton Omale, NTLD-P, the writing team at all levels for their extensive knowledge and expertise in putting together all the materials for this NSP, and all the staff of various units and departments within the Ministry of Health, county and sub-county officials, as well as bilateral and multilateral donors, agencies, non-governmental, and civil society organizations who made valuable contributions.

As TB fraternity, let me make a special mention of the following longterm partners of the NTLD-P: National HIV/AIDS and STI Control Program (NASCOP), WHO, USAID, Stop TB Partnership - Kenya, Centre for Health Solutions - Kenya (CHS), Amref Health Africa, Kenya Association for the Prevention of Tuberculosis and Lung Disease (KAPTLD), Kenyatta National Hospital (KNH), Kenya AIDS NGOs Consortium (KANCO), KEMRI, CDC, Ampath Kenya, International Organization for Migration (IOM) and Japanese Agency for Cooperation (JICA), among others.

Finally, on behalf of the writing team, I wish to thank Professor Christy Hanson of Bill & Melinda Gates Foundation, Prof Nim Pathy and Dr Juan Vesga of Imperial College London; the consultants – Dr Kasera Kadondi and Dr Matiko Riro, who led the NSP development process. The NTLD-P also wishes to thank the design and formatting team lead by Mr Felix Mbetera – Communication Specialist, and other NTLD-P staff for conducting background literature reviews, data analysis, geographic mapping, and assisting in writing this document.

This multi-sectoral and partnership approach ensured that this patientcentred NSP is realized. The Ministry of Health is grateful for generous financial support from USAID, through CHS TB ARC II, and the Global Fund, which enabled the numerous stakeholder meetings and workshops of the writing team.

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Dr Kamene Kimenye Head, National TB, Leprosy and Lung Disease Program



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EXECUTIVE SUMMARY

The National Strategic Plan (NSP) for Tuberculosis, Leprosy and Lung Diseases 2019 - 2023 represents an evolution in the Government of Kenya's response to these scourges. **New data acquired** over the past four years will drive a targeted and prioritised approach. This NSP reflects a **patient-centred approach** to planning and **evidence-based prioritisation of resource allocation** to close the gaps along the patient pathway to quality care. The NSP is operationalised through a **partnership framework** aligned to each stakeholder's comparative advantage. The activities embodied under this NSP will address systemic and root causes of the gaps along the patient pathway, suggesting the complementary roles of county and central governments, departments across the Ministry of Health, partners and other sectors.

This NSP lays out the **strategic and technical direction** for the elimination of TB and leprosy nationally. It presents the full aspiration of the country, including outcome and impact targets that align with international goals, and the full portfolio of activities needed to reach these goals. It assumes a fully funded NSP. In acknowledgement of likely funding gaps, an evidence-based optimisation of resource allocation is presented alongside **alternative impact targets given reduced funding scenarios**; i.e. a) 2018 - 2019 funding levels from domestic and international sources; and b) 2018 - 2019 funding plus 25 percent. An upcoming supplement to the NSP will document the full operational plan behind this NSP and articulate the **county-specific commitments** that will contribute to the attainment of national goals.

The Problem: A Summary

Laberculosis is the **leading infectious disease killer** in Kenya. A 2015/2016 prevalence survey revealed that the burden of tuberculosis (TB) in Kenya was 426 cases per 100,000 population – suggesting there was more than twice as much TB as previously estimated. This was a wake-up call for the country. After five years of declining case notifications, the results of the prevalence survey prompted intensified efforts to understand where people with TB were being missed by the system and to mount innovative responses. In both 2017 and 2018, TB case notifications increased by more than ten percent, respectively, over the previous year. Still, **nearly half of all estimated TB cases were not diagnosed, notified and or treated in 2018.** Among children with TB, nearly two-thirds were not diagnosed; and nearly 80 percent of people with drug-resistant TB were missed.



Number of cases per **100,000** population – suggesting there was more than twice as much TB as previously estimated.

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Kenya is a low endemic country for leprosy and has achieved and sustained national elimination status for several years. However, there are still **six high burden counties** that accounted for 73 percent of notified cases from 2014-2016. The majority of these cases were multi-bacillary, some had grade 2 disabilities, and included children under 15 years of age, **signifying continuing recent communitybased transmission** of infection. The NSP reflects a focus on earlier identification of people with leprosy and quality care.

Respiratory illness is the leading reason for healthcare seeking in Kenya. It accounts for a considerable burden of morbidity and mortality in all age groups with ten percent of self - reported reasons among patients seeking outpatient services complaining of respiratory symptoms, this is the most frequent complaint. This translates to an annual eight million outpatient visits from respiratory symptoms among health facilities that report on the routine health management information system, DHIS2. Among the respiratory diseases, the most frequently occurring that result in significant morbidity and mortality are lower respiratory infections, drug-susceptible TB, drug-susceptible HIV/AIDS - TB and chronic obstructive pulmonary disease (COPD).

The evidence-base

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The previous NSP (2015-2018) represented a period of learning and innovation. The plan was launched as devolution was first being executed and the Ministry of Health was redefining how to manage a cohesive national response to TB, leprosy and lung diseases in coordination with autonomous counties. The startling results of the TB prevalence survey forced the country to re-visit how to better reach all people with TB. The NTLD-P undertook numerous studies to build an evidence-base in support of a refined approach. Between 2016-2018, the NTLD coordinated over 15 studies with an overarching objective of better understanding the experience(s) of people living with TB and how they experience barriers to quality care. This body of evidence shed light on where people with TB may be missed by the health system. The TB prevalence survey found that nearly two-thirds of people with symptoms for TB had not yet sought treatment. Of these, the majority (82 percent) did not seek care because they felt the symptoms were not serious. It is widely believed that symptoms worsen over time, driving people to seek care.

The survey also found that half of the people with confirmed TB were not identified using symptom screening for cough. However, chest radiography was found to be a highly sensitive screening tool for identifying people with TB. Of those who sought care, a patient pathway analysis suggested that only 43 percent of people accessed a facility with TB diagnostic services (or specimen transport). Nearly onethird of care seeking was in the formal private sector, where TB service availability was less available. The misalignment between care seeking and TB service availability resulted in repeat care-seeking. A study of patient costs associated with seeking and receiving care for TB found that the proportion of TB affected households facing catastrophic total costs (that were more than 20 percent of their annual household expenditure) due to TB was 27 percent. The proportion of DR-TB patients who experienced catastrophic expenditure was three times more than that of DS-TB patients (66 percent). Once on treatment, a study on treatment adherence found that 35 percent of people were non-adherent¹.

¹ Non-adherent was defined as: missed taking pills for more than two days in the four days prior to the interview; missed taking pills more than once every week or daily in the four months prior to the interview; and/or scored less than 80% on the visual analogue scale.

Concurrent with the flurry of research activities, the NTLD-P rolled out its electronic TB patient-management and recording system, TIBU, nationwide. An inventory study completed in 2016 revealed that over 20 percent of people with TB who were diagnosed were not notified into TIBU. Reporting by the private sector accounted for the greatest gap among provider types. TIBU is now linked to the national health management information system and under this NSP, will be linked to the national database for social protection programmes.

The approach

The NSP 2019-2023 consolidates the learning from the last few years and prioritises approaches that will further accelerate progress to reaching and curing all people with TB. A systematic approach to the review of data and evidence was undertaken as the foundation for this NSP.

Data and findings from routine surveillance and 15 studies were mapped to the patient care continuum. In a kickoff workshop, over fifty international, national and local stakeholders reviewed and discussed the relevant study results applied to three unique planning steps: (1) Problem Prioritisation, (2) Root Cause Analysis and (3) Strategic Intervention Optimisation. The process nurtured country-level planning that centred on asking the questions, (1) What are our biggest problems, (2) Why are they happening and (3) What should we do about them.



Number of studies coordinated by the NTLD between 2016-2018, with an over-arching objective of better understanding the experience(s) of people living with TB and how they experience barriers to quality care



TWO-THIRDS

Approximate number of people with symptoms for TB and had not yet sought treatment. Of these, the majority (**82 percent**) did not seek care because they felt the symptoms were not serious. (*TB prevalence survey*)



Figure 1A: People-centred framework for data consolidation and prioritisation

1. Epidemiology Drug Sensitive Image: Drug Resistant TB HIV 2. People who are not in High-risk for TB infection or breakdown to the health system Asymptomatic disease, not seeking care Symptomatic disease, not seeking care 2. People with TB in the	Pulmonary EPTB Pediatric Special Populations - - disease - -	
Drug Resistant TB HIV 2. People who are not in High-risk for TB infection or breakdown to the health system Asymptomatic disease, not seeking care Symptomatic disease, not seeking care 2. People with TB in the	EPTB Pediatric Special Populations	
Drug Resistant TB HIV 2. People who are not in High-risk for TB infection or breakdown to the health system Asymptomatic disease, not seeking care Symptomatic disease, not seeking care 2. People with TB in the	Pediatric Special Populations - - disease - -	
Drug Resistant TB HIV 2. People who are not in High-risk for TB infection or breakdown to the health system Asymptomatic disease, not seeking care Symptomatic disease, not seeking care 2. People with TB in the	Special Populations disease	
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2. People who are not in High-risk for TB infection or breakdown to the health system Asymptomatic disease, not seeking care Symptomatic disease, not seeking care	disease	
the health system Asymptomatic disease, not seeking care Symptomatic disease, not seeking care Asymptomatic disease, not seeking care	-	
Symptomatic disease, not seeking care		
2. Decode with TB in the Deconstinuity has been the facility of the distance	-	
5. People with 16 in the Presenting to health facilities; not diagnose	ed -	
health system, but not Diagnosed by private sector, not notified	-	
Diagnosed by public sector, not notified	-	
4. People with TB are People diagnosed with TB but not started	on treatment -	
notified, but not cured On treatment without treatment success	-	
Complete Rx, w/out durable, relapse-free	cure -	
Priority [Green: Low Priority, Red: High Priority]		
2.0		5.0

Figure 1B: Prioritisation results from the people-centred framework

They first identified priorities based on data, tracked gaps in the evidence, and emerged with priorities that were consensus-based at the national level. The process was repeated with representatives from the 47 counties, and through focus groups with patients and healthcare providers. A triangulation of the priorities across stakeholder groups was completed. Sub-national differentiation was documented, resulting in an NSP that responds to local as well as national priorities. The full cost of the NSP and corresponding targets are presented in Chapter 5 of the NSP, which also acknowledges funding gaps and resource constraints.

Mathematical modelling of impact was applied in combination with cost models to consider the Incremental Cost-Effectiveness Ratios of interventions. A sub-set of interventions were selected to optimise the impact of available resources on the epidemic overall and for selected special populations. Reduced impact targets aligned to the reduced level of effort are presented.

The priorities for action

This NSP lays out the strategic and technical direction for the elimination of TB, Leprosy and Lung Diseases nationally. It presents the full aspiration of the country, including outcome and impact targets that align with international goals, and the full portfolio of activities needed to reach these goals. It assumes a fully funded NSP. The county-specific commitments which prioritises action and defines alternative impact targets, given reduced funding scenarios; i.e. a) 2018 - 2019 funding levels from domestic and international sources; and b) 2018 - 2019 funding levels plus 25%, will contribute to the attainment of national goals. The plan at 2018 - 2019 funding levels will be used for immediate action, while the higher budget tiers will be used as the basis for future funding requests.

Evidence drives the priorities for action under this NSP. Given the evidence base summarized above, resources will be prioritised, first and foremost, to ensuring timely access to quality services for all people already in or entering the health system. Extending from a foundation of

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quality services across the health system, the NSP then prioritises reaching out to actively screen (for treatment or preventive therapy) the contacts of TB patients, especially children and people living with HIV, as well as highrisk populations, such as healthcare workers. Supportive systems to underpin effective patient care are embedded in the Ministry of Health's plans for Universal Health Coverage and link people with TB, leprosy and lung diseases to social protection, health insurance, and stable commodity supplies.



Meet people who are seeking care anywhere in the health system with quality TB, leprosy and lung health services.

Differentiate the package of priority activities according to local patient careseeking patterns and infrastructure

This NSP represents the first time an NSP includes county-specific operational plans, developed and budgeted within county plans and aggregated under the national plan. Each county considered the local surveillance and programmatic performance data, patient pathway analysis, and MATCH (population and facility mapping) analysis as they determined local priorities and approaches.

Close the diagnostic gap

This NSP represents the operationalization of three new national policies in support of appropriate and timely diagnosis, namely: 1) expanded use of x-ray screening for TB; 2) Xpert as the preferred confirmatory test; and 3) all confirmed TB patients to receive drugsensitivity testing. These policies will put pressure on the existing infrastructure. The NSP calls for an optimisation of the diagnostic network, in line with the modeling analysis completed in 2018, to ensure each person who accesses care can immediately be screened and tested for TB. The optimisation has informed the repositioning of existing technology and suggested specimen transport networks. It will also guide plans for efficient expansion of Xpert and x-ray technology. The NSP anticipates the efficiencies that may be gained by the rapid introduction of new diagnostic tools when they become commercially available, especially LAM for screening and stool-based preparations for Xpert to diagnose paediatric TB. In the meantime, the NSP plans for all healthcare facilities to have either Xpert capacity on-site (where efficient) or a specimen transport arrangement to a qualified laboratory. Successful implementation of these policy shifts will require enhanced collaboration between communities, care facilities and laboratories. Such collaboration will require enhanced capacity among health staff and laboratories, as well as connected patient management data systems to follow patient progress.

Close the private sector gap

This NSP represents a bold strategy to network all care providers into a cohesive web of support for people with TB, leprosy and lung diseases. Recognizing the variability of private providers across the country, the NSP defines six distinct models of private sector engagement. The establishment of supporting systems will be prioritised, namely strategic purchasing of private sector services, contracting for linkages to public sector capacities (such as diagnostic technology) and commodities (such as drugs), and enhanced functionality of the data system to link patient care with notifications and payments. The activities capitalize on the concurrent expansion of Universal Health Coverage and the potential for national health insurance to incentivize private providers to deliver quality care.

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Close the public sector gap, especially for special populations

This NSP reinforces efforts to identify TB among key populations that may be accessing care in specialized facilities and are missed for TB care. In particular, the NSP prioritises reaching children being seen by paediatricians and in MNCH services, people living with TB being seen for ART care, and those with DS-TB and DR-TB who may be seeking care for concomitant disease such as diabetes. This NSP sustains the gains made with routine HIVtesting of TB patients and anticipates early adoption of LAM for screening HIV-positive people for TB. The NTLD-P acknowledges that a paucity of data about the magnitude and characteristics of the TB burden among special populations, as well as impact data regarding what works to best serve them, must be overcome during this NSP period to enable more evidence-based approaches in future.

Close the treatment adherence gap

This NSP represents the first time that treatment adherence has been categorically prioritised within a national response to TB and leprosy. This NSP addresses some of the known root causes of poor adherence, including the indirect cost of care, side-effects. and lack of information. A multi-sectoral approach has been adopted to enable patient support to occur through national social protection programmes, such a nutrition and financial subsidies. Concurrently, the NSP calls for elimination of the fees associated with diagnostic testing for TB, including chest radiography. An evolution of the data management system, TIBU, into a patient care management system is anticipated to enable early detection and differentiated care responses for those people facing barriers to continued treatment.

2nd PRIORITY

For people at risk for TB and leprosy disease; screen for and treat TB infection.

Close the gap of pre-care seeking

This NSP represents a paradigm shift in the strategies used to reduce TB prevalence in the country. While maintaining a focus on the provision of quality treatment for all those ill with TB disease, this NSP also aims to identify people with TB even before they seek care. This NSP represents an ambitious scale-up of contact tracing for TB screening and the use of preventive treatment of TB infection among contacts, health workers and people with HIV. This NSP embraces the adoption of the new, shorter regimen (Rifapentine and Isoniazid for three months) for the treatment of TB infection and presents an ambitious partnership with community health volunteers, large employers, and the Ministry of Education to enable contact tracing for workplace, school-based and household contacts of TB patients, as well as among people with HIV. The move away from monotherapy is expected to overcome provider hesitation to treat TB infection. The NSP also anticipates the early adoption of new TB screening tests as they become globally endorsed and commercially available.

3rd PRIORITY

The UHC Essential Benefit Package (EBP) makes explicit provisions to cover infectious diseases: Malaria, HIV/AIDS and TB.

Moreover, it provides for financing of health promotion, prevention and community health services which could serve to provide resources required to find missing TB cases. The UHC-EBP also recommends coverage for respiratory illness such as pneumonia and COPDs, which could serve the overall goal of improving lung health.



AT A GLANCE

46.6 MILLION

Estimated population of Kenya as of 2017.

INTRODUCTION

UNE CON

INTRODUCTION

The National Strategic Plan (NSP) for Tuberculosis, Leprosy and Lung Diseases 2019 - 2023 represents an evolution in the Government of Kenya's response to these scourges. New data acquired over the past four years will drive a targeted and prioritised approach. This NSP reflects a patient-centred approach to planning and evidence-based prioritisation of resource allocation to close the gaps along the patient pathway to quality care. The NSP is operationalised through a partnership framework aligned to each stakeholder's comparative advantage. The activities embodied under this NSP will address systemic and root causes of the gaps along the patient pathway, suggesting the complementary roles of county and central governments, departments across the Ministry of Health, partners and other sectors.

This NSP lays out the strategic and technical direction for the elimination of TB and leprosy nationally. It presents the full aspiration of the country, including outcome and impact targets that align with international goals, and the full portfolio of activities needed to reach these goals. It assumes a fully funded NSP. In acknowledgement of likely funding gaps, an evidence-based optimisation of resource allocation is presented alongside alternative impact targets given reduced funding scenarios; i.e. a) 2018 - 2019 funding levels from domestic and international sources; and b) 2018 - 2019 funding levels plus 25 percent. An upcoming supplement to the NSP will document the full operational plan behind this NSP and articulate the county-specific commitments that will contribute to the attainment of national goals.



VISION

A Kenya free of TB and leprosy, and reduced burden of lung disease.



2

MISSION

To ensure provision of quality care and prevention services for all people in Kenya with TB, leprosy and lung diseases.

IMPACT TARGETS (BY 2030)



PRIORITY OUTCOME TARGETS (BY 2023)



treat **4,500** people with MDR-TB.

3



children with TB.

TB Preventive Therapy provided to at least **900,000** people at risk of TB by **2023**

adults with TB.

STRATEGIC FOCUS



Close the gaps along the care continuum to find and cure ALL people with TB



Differentiated response by counties to address TB in local contexts



Optimise the implementation of TB, leprosy and lung health services within UHC



Prevent infection, active disease, morbidity and mortality due to TB, leprosy and lung diseases



Patient-centred approach that promotes quality of care

1.1 THE KENYAN CONTEXT

1.1.1 Geography

Kenya is situated in the eastern part of the African continent, bordering Ethiopia (North), Somalia (Northeast), Tanzania (South), Uganda (West), and South Sudan (Northwest). The country is administratively divided into 47 counties.

1.1.2 **Demographic**

Kenya's population is estimated to be 46.6 million in 2017². Males and children aged less than 15 years make up 50 percent and 43 percent of the population respectively³. The life expectancy at birth is 67 years^{4,5}.

1.1.3 Socio-Economics and Economic Development Agenda

Kenya's gross domestic product (GDP) is USD 79.263 billion while the per-capita gross national income (GNI) is USD 1,460⁶. Thirty – six percent of the population live below the national poverty line while the gross school enrollment ratio is 103 percent.

² Kenya National Bureau of Statistics. (2018). *Economic Survey 2018*. Nairobi: Kenya National Bureau of Statistics.

³ Kenya National Bureau of Statistics. (2017). The 2009 Kenya Population and Housing Census; Population Distribution by Age, Sex and Administrative Units: Kenya National Bureau of Statistics.

⁴ World Bank. (2018, November 9). The World Bank | Data Kenya. Retrieved from World Bank: https://data.worldbank.org/country/kenya

⁵ Kenya National Bureau of Statistics. (2016). 2016 FinAccess Household Survey. Nairobi: Central Bank of Kenya.

⁶ World Bank. (2019, February 19). The World Bank | Data Kenya. Retrieved from World Bank: https://data.worldbank.org/country/kenya

Kenya's development agenda is anchored on Kenya Vision 2030 and its realization is through incremental implementation of medium-term plans. The health sector, under the social pillar, is identified by Vision 2030 as an essential component to national development with its main goal being to improve the overall health outcomes and indicators. Thus, the sector has aligned its goal of attaining the highest possible standards of health of all with the constitution and Vision 2030. Kenya's health sector thus provides one of the most important components for addressing issues of equity and the broader national socio-economic agenda. Following an executive order in December 2017, the country has set out to attain Universal Health Coverage (UHC) for all by 2022 with the Ministry of Health spearheading these efforts within the sector.

As of October 2018, the UHC - Essential Benefits Package (UHC- EBP) services were defined and costed by the Health Benefits Package Advisory Panel7. In it, the services covered include management of TB and respiratory tract conditions e.g. pneumonia and chronic obstructive pulmonary disease (COPD). It also covers health promotion, prevention and community health services.

1.1.4 Health System

Health Leadership and Governance

The vision of the health sector is "A healthy, productive and globally competitive nation", while its mission is "To build a progressive, responsive and sustainable Health care system for accelerated attainment of the highest standard of health to all Kenyans" with an overall goal being "To attain equitable, affordable, accessible and quality health care for all". The sector is led by the cabinet secretary of health with the core mandate of health policy, health regulation, national referral health facilities, capacity building and technical assistance to counties⁸. Following devolution, 47 county governments were established and health service delivery became one of their core mandates. The sector has developed a partnership framework that has outlined the Health Sector Partnership Coordination Framework that outlines how the Ministry of Health, county governments, external and non - state partners will interact with each other.

^{46.6} MIL ION





Kenya's gross domestic product (GDP)



Kenya's per-capita gross national income (GNI)



Year set out for attaining Universal Health Coverage (UHC) for all following an Executive Order in December 2017

² Cabinet Secretary of Health. (2018). The Kenya Gazette (Vol. CXX — No. 69). Nairobi: The Government Printer.

⁸ Ministry of Health. (2018, November 9). About Ministry. Retrieved from Ministry of Health: http://www.health.go.ke/?page_id=126

The Kenya Health Policy 2014 – 2030 demonstrates the sector's commitment, under the government's stewardship, to ensuring that the country attains the highest possible standard of health that is responsive to the needs of the population.

Health Workforce

The community is the first level of health service delivery according to the Kenya Health Policy Framework 2014 - 2030. This policy boosts Kenya's focus on the role of community participation in health and socio-economic development aeneral actions. The community unit (CU) structure comprises Community Health Committees (CHCs), Community Health Extension Workers (CHEW). Community Health volunteers (CHVs), households, public health officers and technicians, social workers and affiliate health facilities. The nearest health facility is the community's link for seeking all health services. The community unit, which draws its membership from the catchment area, is led by the CHCs and CHEWs to support the CHVs in their community-related health work. Postdevolution, there is increased investment by counties on the community strategy.

Additionally, a community health services policy has been drafted and is under final review. Regarding capacity building for the CHVs and CHEWs, a curriculum of 13 modules for CHEWs has been developed as well as six basic and seven technical manuals for community health volunteers. The introduction of four contextualized CHEWs (e.g. urban, nomadic, agrarian etc.) is being explored. Currently, there are 4,587 community units established with 4,048 CHEWs and 90,758 CHVs.

Kenya has eight health regulatory agencies established through acts of parliament stipulating that health regulatory agencies

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are government agencies responsible for regulating the training and practice of various health professionals. They include, Nursing Council of Kenya (NCK), Medical Practitioners and Dentist Board (MPDB), Clinical Officers Council (COC), Kenya Medical Laboratory Board **Technicians** and **Technologists** (KMLTTB), Pharmacy and Poisons Board (PPB), Public Health Officers and Technicians Council (PHOTC), Radiation Protection Board (RPB), and Kenya Nutritionists and Dieticians Institute (KNDI). Society of Radiographers of Kenya (SORK) is the only professional agency that represents radiographers in any professional forum, it vets radiographers for professional regulation in training and practice. All health professionals are required to be trained in an approved training institution and licensed to practice by their respective regulatory agency, regardless of whether or not they are employed in the public, private or faith-based health sectors.

There is an increasing trend in the registration of health professionals, except for pharmacists, whose numbers have fluctuated. In cumulative terms, the majority of ever-registered health professionals in Kenya are nurses with a total of 51,649 nurses below 60 years of compared with medical doctors (9,497), dentists (1,066), clinical officers (13,913), medical laboratory technologists (6,626) and medical laboratory technicians (4,445), pharmacists (2,377), and pharmaceutical technologists (7,243). The retention of health professionals represents the active health workforce. Retention is based on the renewal period established by each regulatory agency. For example, nurses renew their licenses every 3 years. From 2012 to 2014, the nursing council issued 31,896 renewal licenses for nurses practicing in Kenya. The ratio of currently practicing nurses to population in Kenya is 8.3 nurses per 10,000 population compared with the WHO recommendation

of 25 nurses per 10,000. By 2015, Kenya had 5,660 doctors and 603 dentists retained in the country which translated to approximately 1.5 doctors and 0.2 dentists to 10,000 population, against the WHO recommended minimum staffing level of 36 doctors per 10,000 population. There were 10,562 clinical officers retained in 2015; 1,616 pharmacists and 4,671 pharmaceutical technologists from nongovernmental facilities, and 5,203 medical laboratory technologists and 3,213 medical laboratory technicians. This translates to 2.7 clinical officers and 2.2 medical laboratory officers per 10,000 population. The pharmacists to population ratio in Kenya is 0.5 per 10,000 while that of pharmaceutical technologist is 1.2 per 10,000 population⁹.

There is large disparity in health workforce distribution across the country, which is influenced by demographics, number of health care facilities and epidemiological profile of individual counties.

There are various cadres of health care workers involved in the TB response. At the national level, there is a mix of epidemiologists, specialist and general medical practitioners, pharmacists, clinical officers, nurses, laboratory personnel and others working at the NTLD-P. At the county level, TB services are coordinated by County TB and Leprosy Coordinators (CTLCs) and receive requisite support from County Pharmacists and County Medical Laboratory Coordinators (CMLCs) for commodity and diagnostics support. These are mirrored at the sub-county level, with the sub-County TB and Leprosy Coordinators (SCTLCs) providing oversight of TB services at health facilities and responsible for notification of patients on TIBU. Sub-county Pharmacists and Medical Laboratory Coordinators (SCMLCs)



Kenya has **eight** health regulatory agencies established through acts of parliament stipulating that health regulatory agencies are government agencies responsible for regulating the training and practice of various health professionals.

provide commodity and diagnostics support. At service delivery level, TB services are largely provided by nurses and clinical officers in the public sector, and a mix of nurses, clinical officers and doctors in the private sector. Laboratory and radiology units and staff are involved in the diagnosis. Community health workers are involved in referral of presumed TB cases to health facilities for diagnosis in in tracking patients who default on treatment.

Ministry of Health. (2016). Kenya Health Workforce Report: The Status of Healthcare Professionals in Kenya, 2015. Nairobi: Kenya Health Workforce Project | Emory university.

Health Financing

While the total health expenditure (THE) increased by 28 percent to KES 346 billion (USD 3,476 million) in financial year 2015/16 from KES 271 billion (USD 3,188 million) in FY 2012/13, there was a decrease of the proportion of THE as a percentage of the nominal GDP to 5.2 percent from 6.8 percent over the same period. In net present values, there was a marginal increase in the per capita expenditure from KES 6,602 (USD 77.4) in FY 2012/13 to KES 7,822 (USD 78.6) in FY 2015/16 due to the weakening of the Kenyan Shilling against the US Dollar.

Revenues to finance health come from three major sources namely the government, households and donors (rest of the world). The government and households are the two major financiers of health contributing 33 percent of current health expenditure (CHE) each in FY 2015/16, while donor contribution is 22 percent and corporations account for the last 12 percent.

Regarding healthcare financing schemes for revenues of CHE in FY 2015/16, the largest proportion (37 percent) was mobilized through government schemes, while household outof-pocket payment (OOP), excluding cost sharing, mobilized 28 percent. Financing schemes of non-profit institutions serving households (NPISH) mobilized 16 percent of CHE funds and voluntary health insurance schemes, 11 percent. Social health insurance schemes and enterprise financing schemes mobilized five and three percent respectively. Financing agents are institutional units that manage the financing arrangements for raising revenue, pooling or managing resources, and purchasing services. The role of the MOH as a financing agent decreased to 19 percent (FY 2015/16) of CHE from 32 percent (FY 2012/13) following the devolution of health service delivery to counties who managed 18 percent (FY 2015/16). Households through OOPs and NPISH controlled 28 percent and 16 percent of CHE respectively (FY 2015/16).

According to the system of health accounts (SHA), providers of health care are institutional units or entities that receive money from financing agents in exchange for or in anticipation of producing the required healthcare services. These include public and private health facilities, pharmacies and shops, traditional healers, community health workers, providers of public health programs and general administration among others. Public owned health facilities utilized 36 percent of CHE (FY 2015/16) down from 42 percent (FY 2012/13). Providers of health administration utilized 20 percent while providers of preventive health programs utilized 14 percent of CHE over the same period.

Healthcare functions consist of goods and services provided and activities that are performed by healthcare providers within the boundary of the health accounts. General healthcare functions curative include care (inpatient and outpatient), provision pharmaceuticals independent of from pharmacies, prevention and public health programs, health care administration, and capital formation. The largest proportion of CHE was spent on outpatient care, 40 percent, while both inpatient care and administration of health finance accounted for 20 percent each. The choice of priority disease, HIV/AIDs took the largest share of resources for health at 20 percent, followed by reproductive health at 12 percent and malaria 10 percent. On the other hand, tuberculosis share stagnated at

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1.4 percent¹⁰ though it causes more mortality than malaria¹¹

Health Information System

Recent years have seen an increasing focus on the strengthening of national health information systems in Kenya with a vision of being a center of excellence for quality health and health-related data and information for use by all. The mission is to provide timely, reliable and accessible quality health service information for evidence-based decision making to maximize utilization of scarce resources in the health sector. The country then made a bold step to adopt a web-based system for data management. This was due to the improvement of the internet using the mobile telephone networks in the country. The ability to implement District Health Information System 2 (DHIS2) online on one central server made it significantly "easier" to roll out the system countrywide, as compared with the alternative of having to support and maintain separate installations in all districts, hospitals and health facilities around the country.

There has also been an acceleration of disease control initiatives setting up their own information systems e.g. the treatment information from basic unit, TIBU.

TIBU is a national case-based electronic surveillance system that maintains records of all TB patients enabling real time evaluation of program performance. It is decentralized to the sub-county level and data can be aggregated to the national level. In addition, TIBU has a payment module that utilizes a mobile money transfer process (MPESA) to transfer funds to National Tuberculosis, leprosy and Lung Disease Program (NTLD-P) staff and multidrug resistant TB (MDR TB) patients to reimburse for support supervision and patient financial support respectively. The payment module enhances governance and accountability of funds transfer. The TIBU system is currently being integrated with the routine DHIS2 system.

Health Products and Technologies

In order to increase access to modern health infrastructure in public hospitals, Kenya is pioneering a large, sustainable healthcare project involving the provision, management and servicing of state-of-the-art medical equipment to 98 hospitals through the Managed Equipment Service (MES) project in partnership with private firms.

This has enabled lease state of the art equipment and or services over an agreed period, with the government making regular, pre-arranged payments based on agreed performance parameters. Instead of huge capital outlays that would otherwise be required for building or equipping hospitals, MES arrangements offer public entities an opportunity to spread costs over the contract period, thereby allowing for long-term, sustainable budgeting. Categories of the leased equipment include state of the art radiology, critical care, dialysis and surgical. Training of healthcare workers is embedded into the MES arrangement to include on-thejob user and maintenance training, specialized training, and clinical training in specified fields. Moving forward, plans are underway to lease laboratory equipment to increase access to modern diagnostics across the 98 hospitals.

Some of this equipment, such as radiography, are important in diagnosis of TB, more so with the increased importance of radiography in TB diagnosis.

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¹⁰ Ministry of Health. (2017). Kenya National Health Accounts 2015/16. Nairobi: Health Policy Plus.

¹¹ Global Burden of Disease, 2017 (Accessed February 19, 2019) http://www.healthdata.org/kenya

Service Delivery and Health Sector Achievements during MTP II (2013 – 2018)

Several achievements have been realized by the health sector during the Medium-Term Plan II (2013 - 2018). In reproductive, maternal, neonatal and child health, infant and under five mortality rates have reduced to 39 and 52 per 1,000 live births respectively. These can partially be attributed to increase in immunization coverage to 84 percent and introduction of new vaccines (Rota virus, pneumococcal and Measles - Rubella). Malnutrition among children reduced to 26 percent. Launch of the free maternal services policy, Linda Mama, has been associated with an increase in skilled deliveries to 62 percent with a concomitant reduction in maternal mortality to 362 per 100,000 live births. The contraceptive prevalence rate increased to 61 percent with an attendant reduction in total fertility rate to 3.9 births per woman¹².

During the five-year period of Medium-Term Plan II. tremendous efforts have been made to combat communicable diseases. Malaria prevention and treatment interventions such as mass and routine mosquito net distribution programs to attain universal coverage, intermittent preventive treatment for malaria during pregnancy, and parasitological diagnosis and management of malaria cases have led to a reduction in the prevalence among children to eight percent¹³. Prevalence of HIV in the general population has remained relatively stable, at 4.8 percent¹⁴. The stabilization of the prevalence is largely attributed to the scale up of HIV treatment and care. The major thrust is how to identify the new cases while scaling up treatment and care.

Efforts to estimate the burden and thereby control non – communicable diseases have been ramped up. The country conducted its first STEPwise survey that estimated the burden of a number of non – communicable diseases and their risk factors¹⁵. In addition, the burden of cigarette use was estimated among both adults and youth over the same time period.

To increase access to primary health care, user fees for Level 2 and Level 3 facilities have been waived and county governments compensated for the forgone revenue by the national government. To enhance social protection of the vulnerable groups, including the elderly a Health Insurance Subsidy Program was launched and has 182,000 indigents. In addition, 42,000 elderly and persons with disabilities (PWD) have been insured with by the Ministry of Health through National Hospital Insurance Fund (NHIF). As the country is transitioning to implementing the MTP III 2018 – 2022, there are outstanding challenges facing the health sector. Communicable and non-communicable diseases including injuries continue to exert pressure to the health care system. Likewise, high out of pocket expenditure for health care creates a barrier in accessing quality health care for a majority of the population, this is further compounded by a high-income inequality. Other emerging challenges include anti-microbial resistance, biosecurity, climate change, reducing fiscal space among others.

The overall objective of MTP III 2018 – 2022 is to accelerate the attainment of Universal Health Coverage through: (i) Enhancing efficiency in provision of health care services, (ii) Improving availability of essential health

¹² Kenya National Bureau of Statistics. (2014). Kenya Demographic and Health Survey. Nairobi: Kenya National Bureau of Statistics.

¹³ Ministry of Health. (2015). *Kenya Malaria Indicator Survey 2015*. Nairobi: Ministry of Health.

¹⁴ UNAIDS. (2018, September 11). Country factsheets Kenya 2017. Retrieved from UNAIDS: http://www.unaids.org/en/regionscountries/countries/kenya

¹⁵ Ministry of Health (2015) Kenya STEPwise survey on non-communicable disease risk factors 2015

services, (iii) Ensuring equity in access of essential health services, and, (iv) Enhancing the human resource capacity for health service provision.

1.2 SITUATION ANALYSIS AND PROGRESS UNDER NSP 2015-2018

1.2.1 Epidemiology of Tuberculosis

Prevalence: In 2015/2016, the country conducted its first postindependence TB prevalence survey which revealed that the true burden of TB in Kenya was 426 cases per 100,000 population. It is estimated that 158,000 persons fell ill with TB in 2017¹⁶, yet only about 85,5185 were notified. This, therefore, means that about 50 percent of estimated TB cases were not diagnosed, treated and or notified annually. The trends for children are presumed to be similar. Mortality among people with TB is high with an estimated 43,000 deaths. A majority of the notified TB cases are male, 64 percent. Children under 15 years account for nine percent (see Figure 2). With regard to drug resistant TB (DRTB), it is estimated that Kenya had 2,800 incident cases in 2017 out of whom 577 were detected and notified over the same period¹⁷.

Case Notification: TB notifications and notification rates of all forms declined steadily in Kenya during the period of the previous Strategic Plan from 98,400 in 2012 to 75,898 in 2016, declining by a factor of 10 – 20 percent every year as shown in Figure 1. This decline took place in the context of various shifts of funding and responsibility between central to county levels during the process of devolution. In 2017, there was a 12 percent increase in case notification to 85,188 compared 75,896 in 2016. This increase can be attributed to strengthened collaboration between county and national governments, systematic notification of all TB patients diagnosed at the point of care, scale-up of the availability and use of GeneXpert with it becoming the recommended first diagnostic test in 2015, refreshed capacity building and onsite mentorship of health care workers, facility-based active case finding, and screening among high-risk populations.



Estimated number of persons that fell ill with TB in 2017, according to World Health Organization. (2018). *Global Tuberculosis Report*.



Estimated number DRTB incident cases in 2017out of whom **577** were detected and notified over the same perio



Percentage increase in case notification to **85,188** in **2017** compared to **75,896** in **2016**

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¹⁶ World Health Organization. (2018). *Global Tuberculosis Report.* Geneva: World Health Organization.

¹⁷ National Tuberculosis, Leprosy and Lung Disease. (2018). Annual Tuberculosis Report. Nairobi: National Tuberculosis, Leprosy and Lung Disease

Figure 1 shows the trend in TB notification over time among adults and children, while Figure 2 shows the characteristics of patients with drug sensitive TB in 2017.

Notified cases were predominantly in the economically productive age groups 15-44 among both males and females but with higher rates among males than their female counterparts.

Treatment outcomes Drug Susceptible TB: Treatment success rates for drug susceptible TB among the 2016 cohort are 81 percent and 85 percent among all patients and children, respectively (see figures 3 and 4). Mortality rate, on the other hand, showed an upward trend from about 15 per 1000, 000 population (2000) to 20 per 100,000 population (2015).

Figures 3 and 4 show treatment outcomes for all patients and children respectively, for drug susceptible TB, 2016 cohort.

Childhood TB: Finding of children with TB in the age group 0 - 14 years improved with a number of children diagnosed and put on treatment increasing from 4,483 (2015) to 6,619 (2016) and 7,714 (2017). The proportion

of bacteriologically confirmed children increased from 10 percent (2015) to 18 percent (2017). Child-friendly treatment formulations were introduced in 2016 which has resulted in improvement of treatment success rate (TSR) among children from 79 percent (2016) to 85 percent (2017). The proportion of child contacts of people with TB who were initiated on TB Preventive Therapy (TPT) improved slightly from 11 percent (2016) to 14 percent in 2017. Treatment completion for TPT under five years is at 72 percent in the 2016 cohort.

TB/HIV: HIV testing among TB patients is universal with the ART uptake among HIV positive TB patients at 95 percent (2017) compared to 87 percent (2014). Tuberculosis preventive therapy for patients living with HIV (PLHIV) was rolled out in 2015 and by 2017, 632,736 PLHIVs had been cumulatively initiated on TPT. This is against a 90% target of TPT among all PLHIV, translating roughly to 1.08 million people.

Drug Resistant TB Situation in Kenya: Due to increased access to drug sensitivity testing (DST) to 46 percent in 2017, there has been a commensurate increase in DRTB case notification from 112 cases in 2010 to 577 in 2017.

Figure 2: Trend in case notification (All forms and proportion of children 0-14 years in 2009 - 2018)



Figure 3: Summary of characteristics of DS TB patients in 2017



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Figure 4: Treatment outcomes for Drug Susceptible TB Patients, 2016 Cohort



Figure 5: Treatment outcomes for childhood TB in Kenya, 2016 Cohort

Total Number of			Outcomes	•
6,369	85%	Indicator All Forms	Previously Treated	
	Completed Treatment	TSR	85%	85%
Proviously		CR	67%	53%
Treated 158		Death Rate	4%	9%
		Loss to Follow-up	3%	3%
		Not Evaluated	7%	3%

1.2.2 **Progress Under NSP** 2015 – 2018

The NSP 2015-2018 aimed to contribute to the elimination of TB by 2030, maintain the country's leprosy post elimination status, and reduce the burden of lung diseases. It coincided with the implementation of the devolved governance structure, transition to the End TB Strategy, and transition to the Sustainable Development Goals (SDG) era.

The prevalence (2016) and drug resistance (2015) surveys were successfully completed shedding light on hitherto unknown epidemiological distributions of disease among the Kenyan population.

The NTLD-P undertook numerous studies to build an evidence-base in support of a refined approach. Between 2016-2018, the NTLD coordinated over 15 studies (highlighted in Table 1) with an over-arching objective of better understanding the experience(s) of people living with TB and how they experience barriers to quality care. This body of evidence shed light on where people with TB may be missed by the health system and why. The first national post-independence TB disease prevalence survey (2016) found that nearly two-thirds of people with symptoms for TB had not yet sought treatment. Of these, the majority (82 percent) did not seek care because they felt the symptoms were not serious. It is widely believed that symptoms worsen over time, driving people to seek care.

The survey also found that half of the people with confirmed TB were not identified using symptom screening for cough. However, chest radiography was found to be a highly sensitive screening tool for identifying people with TB. Of those who sought care, a patient pathway analysis suggested that only 43 percent of people accessed a facility with TB diagnostic services (or specimen transport). Nearly onethird of care seeking was in the formal private sector, where TB service availability was less available. The misalignment between care seeking and TB service availability resulted in repeat care-seeking.

A study of patient costs associated with seeking and receiving care for TB found that the proportion of TB affected households facing catastrophic total costs (that were more

Table 1: Surveys Conducted during the NSP 2013 -2018

Resource Title	Year	Problem Prioritisation	Root Cause Analysis	Solution Optimisation
Surveillance, Surveys and Studies				
TB Surveillance Data (TIBU)	All	х	х	
TB Prevalence Survey 2015/2016^	2016	х	х	
Adherence Survey 2017^	2017		х	
TB Patient Cost Survey 2017^	2017		х	
Inventory study 2014/2015^	2016	х	х	
Drug Resistant Survey 2014/2015	2015	х		
Delay in Diagnosis 2013/2014*	2014		х	
Kenya Demographic and Health Survey (KDHS) 2013^	2013	х	х	
KAIS 2012*	2012	х	х	
GXpert Impact Survey 2017*	2017		х	х
Community Survey 2017*	2017		х	
Keheala study to improve Treatment Adherence*	2017		х	х
SARAM Survey 2013	2013	х	х	х
Health ExpenditureUtilization Survey 2016	2016	х	х	
Analyses				
Patient Pathway analysis 2017^	2017	х	х	
Legal environmental assessment by KELIN 2017*	2017		х	х
Data for action for Key, Vulnerable and underserved population by KELIN 2017/2018'	2018	х	x	
Gender barriers to TB by KELIN 2017*	2018		х	
TB/DM by AMPATH*	2017		х	

than 20 percent of their annual household expenditure) due to TB was 27 percent. The proportion of DRTB patients who experienced catastrophic expenditure was three times more than that of DSTB patients (66 percent). Once on treatment, a study on treatment adherence found that 35 percent of people were non-adherent.

Figure 6: Flow chart of care seeking among prevalent TB cases





analvsis of patient pathways An was conducted to determine where patients seek care, and the capacity of these facilities to provide TB diagnosis and treatment services. It found that while a significant number (41 percent) of patients seek care in the private sector, a majority of these lack diagnostic and treatment capacity; a gap that is greatest in the informal private sector. Further, access to GeneXpert testing is low in many facilities, more so in the public sector. This mismatch between care seeking and service availability hampers TB diagnosis and treatment. This is shown in Figure 6.

A study looking at costs incurred by TB patients and their families found that about 26 percent of DSTB patients and 86 percent of DR TB patients incur catastrophic costs at a threshold of over 20 percent of their annual household expenditure. A study on factors affecting adherence to TB treatment found that over a third of TB patients are non-adherent to TB treatment. The following groups were less adherent to TB treatment: HIV uninfected persons, those abusing drugs/ substances and those with extra-pulmonary TB. This is detailed in Figure 8.





Table 2. Adherence study found that 35 percent of people on TB treatment were classified as being *"non-adherent"*

Characteristics Category		Univariate An	alysis			Multivar	iate Analys	is	
Characteristics	Category	OR	[95% CI		p-value	OR	[95% CI		p-value
HIV Status	Positive	(ref)							
	Negative	0.753	(0.613,0.9	998)	0.039	0.753	(0.568,0.9	997)	0.048
Substance Use	Yes	(ref)							
	No	0.582	(0.410,0.3	825)	0.002	0.450	(0.294,0.6	687)	0
Side Effects	No	(ref)							
	Yes	0.709	(0.572,0.8	879)	0.002	0.729	(0.572,0.9	929)	0.01
	Intensive phase	(ref)							
Patient Phase	Continuation phase	2.648	(2.120,3.3	307)	0.000	2.555	(1.984,3.2	289)	0
		•							
Alcohol Use	Yes	(ref)							
	No	0.880	(0.590,1.3	314)	0.532	1.529	(0.950,2.4	461)	0.081
	New	(ref)							
Patient Type	Previously treated	0.986	(0.701,1.3	388)	0.937	0.932	(0.634,1.3	371)	0.722
	Treatment history								
	unknown	Omitted							
Type of TB	ЕРТВ	(ref)							
	РТВ	0.618	(0.474,0.3	806)	0.000	0.710	(0.028,0.5	523)	0.963

In view of the aforementioned turbulent changes in the environment of TB prevention and control, the NTLD-P called for an independent midterm review of the status of implementation of the NSP 2015 – 2018 to identify the main achievements, weaknesses, strategic and programmatic gaps, threats and opportunities to inform realignment of control strategies to the global and local developments and imperatives.

> About **26 percent** of DSTB patients and **86 percent** of DR TB patients incur catastrophic costs at a threshold of **over 20 percent** of their annual household expenditure.

FINDINGS OF THE NSP 2015 – 2018 MID-TERM PROGRAM REVIEW

Program implementation in a devolved governance structure

The TB, leprosy, lung disease coordinators at county and sub-county levels continued to support program implementation at the county level and the central government had continued to finance procurement of first line anti-TB medicines. Need for increased and sustained investment to TB control from both domestic and external sources with country governments allocating resources for TB prevention and control activities through inclusion in country integrated development plans (CIDPs).

Accelerating appropriate diagnosis

There is a well-established and accessible TB laboratory network with a functional external quality assurance (EQA) system. Access in TB diagnosis improved by a 33 percent increase in the number of smear microscopy sites from 1,806 (2013) to 2,409 (2017), four – fold increase in GeneXpert machines from 45 to 189 over the same period. These resulted in a five – fold increase in the proportion of patients accessing GeneXpert from nine percent (2013) to 46 percent (2017). The specimen transportation system was weak and inadequate in terms of coverage and frequency. There is a need to optimise GeneXpert coverage and strengthen the sputum transportation network.

Enhance the multi-sectoral response to TB/HIV

Mainstreamed and integrated collaborative TB/HIV activities at all health care settings resulting in over 95 percent of TB patients tested for HIV and an equally high proportion of those that are HIV positive accessing antiretroviral therapy and cotrimoxazole preventive therapy. Provision of TPT with HIV scaled up significantly during the period of the NSP with a 60 percent coverage. However, provision of TPT for children was low and documentation poor. The review recommended improved supervision for recording and reporting of TPT; development and roll out of contact tracking register to facilitate identification of eligible children; and development of educational materials aimed at improving TPT acceptability among parents.

Childhood TB Prevention and Control

Increased number of children with TB diagnosed and put on treatment from 4,483 (2015) to 7,714 (2017). The proportion of bacteriologically confirmed children also increased from 10 percent to 18 percent over the same period. Child-friendly formulation

was introduced in 2016 that resulted in improved treatment success rate (TSR) among children from 79 percent (2016) to 85 percent (2017). The review recommended increased resources for child TB and application the existing waiver system.

Programmatic Management of Drug Resistant Tuberculosis

Programmatic management of drug resistant TB had been scaled up countrywide with regular updating of internationally compliant national policy guidelines and algorithms. All DRTB patients diagnosed were put on treatment, new molecules had been introduced into treatment regimens, functional clinical review teams were in place and DRTB patients were linked with NTLD - P cash transfer scheme. There was low DRTB case notification with less than 50 percent of estimated cases missed in 2016; low utilization of GeneXpert; and long turnaround time (TAT) of culture and DST results. It was recommended that NTLD - P introduce short course treatment for MDR-TB in line with recent WHO recommendations supported by the availability of second-line DST as a pre-requisite.

Engaging All Care Providers (Public Private Mix, PPM)

The private sector contributed 17 percent of all cases notified in 2016, and treatment outcomes, as well as TB/HIV outcome indicators in the private sector, compared favorably with the public sector. Coverage of private health care providers in the provision of TB control services remained low and uneven across Counties, ranging from zero percent to 65 percent. There were also significant knowledge gaps among private providers in all areas of TB care and prevention. The PPM Action Plan 2017 – 2020 was developed to guide the involvement of the private sector in TB prevention and care in line with the Patient Pathway Analysis findings.

Promote and Strengthen Community Engagement

There had been initiatives to involve the community and community groups in TB control in Kenya with community health volunteer (CHV) groups and civil society organizations (CSOs) providing various levels of support. The main challenge was access to the communities and capacity issues among the volunteers. Need for formation and strengthening of TB support groups to provide psychosocial support to new patients, and piloting of community TB care models for possible adoption and scale up.

Ensure Stable and Quality Supply of Drugs, Diagnostic Tests and Commodities

Countrywide distribution of anti-TB medicines and commodities through Kenya Medical Supplies Authority (KEMSA), and Government financing covered 70 percent of first-line anti-TB medication supply with centralization of TB drugandlaboratorycommodities procurement; and supplies were generally widely available. It was recommended to maintain the centralized procurement of essential TB control medicines and commodities.

Enhance Evidence-Based Program Monitoring and Implementation

A number of key surveys successfully conducted including TB prevalence survey, drug resistance survey (DRS), TB Epi-analysis and patient pathway analysis. There were losses in the TB care and treatment cascade. It was advised to explore reasons for the observed declining notifications and notification rates.

Create an Enabling Environment

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The NSP 2015-2018 was well linked to government policy as stated in key strategic documents such as the Kenya Health Sector Strategic and Investment Plan (KHSSP) 20142018, the Second Medium-Term Plan (MTP) 2014-2018 and Vision 2030. The adopted policies and strategies were also consistent with international recommendations.

Advocacy and Communication

Aspects of TB communication strategy existed, but many were unaware or not utilizing the documents. It was recommended to develop guidelines for TB advocacy at the county level, clearly defining target audiences and channels of engagement, priority issues and potential partners.

Human Rights and Gender

There were documented incidences of human rights concerns regarding the imprisonment of TB patients who were non-adherent to TB treatment. Isolation policy guidelines were developed following the High Court of Kenya ruling that directed the MOH to produce policy guidelines on how patients with infectious diseases should be handled. The NTLD - P to promote awareness of patient charter; work with relevant departments of Government to review laws and policies that take into account human and gender rights as well as public health rights.

Social Protection

Diagnosis and treatment services were free at the point of care, and children under five years were exempted from chest radiograph charges. Drug resistant TB patients received a stipend of KES 6,000 per month and were also eligible for nutritional support while on treatment. Need for targeted strategies to reach hard to reach counties and key populations.

Expand Utilization of Practical Approach to Lung Health (PAL)

Despite notable absence of a functional public health program for lung health in the country, there had been some achievements including development and dissemination of PAL guidelines; development of a training curriculum and manuals; health care worker trainings on PAL; provision of equipment (spirometers); development and dissemination of Information Education and Communication (IEC) materials. It was recommended to embed lung health in the NTLD-P and create a lung health sub-program.

Leprosy

Kenya has achieved and sustained national elimination status since 1989. However, there were still six high burden counties (Kwale, Kilifi, Homa Bay, Siaya, Kisumu and Busia) that accounted for 73 percent of notified cases for the period 2014 to 2016. The majority of these cases were multi-bacillary, some had grade 2 disabilities, and included children under 15 years of age. There was no leprosy focal point at the central level. It was recommended to designate a national focal point for Leprosy control within the NTLD - P and establish a leprosy task force comprising of key partners and representatives of the six high burden counties to plan targeted leprosy control activities.

1.3 NATIONAL STRATEGIC PLAN DEVELOPMENT PROCESS

The Health Sector, in particular the MOH, has grasped the importance of actively developing and sustaining relationships with county governments, private sector, civil society organizations, development partners, affected communities and other stakeholders throughout conceptualization, design and implementation of all interventions in health. This has become more critical following devolution of health, where the risks associated with poor stakeholder relations – and the opportunities provided by constructive ones - are now better understood by all alike. This enhanced stakeholder engagement has led to ownership, improved risk management and better health outcomes on the ground. In the development of this NSP, the centrality of stakeholder engagement to all aspects of the process was key.



Increase in number of smear microscopy sites from **1,806** in **2013** to **2,409** in **2017**



Stipend received per month by Drug resistant TB patients, additional to nutritional support while on treatment.



Percentage of notified Leprosy cases for the period 2014 to 2016 in six high burden counties (Kwale, Kilifi, Homa Bay, Siaya, Kisumu and Busia). With a view to developing an evidence-based and prioritised NSP, the NTLD-P piloted the *"People-Centred Planning Framework"* being developed by WHO. The launch of the NSP development process included a review of all available evidence mapped to the patient care continuum. In a kickoff workshop, over 50 international, national and local stakeholders discussed relevant study results applied to three unique planning steps: (1) Problem Prioritization, (2) Root Cause Analysis and (3) Strategic Intervention Optimisation. The process nurtured country-level planning that centred on asking the questions, (1) What are our biggest problems, (2) Why are they happening and (3) What should be done about it.



Figure 9: People-Centred Planning Framework

Figure 10: People-Centred Framework for data consolidation and prioritised planning



They first identified priorities based on data, tracked gaps in the evidence, and emerged with priorities that were consensus-based at the national level. The process was repeated with representatives from the 47 counties; and through focus groups with patients and healthcare providers. A triangulation of the priorities across stakeholder groups was completed. Sub-national differentiation was documented, resulting in an NSP that responds to local as well as national priorities. For example, MDR-TB was not deemed a priority for all counties, as individually they encounter few cases, but the national level prioritised addressing the issue overall for the country given the severity of the social impact of the disease, and the risk of transmission. Some priorities were identified even amidst a paucity of data. For example, the stakeholders confirmed priority should be given to paediatric TB, with the explicit focus on the need to obtain more data while concurrently scaling up services for what is believed to be a large, underserved population.

Root cause analysis was conducted for each of the priority areas, yielding a prioritized set of socio-economic, health system, and clinical determinants that contribute to the ongoing challenges. This step broadened the group's thinking of possible interventions that could impact the lifecycle of the TB epidemic. It encouraged the teams to think about the role of non-clinical stakeholders, such as those who provide nutritional support, education, and poverty alleviation efforts. Activities reflected in sections 3.1 and 3.2 of the NSP are derived from this exploration of the data.

The groups assessed potential strategic interventions to address identified determinants and root causes. They mapped

the feasibility, and known/potential impact of different interventions, engaging stakeholders across the health and non-health sectors.

Once packages of activities (interventions) were identified, the NTLD-P costed the full plan. The full cost is presented in Table 10. Mathematical modelling of impact was used in combination with cost models to consider the Incremental Cost-Effectiveness Ratios of interventions. Interventions were optimised to identify the package that will achieve the highest impact on the epidemic overall and for selected special populations, within a resource constrained budget.

The NTLD-P considered three resource scenarios; e.g. 2018 - 2019 funding levels, 25 percent increase in funding, and an aspirational/fully financed budget. Under each scenario, the package of interventions that most effectively and efficiently targets root causes and priority problems was determined and is presented in part 2 of the NSP. The budget with 2018 - 2019 funding levels can be used for immediate action, while the other budget tiers can be used as the basis for future funding requests.

The process of developing the NSP followed the roadmap as outlined in Figure 11.

The outcome of this robust stakeholder engagement has been endorsement of the NSP by January 2019. Finally, Ministry of Health approval of the NSP was obtained at the mid of February 2019. After the finalization of Part I of the NSP, the Strategic and Technical Plan, counties were engaged to come up with their operational plans that fed into the national document with targets jointly agreed on.



AT A GLANCE

65%

Percentage of people with TB symptoms who did not seek care, majority of them being men, according to the National TB Prevalence Survey 2015/2016

PILLAR ONE: PATIENT-CENTRED CARE



2.1 SECTION ONE: CONSIDERING THE PATIENT PATHWAY FOR TUBERCULOSIS

2.1.1 Promoting Care Seeking and Prevention in the Community

This NSP represents a paradigm shift in the strategies used to reduce TB prevalence in the country. While maintaining a focus on the provision of quality treatment for all those ill with TB disease, this NSP also aims to scale the use of preventive treatment of TB infection among high-risk populations. Specifically, this NSP embraces the adoption of the new, shorter regimen (Rifapentine and Isoniazid for 3 months) for the treatment of TB infection and presents an ambitious partnership with community health volunteers, large employers, and the Ministry of Education to enable contact tracing for workplace, school-based and household contacts of TB patients, as well as among people with HIV. The move away from monotherapy for TB Preventive Therapy is expected to overcome provider hesitation to treat Latent TB infection. The NSP also anticipates the early adoption of new TB screening tests as they become globally endorsed and commercially available.

Kenya recently conducted the national TB prevalence survey 2015/2016 whose results showed that 65 percent of the people with TB symptoms did not seek care, majority of whom were men²⁰. Further, 75 percent of the participants reported that the symptoms were not serious enough to warrant seeking care²¹. Among the respondents in a TB Knowledge Attitude and Practices (KAP) Survey 2014, knowledge that TB is an airborne disease was mentioned by 74 percent, cough of between two to three weeks as suspicious of TB by 40 percent, awareness that TB services are free by 66 percent and 81 percent were able to identify where TB services are provided²². This clearly points to a gap in TB awareness at the community level and targeted efforts to increase awareness for the demand for TB services.

²⁰ National Prevalence Surveillance Report 2016

²¹ Kenya Demographic and Health Survey 2014

²² Kenya Knowledge, Attitude and Practice Survey Report

The NTLD-P Communication Strategy 2015 recommended enhanced TB awareness targeting general public through various platforms to create demand for TB services through enhanced health care seeking behavior. In addition, the national prevalence survey showed that majority of those people with TB who are missed are men in the productive age group; poor health seeking behavior partly compounded with societal gender pressures have been identified as key factors. The Kenya Patient Pathway Analysis (2017) showed that 14 percent of patients with TB symptoms sought care with informal service providers who have no direct linkage to the NTLD-P.

Community TB prevention is a cornerstone in the End TB Strategy; with increased numbers of people with TB symptoms still in the communities who are not seeking care and further only 13 percent of children on TPT.

Largely, there is need for multi-pronged approach for addressing these key issues ranging from bold policies, enabling environment, behavior change, intensified TB awareness creation and differentiated advocacy and communication approaches.

The strengthening of Stop TB Partnership provided a platform for advocacy and engagement of a multi-sectorial approach and a structured engagement between the Ministry of Health, Civil Society Organizations (CSOs) and Community Based Organizations (CBOs) from the national level through to the counties and communities. Numerous ongoing community-based interventions involving Community Health Volunteer (CHV) groups and CSOs already exist. These include TB awareness-raising, child contact management, screening for TB through home visits, facilitating access to diagnostic services, referral of community members for diagnosis of TB, treatment adherence support and community-led local advocacy services. These interventions have resulted in an increase in the percentage of all notified TB cases that come from CHVs from four percent in 2013 to 10 percent in 2017. At the national level, the TB Inter-agency Coordinating Committee (TB ICC) and technical working groups have representation of TB communities, CSOs and CBOs.

Though TB is an infectious disease that affects everybody, it has not been given a priority by most sectors in their health policies; for example, in the transport sector, the NTSA strategic plan captures the safety of the commuter without considering the vulnerability to communicable diseases like TB. There is thus need to advocate for the inclusion of TB in their health policies.



Percentage increase in all notified TB cases that come from CHVs from **four** percent in **2013** to **10** percent in **2017**



Number of community units established with **4,048** CHEWs and **90,758** CHVs.



At risk, in

community

symptoms, seeking care but not diagnosed

ΤВ

Diagnosed but not on treatment On treatment but not yet cured

Limited TB awareness and updated information levels in communities: In the last few years, whilst a number of resources have been expended in the development of various IEC materials, there still exists a huge gap in terms of TB awareness. Misconceptions and myths amongst populations in regard to TB also contribute highly to poor health seeking behavior. A more proactive approach would be the need to zone various audiences by age, gender, other external factors (geographical, political, economic, religious, cultural) and adopt innovative delivery mechanisms which can be evaluated.

ΤВ

symptoms,

sought care

has not

Ø.

Lack of differentiated advocacy and communication: Clear communication is vital for both awareness and advocacy at all levels in the care continuum; policy makers, health care workers, community and patients. Proper and timely communication impacts on the quality and sustainability of service provided and it ensures a continuous feedback loop. It is important to realize and appreciate that packaging and delivery of information to various stakeholders is different and unique and should be targeted and customized.

TB symptoms not perceived as serious: According to the prevalence survey, it found that there was limited awareness of the cardinal signs and symptoms of TB, and many people either do not recognize these symptoms as symptoms of tuberculosis, or do not take the requisite actions whenever they experience them. This results in patient delays in seeking care and enhances continued active transmission further compounding the TB menace.

Stigma: Stigma still remains a huge impediment to TB care and treatment due to its high correlation to HIV. Poor health care worker attitude continues to fuel this problem as potential patients are discouraged to visit such facilities. Further, stigma among TB patients in the community (household members, neighbors) also adds to this inequality. This results in a negative impact in drug adherence for those already in care and further worsens the poor health seeking behavior.

Inadequate community health system linkages: There exists inadequate community health system linkages between health facilities and community units. This is demonstrated by weak referral mechanisms from health facilities, poor documentation of contribution by CHVs and incomplete feedback loops between the community and the health service providers. These leads to interruption of health service delivery to complete the conduit for optimum care. These are likely to lead to missed opportunities of finding potential TB patients.

Suboptimal access to TB prevention: Kenya's Epidemiological Review, 2017 indicates that though the country has made great strides in providing TB preventive therapy (TPT) to people living with HIV (PLHIV), eligible children under the age of five with contact to bacteriologically confirmed TB have low TPT coverage with of 13 percent. The prevalence survey additionally indicated there is inadequate access to TPT among key groups which include; men (24 to 45 years), elderly women (65 years and above). According to the Legal Environment Assessment for Tuberculosis in Kenya (KELIN, 2018), stigma surrounding TB still prevails in Kenya leading to limited access to TB prevention and other care services. In addition, influx of enrolment in learning institutions without commensurate infrastructure has led to limited infection prevention control measures. Varying knowledge and understanding of TPT among both the community and HCWs has hampered uptake.



STRATEGIC INTERVENTIONS

This NSP represents the operationalization of integration of TB, leprosy and lung health within existing community-based initiatives of other health programs like Community Health Strategy, HIV, RMNCH, PHC.

Innovative patient-centred communication methods: To accelerate care seeking, innovative and patient-centred communication methods targeting Kenya's diverse population will be engaged. In addition, targeted communication interventions will be rolled out to improve care seeking among young people, school going children, and people living in informal settlements. Communication to facilitate the engagement of informal health providers, pharmacies and workplaces in the referral of presumptive cases, will also be developed. This will require sustained and differentiated communication package with use of appropriate media and technology such as digital (new media, media cafes, and community dialogues) adoption of county-based strategies for TB information dissemination informed by the context. A specific focus on genderbased differences in knowledge, care seeking and treatment adherence will inform the communication approach in 2019 - 2023. For example, male targeted communication and male-specific clubs led by male, former TB patients and champions will focus on identifying the key barriers to TB care by men, and overcoming the higher rate of men missing from care and loss to follow up among men. In addition, TB, leprosy and lung health messages will be integrated into community health days and other health-related platforms at community level.

Building of political support and establishing collaborations at all levels: To find all missing people with TB, this NSP supports building of political support and establishing collaborations at all levels that will help mobilize domestic resources while overseeing implementation and monitoring of the progress of the response. In this regard, special institutional collaborations between the NTLD-P and county governments and addition of TB to the agenda in the intergovernmental forum will be done. Communications and advocacy across the national and county governments, broadening ownership of the program will be enhanced. This will include the engagement of the Parliamentary and county assembly health committees, the Stop TB Partnership-Kenya, National parliamentary TB caucus, the Council of Governors (COG) with regular briefs provided by the NTLD-P and county TB coordinators respectively. Political will and domestic resources for TB, leprosy and lung health mobilized at the county level

through development of county specific NSPs that put into context the county burden of these diseases. This will require development of county specific situational analyses and baseline information. This NSP will have county-specific targets to be monitored, including program performance, financial commitments, and funding gaps. They will also include county-specific advocacy and communications plans taking into account the local challenges and opportunities. In addition, it will provide for mechanisms of incorporating issues related to the control of TB, leprosy and lung health into key county fora (like the county assemblies). Additionally, it will also provide a basis of advocating for inclusion of TB, leprosy and lung disease in county integrated development plans (CIDPs).

Empowering Community Actors. Stakeholders and TB Champions: Civil society organizations (CSOs), communitybased organizations (CBOs), community health volunteers (CHVs), community health extension workers (CHEWs), religious leaders and other community leaders will be empowered to inform, educate and support patients, patient families and communities. This will require building their capacity with regular training and adequate mentoring and monitoring. Use of innovative methods for capacity building and communication like ECHO sessions, use of mobile applications, and SMS alerts on updates will be explored. Clear simple protocols for identification of people suspected to have TB and standardized tools to ensure care, monitoring and follow up will be provided in a standardized manner. Identification and empowering of champions for TB from each of the key stakeholders- journalists, governors, religious leaders, parliamentarians, patients, CSOs as well as county-based TB patient/ survivor groups to help strengthen advocacy at the sub-national level.

Community Based Systematic Screening of Key Populations: This NSP will prioritise community based systematic screening of key populations by means of targeted TB outreaches in areas of focalized transmission like urban slums, matatu industry, congregate settings (schools, workplaces, prisons) with index cases among others. Comprehensive policy and guidelines on community based systematic screening for TB will thus be developed and implemented. This NSP will prioritise systematic screening for TB for all household contacts (and workplaces contacts) of people with TB including children under five years. Index cases will be identified at health facility TB and comprehensive information regarding names of contacts and exposure locations (households, schools and or workplaces) will be elicited. The index case will be requested to bring the contacts for screening or a field visit will be conducted by CHVs to the index patients' residence, workplace, school to identify contacts, interview and assess them for TB. Contacts who will be suspected to have TB based on the interviews will be referred to the nearby health facility. Health care worker surveillance will be institutionalized with all HCWs being screened every 6 months. This will require implementation of the occupational health policy as a directive from the highest level within the Ministry of Health, and will therefore require the engagement of all county leadership for support and ownership.

Improving Community-Based Access to TB Prevention: This NSP supports improving community-based access to TB prevention through roll out of alternative approaches for contact tracing (use index cases to bring contacts to the facility; use CHVs to trace contacts who don't respond to appointments) with expansion of existing TPT policy to include community DOTs. Specimen referral and feedback in targeted communities with

high TB burden like informal settlements will be enhanced through community health strategy structures and approaches. This NSP also looks to adopt the new LTBI treatment guidelines that propose shorter TPT regimens for eligible groups, as well as the engagement of community systems to strengthen follow up of patients initiated on these regimens.



Number of GeneXpert machines across the country, with an additional **37** distributed in the private sector.

OUTCOME TARGETS

	Indicator	Baseline	Target
Î	Increase proportion of the people with symptoms of TB from the community that seeks appropriate care from health facilities	40%	80%
	Increase proportion of people with TB referred by community health volunteers and Informal Service Providers	10%	25%
	Increase proportion of eligible children under 5 years who are contacts of people with TB, who are put on TB preventive therapy	13%	90%

2.1.2 Accelerating Appropriate Diagnosis

This NSP represents the operationalization of new national policy that recommends that all confirmed TB patients receive DST. This will require that all diagnostic facilities have either GeneXpert capacity on-site or a specimen referral arrangement to a qualified laboratory. An optimised laboratory network that has been modeled, and has informed county-specific planning about equipment and transport requirements. Successful implementation of this policy shift will require enhanced collaboration between care facilities and laboratories, as patients may undergo multiple rounds of testing. Such collaboration will require enhanced capacity among health staff and laboratories, as well as connected patient management data systems to follow patient progress.



SITUATIONAL ANALYSIS

The Kenya TB laboratory network is a wellestablished tier of 2,409 health facilities with smear microscopy sites, 189 with GeneXpert MTB/RIF and two culture laboratories. The network serves approximately 10,000 public and private health facilities where presumptive TB patients seek care.

GeneXpert is the first line diagnostic test for all presumptive TB cases, except at health facilities where it is not accessible. Laboratory personnel have adequate technical skill to perform smear microscopy (Ziehl-Neelsen/ fluorescence microscopy) as first test where GeneXpert is not accessible. The introduction and roll out of GeneXpert has emerged to be the most important, measurable shift in the tuberculosis diagnostics landscape in Kenya with an increase from 3 (2011) to 189 (2018) machines across the country, with an additional 37 distributed in the private sector.

Use of GeneXpert has led to an increase of the proportion of notified TB cases with a rapid diagnostic test at the time of diagnosis, from nine percent (2014) to 48 percent (2017). There is a real time reporting system, GeneXpert Laboratory Management and Information System (GXLMIS), that conveys results through short messages (SMS) and email alerts. Moreover, the country has witnessed an exponential increase in the number of tests as well as the proportion of bacteriologically confirmed cases from about 50 percent to 67 percent.

Table 4: Annual Number of GeneXpert Tests in Kenya, 2012 - 2017

Year	Tests and Results				
	Total	МТВ			
	Number of Tests	Positive	Negative		
2012	1,273	391	803		
2013	6,430	2,210	3,747		
2014	22,887	5,608	16,130		
2015	83,387	17,084	61,207		
2016	193,169	29,022	156,285		
2017	256,250	34,540	213,206		

There exists sample referral and transportation mechanisms from peripheral facilities to GeneXpert sites in at least 20 counties. Further, there also exists a well-established countrywide sample referral system that transports specimens to the two culture laboratories, for both culture and drug susceptibility testing (DST), and the feedback relayed via email.

A functional external quality assurance (EQA) scheme for all the four diagnostic tests: smear microscopy, GeneXpert, culture and line probe assay (LPA) is in place. The National TB Reference Laboratory (NTRL) attained ISO 15189 accreditation in 2018 allowing it to continuously conduct quality services. It has since validated second line DST and participates in the EQA programs for culture and first and second line DST through Brisbane (Australia) and National Institute for

Table 3: Cumulative Number of GeneXpert Machines in Kenya, 2011-2018

Year	2011	2012	2013	2014	2015	2016	2017	2018
Number of GeneXpert Machines	3	11	24	71	126	131	153	189

Communicable Diseases (South Africa). Line Probe Assay (Hain Life science MTBDRPlus) is performed on all smear positive cases directly from the specimen or from culture, if required. The NTRL also participates in the EQA scheme developed by National Health Laboratory Services (NHLS) in South Africa.

In 2017, the coverage for monitoring performance indicators and enrollment in EQA scheme for smear microscopy was 85 percent of the diagnostic testing sites with 93 percent of the sites passing. Panel testing and EQA for all GeneXpert is also ongoing on a quarterly basis with an overall 91 percent participation and a performance of 99 percent in 2017. There are GeneXpert super-users at every county to support its implementation.

To strengthen reporting and monitoring at the laboratory, there are ongoing efforts to integrate laboratory data systems with routine reporting system to aid in virtual sample referral, tracking referral of patients for DST as well as to promptly reduce time between diagnosis and treatment initiation.

In 2017, the private sector contributed to 18 percent of the total patients diagnosed. Private sector laboratories vary in size and scope, from small informal facilities to large private sector hospital laboratories that are accredited to international standards. There are 285 documented private laboratories in Kenya including 37 that have GeneXpert instruments, five LPA and two culture and DST services.

Figure 12: Map Showing Distribution of Diagnostic Sites in Kenya



Human resource capacity has been developed over time to ensure that quality testing is offered. However, there continues to be high staff turnover as well as inadequate staffing in a number of facilities.

INTERVENTIONS THAT HAVE WORKED AND SHOULD BE SUSTAINED / SCALED

Diagnostic network optimisation analysis conducted in 2018 found that the current GeneXpert capacity is well placed and sufficient for current testing demand. However, long transport coverage from peripheral health facilities to GeneXpert testing sites exist, particularly in hard to reach counties. This suggests the need for placement of additional instruments to improve access to services in these areas. The evaluation also found that the current instrument capacity is under- utilized, with a majority of instruments running less than eight tests per day. Further, most specimens tested originate from the health facilities where instruments are placed, with limited referral of specimens from peripheral sites. To accelerate rapid and accurate detection of TB, significant scale up of GeneXpert testing and sample referral and

Microscopy sites have increased from **1,806** to **2,409** in the last NSP cycle. networking across all counties will be required to meet NSP targets for TB case detection. This would require, increasing the number of counties that have an established TB sample referral system that covers 75 percent of all their Level 2 to Level 6 health facilities to 80 percent.

Proportion of new and previously treated patients notified who received DST tripled during the last NSP cycle stood at 46 percent and 71 percent respectively in 2017. Opportunities exist to scale this up to 90 percent through optimisation of the GeneXpert network as proposed above and strengthening of access to TB culture services. Although there is a well-established sample referral system between counties and culture laboratory using courier service, there are still gaps in tracking of patients with Xpert RIF result or others requiring referral for culture and DST.

Microscopy sites have increased from 1,806 to 2,409 in the last NSP cycle. They will continue to play a significant role in both diagnosis and clinical follow-up of patients with their operations requiring to be sustained in 2019-2023.

Currently through the **Managed Equipment Services (MES)**, the Ministry of Health procured and distributed **98 digital radiography machines** across all counties. In general, there are 987 general radiology machines in Kenya in both private and public facilities.

The two culture laboratories have played a significant role in providing first and second line DST and routine clinical follow-up of DRTB patients.



Low access to WHO recommended rapid tests at time of diagnosis: Only 47 percent of notified TB patients obtain a GeneXpert test at the time of diagnosis. Though the TB diagnostic algorithm provides for GeneXpert MTB/RIF test as the initial test for TB diagnosis, in health facilities without GeneXpert, sputum smear microscopy is performed as the first test. In 2018, GeneXpert was only available in 183 public health facilities with a weak specimen referral system to support transport of sputum across health facilities. Only 20 out 47 counties are covered by sample transport linkages.

Sub-optimal use of existing GeneXpert MTB/RIF equipment:

There is still substantial underutilization of the GeneXpert machines capacity, with the average utilization at 47 percent in 2017. Factors that may contribute to this include weak referral systems that fail to link those that need the test with the facilities that offer the testing and limited screening at peripheral health facilities. In addition, long turnaround time for GeneXpert results with lack of a standardized automatic result transmission system. Equipment downtown due to power outages and consumable stock outs.

Inadequate human resource capacity with regards to regular training, mentoring, monitoring and supervision. This is partly due to lack of updated guidelines for and with inadequate staff knowledge on current TB diagnosis approach and the low index of suspicion for TB among clinical staff.

Inadequate quality assurance of TB diagnostics due to lack of updated guidelines on external quality assurance system for diagnostic tests, limited coverage of panel testing for microscopy and GeneXpert and insufficient feedback mechanisms.



Number of general radiology machines in Kenya in both private and public facilities.



Number of digital radiography machines distributed across all counties by the Ministry of Health through the Managed Equipment Services (MES)

Limited use of chest radiography for TB diagnosis: The Kenya National Prevalence Survey 2016 found that use of chest radiography helps diagnose an additional 52 percent of TB patients. By 2018, chest radiograph used was limited as a tool to aid in clinical diagnosis with its availability is limited to Level 4 health facilities while patients bear its cost.

Insufficient engagement of private laboratories in TB care.



STRATEGIC INTERVENTIONS

Use GeneXpert MTB/RIF as initial TB diagnostic test: To ensure early and complete diagnosis of TB and provide DST to all, this NSP stands for use GeneXpert MTB/RIF as first the TB diagnostic test for ALL adults and children being investigated for TB. The NSP proposes progressive achievement through increasing GeneXpert equipment placement across the country the optimum number 450 - 500 as provided for GeneXpert Network Optimisation Report. However, in counties with vast distances between health facilities, priority will be on placement of more GeneXpert equipment to improve access rather than equipment utilization.

Integrated sample referral system: This NSP represents improving the efficiency GeneXpert network structure by increasing the number of counties that have an established TB sample referral system to 80 percent. To achieve this strategic approach, NTLD-P will in collaboration with NPHLS establish a policy and implementation framework of sample referral across diseases and implementing partners. The policy will facilitate the streamlining of the diagnostic network to ensure appropriate specimen collection and transport countrywide with electronic tracking. County governments will be engaged for development and financing of county integrated sample transport network together with their local implementing partners. The NTLD-P and NTRL will in turn offer technical assistance. The plans will focus on turnaround time as a key performance indicator and will help improve the GeneXpert MTB/RIF utilization to 80 percent.

Use of new WHO –recommended diagnostic tools and approaches: This NSP supports the rapid adoption of new WHO endorsed diagnostic methods including point-of-care tests once they have been approved by WHO. These include (and is not limited to) rapid adoption and implementation of ultracartridge, roll out of TB -LAM for severely ill PLHIV, GeneXpert Omni especially in the hard to reach counties, use of stool for TB diagnosis among children.

Scale up access to quality LPA/culture by ensuring universal access for 1st and 2nd line DST for all rifampicin resistant TB patients and other eligible patients: To achieve this, the NSP will support the establishment of an additional three culture labs while improving the capacity of the existing two.

Use of a broader/more sensitive TB screening criteria: In line with recommendations of the Kenya National Prevalence Survey 2016, this NSP supports the adoption of a screening approach that combines a sensitive and broader symptom screening criterion with additional use of chest radiography for triage. The NTLD-P will validate and roll-out an updated screening and diagnostic algorithm. In addition, the NTLD – P will leverage on the telemedicine using the ICT network laid out by the MES project to increase the uptake digital chest radiography. Strengthening of quality of laboratory services is of critical importance in ensuring people with TB are get correct and timely diagnosis. This NSP therefore stands for the development and roll-out for quality assurance system for all diagnostic tests. This will be through strengthening implementation external quality assurance (EQA), blind rechecking for smear microscopy, panel testing (PT) for GeneXpert and PT for culture and DST. This will include laboratories in private and public health facilities. In addition, continuous quality improvement (CQI) will be implemented through the development of a CQI plan, tools, standard operating procedures and technical assistance. The NTRL is now accredited for SLMTA and maintenance of the status will be supported. Strengthening biosafety and biosecurity at the two culture laboratories (NTRL and Kisian) and across other TB diagnostic laboratories (GeneXpert and smear microscopy). Establish systems for corrective and preventive actions this includes microscopy, GeneXpert and culture and DST (CAPA: checklist, technical assistance and mentorship). Automation of feedback mechanism to include online system for PT results transmission and online feedback.

Appropriate human resource with regular training and adequate mentoring, monitoring and supervision. This NSP will (i) Advocate for continuity of services and succession mentorship (ii) Ensure that the training institution update the training curriculum (iii) Trainings that encompass new training, refresher training, mentorship, and competency testing on TB operating procedures. Have regional OJT centres for practical training of staff (iv) Establishing a frame work for TB culture decentralization (v) Establish a system for maintaining BSL III (vi) Build capacity of NTRL to do MIC for different TB medication.

Remove cost barriers to TB diagnosis: This NSP supports the establishment of a framework for engaging private laboratories in TB diagnosis. The NTLD-P will be required to develop a coordination mechanism and regular engagement with private laboratories while providing consumables such as GeneXpert cartridges at reduced prices to ensure minimal costs to patients.

2008

The year Kenya became the first country in Africa to achieve WHO targets for case detection and treatment success of new smear-positive pulmonary TB cases

96%

Percentage of notified TB cases receiving HIV testing and counselling services, while **95 percent** of HIV positive TB patients receiving life-saving ART





OUTCOME TARGETS

	Indicator	Baseline	Target
Î.	Increase proportion of notified TB cases that receive a rapid diagnostic test (GeneXpert MTB/RIF) at the time of diagnosis	47%	90%
	Increase proportion of notified patients with Rifampicin resistant who receive Second Line DST results	Data unavailable	100%
11	Increase proportion of diagnostic testing sites that monitor performance indicators and are enrolled in an EQA system for all diagnostic methods performed	85%	100%

2.1.3 Quality of Care and Ensuring Cure



SITUATIONAL ANALYSIS

Kenya is globally recognized as a pathfinder for TB and leprosy control. Within the African region, Kenya was the first country to achieve WHO targets for case detection and treatment success of new smear-positive pulmonary TB cases in 2008. Additionally, Kenya continues to demonstrate great success in the integration of TB/HIV programming, with 96 percent of notified TB cases receiving HIV testing and counselling services, while 95 percent of HIV positive TB patients receiving life-saving ART²³.

This has further been strengthened through engagement of HIV partners and stakeholders in support for TB activities, such as increasing uptake of TPT for PLHIV. As of September 2018, 612,000 PLHIV were initiated on TPT. This engagement has further been strengthened with the private sector with up to 18 percent of all TB cases notified, being contributed by the private sector. In regards to diagnosis, Kenya is a pioneer at adopting globally proven interventions for TB care including scaling up GeneXpert testing in order to provide DST for all TB patients. Various sample networking models such as the use of riders for health, couriers and public transportation provide access for patients outside GeneXpert testing sites. In 2017, 64 percent of bacteriologically confirmed patients accessed DST while up to 71 percent of previously treated patients received DST²⁴.

The NTLD-P has developed structures to provide decentralized TB care for all patients with 4,230 TB treatment sites available across the country. Supportive supervision is provided at all levels with 49 county and 290 sub-county coordinators supported to mentor health workers in all treatment sites.

Tuberculosis care in Kenya is standardized, and in keeping with international standards with drug sensitive TB patients (DSTB) treated for six months, while drug resistant TB patients (DR TB) treatment regimen and duration is

 ²³ National Tuberculosis Leprosy and Lung Disease Program: Annual Report, 2017.
 ²⁴ National Tuberculosis Leprosy and Lung Disease Program: Annual Report, 2017.

based on resistant patterns. Care follows the DOTs strategy, with The TB care cascade below outlining the various components affecting TB care.

Following the Kenya Prevalence Survey 2016 findings, the country put in place several initiatives to find the 'missing people' with TB. These strategies included active case finding in high volume facilities in 13 selected counties, immediate and prompt notification of all TB patients diagnosed at their point of care, capacity building and onsite mentorship of health care workers, scale up of GeneXpert machines. In addition, the diagnostic algorithm was updated with the inclusion of GeneXpert as the first test of choice. These interventions have led to a 12 percent increase in TB case notification between 2016 and 2017.



Figure 13: The TB Care Cascade

Figure 14: TB Care Cascade, 2016 Cohort



Table 5: Percentage Change in TB Cases Notified during Active Case Finding (ACF) in 13 High Burden Counties, A Comparison between County Referral Hospitals and Total County Case Notification

	County Referral Hospital	Percentage Change in Cases Notified	County	Percentage Change in Cases Notified
1	Coast PGH	422	Mombasa	7
2	Garissa PGH	1	Garissa	6
3	Homa Bay CRH	127	Homa Bay	8
4	Kakamega PGH	95	Kakamega	35
5	Kericho CRH	65	Kericho	21
6	Lodwar CRH	81	Turkana	27
7	Machakos L5H	129	Machakos	24
8	Mama Lucy Kibaki Hosp	257	Nairobi	2
9	Meru CRH	243	Meru	34
10	Nakuru PGH	241	Nakuru	10
11	Nyeri PGH	64	Nyeri	29
12	Siaya CRH	78	Siaya	8
13	Thika L5H	-26	Kiambu	7

According to the Mid Term Review of the NTLD-P (2017) there is countrywide distribution of anti-TB medicines and commodities through KEMSA, and government financing covers 70 percent of first-line anti-TB medication supply. There is also centralization of TB drug and laboratory commodities procurement; and supplies are generally widely available. Systems have also been put in place to ensure patients, particularly DR TB patients on treatments are monitored for adverse drug reactions (ADRs).

In the period of the NSP 2013-2018, several surveys have been conducted and results disseminated. The Prevalence Survey described patient care seeking habits while also identifying specific patient groups that are mostly affected by TB such as men, 25-44 age group, and those in urban settings. The Adherence Study identified patient groups at the highest risk for non-adherence such as men, HIV negative status and patients with

extra-pulmonary TB, while the Patient Pathway Analysis 2016 has been useful in determining service provision and care seeking behavior for TB patients within the health system.

Treatment outcomes among TB patients are diverse across different patient groups, with the Annual TB Report 2017 showing mortality rates of 10 percent among TB/HIV co-infected patients, compared to six percent among all TB patients. Cure rates are also lower among the TB/HIV co-infected patients (63 percent), compared to the non-co-infected (73 percent). Additionally, treatment success rates among DRTB patient outcomes were 73 percent with a mortality rate of 15 percent for the 2016 cohort. This implies different approaches are required for different patient groups at risk for poorer treatment outcomes. This NSP looks to strengthen holistic care for all TB patients that promotes treatment completion under an enabling, patient-centred environment.



According to the Prevalence Survey (2016), **approximately half of TB cases remain undetected and untreated**, while over threequarters of people with TB symptoms who seek care within the health system do not get diagnosed and are missed. In addition, the survey showed that symptomatic screening missed TB patients, while chest radiography emerged as a useful tool for TB screening. Studies have shown that a typical TB patient will visit a health facility up to 5 times before a diagnosis of TB is made²⁵. This is due to the low index of suspicion for TB within the community and amongst HCWs.

There are many **losses within the health system** along the TB care cascade. The Inventory Study (2015) showed up to 21 percent of smear positive patients were lost between diagnosis and treatment initiation or notification²⁶. Additionally, up to five percent of patients initiated on TB treatment in 2016 were lost to follow up and six percent died²⁷.

Following the data synthesis and prioritisation workshop conducted in 2018, several root causes were identified that affect the quality of TB care in Kenya. The causal factors contributing to patients not being cured include being lost to follow up or dying while on treatment. Factors associated with being lost to follow up include: patients stopping medication as a result of high pill burden, adverse drug reactions, malnutrition, and inflexible timings interfering with their source of income, substance abuse and mental illnesses, long duration of TB treatment, selfstigma and inadequate patient-centred care. The 2017 epidemiological review noted the declining cure rates of bacteriologically confirmed TB patients over the years. This may imply suboptimal monitoring and follow up of bacteriologically-confirmed TB patients and as a proxy, TB patients in general. Overall treatment success rates have also been declining, a reflection on the suboptimal quality of care that is negatively impacting treatment outcomes.

Suboptimal monitoring and follow up during

TB care: Patients on TB treatment need to be regularly monitored for adherence, drug to drug interactions, adverse events, as well as response to treatment particularly for those with bacteriologically confirmed TB. The Adherence Study (2017) found up to 35 percent of TB patients interrupt treatment in the course of therapy with non-adherence being worse in those who reported side effects. In addition, patients who waited for more than 30 minutes to be served were more likely to be non-adherent, with the risk of non-adherence

²⁵ Harries A D, Nyirenda T E, Godfrey-Faussett, P, et al: *Defining and assessing the maximum number of visits patients should make to a health facility to obtain a diagnosis of pulmonary tuberculosis, 2003,* Int J Tuberc Lung Dis 7(10):953–958

²⁶ Tollefson, D., Ngari, F., Mwakala, M., Gethi, D., Kipruto, H., Cain, K., & Bloss, E. (2016). Under-reporting of sputum smear-positive tuberculosis cases in Kenya. *International Journal of Tuberculosis and Lung Disease*, 1334–1341.

²⁷ National Tuberculosis Leprosy and Lung Disease Program: Annual Report, 2017.

being highest among men, age group 25-44 years, HIV negative, EPTB, and those who experienced increased cost of transportation to health facilities.

Inadequate TB patient knowledge: According to patient evaluations conducted during the 2017 Mid Term Review, it was established that there is suboptimal patient knowledge on TB as a result of inadequate counseling during treatment initiation. Inadequate patient knowledge is a key factor affecting adherence. Patients with TB require counseling on the duration and course of treatment, potential side effects, pill burden, timing of medications, infection control, nutrition, treatment support at household and community level and positive living. Inadequate patient empowerment may result in adverse outcomes such as medication fatigue due to high pill burden, treatment interruption due to adverse drug reactions, substance abuse and self-stigmatization.

Suboptimal patient-centred care in the context of TB can be described as poor engagement of patients in their care, resulting from poor integration of services for TB patients with comorbidities, inflexible opening hours and care, unfriendly HCW attitude and inadequate HCW capacity. According to the Prevalence Survey, TB mostly affects the economically productive age groups. It is also prevalent in the urban settings, with many of these patients being in the lower economic bracket. This means that hours spent seeking care translate to lost income. Tuberculosis care on the most part is provided during standard working hours with poor flexibility to cater for those seeking care outside the specified hours. In addition, TB medications are only provided within the TB or chest clinics and

are unavailable in other departments. Patients with comorbidities often face unintegrated systems and HCWs inadequately equipped with knowledge on how to detect and manage the other comorbidities.

Patients with TB may die in the course of treatment due to several factors including delayed and, or missed diagnosis and comorbidities^{28,29.} Comorbidities majorly affecting TB patients include HIV, diabetes, and malnutrition. In 2017, 82 percent of patients were assessed for their nutritional status. Of those assessed, 48 percent were malnourished, while those found to have moderate acute malnutrition, only 28 percent were put on nutritional support, and of those with severe acute malnutrition, only 15 percent were initiated on food support. This shows a gap in the nutritional care cascade of TB patients.

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STRATEGIC APPROACHES

Following the identified priority gaps in TB care, this NSP will focus on to putting in place strategies that will 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. This NSP more importantly looks to optimise cure among patients initiated on treatment, and address underlying causes of mortality during TB care.

Strengthened engagement of county and facility leadership will be an overarching intervention for providing integrated patient-centred and high quality of care

²⁸ Chou-Han L,¹ Chou-Jui L,² Yao-Wen K, et al: Tuberculosis mortality: Patient characteristics and causes: 2014 BMC Infect Dis. 2014; 14: 5

²⁹ Lijlana S, Mirjana T, Vladimir M et al: The causes of death among patients with tuberculosis 2015, European Respiratory Journal 46: PA2713

and interventions. The county leadership will be targeted prior to introduction of any interventions, through county engagement forums at both national and county levels, as well building the capacity of county management teams to steer any new initiatives in TB control. These will promote ownership, sustainability and TB-supportive approaches into the health system.

Additionally, two specific interventions within counties will be implemented: (i) Development of TB Centers of Excellence. The NTLD-P will identify regional hubs that would support provision of high-quality care for TB patients, as well as to serve as training hubs for residential mentorship. In collaboration with counties, these facilities, will be equipped with the human resource, equipment and commodities to support high level TB care. (ii) Integration of TB into facility Multi-Disciplinary Team (MDT) meetings: Most facilities have multidisciplinary teams to monitor, track and evaluate performance in their service delivery points. It is imperative that TB is integrated into these MDTs for facility ownership and support. This will also reduce the stigma associated with TB amongst HCWs.

Facility-based case finding, riding on the Practical Approach to Lung Health (PAL) strategy. This NSP looks to support patients presenting to any service delivery point (SDP) in order for the, to be screened for TB and any patient found to have respiratory symptoms will be triaged appropriately based on the diagnostic and management for other respiratorydiseasessuchasasthma,pneumonia and chronic obstructive pulmonary disease (COPD). This approach will ensure patient centred and holistic care for those patients with respiratory symptoms. Additionally, this will increase the index of suspicion for TB, among all HCWs across all SDPs. Different modalities



According to patient evaluations conducted during the 2017 Mid Term Review, it was established that there is suboptimal patient knowledge on TB as a result of inadequate counseling during treatment initiation.

of active case finding will be implemented to ensure early diagnosis of TB, and reduction of TB complications. These interventions will include (i) Use of informal service providers (ISPs) to refer and link presumptive TB patients to the health system, (ii) Targeted outreaches among high risk populations such as health workers, people who inject drugs (PWIDs, in congregate settings, drug dens, matatu SACCOs, TB screening within corporates as a means of providing screening services to men,

and people within their work place and TB screening by pharmacies or chemists for those presenting with respiratory illnesses. Counties will be engaged in mapping of high-risk populations for TB in their areas of jurisdiction. The use of other **TB screening modalities such as chest radiographs** (CXR) will be necessary for particular patient groups such as children, PLHIV as recommended in the new diagnostic algorithms, while utilization of telemedicine to link digital images to radiologists for high quality reporting will be critical in improving access.

Strengthen linkage of all diagnosed patients

to care: Diagnosed patients in health facilities require treatment initiation to reduce facility and community transmission. Strategies to ensure all diagnosed patients are initiated to treatment will include physical linkage of patients between laboratories and chest or TB clinics using facility volunteers, integration of laboratory information management systems to TIBU for timely identification of diagnosed patients not notified and strengthening of the use of recording of laboratory request forms to adequately capture patient details for tracking. Additionally, movement of patients between facilities will require monitoring to ensure all patients transferred in and out of facilities can be accounted for by strengthening linkage and referral mechanisms. This will involve development of transfer tools, facility directories, networks and strengthening the TIBU system.

Organization of TB services around the needs of patients: Integration of TB services, providing convenient opening hours and implementing patient-centred adherence strategies will be useful for strengthening adherence to treatment. Integration of care will involve organizing services to manage TB with other comorbidities holistically in a *'one*- stop shop' manner to reduce time taken within the health system, reduce the likelihood of treatment interruption, early detection of drugdrug interactions from different comorbidities and seamless healthcare service. Opening hours that affect the livelihood of patients result to non-compliance. This may be addressed by creating patient-friendly hours based on patients' convenience such as weekend clinic days specifically targeting formally employed patients, school-going children, adolescents and young adults.

Other methods of organizing TB services around the needs of patients will include the following; (i) **Differentiated care** will be considered as a means of profiling patients and providing need-based care for TB patients based on clinical and psychosocial status. Patients who are clinically stable, adherent to medications, and well empowered may be given longer clinic return dates, while patients who are not stable or likely to be non-adherent, will be provided closer follow up, frequent counselling, attachment to peer educators and expert clients, and evaluation to address underlying psychosocial factors.

County differentiated mechanisms will be considered particularly for nomadic and other hard to reach counties where patient monitoring must be tailor-made for those settings. This may include re-vamping TB manyattas, and engagement of county leadership to support them to ensure patients can receive care in an 'ideal' setting despite prevailing circumstances. (ii) Service decentralization will require engagement with counties to ensure majority of health facilities, whether private or public, are empowered to provide TB prevention, diagnosis, care and treatment services. This will reduce the cost of patient transportation. Additionally, all facilities should be supported to provide TB commodities outside TB or chest

clinics after routine working hours and during weekends to ensure patients visiting these facilities outside routine hours for various reasons (such as work or school commitments) can access care. The NTLD-P will work closely with NHIF to support the accreditation of up to 10,000 health facilities in both the private and public sectors to provide TB services.

Patient empowerment through counseling and patient education: Being a chronic illness, a TB patient requires extensive counseling on various areas of their care. These include the duration and course of treatment, potential side effects, pill burden, timing of medications, infection control, nutrition, treatment support at household and community level and positive living. Counselling should be conducted at initiation of treatment and emphasized throughout the course of treatment. Information education and communication (IEC) and behavior change communication (BCC) materials will be developed and displayed in key areas accessed by patients, while patients' rights' and responsibilities disseminated, and shared with all care providers and patients.

Patient-centred adherence strategies include the use of **digital solutions** for patient reminders and education through short message services (SMS), social media platforms such as WhatsApp and facility hotlines. Development of peer counselors, expert clients and support groups to provide patient support during treatment as well as to conduct TB outreaches will be useful in reducing stigma among patients.

Building HCW competency to provide holistic TB care (clinical, nutritional, and psychosocial) to care. On the most part TB care is provided by nurses and clinicians who may not be empowered to meet all TB patient needs. Health care workers' capacities will be built to monitor and follow up every aspect of TB care such as screening and management of adverse drug reactions. To this end, standardized checklist tools will be developed to ensure care, monitoring and follow up is provided in a standardized manner. Innovative methods of training and capacity building will be employed to ensure as many HCWs are reached as possible within a short time and that information is provided in a simple, innovative, accessible manner outside the standard didactic trainings. Such methods will include ECHO sessions, use of mobile apps and SMS alerts on updates. These capacitybuilding mechanisms will include all HCWs with phones both within the private and public sectors.

Linkage of training modalities to Continuous Professional Development (CPD) points will ensure buy in by HCWs, while professional bodies such as the Kenya Medical Association (KMA) will be engaged to link NTLD-P to professionals outside the Programme's reach. Bacteriological monitoring (whether DSTB or DRTB) will require emphasis to ensure all bacteriologically confirmed TB patients access the requisite follow up tests and are cured. Health care workers will be empowered on adherence monitoring, including assessment for the type of DOTs supporter required, as well as how to manage patients who return after loss to follow up.

Addressing stigma and discrimination among HCWs: The reduction of stigma and discrimination of patients by HCWs or of HCWs affected by TB will be attained by intense TB health education outside the TB fraternity. Healthcare worker directed messages will reduce stigma and discrimination as more HCWs will be empowered on TB prevention, transmission, care and follow up. **Pharmacovigilance and aDSM** particularly for those on newer DRTB molecules (bedaquiline and delamanid) will be strengthened, while standard checklists provided, for management of both DSTB and DRTB patients.

Post TB Care and Complications: All DSTB patients completing TB care, will be followed up for a period of six months, while those completing DRTB care for two years. This will ensure that any arising complications such as emphysema, COPD, lung fibrosis and collapse and sequelae of adverse drug reactions are identified, and managed. Patients will be counseled on possible complications from TB disease and need for follow up. Referral and linkage to specialists, including pulmonologists and thoracic surgeons to manage arising complications will be necessary to optimise quality of care. Additionally, patients requiring social protection such as those with arising disability will be linked to the existing schemes.



Estimated percentage of TB patients who interrupt treatment in the course of therapy with nonadherence being worse in those who reported side effects. (*The Adherence Study (2017)*



ΔΔ

OUTCOME TARGETS

	Indicator	Baseline	Target
F	Proportion of presumptive TB (with respiratory symptoms) patients tested for TB		80%
	 Treatment success rate (TSR) for all DSTB cases Cure rate among bacteriologically confirmed (BC) TB patients 	 TSR for DSTB - 81% (2016 cohort) Cure rate among BC TB patients (2016 cohort) was 67% 	 TSR for DSTB of 90% Cure rate among BC TB patients increased to 95%
	Treatment Success Rate among DRTB patientsReduce Mortality among DR TB patients	 TSR for DRTB - 73% (2016 cohort) Mortality among DRTB patients (2016 cohort) was 15% 	 TSR among DRTB 85% Mortality among DR TB patients - <5%

2.2 SECTION TWO: TARGETED EPIDEMIOLOGIES AND POPULATIONS

2.2.1 **Programmatic Management of Drug – Resistant Tuberculosis**



SITUATION ANALYSIS

In 2017, Kenya is one of the high MDR TB burden countries with an estimated 2,800 MDR/ RRTB among notified pulmonary TB cases³⁰. The prevalence of MDRTB and RRTB among new smear positive cases is 0.7 percent and 1.3 percent respectively³¹. Mortality levels are disproportionately high among MDRTB patients standing at 15 percent^{32,33}. In addition, 86 percent of DRTB patients experience catastrophic expenditure, three times more than that of DSTB patients which is at 26 percent. Further, patients with DRTB incur six times higher total costs per TB episode in comparison to DSTB patients and presence of DRTB is a significant predictor for experiencing catastrophic costs³⁴.

Notable achievements in programmatic management of DRTB include in the lapsed NSP include: (i) Establishment of a robust incountry diagnostic capacity for drug resistant TB using conventional culture and DST, liquid culture, and rapid molecular testing using GeneXpert MTB/Rif and first line and second Line Probe Assay supported by various models of specimen referral networking. In specific regard to GeneXpert, there has been a nine – fold increase in the number of machines from 24 (2013)³⁵ to 183 (2018)³⁶.

This capacity has however, not been fully utilized due to the fragmented nature of sputum networking models used currently. (iii) Scale-up of programmatic management of DRTB countrywide with regular updates of national policy guidelines and algorithms. (iv) Implementation of functional treatment programs in all counties using ambulatory and facility treatment models. (v) Establishment of a fund to undertake baseline and follow up laboratory investigations. However, this has had a low uptake due to inadequate capacity at clinical team level. (vi) Ensuring (largely) uninterrupted availability of second line anti-TB medicines (SLDs). (vii) Roll-out of shortterm regimen for DRTB. (viii) Introduction of new molecules into treatment regimens, bedaguiline and delamanid. (ix) Expansion of functional clinical review teams. (x) Existence of social protection schemes for DR-TB cases, notably nutritional support and a monthly financial stipend for all DR-TB patients on treatment.

³⁰ World Health Organization. (2018). Global Tuberculosis Report. Geneva: World Health Organization.

³¹ National Tuberculosis and Leprosy Program. (2015). Kenya Drug Resistance Tuberculosis Survey. Nairobi: Ministry of Health

³² National Tuberculosis, Leprosy and Lung Disease. (2018). Annual Tuberculosis Report. Nairobi: National Tuberculosis, Leprosy and Lung Disease.

³³ Huerga, H., Bastard, M., Kamene, M., Wanjala, S., Arnold, A., Oucho, N., Chikwanha, I., Varaine, F. (2017). Outcomes from the first Multidrug-resistant Tuberculosis Programme in Kenya. *International Journal of Tuberculosis and Lung Disease*, 314–319.

²⁴ National Tuberculosis, Leprosy and Lung Disease Program. (2017). The First Kenya Tuberculosis Patient Cost Survey. Nairobi: Ministry of Health.

³⁵ National Tuberculosis, Leprosy and Lung Disease Program. (2014). *Annual Tuberculosis Report.* Nairobi: National Tuberculosis, Leprosy and Lung Disease Program.

³⁶ National Tuberculosis, Leprosy and Lung Disease. (2018). Annual Tuberculosis Report. Nairobi: National Tuberculosis, Leprosy and Lung Disease.



ΤВ At risk, in Diagnosed On community *6* D symptoms, but not on symptoms, treatment has not seeking treatment but not yet sought care care but not cured diagnosed

Low DRTB Case Detection: A low case detection of people with DRTB with 79 percent being missed. This is attributed to only 47 percent of notified TB patients received DST (2017), lack of a bold policy on universal DST for people with TB, low index of suspicion and poor knowledge among HCWs and suboptimal contact tracing and screening of DRTB contacts.

The laboratory capacity to diagnose DRTB is limited at health facility level where it is most required. A majority of TB patients (60 percent) seek initial care at Level 2 and Level 3 health facilities, but access to DRTB diagnosis is limited at these levels of care. When disaggregated by ownership, public and private, among Level 2 health facilities, GeneXpert referral services are available in 17 percent and 6 percent respectively. On the other hand, GeneXpert referral services are available in 44 percent and 19 percent in public and private Level 3 health facilities respectively³⁷. Case detection for DRTB is 21 percent of the estimated prevalent cases^{38,39}.

Suboptimal Quality of Care: There is suboptimal quality of DRTB care once diagnosed. This includes and is not limited

to: (i) Delays in treatment initiation, in some instances. (ii) Low coverage of baseline and follow-up tests, including specialized tests such as ECG and audiometry services. (iii) Inadequate provision of holistic DR TB care: clinical, nutritional psychosocial and post treatment care. (iv) Lack of palliative care practices, guidelines and policies. (v) Weak linkages with other stakeholders especially private sector (vi) Inadequate post-treatment care. (vii) Sub-optimal active drug safety monitoring (aDSM) and ADR management. (viii) Weak county DRTB clinical teams. (ix) Inadequate access to new medicines. (x) Inadequate HCW knowledge on DRTB management. These gaps and challenges lead to poor adherence to treatment resulting in a stagnant high mortality of 15 percent among DRTB patients enrolled on care^{40,41.}

Inadequate Infection Prevention and Control Capacity: There is inadequate isolation capacity in country with few counties having isolation facilities, for instance there is a gap of 100 beds in the country for admitting MDRTB patients for inpatient or specialized care. To compound this further, there is inadequate patient and community education on TB prevention and control.

³⁷ Masini, E., Hanson, C., Ogoro, J., Brown, J., Ngari, F., Mingkwan, P., Makayova, J., Osberg, M. (2017). Using Patient-Pathway Analysis to Inform a Differentiated Program Response to Tuberculosis: The Case of Kenya. *The Journal of Infectious Diseases*, S714–S723.

³⁸ World Health Organization. (2018). *Global Tuberculosis Report.* Geneva: World Health Organization.

³⁹ National Tuberculosis, Leprosy and Lung Disease. (2018). Annual Tuberculosis Report. Nairobi: National Tuberculosis, Leprosy and Lung Disease.

⁴⁰ National Tuberculosis, Leprosy and Lung Disease. (2018). Annual Tuberculosis Report. Nairobi: National Tuberculosis, Leprosy and Lung Disease.

⁴¹ World Health Organization. (2018). *Global Tuberculosis Report.* Geneva: World Health Organization.

⁴² National Tuberculosis, Leprosy and Lung Disease Program. (2017). The First Kenya Tuberculosis Patient Cost Survey. Nairobi: Ministry of Health.

Catastrophic Costs associated with DRTB: The Kenya TB Patient Cost Survey 2016 showed that DRTB is a predictor of incurring catastrophic medical costs with DRTB patients incurring six – fold medical costs as compared to DSTB patients⁴². In regard to composition of the costs, non-medical costs and indirect costs such as costs associated with transport, food, loss of income and post treatment complications accounted for 96 percent of the total costs.



STRATEGIC INTERVENTIONS

Universal DST for all Confirmed TB Patients: This NSP represents the operationalization of new national policy that recommends that all confirmed TB patients receive DST. This will require that all diagnostic facilities have either GeneXpert capacity onsite or a specimen referral arrangement to a qualified laboratory. An optimised laboratory network that has been modeled, and has informed county-specific planning about equipment and transport requirements. Successful implementation of this policy shift will require enhanced collaboration between care facilities and laboratories, as patients may undergo multiple rounds of testing. Such collaboration will require enhanced capacity among health staff and laboratories, as well as connected patient management data systems to follow patient progress. Further, laboratorybased DRTB surveillance will be established and linked to TIBU.

Optimisation of Quality of Care: This NSP envisages to optimise the quality of care for DRTB patients through timely initiation of treatment (within one week of diagnosis), strengthening of county and facility based clinical review multi-disciplinary teams, enhanced ADR and aDSM monitoring, increased health staff knowledge on management of DRTB, scaled up utilization of new medicines (bedaquiline and delamanid), increased coverage of baseline and routine follow-up tests including ECG and audiometry. In addition, enhanced and expanded package of patient clinical, social and psychological support is critical and mortality audits. Further, explicit guidelines on post-TB care, rehabilitation and palliative care will be developed.



Estimated percentage of TB patients who seek initial care at **Level 2** and **Level 3** health facilities



100 Beds

Estimated gap in the country for admitting MDRTB patients for inpatient or specialized care

⁴² National Tuberculosis, Leprosy and Lung Disease Program. (2017). The First Kenya Tuberculosis Patient Cost Survey. Nairobi: Ministry of Health.

Establishment of Admission and Isolation Facilities at County Level: This is geared towards expanding the number of isolation health facilities that can offer admission should DRTB patients warrant inpatient services.

Sustain social protection cash transfer for DRTB patients. Continue to provide social support to DRTB patients in form of NHIF payment and cash transfers for transport based on the minimum wage in tandem with existing labor laws.



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OUTCOME TARGETS

	Indicator	Baseline	Target
T	Proportion of notified TB patients who receive DST	47%	95%
	Proportion of DRTB cases detected	21%	80%
	Proportion of eligible DRTB patients on new molecules	13%	90%
A	Proportion of DRTB patients' households incurring catastrophic costs	86%	43%

2.2.2 Childhood Tuberculosis

SITUATIONAL ANALYSIS

While there has been significant progress in the fight against childhood TB with about 30,000 children diagnosed and put on treatment from 2014 to 2017, its burden remains immense. In 2017, about two thirds of estimated children with TB in Kenya were missed. Compared to 46 percent reported to be missing from care in all to other age groups combined, the TB case detection gap is biggest among children.

The WHO estimates that 10 to 15 percent of notified TB cases should be children. In 2017, children aged zero to 14 years comprised nine percent of the notified TB cases in Kenya as shown in Figure 15.



Estimated number of children diagnosed, and put on treatment from 2014 to 2017


Figure 15: Trends of Childhood TB Cases Notified in Kenya between 2009-2018

Table 6: Progress Made and Remaining Gaps in Childhood TB in Kenya

Progress made 2014-2018	But Gaps Remain
Contact investigations and TB prevention are included in national guidelines for childhood TB. The number of children under 5 initiated on TB preventive therapy increased from 734 in 2014 to 6,079 in 2017	Child contact investigation and preventive therapy not fully implemented to scale across the country- only 13% of the eligible household child contacts accessed IPT in 2017
Updated training materials, job aids and algorithms based on the latest global guidance were developed and widely disseminated among health care workers	Many frontline health care workers in public and private sectors still do not have adequate knowledge and confidence to undertake prevention and diagnosis of childhood TB

Progress made 2014-2018

But Gaps Remain

County level expertise and leadership in childhood TB has been fostered through capacity building of nutritionists, reproductive maternal neonatal child health (RMNCH) staff and TB coordinators.	Diagnosis of childhood TB is still predominantly done at the higher-level health facilities (level 4 to 6) with limited capacity at the peripheral health centers and dispensaries.
Engagement of pediatricians from across 47 counties through the Kenya Pediatric Association was done to enable them provide leadership for childhood TB diagnosis and treatment in public and private hospitals	Engagement of pediatricians in childhood TB has not been fully realized in the private health sector
Childhood TB services are fully decentralized across the 47 counties with capacity to conduct child contact management and provide child friendly TB treatment	Weak linkages and limited integration with maternal, child health and nutrition departments still persist in many health facilities leading to missed opportunities for diagnosis. Capacity for diagnosis and treatment of DR-TB among children is limited across the country
Gene Xpert is increasingly being used for childhood TB diagnosis. The expanded use has led to an increase in the proportion of children with TB bacteriologically confirmed from 10% in 2012 to 18% in 2017. Use of nasopharyngeal and gastric aspiration for sputum collection in children has been successfully piloted in Nairobi, Mombasa, Kericho, Siaya, Kirinyaga, Machakos, Makueni and Garissa counties. In addition, childhood TB screening is incorporated in the active case finding initiatives in the health facilities and community care settings	Two thirds of children with TB were missing from care 2017. The innovative methods for sample collection not widely practiced in health facilities across the country.
Focused national stewardship of childhood TB with a strengthened national technical working group, and a childhood TB focal person	Lack of functional broad- based technical working groups at the county level to steward childhood TB services.
Treatment success rate improved from 79 % to 85% partially attributed to the improved quality of care associated with the introduction of new child friendly pediatric formulations	Adoption of pediatric friendly DRTB formulations is yet to be realized



Service level innovations. FIKIA project increased TB case finding in children

To increase efforts to find more children with TB, Centre for Health Solutions -Kenya established the FIKIA project. This was a 14-month project in collaboration with National Tuberculosis Leprosy and Lung Disease Program, County Health departments and supported the Stop TB partnership's TB REACH initiative. The project aimed to increase TB case finding in children under 14 years across 14 counties with a high burden of TB Nairobi, Mombasa, Kericho, Siaya, Kirinyaga, Machakos, Makueni and Garissa.

To conduct active case finding in the nine counties, a total of 201 facility volunteers were trained to systematically screen children at the pediatric outpatient and maternal and child health departments in all 100 project facilities. Facility volunteers were critical in reducing initial loss to follow up by linking all children with symptoms of TB to clinicians, laboratories, radiologists and chest clinics for further evaluation and management.

Facility volunteers and clinicians carried out contact management at chest clinics. A combined Child Contact Management (CCM) register was developed to record and monitor all child contacts. All bacteriologically confirmed index patients had their child contacts enlisted in the CCM register and were invited for screening. All children who tested positive for TB were started on anti-TB medication and those under five years old who did not have symptoms of TB were initiated on TPT. Some of the critical lessons learned were that health care workers were not actively asking about child contacts and the cost of transport limited the number of children contacts coming in to the health facilities for evaluation. To address these issues, the project created awareness about the importance of child contact management, trained health care workers to use the child contact management register to track and monitor child contacts and further provided USD 3 to every index patient who brought in their child contacts for screening. The health care workers capacity building and transport incentive increased the number of invited contacts from 27 percent at the beginning of the case finding activities in August 2017 to 91 percent at the close of the project in September 2018. Another factor that limited TB case detection was the cost of chest radiograph services, which is a critical tool in diagnosing TB in children, who are often unable to produce sputum. To make chest radiographs available to more patients, the FIKIA project formalized agreements with both public and private radiology centers to provide the service to patients for free, while the costs were reimbursed by the project. The intervention allowed more children to benefit from chest radiography, which also helped to improve diagnosis.

From August 2017 to September 2018, a total of 37'551 [TN1] children were screened by the project out of which 4'012 entered through Maternal and Child Health, 33'053 through the Outpatient Department and 436 through other entry points at the facilities. 13'434 (36 percent) were tested for TB and a total of 68 (one percent) children tested positive and were initiated on treatment. In Q3 2018, a total of 825 children with TB were notified, compared to 480 during the same guarter in 2017. A review of the counties data revealed an increase in the proportion of children notified for TB from seven percent in Q3 2017 to nine percent in Q3 2018. Through the contact management process done by facility volunteers and clinicians at chest clinics, 8'060 bacteriologically confirmed index patients were registered and 2'022 contacts were identified at supported facilities. Amongst the screened children, 1'610 (85 percent) were initiated on IPT. 119 contact children were found to have TB and were initiated on anti-TB treatment. FIKIA was able to identify the children most at risk and improve both disease diagnosis and provision of IPT simultaneously by focusing on improving child household exposure and the child contact management cascade. The project has concluded case finding activities and is now disseminating findings and conducting advocacy to various stakeholders, including the National TB Program, the Ministry of Health, County Governments and partners (USAID). The aim is that they can integrate into their programs the successful FIKIA project interventions for country-wide scale up. The project is also advocating for allocation of funds for pediatric TB activities within the counties.



This NSP targets to **ensure that 90 percent** of child contacts aged less than 5 years of patients with TB access TB prevention treatment. To accelerate the process, NTLD-P will develop and cascade county targets for child contact management and TB prevention therapy. The counties and their implementing partners will use the community health systems to provide public education and create demand. They will implement active contact screening and preventive therapy through engagement with and support for community and primary health care providers. In addition, the NTLD-P will **introduce and**

scale up shorter and safer regimens to treat TB infection in child contacts. Child contacts of patients with drug resistant TB will be routinely evaluated according to existing policy guidelines for treatment for disease and prevention of transmission.

This NSP targets to **increase the proportion** of children with TB who are detected to 70 percent. Training materials, job aids and algorithms will be continuously updated based on the latest global guidance and prevailing local evidence to facilitate the work of health care workers. In addition, annual national and county targets will be developed and widely disseminated to guide childhood TB case finding.

Training, mentorship and supervision- Health care workers in the public and private sectors will be capacitated to be aware of and to be able to identify TB symptoms, and evaluate, diagnose, manage and report children with TB. In addition, centers of excellence for pediatric TB will be established to foster county level expertise for childhood TB.

Diagnosis – All health facilities will screen for TB at the pediatric outpatient and maternal and child health departments. Health care workers will be capacitated to collect child TB samples and access GeneXpert for diagnosis. Emphasis will be laid on clinical diagnosis as well as embrace WHO recommended emerging diagnostics.

Strengthened collaboration with RMNCH services, HIV programs, education institutions, the private health-care sector, health care

workers professional bodies, medical training institutions, community-based and nonorganizations, governmental community leaders and community health workers. The collaboration will focus on strengthening the implementation of TB screening in and outpatient; nutrition; HIV; adolescent health; antenatal care (ANC) and immunization settings in both public and private health facilities. As well as incorporation of childhood TB in school health programs, in pre-service medical training and in community interventions.

Increase pediatric TB treatment success rate to go percent: This NSP stands for ensuring availability of child-friendly formulations of TB & DR-TB medicines in both the public and private health sectors. As well as supporting a patient-centred care approach in treatment of childhood TB based on the child's needs with counselling and social support to ensure adherence.

Implementation research to optimise the impact of childhood TB interventions: New service delivery models will be adopted to help eliminate barriers faced by children in accessing TB prevention, diagnostic and treatment services. NTLD-P will partner with relevant organizations to undertake operation research to determine such service models. Focus areas are new service delivery approaches for improved service coverage for TPT (child contact management); improved collaboration with **RMNCH** department and scale up child friendly methods of sample collection.

3

OUTCOME TARGETS

Indicator	Baseline	Target
Proportion of children with TB who are detected	> 35%	70%
Pediatric TB treatment success rate	85%	90%
Proportion of children aged less than 5 years contacts with bacteriologically confirmed cases on LTBI treatment	13%	90%

2.2.3 **TB / HIV and other Co-Morbidities**



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SITUATIONAL ANALYSIS

Kenya has an estimated HIV prevalence of 4.8 percent, translating to 1.5 million adults and children living with HIV, one of the largest epidemic in absolute numbers. Anti-retroviral therapy (ART) coverage for PLHIV is 75 percent (1.1 million) while the proportion with viral load suppression is 63 percent (940,000)43. Human Immunodeficiency Virus remains an important driver of the TB epidemic in Kenya with the country listed among those with high TB/HIV burden with an estimated annual incidence of 45,000 TB/HIV cases⁴⁴. Mortality rate among HIV - positive TB cases is disproportionately high at 37 per 100,000 population⁴⁵, even though HIV infection is not a predictor of incurring catastrophic health expenditure among HIV – positive TB cases⁴⁶.

The country has experienced significant progress in the TB/HIV indicators and these gains need to be sustained. In the past NSP (2015 – 2018), notable achievements with matters TB/HIV include universal HIV testing among TB patients (97 percent) with almost all who test HIV - positive initiated on ART (95 percent). In addition, 65 percent of PLHIV have cumulatively been initiated on TPT. These gains have been realized partially due to integration of TB/HIV services, human resource capacity building, commodity security and availability of reporting tools. TBHIV coinfection rates have dropped from 35 percent in 2014 to 28 percent in 2018. However, there is still need to focus on strategies that will optimise innovative tools to enhance early case detection, TB prevention and improve on TB treatment outcomes.

Approximately 51 percent of TB cases among PLHIV are detected and notified, to optimise case detection among PLHIV population, TB screening needs to be of quality and the proportion of PLHIV screened at every

⁴³ UNAIDS. (2018, September 11). Country factsheets Kenya 2017. Retrieved from UNAIDS: http://www.unaids.org/en/regionscountries/countries/kenya

⁴⁴ World Health Organization. (2018). *Global Tuberculosis Report*. Geneva: World Health Organization.

⁴⁵ World Health Organization. (2018). *Global Tuberculosis Report*. Geneva: World Health Organization.

⁴⁶ National Tuberculosis, Leprosy and Lung Disease Program. (2017). The First Kenya Tuberculosis Patient Cost Survey. Nairobi: Ministry of Health.

clinic visit should be more than 95 percent. In addition, improving treatment outcomes among HIV positive TB patients will conversely reduce mortality. Treatment success rate among HIV - positive TB patients is lower (79 percent) compared to TB patients who are HIV negative (87 percent). Likewise, HIV positive TB patients experience a 3 - 4 times higher mortality than those who are HIVnegative. Finally, TB preventive therapy (TPT) is key in the reduction of burden in the PLHIV population, the current national guidelines recommend that all eligible PLHIV take TPT and cumulative coverage is 65 percent. Data on TPT adherence and completion of therapy is scanty, and uptake not uniform nationally^{47,48}.

Besides HIV, there is a growing body of evidence describing the causal links between TB disease and a number of non – communicable diseases (NCDs), the most notable being diabetes mellitus (DM), and other risk factors such as smoking- and alcohol-related conditions^{49,50}. Mortality rates among TB cases with DM are twice the rate of those without DM⁵¹. In Kenya, prevalence of DM in adult TB patients is five percent⁵², double the burden of general adult population which is two percent^{53,54}. Diabetes mellitus is not a predictor of incurring catastrophic health expenditure among TB cases with DM. The relationship between DM and TB is well established however data specific to Kenya is scanty. Collaboration of activities is still at infancy stage and will require robust approaches in solidifying it to the levels comparable with that of TB/HIV and this will be prioritised given the rising cases of noncommunicable diseases. Lack of TB/DM policy framework and coordination mechanisms hinder integration of TB services with DM care and management. An approach to TB/ DM in Kenya will start with development of a comprehensive collaborative framework. Once developed and adopted, measuring impact of TB/DM interventions and activities to monitor progress and identify missed opportunities for screening of DM in TB patients and vice versa.

The burden of TB/HIV in the country varies across counties, whereas the average coinfection rate in the country was 28 percent in 2017, some counties such as Homa Bay had high TB/HIV coinfection rates at 61 percent while other counties had low rates such as Wajir at one percent (TIBU, 2017). Ten counties contributed more than half of TB/HIV deaths for patients who were notified in 2016 (TIBU, 2016).

⁴⁷ World Health Organization. (2018). *Global Tuberculosis Report*. Geneva: World Health Organization.

⁴⁸ National Tuberculosis, Leprosy and Lung Disease Program. (2018). *Annual Tuberculosis Report.* Nairobi: National Tuberculosis, Leprosy and Lung Disease Program.

⁴⁹ Kasera, G., Karanja, S., Mwachari, C., Kioko, J., & Masini, E. (2016). PD-1095-29 Risk Factors for Tuberculosis Going Beyond HIV: A Case Control Study in Western Kenya. Abstract Book: 47th World Conference on Lung Health of the International Union Against Tuberculosis and Lung Disease (The Union), (p. S478). Liverpool.

⁵⁰ Lönnroth, K., Roglic, G., & Harries, A. D. (2014). Improving tuberculosis prevention and care through addressing the global diabetes epidemic: from evidence to policy and practice. *The Lancet Diabetes & Endocrinology*, 730-739.

⁵¹ Workneh, M. H., Bjune, G. A., & Yimer, S. A. (2016). Diabetes mellitus is associated with increased mortality during tuberculosis treatment: a prospective cohort study among tuberculosis patients in South Eastern Amahra Region, Ethiopia. *Infectious Diseases of Poverty*, 1-10.

⁵² Owiti, P., Keter, A., Harries, A. D., Pastakia, S., Wambugu, C., Kirui, N., Kasera, G., Momanyi, R., Masini, E., Some, F., Gardner, A. (2017). Diabetes and pre-diabetes in tuberculosis patients in western Kenya using point-of-care glycated haemoglobin. *Public Health Action*, 147-154.

⁵³ International Diabetes Federation. (2017). *IDF Diabetes Atlas - 8th Edition*. UK: International Diabetes Federation.

⁵⁴ Ministry of Health. (2015). STEPwise Survey. Nairobi: Ministry of Health.

Figure 16: HIV Prevalence among Notified TB Patients in Kenya, 2017



Low TB case detection rates among PLHIV at the community level currently at 51 percent^{55,56}, this is attributed to suboptimal integration of joint TB/HIV at community level,

weak linkages between communities and facilities with limited access to TB screening between HIV clinic visits.

⁵⁵ National Tuberculosis, Leprosy and Lung Disease Program. (2018). *Annual Tuberculosis Report.* Nairobi: National Tuberculosis, Leprosy and Lung Disease Program.

⁵⁶ World Health Organization. (2018). *Global Tuberculosis Report.* Geneva: World Health Organization.

Low TB case detection among PLHIV in the health system: PLHIV with TB are missed in the health system due to suboptimal TB symptom screening among PLHIV hence there is need to adopt newer screening and diagnostic technologies that are appropriate to the PLHIV population.

Missed opportunities in TB screening of all people undergoing HIV testing, as much as active TB case-finding has been initiated within HIV testing settings, there is a there are outstanding gaps in treatment outcomes among HIV – positive TB patients as there is late presentation of HIV/AIDS at the facility, HCW knowledge gaps in identification and management of comorbid conditions and HIV treatment failure all lead to high mortality.

Suboptimal TPT uptake coupled with poor documentation, reporting of outcomes and adverse events.

Weak TBDM Implementation Framework: Gaps in TBDM interventions include lack of policies and guidelines to support integration of TBDM control activities, lack of integrated monitoring and evaluation framework, low capacity of HCW on integrated TBDM management and lack of awareness of TBDM interaction among the public.



STRATEGIC INTERVENTIONS

This NSP represents a shift in TB/HIV programming following operationalization of new national HIV policy that recommends that all confirmed HIV positive people receive immediate ART. It also anticipates the availability of new diagnostic and treatment options over the life of this NSP. This NSP will seek to:

Strengthen integrated community TBHIV case finding through establishing systems for TB/ HIV service linkages between communities and health systems, contact and defaulter tracing activities, integration of systematic TB screening among PLHIV receiving ART in the community differentiated HIV care model.

Strengthen TB case detection among PLHIV in care within the health system by improving the quality of TB screening through expansion of the already existing TB screening questionnaire, addressing all quality issues and introduction of new diagnostic algorithms that include point of care tests (TB- LAM). In addition, TB infection control activities will be optimised in TB and HIV care settings.

Reduce mortality among HIV positive TB patients through provision of a care package that includes HIV treatment optimisation and viral suppression, nutrition, adherence and counseling support, and monitoring of adverse drug reactions.

Sustain proportion of PLHIV initiated on TPT through maintaining high service coverage for TPT. In addition, a comprehensive framework for LTBI management that include use of WHO recommended shorter TPT regimen with regular monitoring and outcome evaluation will developed and implemented.

Scale up TB/DM collaborative management by establishing, implementing and monitoring a comprehensive TB/DM framework that will include a monitoring and evaluation reporting system.

Strengthen TBHIV coordination bodies: To support the above interventions, priority will be given to strengthen TBHIV coordination bodies at the national and county Levels. These bodies will enhance engagement with key stakeholders (MOH, CSOs, FBOs, county governments).



OUTCOME TARGETS

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Indicator	Baseline	Target
Proportion of TB cases notified among PLHIV	51%	90%
Treatment success rate among HIV positive TB cases	79%	85%
Proportion of newly identified PLHIV initiated on TPT	65%	>90%

2.2.4 Lung Health

SITUATIONAL ANALYSIS

Respiratory diseases account for a considerable burden of morbidity and mortality in all age groups in Kenya. Ten percent of self - reported reasons among patients seeking outpatient services complain of respiratory symptoms, this is the most frequent complaint⁵⁷. This translates to an annual eight million outpatient visits from respiratory symptoms among health facilities that report on the routine health management information system, DHIS258. Among the respiratory diseases, the most frequently occurring that result in significant morbidity and mortality are lower respiratory infections, drug susceptible TB, drug susceptible HIV/ AIDS – TB and chronic obstructive pulmonary disease (COPD)⁵⁹ as illustrated in Table 6. The aforementioned burden of respiratory illness is further compounded by a notable increase in a number of risk factors such as tobacco smoking, HIV epidemic, urbanization, industrialization, atmospheric pollution, and the deterioration of socioeconomic conditions.

Table 7: Proportion of Deaths due to Respiratory Diseases among the Top 25 Causes of Death in Kenya, 2016

Rank	Disease	Number of Deaths	Percentage of Total Deaths
3	Lower respiratory infections	23,236	8.6%
5	Drug susceptible TB	9,621	3.6%
7	Drug susceptible HIV/AIDS – TB	6,712	2.5%
17	COPD	3,323	1.2%

Source: (Institute for Health Metrics and Evaluation, 2018)

⁵⁷ Ministry of Health. (2018). Kenya Household Health Expenditure and Utilization Survey. Nairobi: Ministry of Health.

⁵⁸ Ministry of Health. (2018, September 12). DHIS2 Pivot Tables. Retrieved from HIS Kenya: https://hiskenya.org/dhis-web-pivot/

⁵⁹ Institute for Health Metrics and Evaluation. (2018, July 10). GBD Compare | Viz Hub. Retrieved from GBD Compare : https://vizhub.healthdata.org/gbdcompare/



Absence of an operational public health program for lung health: There is no operational public health program charged with prevention and control of respiratory medicine domiciled within the Ministry of Health. This has resulted to lack of standardized and integrated diagnostic and management algorithm for respiratory diseases, most notable being lower respiratory tract infections in adults, asthma and chronic obstructive pulmonary diseases (COPD). In addition, there are no indicators routinely monitored on the DHIS2 and there are knowledge gaps on management of respiratory conditions among healthcare workers. The coordination of management of respiratory conditions is fragmented and disjointed with various programs and units within the Ministry of Health undertaking different components; resulting in lack of ownership and oversight of the key performance indicators.



STRATEGIC INTERVENTION

This NSP represents a seismic shift by the **establishment and operationalization of a full** – **fledged lung health program**. This strategic approach is envisaged to lead to improved management of respiratory medicine. It will also increase case detection and notification among people with TB who interact with the health system and were previously either undetected or unnotified resulting in reduced mortality attributable to TB at a population level. To detect and notify TB in this population will require high priority interventions centred around primary level of healthcare. Robust bidirectional tracking of indicators is paramount to ensure sustainability of any intervention. For

proper monitoring and evaluation, an efficient (data quality components) integrated system with a mandatory reporting interface such as DHIS2 provides a more plausible way for countrywide coverage.

Activities that will support the setting up of a management system for lung health will include the following; (i) Deployment of a technical officer at the NTLD - P to coordinate implementation of lung health. (ii) Review and adoption of the lung health policy guidelines and training materials including the development of diagnostic and management algorithm for lung health. (iii) Capacity building of healthcare workers on lung health and ensure provision of good quality of care supported by technical assistance from wellperforming health facilities and expert lung health specialists. (iv) Ensure supply of essential equipment and commodities to support diagnosis and treatment at health facilities. (v) Define monitoring and evaluation plans for lung health through establishment of reporting systems for respiratory medicine. This will require development and printing of recording and reporting tools and establishment of an integrated reporting system using DHIS2. (vi) Strengthen coordinating mechanisms for lung health by revamping the national and county technical working groups (TWGs) and ensure regular quarterly meetings. Promote county forums with management teams and stakeholders to establish political commitment for the management of respiratory conditions at County level. (vii) To support health financing for lung health, mapping of partnerships and resources from organizations and institutions with common interests for leveraging will be established.



OUTCOME TARGETS

Indicator	Baseline	Target
Operational lung health program	No lung health program within the Ministry of Health	Establish and operationalize a full-fledged lung health program

2.2.5 Leprosy

🛐 SITUATIONAL ANALYSIS

Kenya is in the post – elimination phase of leprosy having achieved one case per 10,000 population in 1989⁶⁰ which has been as a result of widespread use of Multidrug Therapy (MDT). Early diagnosis and prompt treatment of all new cases of leprosy with multidrug therapy (MDT) remains the key strategy for leprosy control. In Kenya, 35 percent of leprosy cases present with disability grade 2 at diagnosis, an indicator of late diagnosis. In addition, there is evidence of ongoing transmission in the community with notification of childhood leprosy cases. In 2017, the number of leprosy cases notified increased by 11 percent to 126 cases, out of whom seven (six percent) were children. About half of the counties notified at least a case of leprosy in 2017, a 78 percent increase in the geographical distribution of the disease⁶¹. Over the past five years, 82 percent of leprosy notifications have been observed in the high burden counties of Kwale, Kilifi, Homa Bay, Siaya, Busia, Kisumu and now Mombasa. Sporadic cases have been reported across 20 non – endemic counties over the same period⁶².

County	2014	2015	2016	2017	Total
Kwale	49	24	8	16	97
Kilifi	18	24	28	27	97
Homa Bay	27	10	8	3	48
Siaya	11	12	5	4	32
Busia	8	10	6	13	37
Kisumu	11	10	2	3	26
Mombasa	10	9	16	4	20
	134	99	73	70	357

Table 8: Trends of Leprosy Case Notification among Top Six Counties in Kenya between 2014 - 2017

⁶⁰ National Tuberculosis, Leprosy and Lung Disease Program. (2018, September 13). *Tuberculosis and Leprosy Situation*. Retrieved from National Tuberculosis and Leprosy Program: https://www.nltp.co.ke/services/tuberculosis-leprosy-situation/

⁶¹ National Tuberculosis, Leprosy and Lung Disease Program. (2018). Annual Tuberculosis Report. Nairobi: National Tuberculosis, Leprosy and Lung Disease Program.

⁶² National Tuberculosis, Leprosy and Lung Disease Program. (2017). Report of an independent Mid-Term Review of the Implementation of the Kenya National Tuberculosis, Leprosy and Lung Disease Program Strategic Plan 2015-2018. National Tuberculosis, Leprosy and Lung Disease Program. Figure 17: Distribution of Leprosy Cases in Kenya, 2017





Lack of Political Commitment in Leprosy Control: Political commitment in leprosy control is weak. No budget is allocated for leprosy control activities. Involvement of state and non-state actors is weak and there is no legislation against discrimination and stigma of persons affected by leprosy.

Missing People with Leprosy: The available data does not show systematic contact screening and no data in contact management for leprosy patients. Household contacts of all leprosy cases are not screened for leprosy. Lack of data on community referral



Estimated percentage of leprosy notifications that have been observed in the high burden counties of Kwale, Kilifi, Homabay, Siaya, Busia, Kisumu and now Mombasa over the past five years

points to weak sensitization of health care workers and weak community awareness on leprosy. Diagnosis of leprosy is a challenge due to knowledge gap among HCWs and lack of well-equipped facilities.

Weak provision of quality of care for leprosy patients and patients affected by Leprosy: There is limited use of EHF score (Eye-Hand-Foot sum of impairment score) for periodic disability assessment which is a standard of care. The policy and guidelines and SOPs to address rehabilitative needs and social protection is lacking. There is erratic supply of leprosy commodities. Current checklist does not adequately address quality of care.

Weak surveillance and health information systems for Leprosy program monitoring and evaluation: The data quality captured in the routine system is weak and the tools for capturing information is outdated. Prevalence of Leprosy is unknown and depends on the WHO estimates.



STRATEGIC INTERVENTIONS

Key interventions to improve early diagnosis and prompt treatment of all new cases of leprosy and stop ongoing transmission in the community will be centred around strengthening ownership, coordination and partnership; promotion of inclusion and stopping discrimination, and mobilization of increased resources.

Strengthen the political commitment on leprosy: Promotion of partnership with state and non-state actors, and provision of dedicated budget allocation by the national and county governments is key to address leprosy control in the country. In addition, discriminatory and stigma legislation against persons affected by leprosy are key in improving the quality of life. Promote early case detection through active case finding: The focus will be in high endemic counties and contact management through community awareness on leprosy using facility health talks, community dialogues, radio talk shows, skin camps, use of IEC materials and social media. Development and adoption technology applications for leprosy of awareness. Household and close contacts of all leprosy cases will be registered, educated and screened for leprosy. New innovative approaches e.g. ECHO, e-learning modules among others will be used to build the capacity of HCWs and sensitize them on Leprosy. There are few set out equipped facilities to manage leprosy, this should be scaled up. Supply of leprosy commodities will be strengthened.

Strengthen surveillance and health information systems for program monitoring and evaluation: Improve data quality for purposes of monitoring progress through revision of data capture tools including development of screening tools for leprosy. Optimizing opportunities created by other universal health coverage programs (e.g. NHIF, social protection, disability programs). Revision of supervision checklist to capture quality of care indicators among leprosy clients

Promote disability prevention and management to improve quality of life among leprosy patients: EHF will be used for periodic disability assessment to ensure disability is detected on time to avoid progression to worse grade. Linkage will be made with available stakeholders who are engaged in rehabilitation. Periodic update of leprosy guidelines will ensure the program is in line with international standards and local needs. Leprosy drugs will be included in the dashboard to ensure commodity security.



OUTCOME TARGETS

	Indicator	Baseline	Target
¥.	Proportion of childhood leprosy cases among notified cases	6%	3%
Ŀ.	Proportion of newly diagnosed leprosy patients with disability grade 2	> 35%	<10%

2.2.6 Key Populations

🔏 SITUATION ANALYSIS

Key populations are people who are disadvantaged compared to others mainly due to limited access to medical services or because of underlying determinants of health. Evidence from routine national TB surveillance data, the National TB Prevalence Survey 2016 and an assessment conducted by KELIN in 2017 identified the following key population: slum dwellers, uniformed personnel, persons living with HIV (PLHIV), contacts of TB patients, health care workers, refugees, prisoners, diabetics and malnourished individuals, urban slum dwellers, men aged 24-34 years, and the elderly over 65 years. These groups pose a challenge for TB control due to their vulnerability and their underserved situations as shown in Table 8.

Table 9: Categorization of Key Populations in TB Control

Category	Identified key populations in Kenya
People who have	Household contacts including children
increased exposure of	People who live in urban slums
TB due to where they	Health care workers
	Prisoners
	People living or working in congregate settings with an index case - school going children in boarding schools, informal workers in factories/ plantations with large number of employees
People at an increased	People who are undernourished
risk of TB because	PLHIV
of their biological or behavioral factors that	People with cancer/ undergoing immunosuppressive therapy
compromise immune	People who have diabetes
function	People with cancer/ undergoing immunosuppressive therapy
	People who misuse alcohol, PWIDs
	Elderly over 65 years

Category	Identified key populations in Kenya
People who have	Men 25-34 years
limited access to	Refugees
quality services	Mobile populations
	PWIDs, people who misuse alcohol
	Homeless/street families, MSM

These key populations that are at risk of TB disease are the same populations that don't have access to health care and have poor health seeking behavior. Factors such as stigma, discrimination and criminalization cause these populations to shy away from the health services they need.

Undernourished individuals: Under nutrition is the leading underlying cause for TB in Kenya with more than 43 percent of TB patients suffer from either moderate or severe acute-malnutrition at the time of diagnosis. Tuberculosis deteriorates nutritional status of patients, which makes treatment difficult, resulting in unfavorable treatment outcomes. An analysis of TB patients notified between 2012 to 2016 who had body mass index (BMI) less than 18.5 kg/m² revealed an overall 51 percent death rate among them⁶³. Despite availability of food support for the TB patients, its distribution is not well aligned with need and a significant number of malnourished patients have no access to prompt screening for TB. These individuals present to other health service delivery points.

Prisoners: Case notification rate of TB among prisoners is high at 1,142 cases per 100,000 population (TIBU). This shows the magnitude

of the problem among prisoners. Systematic screening for TB in prisoners is undertaken only at entry of prison and wardens have been capacity built to diagnose and manage TB. In addition, there are GeneXpert machines available in three health facilities within prisons. Further, there is an implementing partner supporting TB prevention and control services in partnership with the Ministry of Health and Kenya Prison Services.

Healthcare workers: Healthcare workers are exposed to TB infection as an occupational hazard. However, data to support the burden of TB among this subpopulation is lacking due to the fact that the TB control measures for this group are not well documented.

Urban Slum Dwellers: The National TB Prevalence Survey reported a higher burden of TB in urban (760 per 100,000 population) compared to rural settings (453 per 100,000 population), this is consistent with routine TB data which shows higher notification rates in the big cities. Transmission of TB in low income settlements fueled by a combination of socioeconomic factors including poor housing, overcrowding, poverty, alcohol and drug abuse among others.

⁶³ National Tuberculosis, Leprosy and Lung Disease Program. (2018). Annual Tuberculosis Report. Nairobi: National Tuberculosis, Leprosy and Lung Disease Program

Men aged 25 – 34: According to Kenya TB Prevalence Survey, majority 65 percent of those with symptoms who did not seek treatment were men. In addition, they were found to have a disproportionately high burden of TB two and half times that observed in females. Further, men are associated with various risky occupation and behavior that may contribute to the higher burden of disease.

People living or working in other congregate settings with an index case: School going children in boarding schools, informal workers' in factories or plantations with large number of employees. Sporadic outreaches for case detection in these settings have been conducted.

Elderly (over 65 years): Prevalence to notification gap was highest in the age group 25-34 and those over 65-year-old.

Others include **migrants (refugees, cross border population) and mobile population; pastoralists.**



PRIORITY GAPS

No policy and guidelines to support regular to screening of all key populations: Current outreach screening approach is not regular and does not cover all defined key populations, except for HIV, prisoners and children under five years. For example, the regular six-month screening of HCWs is not implemented.

Limited TB awareness among key populations: This hinders demand for TB services, fosters stigma and impedes compliance to treatment among key populations (high opportunity cost). **Operational factors that hinder access to diagnosis and treatment** for instance unfriendly working hours at service delivery points, indirect cost and geographical factors. Limited resources to support TB services among the high-risk groups.

Legal factors that exacerbate discrimination against key and vulnerable populations hindering their access to TB services.

Limited involvement of key population in TB programming including TB interagency coordinating committee and technical working groups at national and county level.

TB surveillance data does not capture all key population: There are no key populations (KP) measures (indicators) in the TB surveillance system to capture specific TB risks, drivers and service access barriers such as behavioral, socio economic and legal factors.



STRATEGIC INTERVENTIONS

Promote engagement of key population in planning, implementation, monitoring and evaluation of tuberculosis care. This will be conducted through development of an engagement plan for key populations and involvement in TB ICC meetings. Counties will add prioritised key populations to their county TB plans based on the local epidemiology.

Prioritise systematic screening of key populations based to their contribution to the TB burden. Guidelines and algorithm for screening key populations will be developed to define ACF modalities per key population and /or per setting.

Create demand for TB services among key population: This will require development of targeted messages (IEC) for key populations, use of mass media and digital platforms, use of health behavior models to predict behavior and plan interventions.

Service integration into existing health programs targeting key population through multi-sectorial collaboration and strategic partnership with other stakeholders. Integration of TB services into the special clinics of the key populations. In addition, develop a linkage framework between special clinics and TB treatment sites. County governments will integrate TB services focusing on key populations into existing health outreach programs. Referral tools will be developed and a tracking mechanism will be established.

Implementation of primary prevention in high-risk occupations through establishment or strengthening TB workplace programs tuberculosis surveillance and infection prevention and control in healthcare settings, organizations will be engaged to advocate for workers self-protection, job protection and routine TB screening.

Inclusion of TB performance indicators to monitor key population. Availability of quality data on key populations at national and county levels to fill program and service planning data gaps. The TIBU system will be strengthened to include key population variables as part of the current surveillance system (refer to MER). Special surveys to identify of key populations at high risk of TB will be conducted at county level.



Contribute to increased case detection and improved treatment outcomes.



3

AT A GLANCE

48%

Estimated percentage of all health care provided collectivelly to Kenyans by the non-state or private health care sector

PILLAR TWO: BOLD POLICIES AND SUPPORTIVE SYSTEMS

3.1 MULTI-SECTORAL COLLABORATION & ENGAGING ALL CARE PROVIDERS

SITUATIONAL ANALYSIS

ffective implementation of the End TB Strategy requires effective government stewardship, high-level political commitment and enhanced resources. Active coordination across government ministries as well as engagement and collaboration with communities, civil society and all public and private care providers is essential. The non-state or private health care sector collectively provides 48 percent of all health care provided to Kenyans. The private sector is composed of formal and informal health service providers. Formal private providers include not-for-profit formal institutions such as faith-based organizations (FBOs) and non-governmental organizations (NGOs) as well as for-profit providers including private self-financing institutions, individual private providers, retail pharmacies, chemists, laboratories, corporate and non-qualified or informal providers. The large private institutions, which mainly serve the affluent or those covered under corporate insurance, mostly provide tertiary health care services. The medium-small sized hospitals, also called nursing homes mainly provide health and TB services for a fee. Individual private practitioners include medical doctors, clinical officers, nurses, medical laboratory technologists among others. Corporate sector provides health services at workplace for employees and their dependents but opportunities to engage more with corporate in industries attracting vulnerable populations should be explored. The informal sector (those who practice conventional medicine and those who do not) comprises of unregistered or unregulated skilled personnel service providers who include: herbalists, faith healers, grocers and shopkeepers, community health volunteers, traditional birth attendants among others.

In 2017, the private sector had a contribution of 18 percent of all notified TB cases⁶⁴. Treatment outcomes as well as TB/HIV outcome indicators in the private sector compare favorably with the public sector. Under this approach, the engaged facilities use national policies and guidelines, monitoring and evaluation tools, and NTLD-P provides medicines and other essential commodities for diagnosis and treatment. Engaged private facilities benefit from routine supervisory visits by county health

⁶⁴ National Tuberculosis, Leprosy and Lung Disease Program. (2018). Annual Tuberculosis Report. Nairobi: National Tuberculosis, Leprosy and Lung Disease Program.

management teams. Despite the long period of PPM implementation, coverage of private health care providers in the provision of TB control services remains low and uneven across counties, ranging from zero percent to 65 percent. Majority of these providers have not been engaged and those engaged are not yet optimally providing the TB services and reporting to the national system. Coverage for smaller private providers (unregistered or unregulated individual clinics) are unknown and there is hardly any information regarding corporate sector providers, pharmacies and informal providers. Further, a significant number of TB patients may be diagnosed and even treated but not notified⁶⁵. Patient pathway analysis revealed that 42 percent of the population first seeks services in private health facilities, with 27 percent and 15 percent being formal and informal private sector respectively⁶⁶. This is augmented further by findings from the National TB Prevalence Survey showing that 21 percent of prevalent TB cases had sought care in private clinics and pharmacies⁶⁷.

WHAT HAS WORKED AND SHOULD BE SCALED UP

The NTLD-P has developed a Public Private Mix Action Plan 2017-2020 which outlines six key models of private sector engagement both at national and county levels.

Private Sector (Institution and Individual Provider) Model: The interventions under this model are aimed to improve access, equity, efficiency and quality TB care through

structured and sustainable engagement of the formal private health providers.

Pharmacist Model: The objective of this model is to promote identification of presumptive TB cases by the pharmaceutical personnel and their prompt referral to the network of NTLD-P network of providers to facilitate early diagnosis and management. In 2017-2018, 864 pharmacies and chemists in five counties were mapped and engagement commenced.

Pediatric TB Model: The model aims at engaging the private providers to expand access to TB services for children. This involves integration between MCH clinics, pediatric clinics and TB service providers to facilitate childhood TB diagnosis and treatment. In 2017, 92 pediatricians in Nairobi, Mombasa and Kisumu counties were trained and engaged on childhood TB.

Laboratory Model: This model aims to strengthen the collaboration with the private laboratories and put up mechanisms to link diagnosed cases from the private laboratories to the NTLD-P network of providers for appropriate case management. A total of 285 private laboratories are currently providing TB diagnostic services mainly through smear microscopy and 90 percent are enrolled in the national EQA system.

Corporate Model: The aim of this model is to engage corporate organizations and work places in implementation of interventions that target the employees at their workplaces in TB care and prevention. Some activities have been undertaken in collaboration with NTLD-P,

⁶⁵ Tollefson, D., Ngari, F., Mwakala, M., Gethi, D., Kipruto, H., Cain, K., & Bloss, E. (2016). Under-reporting of sputum smear-positive tuberculosis cases in Kenya. International Journal of Tuberculosis and Lung Disease, 1334–1341.

⁶⁶ Masini, E., Hanson, C., Ogoro, J., Brown, J., Ngari, F., Mingkwan, P., Makayova, J., Osberg, M. (2017). Using Patient-Pathway Analysis to Inform a Differentiated Program Response to Tuberculosis: The Case of Kenya. *The Journal of Infectious Diseases*, S714–S723.

⁶⁷ National Tuberculosis, Leprosy and Lung Disease Program. (2018). Kenya Tuberculosis Prevalence Survey. Nairobi: National Tuberculosis, Leprosy and Lung Disease Program.

Private Sector Consortium and implementing partners to reach out to the business world (corporates) in an effort to accelerate finding missing people with TB.

Informal Service Providers (ISPs) Model. The objective of this model is to expand the number of informal service providers engaged. By 2017, seven counties had commenced implementation of this model and this will be expanded to 25 counties by 2020. Few initiatives of outreaches for TB screening have targeted a few priority ones like factories, flower farms and other congregate settings like learning institutions with linkage to public facilities for treatment. PRIORITY GAPS

Inadequate multisectoral engagement: Engagement across government ministries and collaboration with communities, civil society and all public and private care providers is essential. Keeping the goal of ending the TB epidemic should be high on development agenda. The government should provide overall stewardship and coordination to ensure the goal is met. An accountability framework to support the involvement of the government ministries, private sectors and stakeholders is lacking. The framework will be developed to

Figure 18: Proportion of TB Cases Notified by Private Sector in Kenya, 2017



ensure high-level government stewardship and effective coordination of stakeholders in TB control.

Suboptimal engagement of private sector care providers: PPM activities have largely been concentrated in major towns and focused on institutional providers. Less than half of the counties are actively engaging in PPM activities and in them not all private providers have been reached. Critical challenges identified include: limited financial resources restricting scale-up for effective implementation of TB care, poor referral linkages for diagnosis and or treatment, weak treatment adherence and patient support systems and sub-optimal follow up of patients. In addition, small standalone formal and informal private providers are not engaged. These include chemist or pharmacies, individual clinics, private laboratories and private imaging centers. Other informal providers mainly consist of herbalists, drug sellers, traditional healers, and traditional birth attendant among others. There is suboptimal engagement of these providers mainly due to the lack of information on their locations, the services they offer and poor networking and referral mechanisms available to them.

Limited engagement of corporate and workplaces: There are a number of corporate organizations includina workplace and institutions that provide health services through wellness clinic to their employees, dependants and in some cases the neighboring community. The workers in these places hardly have time to access public health facilities due to scheduled working hours. These facilities attend to large number of clients but have not been engaged to provide TB services. There is need to target implementation of workplace interventions among corporate, factories and industries.

Inadequate capacity to diagnose and manage TB patient in private sector: There is a significant knowledge gap among private providers in all areas of TB care and prevention. Clinical management of diseases including TB in private facilities has been found to be inadequate and non-conforming to national TB guidelines. The capacity gaps are due to inadequate inclusion during trainings or updates on new guidelines and treatment recommendations, high staff turnover making it difficult to retain even the trained ones and competing activities. This results in delivery of fragmented, incomplete, and sometimes inappropriate treatment. According to Patient pathway analysis, access to TB diagnosis is poor in private health facilities due to limited availability of diagnostic equipment and technical expertise. Some private facilities refer patients for GeneXpert tests at public facilities; however, linkage of the patients has been weak with many referred patients being lost in transit and others are experiencing significant diagnostic delays.

Low case notification from the private sector:

The relatively low proportion of patients notified from the private sector against the large number of possible TB patients seeking care in private facilities, points to possible existence of gaps in coverage, quality of service and affordability and, affordability. In addition, the tools used to document TB data are not harmonized which results in gaps in linkage of TB services and notification of TB cases in the private sector. The inventory study showed underreporting of bacteriologically confirmed cases in privately owned health facilities.



STRATEGIC INTERVENTIONS

Private providers play an important role in providing health care services to a large proportion of patients with tuberculosis. There is a need for innovative measures to increase participation of the private sector through interventions that strengthen coordination and stewardship, scale up innovative PPM models of care, strengthen engagement and these will lead to increased notification of TB and quality of care. The following approaches will be adopted through the implementation of this NSP.

Multi-sectoral High-level engagement: government stewardship will ensure coordination of the relevant government ministries and private sectors. In order to address the inadequate coverage of TB service across sector, TB response will be expanded through multisectoral engagement to secure high level of political willingness and commitment. The policy framework will be developed to strengthen health system integration with inter-sectoral collaboration to full integrate TB with other health programs. Collaboration between NTLD-P and County government will provide guidance for development of fully budgeted County Strategic Plan for TB that will be in-line with this NSP. Multi-sectoral engagement forum will be established which will bring together public and private health care providers, social protection secretariat and partners, NHIF, parliament and county government among others.

Engage private sector care providers: The patient pathway analysis shows that almost 50 percent of patients seek care in private sector. Engagement of formal and informal private sector health care providers to provide TB services will be through using different PPM

model including; Informal service provider, Corporate sector, Pharmacy and Laboratory and Pediatric (PPM Action Plan 2017-2020). Incentivization of the private sector is key in engagement since they are there for profit.

Engagement of corporate and workplaces: Employee screening programs, workplace TB services and employment protection policies will be developed and made accessible at the workplaces, and that workers on TB treatment will be protected from wage loss due to the disease, stigma and discrimination. The capacity of wellness clinics in the cooperate organizations will be engaged in providing TB services including referral of patients or sample networking. This will help reach men aged 24 – 34 years (prevalence survey findings).

Improve on quality of diagnosis and management of TB in private sector: In order to ensure quality of care in the private sector, private care provider should provide standardized quality of TB diagnostic and treatment package according to national guidelines. There is need to build the capacity of health care worker in the private sector to provide quality TB care services. Guidelines and training programs will be designed for the private sector and based on level of engagement capacity to diagnose will be developed. Patients-centred treatment support will be provided to ensure adherence to treatment with close supervision by the county teams. The quality of laboratory services in private sector will be improved through linking the diagnostic sites to national EQA system and IQC will be encourage for continue quality assurance program.

Improve on case notification from the private sector: In order to ensure patients diagnosed with TB in the private sector are notified, the private sector will be linked to care and

treatment (TIBU). Mandatory notification will be enforced through the existing legal framework and certification program for the health care workers. The reporting system will be improved through digitalization of the recording and reporting tools that will be customized for use in the private sector. Mobile application will be developed to ensure adequate coverage (USSD codes). This will ensure the presumed TB patients are linked to diagnosis and those with TB linked to treatment and notified to TB program. Sample networking will be ensured, and results feedback mechanism improved through lab information system.

Reduce out of pocket health expenditure due to TB: In order to reduce financial barriers for patients in private sector, the defined UHC EBP covers diagnosis and management of TB services. The review of the NHIF benefit package cover and payment mechanisms to the private sector until patient completes TB treatment. The engaged formal sector will be accredited to benefit from NHIF services. Reimbursement of the patients cost by the government or donor will be explored to provide incentive to the private sector. Patients will be linked to cash transfer, food support and general social protection schemes.



Estimated percentage of all notified TB cases contributed by the private sector in 2017

6

OUTCOME TARGETS

	Indicator		Baseline	Target
	Proportion of private sector providers engaged to provide comprehensive TB services	>	12%	30%
Ē	Number of counties engaging the informal health sector providers in TB care and prevention		7%	47%
	Proportion of the engaged private sector providers recording and reporting TB cases through an e-system		Data unavailable	100%

3.2 UNIVERSAL HEALTH COVERAGE, SOCIAL PROTECTION, HUMAN RIGHTS & NUTRITION

3.2.1 Universal Health Coverage and Social Protection



SITUATIONAL ANALYSIS

Universal Health Coverage (UHC) is defined as ensuring that all people have access to the needed health services of sufficient quality while also ensuring that the use of these services does not expose them to financial hardships. The Government of Kenya is committed to attaining UHC by 2021 through expansion of the population covered with essential health services, strengthening and broadening the primary health care system, increasing health resource base and leveraging on information technology.

UHC, KENYAN CONTEXT

PHASE 1: Four Pilot Counties

To ensure the population in the four phase I Counties (Isiolo, Kisumu, Machakos and Nyeri) continue enjoying access to quality services, the Government has adopted an approach of implementation of UHC with key details as follows:

- a) Strengthening health systems at the County level (with emphasis on Human Resources for Health (HRH), Health Information Systems (HIS)
- b) Strengthening community health services
- c) Strengthening Public Health Services

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- d) Ensuring availability of essential commodities and basic equipment at the facility level
- e) Removal of user fees at level 4 and 5 public health facilities has been proposed in order to further reduce out of pocket expenditures for the population.

This means that the population in the four counties will access services without user fees from Level 2 to Level 5 public health facilities.

PHASE 2: National Scale Up

The Kenya Patient Cost Survey showed that 27 percent of the DSTB affected households including 86 percent of DRTB affected households experienced catastrophic costs due to TB. Drug Sensitive TB patients incurred a median cost of KES 26 041.49 per TB episode (equivalent to USD 260) while the MDRTB incurred KES 145,109.53 per TB episode (equivalent to USD 1,450)68. The high catastrophic continuously drive households as well as to individuals into poverty. A huge proportion of these costs were mainly indirect non-medical costs such as nutrition and travel costs.

The direct non-medical costs due to nutrition and food supplements account for 69 percent of the expenses (KES 17,739.71). These costs

⁶⁸ National Tuberculosis, Leprosy and Lung Disease Program. (2017). The First Kenya Tuberculosis Patient Cost Survey. Nairobi: Ministry of Health.

have been identified as barriers to accessing the full scope of TB services. This financial hardship resulting from direct and indirect costs when accessing health care for TB may adversely affect living standards and the capacity of household to pay for basic needs⁶⁹. Further, the Kenya TB Patient Costs Survey, demonstrated the negative consequences faced by TB patients including 28 percent took out loans, 63 percent lost jobs, nine percent of the household's children disrupted school and 36 percent faced social exclusion. These negative consequences make TB patients less likely to present for care, complete testing, initiate and adhere to treatment, leading to increased transmission of the disease, morbidity and mortality⁷⁰.

To operationalize the commitments of the constitution, a National Social Protection Policy (NSPP) was adopted in 2012 and a National Social Protection Secretariat (NSPS) was established in the Ministry of Labor, Social Security and Services in 2014. The Kenya Health Sector Strategic and Investment Plan 2014-2018 features social protection as a central theme. As a result of this increasing attention

Patients with DRTB patients and are on treatment, are enrolled on NHIF medical cover as a social protection. In addition, they receive **KES 6,000** monthly to support their livelihood. to social protection, government spending on social protection has steadily increased. The social protection interventions, as defined by the Kenya National Social Protection Policy (2011), are divided into three main categories: (i) Social Assistance, (ii) Social Security, and (iii) Social Health Insurance. In 2018, a new Kenya National Social Protection Policy was being developed with discussions to include TB.

The programs include cash transfers of KES 2,000 per month to vulnerable households, and a hunger safety net program that provides food to malnourished populations. The cash transfer program serves nearly 300,000 households that include orphans and vulnerable children, or people with disabilities. A single registry system to consolidate data on and ensure coordinated support to the beneficiaries of governmental and non-governmental social protection programs exists. For example, the registry incorporates information about and data on social protection schemes implemented by partners, such as additional food support programs. Patients with DRTB patients and are on treatment, are enrolled on NHIF medical cover as a social protection. In addition, they receive KES 6,000 monthly to support their livelihood.

The NTLD-P hosts an inter-agency task force on social protection on TB that includes members of the Social Protection Secretariat, NHIF, Health Policy and Department of Health Policy and Planning within the Ministry of Health, and partner organizations such as UNICEF and the World Food Program. A TB social protection policy has been developed that provides policy guidance for inclusion of TB patients in the existing social protection schemes.

⁶⁹ National Tuberculosis, Leprosy and Lung Disease Program. (2017). *The First Kenya Tuberculosis Patient Cost Survey*. Nairobi: Ministry of Health.



High costs associated with TB diagnosis and treatment creates a barrier to care: The TB patient cost survey showed that TB patients and their households face debilitating and often catastrophic total costs due to the disease, related to indirect costs such as income loss, direct medical costs transport or food costs. These high costs create barriers to access and adherence to medication thereby increasing the risk of disease transmission and poor outcomes. This is coupled with low medical insurance coverage among TB patients of 14 percent⁷¹.

Lack of formal linkage for TB affected households to existing food and nutrition security programs: In as much as a huge proportion of TB affected households face food and nutrition insecurity, there are no linkages between these vulnerable households to existing food and nutrition programs at the community level.

Lack of linkage of vulnerable TB patients requiring support to existing government social protection schemes: There are a number of existing social protection schemes and while it has been noted that a number of TB patients develop post – TB complications that reduce their quality of life, they are not considered vulnerable to be enrolled into these schemes.

Weak labor protection laws for TB patients: Existing labor laws provide inadequate protection for people with TB leading to loss of jobs, stigmatization among others.



STRATEGIC INTERVENTIONS

In order to eliminate catastrophic costs for TB patients and monitor progress towards the high-level End TB Strategy target to achieve zero catastrophic costs by 2035, this NSP will seek to reduce the catastrophic cost incurred by TB patients by half by 2023 through the following interventions:

Inclusion of all elements of TB care in the UHC essential benefits package: Elements of TB care have been covered in the defined UHC EBP since it involves provision of public health commodities that includes treatment for pneumonias, DSTB among others. There is need to expand the package to include awareness creation, screening, TB diagnostic package (for general patients), treatment package for DRTB, follow up (post TB complications package) and contact investigation and prevention. In addition, advocacy for subsidized TB related costs in all public health facilities in Kenya. This includes TB-related chest radiographs and admissions.

Sustain social protection cash transfer for DRTB patients: Continue to provide social support to DRTB patients in form of NHIF medical insurance cover and cash transfers for transport based on the minimum wage in tandem with existing labor laws.

Linkage of eligible TB patients to existing social protection programs in the country through inclusion of TB as a vulnerability criterion in the National Social Protection Policy. Alignment of food support with the need by extending it to cover all TB patients with moderate to severe malnutrition.

⁷¹ National Tuberculosis, Leprosy and Lung Disease Program. (2017). The First Kenya Tuberculosis Patient Cost Survey. Nairobi: Ministry of Health.

The NTLD-P to collaborate with Ministry of Labour and Social Protection to include TB in the labour protection laws and incorporate TB in workplace policies. This will remove workplace discrimination and uphold the rights of TB patients.



OUTCOME TARGETS

Indicator	Baseline	Target
Proportion of households affected by TB facing catastrophic costs	DSTB 26%	13%
	DRTB 86%	43%



Estimated direct non-medical costs due to nutrition and food supplements accounting for **69 percent** of the expenses. These costs have been identified as barriers to accessing the full scope of TB services, according to *The Kenya Patient Cost Survey*

3.2.2 Human Rights and Gender



SITUATIONAL ANALYSIS

Tuberculosis approaches and responses at the international level are anchored in international and regional human rights instruments. These laws recognize that all human beings have equal rights regardless of their nationality, ethnic origin, sex, race, religion, or any other status and are built around core human rights principles.

The Constitution of Kenya (CoK) has an expansive and progressive Bill of Rights that sets out the stage for the promotion and protection of the rights of all persons, persons with TB included. Article 19 (1) provides that the Bill of Rights is an integral part of Kenya's democratic state and is the framework for social, economic and cultural policies. Article 10 of the CoK is particularly important to the TB response as it provides guidance in relation to formulation and implementation of laws, policies, and strategies on TB prevention and management. TB strategies in Kenya must be formulated and implemented in a manner that respects the national values, especially through ensuring the participation of TB affected communities. The most prominent provision of the CoK in the TB response is Article 43 that guarantees the right to the highest attainable standard of health. The State is under an obligation to take legislative, policy and other measures, including



Estimated percentage medical insurance coverage among TB patients in Kenya, according to *The First Kenya Tuberculosis Patient Cost Survey, 2017*

the setting of standards, to achieve the progressive realization of the right to health⁷². By virtue of Article 2 (6) of the CoK, international instruments that Kenya has ratified form part of the Laws of Kenya. These international instruments provide a sound framework and basis for holding the government accountable where gaps exist at the domestic level.

The Health Act 2017 prescribes the right to heath as: (i) progressive access for provision of promotive, preventive, curative, palliative and rehabilitative services; (ii) right to be treated with dignity, respect and have their privacy respected; (iii) right to health information; (iv) right to informed consent; (v) right to privacy and confidentiality, among others. Article 21 (3) provides: All State organs and all public officers have the duty to address the needs of vulnerable groups within society, including women, older members of society, persons with disabilities, children, youth, members of minority or marginalized communities, and members of particular ethnic, religious or cultural communities⁷³.

Health providers on the other hand have, among other rights, the right to a safe working environment that minimizes the risk of disease transmission. This is important in protection of HCW in the TB response.

This NSP acknowledges that gender inequalities can impact health risks, health seeking behavior and responses from health systems, which lead to poorer outcomes. There is need to undertake responsive programming, which considers the prevailing gender norms or undertakes gender transformative programming, so as to mitigate harmful gender norms that are barriers to accessing health services.

Integrating TB services into reproductive maternal and child health (RMNCH)-related health services to facilitate access by women and girls is another priority within the NSP. However, there are no interventions targeted towards men (who are disproportionately affected by TB in Kenya) to reduce their barriers to accessing TB services.

PRIORITY GAPS

A rights-based approach is yet to be realized in the management, treatment, care and support of TB patients in Kenya. Despite the diagnosis and treatment of TB being free, patients still incur costs and suffer the pain of an ailing public health system characterized by delays in provision of services, poor dissemination of information on TB, and a lack of involvement of communities of TB survivors in decision making processes.

The **lack of legal guidance on isolation of patients, and the few isolation units** is a loophole for possible human rights violations of TB patients. Further, there is hardly any guidance on addressing TB related discrimination and violation of human rights at health facility and policy level. Empowerment and education of patients on rights and about TB is largely left to community based, civil society and partner organizations.

⁷² Attorney General. (2010). *The Constitution of Kenya*. Nairobi: Government Printers.

⁷³ The National Assembly. (2017). Kenya Gazette Supplement No. 101 (Acts No. 21). Nairobi: The Government Printer.

Gender related barriers to TB services: Though generally there is poor access to health care among women due to lack of decision making and economic power, this have not affected access to TB services. The prevalence survey (2016) showed that there is a notification gap for TB among men. In addition, a large burden in TB have been reported in young men across the counties associated with economic activities like public transport sectors (*matatus* and *boda boda*), *jua kali*, mining and fishing. In addition, a higher risk of TB has been reported in young men abusing alcohol and injecting drug users.

Weak labor law to protect HCW workplace compensation: Lack of a policy for health worker compensation in cases where they contract TB in the line of duty.



STRATEGIC INTERVENTIONS

To ensure a human rights' and gender-based approach to TB management and care, this NSP proposes to undertake the following strategic interventions.

Sensitization of lawmakers, law enforcement agents and HCW: This will be achieved by the successful implementation of programs that (i) Sensitize law makers, law enforcement agents regarding TB, leprosy and lung diseases and how it is and is not transmitted and the negative consequences of illegal police activity on justice and on the TB, leprosy and lung diseases response; (ii) Facilitate discussions and negotiations among TB, leprosy and lung diseases service providers, those who access services and police to address law enforcement practices that impede prevention of TB, leprosy and lung diseases, treatment, care and support efforts; (iii) Information and sensitization sessions for parliamentarians,



This NSP acknowledges that gender inequalities can impact health risks, health seeking behavior and responses from health systems, which lead to poorer outcomes.

member of county assemblies, governors, judicial officers, prosecutors, lawyers, staff members of human rights and gender commissions, on the legal, health and human rights aspects of TB, leprosy and lung diseases and on relevant national laws and the implications for enforcement, investigations and court proceedings; (iv) Training for prison personnel regarding the prevention, health care needs and human rights of detainees infected with or at risk of TB, leprosy and lung diseases infection and TB, leprosy and lung diseases in the workplace programs for law

makers and enforcers; (v) Training to ensure that health care providers know about their own human rights to health (TB, leprosy and lung diseases prevention and treatment, universal precautions, compensation for workrelated infection) and to nondiscrimination in the context of TB, leprosy and lung diseases and reduce stigmatizing attitudes in health care settings and to provide health care providers with the skills and tools necessary to ensure patients' rights to informed consent, confidentiality, treatment and nondiscrimination.

Removal of the legal, human rights and gender barriers to access of TB, leprosy and lung diseases services: This NSP aims to attain this by implementation of programs that (i) Reduce stigma and discrimination at the community-level; (ii) Conduct legal literacy (know your rights) campaigns to improve legal and human rights literacy of people infected and affected by TB, leprosy and lung diseases; (iii) Provision of TB, leprosy and lung diseases related legal services to those who face human right violations; (iv) Active case finding in communities affected by TB, reaching out to women and other economically disadvantaged who do not have means to access services without paying for transportation. Integrate TB services into Reproductive Maternal and Child Health (RMNCH) related health services to facilitate access by women and girls.

Monitoring and reforming laws, regulations and policies relating to TB, leprosy lung diseases: This will be attained through (i) Assess access to justice for people infected with TB, leprosy and lung diseases or vulnerable to TB, leprosy and lung diseases infection; (ii) Advocate and lobby for law and policy reform with the relevant stakeholders on matters relating to TB, leprosy and lung diseases; (iii) Promote enactment and implementation of laws, regulations and policies that prohibit discrimination and support access to TB, leprosy and lung diseases prevention, treatment, care and support; (iv) Develop tools to monitor incidents of rights violations includina discrimination. aender-based violence and denial of healthcare services for TB, leprosy and lung diseases patients, and this will be coupled with (v) Training community groups on how to use the tools and report incidents of human rights and gender-based violations.

Formation of intersectoral partnerships between the Ministry of Health (NTLD-P) and other Departments within Government to embed TB, leprosy and lung diseases concerns: This will be attained through (i) Sensitization of relevant Government staff to ensure equal access for TB, leprosy and lung diseases patients to agricultural subsidies, housing allocation and other social benefits; (ii) Sensitization of national human rights institutions. Gender Commission and Office of the Ombudsmen on human rights dimensions of TB, leprosy and lung diseases.

Nutrition 3.2.3



SITUATION ANALYSIS

Malnutrition is a risk factor for the progression of TB infection to TB disease and is a predictor for increased risk of death, and TB relapse⁷⁴. While malnutrition results in weakening immune system, TB disease results in poor appetite, malabsorption, wasting and further deterioration of the immune system. This results in a vicious cycle of disease and

⁷⁴ World Health Organization. (2013) Nutritional care and support for patients with tuberculosis. Geneva: World Health Organization; Retrieved from http:// www.who.int/nutrition/publications/en/



Figure 19: Relationship Between Under-nutrition and TB Infection

Source: Food and Nutrition Technical Assistance, 2014

malnutrition⁷⁵. Additionally, studies indicate that malnourished TB patients have delayed recovery and higher mortality rates than well-nourished patients. Nutritional status of patients also improves during TB treatment⁷⁶.

In Kenya, malnutrition is a key co-morbidity for TB patients, 68 percent of patients notified with TB in 2017 were malnourished.



The risk of TB increases with falling body-mass index (BMI) (Data from six countries with different background TB burden. Source: Lönnroth et al. Int J Epidemiology 2009; 9: 149-55.)

Nutritional assessment is therefore an essential prerequisite to the provision of nutritional care⁷⁷.

The NTLD-P has put in place systems to ensure nutritional assessment is conducted for TB patients at the point of diagnosis. The NTLD-P and her partners have supported the procurement of weighing machines and

PMI Classification	Notified TB Patients		Food Support	
	Number	Proportion	Number	Proportion
Normal	29,087	34%	2,289	8%
Moderate Acute Malnutrition	23,958	28%	9,506	40%
Severe Acute Malnutrition	12,609	15%	7,202	57%
Overweight	3,079	4%	151	5%
Obese	913	1%	32	4%
Not Evaluated	15,542	18%	3,540	23%
Total	85,188		22,720	

Table 10: Nutritional Status of Drug Susceptible TB Patients in 2017

Source: NTLD-P, Annual TB Report, 2017

⁷⁵ Food and Nutrition Technical Assistance (2014). Why Good Nutrition Is Important in the Treatment of TB. Retrieved from https://www.fantaproject.org/ news-and-events/why-good-nutrition-important-treatment-tb

76 Gupta, K. B., Gupta, R., Atreja, A., Verma, M., & Vishvkarma, S. (2009). Tuberculosis and nutrition. Lung India: official organ of Indian Chest Society, 26(1), 9-16.

⁷⁷ National Tuberculosis Leprosy and Lung Disease Program: Annual Report, 2017

height-meters for use at facility level, while TB guidelines clearly outline conducting nutritional assessments for all TB patients at diagnosis as part of the package of care provided for all TB patients. Nutritional training is conducted for county nutritionists to support provision of appropriate nutritional commodities to patients. From the table above, overweight and obese people receiving nutritional support points to capacity gap in nutritional intervention among the healthcare workers.

Nutritional commodities have been procured by the Ministry of Health and is availed to patients found eligible for nutritional support. This is distributed through a centralized supply chain system, with commodities distributed from the Kenya Medical Supply Agency (KEMSA). Provision of nutritional commodities is based on the robust surveillance system that is currently in place, which captures TB patients diagnosed with malnutrition. This is supported by the monitoring and evaluation tools currently in place at facility level to capture nutritional assessment at patient level. Following the recently disseminated TB Patient Cost Survey (2017) in Kenya, the NTLD-P enhanced advocacy towards getting more resources committed towards mitigating direct non-medical costs, particularly food expenses and nutritional supplements.

Figure 20: Distribution of Severely Malnourished TB Patients in 2017



Significant variance in proportions of TB patients with malnutrition can be seen across the country with higher proportions of malnutrition in the arid and semi-arid region of Northern Kenya, where food insecurity is a major challenge.



Low numbers of malnourished TB patients on nutritional support: In 2017, 82 percent notified of TB patients underwent nutritional assessment. Out of those assessed, 55 percent of the DSTB and 60 percent of DRTB were found to be undernourished at the time of diagnosis. Of those found to have moderate acute malnutrition, only 28 percent were put on nutritional support, while of those with severe acute malnutrition, only 15 percent

were initiated on food support.

Suboptimal TB screening among people with malnutrition: Despite nutrition assessment being conducted routinely for TB patients, there is suboptimal TB screening among people who are malnourished patients at other service delivery points (health facility or community). This is because of the low index of suspicion among HCWs providing nutritional services on the most part, and more so among malnourished children presenting with respiratory illnesses with chronic malnutrition.

In Kenya, **mortality** during TB treatment is **significantly higher among patients with under nutrition** (13 percent) compared to those without malnutrition (6 percent). An evaluation of patients treated in 2012 - 2013 demonstrated that patients who received food support were 20 percent less likely to default from TB treatment than those who did not receive caloric support while an analysis of TB patients notified between 2012 and 2016 who had BMI less than 18.5 kg/m² revealed a 51 percent mortality among malnourished TB patients⁷⁸. Despite the availability of food support for the TB patients, its distribution is not well aligned with the need and a significant number of malnourished persons at the community level do not have access to prompt screening for TB. Some of these individuals may also present to health service delivery points.

According to the Patient Cost Survey (2018), up to 26 percent and 86 percent of DSTB and DRTB patients incur catastrophic costs respectively. A significant proportion of these costs were **non-medical costs such as nutrition** and travel costs. These costs have been identified as barriers to accessing the full scope of TB services.

According to a data synthesis exercise held in April 2018, **the logistics management of nutritional commodities** was considered a challenge due to several gaps within the health system, such as poor documentation of nutritional status for patients resulting in inadequate provision of commodities for patients, delays in distribution of nutritional commodities and sub optimal prescription and administration of nutritional commodities for different patient groups.

Kenya health system promotes **community health nutrition programs** that target household to develop health eating habits through income generating activities. These focus on growing of nutritious foods as well rearing of animals that provide nutritious feeds such as eggs. Unfortunately, majority of these community health nutrition programs have not been integrated into TB nutritional care, limiting the scope of which nutritional support for TB patients is provided.

⁷⁸ National Tuberculosis Leprosy and Lung Disease Program: Annual Report, 2017



STRATEGIC INTERVENTIONS

This NSP proposes to reduce the impact that malnutrition has on the treatment outcomes of TB patients through universal nutritional assessment and optimisation of nutritional management for eligible patients at household and community level. It is hoped that these interventions will further mitigate the mortality associated with malnutrition among TB patients.

Strengthening collaborations and partnerships across sectors and with ministries such as those of Agriculture and Social Protection. Through the NTLD-P, this NSP proposes coordination of engagement forums to identify the areas of support that various departments, government agencies and development partners would provide. Joint forums with the National Treasury, Ministry of Labor and Social Protection, Ministry of Devolution, Ministry of Agriculture, Livestock, Fisheries and Irrigation, NHIF, World Food Program, as well as development partners such as DFID, USAID, World Bank, WHO, UNICEF will be held to identify areas for leveraging of resources and expertise towards provision of food security at national and county level. Through the National Parliamentary health committee, the NTLD-P will lobby the parliament to develop a legal and policy framework for social protection to cushion the TB, leprosy and lung disease patients and their households. The Ministry of Labor and Social Protection in particular, will be engaged to guide and support the inclusion of TB and leprosy in the available social protection schemes at national and county level.

Food security as one of the major pillars of the President's '*Big Four' Agenda* and will be a critical component to reducing malnutrition for patients at risk for TB, thus breaking the cycle

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of malnutrition and TB infection progressing to disease. This NSP therefore looks to develop a multi-sectoral approach towards working closely with stakeholders whose mandate includes improving food security within communities and among patients at risk. At patient and community level, this NSP, in collaboration with county government, proposes to identify nutritionally vulnerable households and link them to existing state and non-state social protection programs at county level. This will involve mapping out food and community nutrition programs within counties to enhance linkage with TB and leprosy patients. This will also include establishing a focal person in the community (e.g. social worker, CHEW) to coordinate the linkage with facilities to ensure sustainability, while linking nutritionally vulnerable patients to food security solutions such as linkage to community-coordinated income generating activities (IGA)s and community nutrition programs that provide household counseling on healthy eating habits.

Universal nutritional assessment for all TB patients: This NSP looks to support systematic, universal nutritional assessment for all TB patients by empowering HCWs to conduct nutritional assessments for TB patients at treatment initiation and for monitoring patients on a monthly basis, provision of equipment for all health facilities towards nutritional assessments, and printing and distribution of recording tools for documentation of nutritional assessments.

Optimisation of nutritional management for all eligible TB patients: This NSP also seeks to support capacity building of nutritionists and HCWs managing TB patients to provide targeted nutritional interventions for eligible patients as indicated. This will involve provision of targeted nutritional
commodities based on WHO and Kenya national guidelines with targeted therapeutic feeding for all severely malnourished adults and children; both in and outpatients, as per WHO/ IMAM recommendations, targeted supplementary feeding for all moderately malnourished TB patients meeting the criteria of BMI less than 18.5 kg/m2, as outpatients, availing alternative feeding options to infants born of MDR-TB/PLHIV if and when mothers are unable to breastfeed exclusively on demand for the first six months and providing multiple Micronutrient supplementations for all TB and leprosy cases during the intensive phase of treatment.

Strengthening systems surrounding nutrition commodity forecasting, quantification and supply chain management: As an intervention to avail nutritional commodities where they are needed, this NSP looks to streamline prevailing supply chain management challenges that affect the availability of commodities to patients. This includes strengthening documentation of patient nutritional status, improved collation of nutrition reports, strengthened forecasting and quantification of nutritional commodities, and more importantly, aligning the supply of nutritional commodities to TB commodities. This intervention will include strengthening DHIS reporting as a key component of closing the loop between the patients identified with malnutrition and those receiving nutritional support.

Bidirectional screening for TB within nutrition settings: This NSP proposes working closely with the Nutrition and Dietetics Unit within the Ministry of Health, to support **TB screening within nutrition settings,** even as nutrition assessment is being conducted during TB care. This will also include integration of TB screening during community outreaches and maternal and child health settings. This will involve engagement of national and county nutrition departments in the development of a policy and SOP for bidirectional screening of TB screening nutritional settings, capacity building of HCWs providing nutritional and MCH care, and provision of reporting tools for TB screening. Lastly, a robust monitoring and evaluation system will be put in place to support the bi-directional screening activities.



Estimated percentage of mortality in Kenya during TB treatment, which is **significantly higher among patients with under nutrition**, compared to those without malnutrition (6 percent)



Estimated percentage of DSTB patients incurring catastrophic costs in Kenya, according to The *Patient Cost Survey, 2018*



Estimated percentage of DRTB patients incurring catastrophic costs in Kenya, according to The Patient Cost Survey, 2018

OUTCOME TARGETS



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

3.3 SUPPLY CHAIN MANAGEMENT AND aDSM

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SITUATIONAL ANALYSIS

Availability and accessibility of commodities plays a key role in determining provision of services in health facilities and building confidence of patients in the health system. This document espouses an integrated supply chain system that ensures the availability of high quality, efficacious TB medicines, diagnostic tests and nutritional commodities to all levels. It aims to strengthen forecasting of TB medicines, laboratory consumables and other related commodities at the national level. Stock monitoring and early warning systems to detect and respond to impending shortages and or excess stocks are included. to ensure the medicines and commodities are available consistently.

The Ministry of Health has continued to increase allocation of funds for the procurement of TB medicines, nutrition commodities and diagnostics, with the allocation enough to cater for 100 percent of first line medicines for TB. This is complemented by partner support mainly The Global Fund grant that complements purchase of second line medicines, laboratory commodities, and GeneXpert consumables. There has been a vast improvement in management of procurement, warehousing, distribution and reporting through the monthly commodity security committee and the national order management team. Annual forecasting and quantification is conducted to determine the country's commodity requirements with biannual reviews to consider emerging issues such as regimen change among others. The forecast then advises the quantities to be procured by the program while identifying sources of funds to support the procurement.

Procurement, warehousing and distribution of TB commodities is carried out centrally at the national level by the Kenya Medical Supplies Authority (KEMSA). Various methods of procurement are in place for this. Most often, open national and international tenders have been used especially for first line and nutrition commodities which has posed challenges due Table 11: Source of Financing for Commodities

NTLD-P commodities & Pharmacovigilance	Partner (%)	Government (%)
First Line Medicines	30	70
Second Line Medicines	100	0
Nutrition Commodities	100	0
Laboratory Commodities	50	50
Gene expert Consumables	100	0
Leprosy Medicines	100	0

to the laws that exist that have led to stock outs and therefore need for framework contracting to maintain consistent supply. Distribution is based on a pull system.

Medicines are delivered to the subcounty level with the sub county pharmacist and TB coordinators ensuring delivery to the lower facilities. Facilities make orders through FDRR which are submitted at subcounty from aggregation which is done manually which is uploaded in DHIS2 platform and consequently validation of orders is done at national level through KEMSA LMIS. This coupled with training of county and sub-county pharmacists on DHIS2 reporting and its integration into KEMSA LMIS and establishment of the national order management team has greatly improved reporting rates from 38 percent to 84 percent.

However, this NSP sets out to have facilities reporting directly through DHIS2 and subcounties supported to do order validation before sending to county for approval and





subsequently national level authorization to KEMSA to supply the requested products.

A functional TB commodity security subcommittee is in place at the national level. The committee provides an oversight role in the implementation of TB commodity management activities including monthly stock status monitoring, forecasting, and procurement planning. Health service is a devolved function to county governments, there is need to devolve order management at county level to improve efficiencies in supply chain for TB commodities.

A pharmacovigilance system hosted by the Pharmacy and Poisons Board of Kenya exists for adverse events and quality of medicinal products.

To ensure quality medicine are available for the patients, there is safety assurance mechanism at each level of the supply chain and postmarket surveillance conducted every year to check on the quality of medicines used by TB patients at the service delivery points.

Adverse drug monitoring system is available for spontaneous reporting which need to be strengthened further to aid decision making programmatically. However, active drug safety monitoring is not in place for new MDRTB treatment drugs which raise safety concerns to the program. .↓.

PRIORITY GAPS

Inconsistent supply for key TB commodities: Due to challenges in procurement lead times for both first lines and second line medicines and other commodities and inefficiencies in distribution to the last mile. First line medicines and most commodities are normally procured via KEMSA open international tender while second line medicines are procured through the Global drug Facility pooled procurement mechanism using the Global Fund. GeneXpert and consumables including maintenance are procured via tripartite with the Principle Recipient 2 (AMREF) for a direct procurement to Cepheid (manufacturer). These varied systems if not well monitored result in stock outs of key TB medicines interrupting treatment.

Logistics management information system reporting: The reporting system has been excel based and a lot of funds have been invested to push to DHIS2 reporting. Counties and sub counties are expected to report via DHIS for all their LMIS indicators.

Irregular supply chain audits: The plan is to invest in regular pharmaceutical supply chain audits that have never been conducted before. This will help in monitoring of key performance indicators; level of stock out for key commodities, level of expiries, order lead times, reporting rates, order fill rates and stock levels for tracer commodities.

Active Drug Safety Monitoring (aDSM): is recommended for all patients on second line treatment and in particular those on new molecules delaminid and bedaquilin. This has not been practiced in the past and there is need to strengthen pharmacovigilance. Capacity building of healthcare workers to monitor adverse events during treatment is also a gap that needs to be filled.



STRATEGIC INTERVENTIONS

This NSP represents lays out strategic approaches that will ensure uninterrupted supply of anti-TB medicines and commodities. This will be achieved through:

Regular Pharmaceutical supply chain audits:

This will be achieved through strengthening monitoring and evaluation and field supervisions/ audits for commodities. These efforts are envisaged to reduce proportion of TB treatment sites reporting stock outs of key commodities, reduce level of expiries at treatment sites; increase reporting rate, subcounties and counties through DHIS2 and increase order fill rate for TB medicines.

Strengthening DHIS2 to include LMIS indicators: In addition, the reporting system for TB commodities will be updated to ensure that the NTLD-P receives timely information from health facilities when sub-counties and counties receive them.

Strengthened forecasting and quantification:

Further, HCWs will be capacity built on use of QuanTB, dashboard and DHIS2 to ensure accurate quantification and good order fill rates.

Active Drug Safety Monitoring: HCWs will be trained on aDSM for patients on treatment with second line medicines. These efforts are geared to ensuring all patients on second line treatment undergo aDSM from the current 20 percent.

3.4 **PROGRAMMATIC MANAGEMENT**



SITUATIONAL ANALYSIS

The NTLD-P has been largely guided by the NSP for TB, leprosy and lung health in implementation of control activities for the period 2015 to 2018. This coincided with implementation of the Constitution of Kenya in 2013. Consequently, lessons learnt during this period of change in governance has informed the paradigm shift in implementation of the current strategic plan. During this period, the global community developed The End TB Strategy, Sustainable Development Goals (SDGs) and new innovations and this strategic plan 2019 – 2023 will be informed on the basis of these developments.

Effective implementation of the End TB requires effective government Strategy stewardship, high-level political commitment and enhanced resources. The human and financial resources required for implementation is commensurate with the enhanced scope of core functions that are integrated effectively within delivery of general health services. Active coordination across government ministries as well as engagement and collaboration with communities, civil society and all public and private care providers will be essential. A sound, fully budgeted national TB strategic plan has been developed and will be implemented with all stakeholders, in line with overall national health and social sector plans.

Strengths of the NTLD-P include a wellestablished program with solid leadership structures, ISO 9000 – 2008 certification, skilled human resources (technical officers and support staffs) and students interns

under attachment (FELTP), availability of infrastructure including office space and equipment (computers, furniture, vehicles), technical support from partners and stakeholders including technical working groups and support to the counties. Others are availability of policy documents and guidelines for TB control: close collaborative networks with other government departments like HIV control programme, disease surveillance, neglected diseases. universities: strona networks with counties in the implementation of TB activities e.g. isolation facilities. IPC, staff. infrastructure: and mechanisms for internal audit control that ensures financial controls are place.

The key opportunity includes inclusion of financing for TB prevention and control activities in county integrated development plans (CIDP).



Suboptimal involvement of county government in TB prevention and control activities: This has led to subpar quality of support supervision since the county TB and leprosy coordinators and subcounty TB and leprosy coordinators are under direct supervision of county health departments. This is further compounded with lack of standard county health management team organizational structures across the country, negatively impacting on leadership and stewardship of health issues at that level.

Narrowing of Fiscal Space: The fiscal space has narrowed with reduction of available financing from the Global Fund and suspension of direct US Government support to the Ministry of Health affecting TB prevention and control activity implementation at the national level. This aggravated the funding gap of the previous NSP 2015 – 2018.

Limited human resource capacity for TB control: With devolution of health services, the has been a weak linkage between the national and county staff involved directly in TB control. The NTLD-P has had challenges in management of staff at the lower levels due to frequent reshuffles, county ownership of staff, capacity building and engagement for TB control. There is need for direct investment for human resource for TB control if we are to achieve elimination.



STRATEGIC INTERVENTIONS

This NSP advocates for increase government investment in TB control to close the gap created by reduced donor funding contribution and increase funding from county government to cover gaps in human resource development, renovation of infrastructures and strengthening community-based initiatives.

Leadership and Governance: Government leaders need to provide the overall stewardship and keep the goal of ending the TB epidemic high on the development agenda. The NTLD-P is led by a program head with support of six section heads of which program officers are attached. The section includes administration and finance, policy planning, monitoring and evaluation, care and treatment section, public health, preventive and promotive health, and commodity section. The national level is responsible for development and policy documents dissemination of in collaboration with partners and technical working groups. The NTLD-P leadership will cultivate and steer the engagement of a wide range of collaborators across and beyond the Ministry of Health including other ministries, county governments, financial partners, civil society and private sector to provide the overall stewardship and keep the goal of ending the TB epidemic high on the development agenda.

Financing of TB Control Activities: This NSP aims to ensure enough financial resources to implement its activities. The NTLD-P will continue to promote efficient use of government resources and systematic inclusion of TB activities under all UHC financing schemes. The NSP also aims to nurture existing partner relationships (the Global Fund, United States Agency for International Development, Centers for Disease Control and Prevention) to ensure cohesion in implementation of activities towards TB control and elimination. This will be attained through ensuring increased financing for TB operational budget, including drugs, and human resource issues from the government, mobilization of resources for TB control from the private sector and NGOs, and strengthened internal controls to ensure efficient utilization of financial resources allocated to the country, to avoid duplication of activities and value for money.

Government spending in TB control hugely increased between 2015 and 2018, largely for first line medicines, infrastructure and human resources. Of the operational budget for TB control activities, 40 percent was contributed from government in 2017.

Human Resource for TB Control: Deployment of appropriate human resources, together with regular training and adequate mentoring, monitoring and supervision at all levels of health-care services are essential. The Global Fund has supported the deployment of both technical and program staff at county and national levels respectively. In addition, USAID and CDC support in the provision of technical assistance at national level and direct support of implementation of TB/HIV activities at county level including laboratory services. The Ministry of Health covers the costs of its staff deployed to the NTLD-P. The program has supported program officers, county staff and national level staff in training local or international courses and conferences as part of capacity building strategy to ensure continuous advancement in the quality of health.

Through government and partner support, the NTLD-P has **improved infrastructure** at the national and county level by renovating buildings (especial laboratory), provision of equipment (GeneXpert) and maintenance of fleet management. In addition, resources have been put in place to improve on infection preventive control measures at all level of health care.

3.5 **ADVOCACY**



SITUATIONAL ANALYSIS

Given current resource availability, the NTLD-P estimates that there will be a budget shortfall of more than half of the total required to fully implement this NSP. Increasing government investments in TB, leprosy and lung health will require political commitment and resource prioritisation by not only the central government but also by the county governments. It will require that the NTLD-P realize efficiency gains through the integration of TB and leprosy control activities into other service delivery platforms (e.g. MCH), financing modalities (e.g. insurance schemes), and policies (e.g. workplace). Complementary and increased funding from donors and partners will be needed to sustain core activities and

enable the roll-out of new innovations. In all cases, targeted communication and advocacy to the respective constituencies will need to be developed and delivered.



Suboptimal political will resulting in inadequate resources allocated for TB, leprosy and lung health activities at national and county levels.



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STRATEGIC INTERVENTIONS

Build political will and mobilize resources at county government level: Building political will and mobilizing resources for TB, TB/HIV, leprosy and lung health at the county level will require that the burden of these diseases in each county be contextualized. Situational analyses that build on this NSP are planned for each county that should yield baseline information and propose county-specific targets to be monitored, including program performance, financial commitments and disbursement, and funding gaps per county. These countyspecific advocacy and communications plans will take into account the local challenges and opportunities. Opportunities for resource mobilization in support of counties with limited local resources will be prioritised.

Issues related to the control of TB, leprosy and lung health can be incorporated into county health fora. Furthermore, medical parliamentarians (i.e. Members of Parliament on the health committee) will be engaged to promote local political will in their home areas. Some illustrative activities include: (i) hosting a breakfast meeting during the Council of Governors just before the annual work planning process; (ii) convening of county stakeholder meetings to review health budgets against yardsticks for funding allocations; (iii) identify TB champions for each county; (iv) develop TB portals within each county's website.

Build political will and mobilize resources at national government level: The NTLD-P must enhance communications and advocacy across the national government, broadening ownership of the program and integrating TB, leprosy and lung health issues into UHC, social protection schemes and other health and non-health sector development plans. The engagement of the Parliamentary Health Committee and the Senate will be sought, with regular briefs provided by the NTLD-P. The NTLD-P must concurrently facilitate access to information about the diseases and its programs among the citizenry and stakeholders.

Build political will and mobilize resources at partner level: The NSP has dual objectives of sustaining close collaboration with existing donors and nurturing new donor partnerships. county-level National and Stop TB Partnerships will be supported to engage new donors from the private and other non-state sectors, including businesses. The NTLD-P and its partners will proactively and creatively mobilize new funds through events; e.g. runs, rhino charge; and innovative financing; e.g. charity pledges. A database of existing and potential donors will be established to better target resource mobilization where large funding gaps remain.



1,155

Number of TB patients among the notified **85,188** TB patients in 2017, who were lost to follow up, and **4,300** (5 percent) not evaluated indicated as transfer out.

PILLAR THREE: RESEARCH AND INNOVATION

4.1 DATA FOR PROGRAMMATIC MONITORING AND PLANNING

🕺 SITUATIONAL ANALYSIS

The NTLD-P has a monitoring, evaluation and research section whose mandate is to coordinate program monitoring and evaluation activities. This is guided by a technical working group (TWG) which reports to Tuberculosis Interagency Coordinating committee (TB ICC). There is a robust surveillance system, TIBU, to report and notify people diagnosed with TB electronically in an effective and efficient manner. This has enabled the country to estimate the reported TB burden, account for diagnosed cases, identify areas for operation and implementation research as well as allocate resources appropriately. The electronic case-based data available is for drugsensitive and drug-resistant TB, leprosy and TPT. The system has undergone various enhancements to adapt to the new WHO guidelines and definitions on reporting and is integrated with DHIS2. TIBU is adaptable to new changes. This integration has led to open access of TB information to the public and stakeholder domain to enable profiling of TB in the local context and decision making at a granular level.

Counties have various electronic medical records systems in use as hospitalbased systems. There are also two national HIV EMR systems (Kenya EMR and IQ care) running in 815 facilities. Laboratory case-based data for people tested using GeneXpert is available electronically at all levels. However, AFB reporting tools are largely manual. Therefore, case-based AFB data is not available for quantification of diagnosis versus treatment. Currently, none of the EMR systems nor the laboratory reporting systems are integrated with TIBU.

One of the major achievements by the NTLD-P is the completion and launch of major impact surveys, these include: Drug Resistance TB Survey 2015, TB Prevalence Survey 2016, Mortality Study 2017 and the Patient Cost Survey 2018. Other reviews and evaluations that have been carried out are: Mid-Term Review 2016, Patient Pathway Analysis, Adherence Study and Inventory Study. Findings from these surveys have provided better evidence on the burden, the magnitude of people missed with TB; health seeking behavior of patients and catastrophic costs incurred by patients while seeking care, which has been instrumental in guiding the country plan for a more patient-centred approach in TB service delivery.

A national vital registration system exists; however, it has a national coverage of 45 percent with low utilization of International Classification of Diseases (ICD) 10 across all the service delivery points including the community. The NTLD-P has been working in close collaboration with the Civil Registration and Vital Statistics Unit (CRVS) in the Ministry of Health and the Civil Registration Department in the Ministry of Interior to strengthen use of ICD-10 in reporting and classification of deaths.



Percentage of bacteriologically confirmed patients lost after diagnosis in Kenya, according to findings of the inventory study

BEST PRACTICE: TB Data4 Action trainings to improve data for decision making

The NTLD-P, The International Union Against TB and Lung Diseases and Centre for Health Solutions-Kenya through USAID funded TB ARC and WHO Kenya in 2016-2017 collaboratively worked at developing a customized seven-day training course based on The Union's international course titled *"Principles of Tuberculosis Care and Prevention: Translating Knowledge to Action"* including a field component. This course was designed to provide the knowledge and skills to county and subcounty TB coordinators and other relevant health professionals to improve management of persons with TB and strengthen programmatic practices. It was also to build capacity for coordinators to use sub national data for programming.

By June 2018, 22 counties had been trained reaching 175 county and subcounty coordinators. This has improved target setting and use of data for decision making at subnational levels. To ensure sustainability, in country trainers have been identified.



Lack of a unique patient identifier (UPI): A key challenge in the TB/HIV landscape in Kenya is the successful identification of TB patients throughout the cascade of care from screening to final outcomes. Lack of a UPI is an obstacle in ensuring clients receive appropriate care over time with movements across the country. From diagnosis, there is no electronic way of monitoring initial loss to follow up as there is no unique linkages of the system. Findings of the inventory study indicated that 21 percent of bacteriologically confirmed patients were lost after diagnosis in Kenya. Duplicative records make it difficult to longitudinally track patients or provide care and assigning correct treatment outcomes. Among the notified 85,188 TB patients in 2017, 1,155 (1.4 percent) were lost to follow up and 4,300 (5 percent) not evaluated indicated as transfer out. The UPI will enable closing of this gap as tracking all patients even when transferred out will be streamlined.

Lack of integration of TIBU system with other

EMR systems: Currently, the TIBU system relies on entry of data from a paper-based health facility TB register leading to delay in notification as the update is not real time. In addition, there are sets of data along the care cascade that are not captured using the current system, these include the screening data. This lack of integration creates parallel systems that lead to duplication of workload.

Underutilization of routine data: Routine data collected at the facility level is not regularly analyzed to form basis for decision making for quality of care and programming by county and sub county health management teams, civil societies and private sector. This is due to lack of data analysis capacity and techniques.

Underreporting and inconsistent TB case notification by private sector: Private providers account for 41 percent (Patient Pathway Analysis) of all initial TB visits in Kenya. However, only 18 percent (TIBU, 2017) of the total cases are notified from the private facilities. Where monitoring and evaluation (electronic and paper based) reporting systems exist in private facilities, they do not conform to the national recording and reporting framework.

Inadequate TB mortality data in the National Vital Registration System: Death notification is done at two levels, health facilities, or community. Classification of the causes of death is not undertaken properly at either of the levels. In addition, children deaths are often not notified at the community across many societies in Kenya.



STRATEGIC INTERVENTIONS

Upgrade and integration of TIBU System with other EMR systems: TIBU system is currently integrated with DHIS2 to ensure data availability for all levels of care. This will be enhanced further in the strategic plan period. In addition, there will be engagement with various stakeholders to ensure TB data tools are incorporated in the existing county EMR and HIV EMR systems, and further linkage to TIBU enabling accurate and real time data at point of care. This will reduce the number of manual tools to be filled by the health care workers hence easing the workload. The laboratory section shall collaborate with NPHLS to include TB indicators in the universal laboratory ware to ensure availability of AFB and other lab data at the national level for ease for data matching with treatment data.

Adoption of unique patient identifier for improved surveillance: In this strategic plan period, there will be adoption of unique identification system to track patients from diagnosis to enrolment of treatment to treatment completion. Various interventions to be considered are use of bar codes, national identification numbers in adults, school going children will be issued with Unique Personal Identifier using the National Education Management Information System (NEMIS) that can be used. In select high burden counties, there will be a pilot of a Unique Patient Identifier (UPI) that uses biometric recognition which uses any android or IOS mobile device.

Strengthening of monitoring and evaluation

systems: There will be development, review, printing and uninterrupted supply of data capture tools, registers, algorithms, job aids. Support for TB/HIV M&E technical working group meetings at national and county level to align and harmonize monitoring activities including implementing partners. Capacity building on M&E tools and SOPs including sensitization of health care workers on how to fill the recording and reporting tools and adoption of e-learning module in TIBU as well as use of ECHO.

Strengthen notification of people identified with TB by the private sector: By engaging the providers, enforcing laws on reporting, providing non-monetary incentives to private sector to encourage reporting, collaborating with other reporting platforms including HIV reporting and Disease Surveillance Reporting Unit (DDSRU). Adoption of simple innovative technologies to ease TB case notification.

Improvedataqualityimprovementmechanisms:Developmentandimplementationofthedataqualityimprovementframework at both national and county levels.

Technical support to be offered by national level and strengthening of county-based data quality audits. Routine programmatic performance review: This entails routine data management processes at the national and subnational levels. There should be monthly data review meetings on TB at subcounty level and quarterly review at county level. National level biannual performance review meetings.

Data for decision making support: Building capacity for data analysis including provision of data analysis techniques, promote use of visuals such as dashboards, maps and infographics to make data consumption attractive and easy to understand. TB Data 4 action trainings will be done for the 25 remaining counties to improve capacity of national, county, subcounty and facility staff for data use. D4D trainings will also be cascaded further to counties. Support for the implementation of *"talking walls"* for selected indicators that need to be monitored or tracked over time at health facilities, at county and sub-county.

Surveys and operations research: Analyze available data to identify program implementation gaps to improve quality through operation research and surveys. Adoption of OR framework to guide in the implementation of OR activities and use of the OR findings. The OR research framework will allow for collaboration between NTLD-P and other relevant research institutions.

Strengthen vital registration systems: Through multisectoral collaboration and capacity building of community health care workers on verbal autopsy.



OUTCOME TARGETS

	Indicator	Baseline	Target
T	Proportion of people with TB who are detected, but are not notified or started on treatment (initial loss to follow up)	21%	0%

4.2 **RESEARCH PRIORITIES**

4.2.1 National Research Priorities

The national research priorities are outlined in Table 11 below.

Table 12: National Research Priorities

Thematic Area	Research Priorities
Promoting Care Seeking and Prevention in the Community	TB knowledge attitude and practices survey
Accelerating Appropriate Diagnosis	Molecular studies- characterization of TB in Kenyan setting
Quality of Care and Ensuring Cure	Measurement of patient quality of care- 'Mystery shopper' evaluations
	Adherence surveys: Uptake of digital solutions and effect on patient follow up and adherence
	Assessment of risk factors and barriers to access to TB services and care
	Assessment of barriers to uptake and retention in TB HIV services in Kenya (ongoing)
	Assessment on outcomes of IPT
	Post TB complications burden and patterns of respiratory complications following TB care
Programmatic Management of Drug – Resistant Tuberculosis	Drug Resistance Survey: to determine the burden of drug resistant TB in Kenya
	Sentinel surveillance for DR TB

TB / HIV and other Co-Morbidities	What is the marginal yield of TB undergoing baseline and periodic CXR screening?	
	Documentation of TB HIV services integration models	
Leprosy	Quality of life studies to inform on the rehabilitative needs of the clients.	
Key Populations	Feasibility study on use of TB Preventive Therapy (TPT) in selected key populations	
UHC and Social Protection	Follow-up survey of TB Patient cost survey in 2023	
UHC and Social Protection Nutrition	Follow-up survey of TB Patient cost survey in 2023 Impact evaluation of nutritional interventions among TB patients	
UHC and Social Protection Nutrition Supply chain and ADSM	Follow-up survey of TB Patient cost survey in 2023Impact evaluation of nutritional interventions among TB patientsRegular assessment of Pharmaceutical management indicators for anti TB medicines	
UHC and Social Protection Nutrition Supply chain and ADSM Data for Programmatic Monitoring and	Follow-up survey of TB Patient cost survey in 2023Impact evaluation of nutritional interventions among TB patientsRegular assessment of Pharmaceutical management indicators for anti TB medicinesTB Inventory study	

4.2.2 Counties and Desktop Reviews

County research priorities and desktop reviews are outlined in Table 12 below.

Table 13: Counties Research Pi	riorities and Desktop F	Reviews
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Thematic Area	Research Priorities
Accelerating Appropriate Diagnosis	Longitudinal data analysis of smear microscopy EQA to determine quality improvement trends and recurrent gaps.
	Longitudinal data analysis on Culture and DST services to determine trends, efficacy and effectiveness
	Effectiveness and impact of specimen referral systems at the national, county and facility levels
	Impact LED microscopy implementation and scaling up Retrospective analysis of smear microscopy EQA impact
Quality of Care and Ensuring Cure	Burden of TB among HCWs
Programmatic Management of Drug – Resistant Tuberculosis	DR TB Treatment outcomes of patients on new molecules
	Modelling of DR TB transmission in Kenya

Childhood Tuberculosis	TPT Outcomes in Children		
	Severe Malnutrition and TB		
	Cost effectiveness of incentives for child contact tracing- Yield of contact tracing		
TB / HIV and other Co-Morbidities	Trends in tuberculosis incidence and case fatality PLHIV on newer ART regimens e.g. dolutegravir based ART.		
Lung Health	Establishing the burden of respiratory conditions (pneumonia, asthma and COPD) in the country		
Leprosy	Contact screening yield among household contacts of former and current leprosy patients.		
Key Populations	Identification and mapping of TB key populations in Kenya (population estimates for TB Key, Vulnerable and Underserved populations in Kenya)		
UHC and Social Protection	Assessment of the effect of the cash transfer for DRTB patients and their households		
Nutrition	Qualitative assessment of the levels of integration of nutrition services with other patient care services.		

AT A GLANCE **KES 29.8 B** Amount required by the NTLD-P for the strategic plan

IMPLEMENTING THE NATIONAL STRATEGIC PLAN 2019 – 2023



period in order to achieve its targets, according to the input-based costing

5.1 FINANCING THE NATIONAL STRATEGIC PLAN 2019 – 2023

SITUATIONAL ANALYSIS

To achieve progress in tuberculosis (TB) prevention, diagnosis and treatment, it is imperative to mobilize and sustain adequate financial resources over many years. Globally, these resources continue to fall short of the amount needed (WHO Global TB Report 2018). This calls for stepping up of efforts and commitments to mobilize both domestic and donor resources. Efforts to curb TB in Kenya have also been hampered by a decline in investments for prevention, diagnosis and treatment. The decline in partner support has largely been due to the fact that Kenya has attained middle-income status. Funding for TB interventions in Kenya is mainly from the Government, United States of America through USAID and CDC, and the Global Fund for AIDS, TB and Malaria (GF).

The NTLD-P National Strategic Plan 2019 – 2023 promotes efficient use of government resources and systematic inclusion of TB activities in the national Universal Health Coverage (UHC) agenda. The NSP also aims to nurture existing partner relationships (the Global Fund, United States Agency for International Development, Centers for Disease Control and Prevention) to ensure cohesion in implementation of activities towards TB prevention and control, sustenance of leprosy elimination and programmatic management of lung diseases.

Domestic spending in TB control increased from approximately KES 5 billion in 2015 to KES 6 billion 2018. This increase was largely applied to first line medicines, infrastructure and human resources. Of the operational budget for TB control activities in 2017, 40 percent was contributed from government in 2017.

5.1.1 Resource Requirements

The NSP articulates the activities that will drive progress toward each of the outcome targets. Activities were costed using an input-based costing (IBC) approach. The IBC uses a bottom-up approach that estimates the cost of all inputs required to achieve NSP targets for the Financial Year 2019/20 to 2023/24. Table 13 outlines the estimated resource requirements towards the full implementation of the NTLD-P

|--|

Priority Area	FY 2019/2020	FY 2020/2021	FY 2021/2022	FY 2022/2023	FY 2023/2024	Total
Pre-care Seeking	1,179,184,800	886,744,800	1,140,466,800	879,140,800	925,846,800	5,011,384,000
Case Detection in Facility settings	12,000,000	12,000,000	12,000,000	12,000,000	12,000,000	60,000,000
Accelerating Appropriate Diagnostics	971,771,500	915,489,100	785,363,500	766,049,700	766,158,700	4,204,832,500
Quality of Care	1,160,838,350	1,732,140,750	1,760,515,950	1,687,450,750	1,710,606,950	8,051,552,750
PMDT	551,929,500	487,323,500	416,002,500	416,002,500	416,002,500	2,287,260,500
Childhood TB	152,780,704	136,636,700	138,304,700	136,636,700	138,304,700	702,663,504
TBHIV	349,322,301	160,677,800	129,006,800	154,662,800	124,542,800	918,212,501
Lung Health	24,222,800	18,629,800	16,889,800	19,089,800	16,889,800	95,722,000
Leprosy	16,380,300	7,979,300	12,243,300	7,979,300	7,979,300	52,561,500
PPM	74,285,600	72,084,600	63,098,100	62,891,000	45,583,000	317,942,300
UHC/Social Protection/Human Rights	269,609,000	210,104,000	224,122,000	226,970,000	277,366,000	1,208,171,000
Nutrition	425,894,000	417,104,000	337,724,000	337,724,000	337,724,000	1,856,170,000
Supply Chain Management	195,669,800	172,566,800	162,336,800	162,111,800	162,336,800	855,022,000
M & E	397,549,700	387,226,700	356,177,800	395,009,200	312,407,500	1,848,370,900
Key Population	173,841,200	160,625,100	126,315,600	94,106,300	95,496,300	650,384,500
Program management	288,438,300	309,990,700	348,110,700	385,490,700	347.650,700	1,679,681,100
Total (KES)	6,243,717,855	6,087,323,650	6,028,678,350	5,743,315,350	5,696,895,850	29,799,931,055

Strategic Plan 2019 – 2023. According to the input-based costing, the NTLD-P requires **KES 29.8 billion** for the strategic plan period in order to achieve its targets. This has further been disaggregated by the NSP priority areas as shown. The operational plan and activity costs that are the foundation for this summary will be published as a supplement to the NSP.

5.1.2 Funding Gap

If funding remains at the 2018 - 2019 levels, it is estimated that KES 14.6 billion will be available during 2019-2023. This is made up of domestic⁷⁹ (KES 5.6 billion) and donor (KES 9 billion) sources. Given the **50% funding gap** for implementation of the full NSP, an evidence-based process for prioritisation of resource allocation was completed.

⁷⁹ The total for domestic funding including GoK MoH Printed Estimates, GoK co-financing of Global Fund grants through GoK Treasury; and GoK human resources and overhead support. It does not include funding from county budgets, which have not been finalized as of the time of printing of this document.

Funding Source	Total (KES, millions)
GOK MOH Printed estimates	2,765
GOK Co- financing through Treasury	2,000
GOK HR and Admin	834
Donors (Global Fund and USG)	8,994
Total Available Funding	14,593
Funding gap	15,207
Full cost of NSP	29,800

5.1.3 Closing the Funding Gap: Recommendations

Domestic Resource Mobilization: The NTLD-P and its partners will intensify advocacy for increased and dedicated national and county levelbudgetallocationstowardsTBprevention, diagnosis and treatment intervention.

Include TB, leprosy and lung diseases within the essential health package under UHC and NHIF: As Kenya takes strides towards attaining UHC, cost efficiencies can be gained where there is full inclusion of TB, leprosy and lung disease prevention, diagnosis and treatment services in the essential health package. This will enable the full engagement of health workers across the health system in screening and caring for people with TB, leprosy and lung diseases as a core component of primary health care. Similarly, inclusion of TB, leprosy and lung disease in the benefits package under the National Health Insurance Fund (NHIF) could facilitate seamless access to appropriate diagnosis and quality treatment. Insurance reimbursements, if well structured, may motivate reporting from and compliance with national care standards by private providers.

Linkage of eligible TB and leprosy patients to existing social protection programs in the country though inclusion of TB and leprosy as a vulnerability criterion in the National Social Protection Policy that will enable them access social support.

Building the capacity of community-based health insurance schemes (CBHIs) in financial management and mobilize them to invest in TB interventions especially in areas with high TB burden.

Provide incentives to innovators working towards scaling up health financing innovations

Mobilizing Donor Funds: To enhance mobilization of donor funds in the NTLD-P, there is need to build capacity of the staff in proposal writing, grant application and grant management. Capacity will be built for evidence-based determination of funding priorities to improve the efficiency and increase the impact of grant funding.

5.2 **PRIORITY SETTING**

5.2.1 Modelling for Kenya Tuberculosis NSP: Scope and Aims

Mathematical modelling of Kenya's TΒ epidemic was completed to project the epidemiological potential impacts and cost-effectiveness of different measures in Kenya's National Strategic Plan 2019 - 2023. Quantifications of the impact took into account the direct benefit of TB care for people with TB as well as the indirect benefits experienced by others in the community due to reduced opportunities for transmission.

Estimating the Impact of Reaching Outcome Targets

For each outcome target, the national-level TB epidemic was simulated to 2030, assuming that interventions are scaled up steadily starting from 2019. As a comparator, we modelled a 'baseline' where the current standard of TB is continued indefinitely. We estimated the 'impact' of a given intervention scenario as the disability-adjusted life-years averted by the intervention (DALYs):

DALYs averted = Years of life saved by the intervention + 0.33 × years of untreated TB disease averted by the intervention

Where the factor of **0.33** is a 'disability weighting' attached to TB disease

15 19 20 21 24 26 35 48 54

Outcome number

13 14

Estimating Incremental Cost Effectiveness

With costs and impact estimated, the NLTD-P sought to understand how different outcomes compare in how efficiently they can achieve health gains. To answer this, incremental costeffectiveness ratio (ICER) was used, defined as:

ICER= (Incremental cost from 2019 to 2030) / (DALYs averted between 2019 and 2030)

Note: The lower the ICER for a given outcome target, the more efficient that outcome is for achieving health gains.

Figure 22 illustrates estimated costeffectiveness for each of the outcome targets listed. As described above, these results are based partly on assumptions, and model findings highlight the need for further primary evidence on these outcome targets in particular.



Figure 22: Model projections for the incremental cost-effectiveness ratio (ICER) for each outcome target acting independently (As described earlier, lower values of ICERs are more favorable)

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Outcome number



Cost Drivers

To cast light on the critical cost drivers in implementation of the NSP, Figure 23 illustrates the incremental costs over time (NSP scenario with all outcome targets combined, relative to 'no intervention' baseline). The figure illustrates that diagnostics account for the greatest share of overall, incremental costs. In particular, this cost arises largely from the sheer number of people with symptoms consistent with TB who are in the community and need to be tested in order to identify TB cases. Under each of the funding scenarios, the ICERs were reviewed as an input to determining the package of interventions that would be most impactful within a fixed budget. This NSP reflects the scenario in which all funding requirements are met. Below are summaries of the prioritisation that would be adopted in case of smaller funding envelopes. Details of the costed operational plan, prioritised to each funding scenario will be published as a supplement to this NSP.

Prioritising Under Budget Constraints

The NTLD-P considered three resource scenarios; i.e. existing funding levels held across the 5 years of the NSP, a 25% increase in funding, and the availability of full financing.

SCENARIO 1: CURRENT FUNDING LEVELS

Under a scenario where the programme must operate with current funding levels, the most **essential components of care** were prioritised. These included **diagnostic commodities, medicines, salaries, and core surveillance** functions. If funded as planned,

Figure 23: Annual incremental costs of full NSP implementation showing four major categories of cost drivers.



In the legend, 'pmo' denotes 'patient months' while 'intvn costs' denotes 'intervention costs', or programmatic spending to facilitate the delivery of interventions (for example, training and human resources). Diagnostic costs account for approximately 70% of incremental programmatic spending between 2019 and 2030.



these core investments would require 70% of the available KES 14.6 billion. Without sufficient funding to enable implementation of all activities aimed at generating demand for services, linking people with presumptive TB to care, or improving the quality of service delivery, it is unlikely that target numbers of people will be screened, tested or treated. As such, commodities were budgeted at 75% of targeted quantities under this scenario, while nutritional support for patients was budgeted at 50% of need.

The programme next prioritised investments aimed at **sustaining the gains** made across all target populations. Based on the prioritised gaps and ICER results, the programme wanted to make fiscal space for intensified action in a few key areas. Careful review of the intervention impact data and cost drivers led to a decision to minimally fund some activities; such as capacity building activities and programmatic monitoring meetings, while other activities were left out completely and are captured in the higher funding scenarios.

Only a **limited number of new areas of work** will be possible under this funding scenario. The programme prioritised 3 new / intensified workstreams: closing the **diagnostic gap**, **operationalizing routine contact tracing**, **and engaging the private sector** through full implementation of the 2018 PPM Action Plan. To close the diagnostic gap, the main areas of work include systematizing specimen transport networks, expanding the use of x-ray and Xpert in line with global recommendations, and rolling-out facility-based screening for TB.

In addition, the program aims to enhance the use of data for improving patient care, specifically by linking and scaling existing TBrelated data systems and introducing **digital monitoring** of people with TB across the care cascade. The programme recognizes the importance of maintaining **up-to-date policy norms** and normative guidance materials. The work to update and disseminate new standards of practice, the diagnostic algorithm, and improve care strategies are included in this scenario.

Figure 24. Budget by cost category using the prioritised operational plan, optimised to an assumption of the availability of funding equivalent to 2018 funding levels



SCENARIO 2: CURRENT FUNDING LEVELS + 25% ADDITIONAL INVESTMENT

With 25% more investment, the NTLD-P would have KES 18.24 billion to allocate toward its operational plan. Under this scenario, commodities were budgeted at 85% of targeted quantities, while nutritional support for patients was budgeted at 70% of need.

In addition to the interventions prioritised under Scenario 1, the ICERs suggested the value of intensifying diagnosis and treatment of TB among children, and increasing treatment success rates for children, PLHIV, people with drug-sensitive and drug-resistant disease; and reducing the loss-to-follow-up post-diagnosis and during treatment.

As such, the full package of interventions targeting improved diagnosis and care for children is included in this scenario. Activities to strengthen the **capacity** of health care workers and **empower patients**, engage **community health volunteers** and civil society for contact tracing and awareness raising, optimise the inclusion of TB in emerging **UHC** platforms, **increase social protections** for patients, and evaluate **differentiated care models** are among the interventions added, aiming to directly improve patient-centred care.

Figure 25: Budget by cost category using the prioritised operational plan, optimised to an assumption of the availability of funding equivalent to 2018 funding levels plus 25%.



The impact targets highlighted in this NSP correspond to a fully funded plan. Revised impact targets were calculated, taking into account the optimised operational plan for each funding scenario.

Figure 26: The NSP Funding funnel



Figure 27: Estimates of the impact of NSP implementation under three funding scenarios, with activities optimised for impact





5.3 RISK MANAGEMENT STRATEGY

Risk can be defined as the effect of uncertainty on the achievement of NTLD-P's objectives. Risk management is, therefore, the process of identifying and managing this uncertainty, or risk, with the goal of achieving objectives. Effective risk management is a key element of good governance and will provide reasonable, but not absolute, assurance that:

- a) Significant risks are identified and monitored, enabling management to make informed decisions and take timely action;
- b) Opportunities are maximized with confidence that risks will be managed; and
- c) Objectives, as set out in the NSP, are achieved.

The Objectives of the Risk Management Policy and Process

The NTLD-P aims to make risk management integral to its culture, strategic planning, decision making and resource allocation. A coordinated approach allows management to proactively manage risk. The management and other personnel must be able to manage risk proactively and take shared responsibility for risk management processes.

The NTLD-P will develop an addendum to the NSP 2019-2023 that will cover the risks during the period of the NSP. The NTLD-P will identify risks and assess them by scoring them for impact and likelihood. Then come up with a risk management action outlining actions to be taken to manage risk. The identified risks will be logged into a risk management plan along with agreed management actions. Finally, monitoring and review to ensure risk management processes are functioning, and up to date and emerging risks are managed. Risk monitoring is embedded in this NSP and is part of NTLD-P's broader performance management processes and linked to performance indicators.

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Indicator	Indicator definition	Frequency	Source of data	Responsible person	Baseline 2017	Year 1 2019	Year 2 2020	Year 3 2021	Year 4 2022	Year 5 2023
Proportion of diagnostic testing sites that monitor performance indicators and are enrolled in an EQA system for all diagnostic methods performed	Numerator: Number of diagnostic sites that monitor performance indicators and enrolled in an EQA system System Denominator: Total number of diagnostic/testing sites	Quarterly	EQA Quarterly reports	Laboratory coordinator	85%	86%	87%	88%	80% 80%	100%
Cure rate for bacteriologically confirmed cases (both New and Relapse)	Numerator: No. of bacteriologically confirmed cases with an outcome cure at the end of treatment Denominator: Total number of bacteriologically confirmed cases notified	Quarterly	TIBU	Ж&Е	69%	70%	80%	80%	85%	%06
Sputum conversion rate at the end of intensive phase of treatment for bacteriologically confirmed cases	Numerator: No. of bacteriologically confirmed cases with a negative smear result at the end of the intensive phase Denominator: Total number of bacteriologically confirmed cases started on treatment	Quarterly	TIBU	ш ळ ∑	75%	80%	85%	%06	% 06	% 06

Indicator	Indicator definition	Frequency	Source of data	Responsible person	Baseline 2017	Year 1 2019	Year 2 2020	Year 3 2021	Year 4 2022	Year 5 2023
Treatment success rate- all forms: Percentage of TB cases, all forms, bacteriologically confirmed plus clinically diagnosed, successfully treated	Numerator: Total number of patients with outcomes cured and treatment completed Denominator: Total number of patients notified	Quarterly	TIBU	ш Х Х	81%	85%	%06	%06	%06	%06
Case fatality ratio (All forms of TB)	Numerator: Total number of TB cases with "died" result in the register Denominator: All notified TB cases	Annual	TIBU	R	6%	<5%	<5%	<5%	~5%	<5%
Number of TB cases with Rifampicin-resistant TB (RR-TB) and/or MDR-TB notified	Number notified	Quarterly	TIBU/ TB4 register	M R R	577	1046	1111	1165	1155	935
Number of cases with RR-TB and/ or MDR-TB that began second-line treatment	Number of cases with RR-TB and/ or MDR-TB that began second-line treatment	Quarterly	TIBU/ DR TB register	Ш Х Х	577	1046	1111	1165	1155	935
Proportion of new and relapse notified TB patients who receive DST	Numerator: No. of notified new & relapse TB cases tested with a WRD as the initial Diagnostic test Denominator: No. notified new and relapse TB cases	Quarterly	TIBU	National Tuberculosis Reference Laboratory (NTRL)	46%	50%	60%	70%	80%	95%

Year 5 2023	80%	%06	70%	% 06
Year 4 2022	79%	85%	68%	79%
Year 3 2021	78%	70%	50%	69%
Year 2 2020	///	50%	51%	59%
Year 1 2019	75%	30%	43%	49%
Baseline 2017	73%	13%	35%	39%
Responsible person	PMDT coordinator	PMDT coordinator	Pediatric TB Coordinator	Pediatric TB Coordinator
Source of data	Quarterly report on TB case registration at the sub- county / TIBU	Quarterly report on TB case registration at the sub- county / TIBU	TIBU	TIBU
Frequency	Quarterly	Quarterly	Quarterly	Quarterly
Indicator definition	Numerator: DRTB patients who started treatment 1-year prior who have completed treatment. Denominator: Total DRTB patients	Numerator: Number of DRTB patients started on new molecules Denominator: Total number of DRTB patients eligible for new molecules	Numerator: Number of notified children (<15 years) with TB Denominator: Total number of notified TB cases	Numerator: Number of eligible children initiated on TB preventive therapy Denominator: Total number of children eligible for preventive therapy
Indicator	Drug resistant TB treatment success rate	Proportion of eligible DRTB patients on new molecules	Proportion of children with TB among notified TB cases	Proportion of eligible children on TB preventive therapy to 90%

Indicator	Indicator definition	Frequency	Source of data	Responsible person	Baseline 2017	Year 1 2019	Year 2 2020	Year 3 2021	Year 4 2022	Year 5 2023
Pediatric TB treatment success rate	Numerator: Number of pediatric TB cases who cured or completed treatment Denominator: Total number of notified pediatric TB cases	Quarterly	TIBU	Pediatric TB Coordinator	85%	86%	87%	88%	%98	%06
Treatment success rate among HIV – positive TB cases to 85%	Numerator: Number of notified HIV positive TB cases who got cured or completed treatment Denominator: Total number of notified HIV positive TB cases	Quarterly	Quarterly report on TB case registration at the sub- county / TIBU	TB/HIV coordinator (NTLD-P)	79%	80%	81%	82%	83%	85%
Proportion of PLHIV initiated on TB Preventive Therapy	Numerator: Number of PLHIV initiated on TB Preventive Therapy Denominator: Total number of PLHIV on care	Quarterly	MOH731 DHIS2	TB/HIV coordinator (NASCOP)	65%	70%	75%	80%	85%	%06
Treatment success rate among TB/DM patients	Numerator: Number of TB cases, diagnosed with DM who got cured or completed treatment Denominator: Total number of notified TB cases diagnosed with DM	Quarterly	Quarterly report on TB case registration at the sub- county / TIBU	TB/DM coordinator (NTLD-P)	Data unavailable					

ndicator	Indicator definition	Frequency	Source of data	Responsible person	Baseline 2017	Year 1 2019	Year 2 2020	Year 3 2021	Year 4 2022	Year 5 2023
Proportion of Indified leprosy Datients with disability grade 2	Numerator: Number of leprosy patients notified leprosy cases with disability grade 2 Denominator: Total number of notified leprosy cases	Annual	Annual report	Leprosy Coordinator	35%	30% 30	25%	20%	10%	<10%
Proportion of notified leprosy cases who are children	Numerator: Number of notified childhood (< 15 years) leprosy cases Denominator: Total number of notified leprosy cases	Annual	Annual report	Leprosy Coordinator	6%	6%	5.5%	5%	4.5%	3%
Proportion of private sector providers engaged to provide comprehensive TB services	Numerator: Number of private sector providers providing comprehensive TB services Denominator: Total number of private providers engaged/ mapped out	Annual	Limited data	PPM Coordinator	Data unavailable					
Number of notified TB cases (all forms) contributed by non-national TB program providers - private/non- governmental cacilities					18%	19%	23%	27%	30%	34%



ANNEXES



LIST OF CONTRIBUTORS

WRITING TEAM					
Name	Organization				
Dr Kamene Kimenye	Head of Program, NT	LD-F)		
Dr Newton Omale	Chair of the Secretari	at, ar	nd Head of Section, Policy & P	lanning, NTLD-P	
Dr Enos Masini	Africa Region Advisc	r for	TB, UNDPs/Stop TB Partners	hip	
Dr Brenda Mungai	Chief of Party, TBARC	, CH	6		
Dr Stephen Macharia	Technical Advisor, NT	LD-F)		
Dr Stephen Muleshe	Head of Section, Care	e and	Treatment, NTLD-P		
Dr Lorraine Mugambi	Deputy Chief of Party	, TBA	ARC, CHS		
Dr Eunice Omesa	Head of Section M&E	, ntl	_D-P		
Dr Kadondi Kasera	Consultant, MoH				
Dr Matiko Riro	Consultant- Costing,	МоН			
Dr Jane Ong'ang'o	Senior Research Offic	er, Kl	EMRI		
Ms Wandia Ikua	M&E Specialist, TBAR	C, Cl	HS		
Ms Maureen Maloba	Policy and Planning, Secretary to the Secretariat, NTLD-P				
Ms Joyce Kiarie	Statistician, NTLD-P				
Ms Drusilla Nyaboke	Program Epidemiologist, NTLD-P				
Mr Felix Mbetera	Communications Officer, NTLD-P				
TECHNICAL ASSISTANCE	ECHNICAL ASSISTANCE				
Prof Christy Hanson	Bill & Melinda Gates F	oun	dation		
Prof Nim Pathy	Imperial College Lone	don			
Dr Juan Vesga	Imperial College Lone	don			
LIST OF REVIEWERS					
Prof. Elizabeth Obimbo	University of Nairobi		Dr Jacqueline Oliwa	University of Nairobi	
Dr Joseph Sitienei	МоН		Dr Wilfred Nkhoma	WHO	
Dr Eliud Wandwalo	Global Fund		Dr Heidi Albert	FIND	
Dr Jeremiah Chakaya	KAPTLD				

STAKEHOLDERS AND PARTNERS

Samuel Kinyanjui	AHE
Titus Kiptai	AMREF
Ulo Benson	AMREF
Hellen Kalili	ARC
Herman Weyenga	CDC
Brian Baker	CDC Kenya
Margaret Mburu	CDC-K
Victoria Wanjohi	CHAI
Philip Muchiri	CHAI
Evelyn Nganga	CHS
Teresiah Njoroge	CHS
Ann Masese	CHS
Sheilla Chebore	CHS
Simon Wachira	CHS
Immaculate Kathure	EGPAF
Heidi Albert	FIND
Christy Hanson	Gates Foundation
Christy Hanson Casey Selwyn	Gates Foundation Gates Foundation
Christy Hanson Casey Selwyn Peter Ihmin Kimuu	Gates Foundation Gates Foundation GF-NT
Christy Hanson Casey Selwyn Peter Ihmin Kimuu John Ochero	Gates FoundationGates FoundationGF-NTGlobal Fund
Christy Hanson Casey Selwyn Peter Ihmin Kimuu John Ochero Soukeyna Sylla	Gates FoundationGates FoundationGF-NTGlobal FundGlobal Fund
Christy Hanson Casey Selwyn Peter Ihmin Kimuu John Ochero Soukeyna Sylla Fiona Muhiri	Gates FoundationGates FoundationGF-NTGlobal FundGlobal FundKEMSA
Christy Hanson Casey Selwyn Peter Ihmin Kimuu John Ochero Soukeyna Sylla Fiona Muhiri Heather Njuguna	Gates FoundationGates FoundationGF-NTGlobal FundGlobal FundKEMSAKEMSA
Christy Hanson Casey Selwyn Peter Ihmin Kimuu John Ochero Soukeyna Sylla Fiona Muhiri Heather Njuguna Lucie Blok	Gates FoundationGates FoundationGF-NTGlobal FundGlobal FundKEMSAKEMSAKIT
Christy Hanson Casey Selwyn Peter Ihmin Kimuu John Ochero Soukeyna Sylla Fiona Muhiri Heather Njuguna Lucie Blok Ente Rood	Gates FoundationGates FoundationGF-NTGlobal FundGlobal FundKEMSAKEMSAKITKIT
Christy Hanson Casey Selwyn Peter Ihmin Kimuu John Ochero Soukeyna Sylla Fiona Muhiri Heather Njuguna Lucie Blok Ente Rood Joseph Mugo Njinju	Gates FoundationGates FoundationGF-NTGlobal FundGlobal FundKEMSAKEMSAKITKITMOH
Christy Hanson Casey Selwyn Peter Ihmin Kimuu John Ochero Soukeyna Sylla Fiona Muhiri Heather Njuguna Lucie Blok Ente Rood Joseph Mugo Njinju Emilly Vuguza	Gates FoundationGates FoundationGF-NTGlobal FundGlobal FundKEMSAKEMSAKITMOHMOH
Christy Hanson Casey Selwyn Peter Ihmin Kimuu John Ochero Soukeyna Sylla Fiona Muhiri Heather Njuguna Lucie Blok Ente Rood Joseph Mugo Njinju Emilly Vuguza Dr Joseph Sitienei	Gates FoundationGates FoundationGF-NTGlobal FundGlobal FundKEMSAKEMSAKITMOHMOHMOH
Christy Hanson Casey Selwyn Peter Ihmin Kimuu John Ochero Soukeyna Sylla Fiona Muhiri Heather Njuguna Lucie Blok Ente Rood Joseph Mugo Njinju Emilly Vuguza Dr Joseph Sitienei Samuel Githui Kimaru	Gates FoundationGates FoundationGF-NTGlobal FundGlobal FundKEMSAKEMSAKITMOHMOHMOHMOH
Christy Hanson Casey Selwyn Peter Ihmin Kimuu John Ochero Soukeyna Sylla Fiona Muhiri Heather Njuguna Lucie Blok Ente Rood Joseph Mugo Njinju Emilly Vuguza Dr Joseph Sitienei Samuel Githui Kimaru Njoki Kimani	Gates FoundationGates FoundationGF-NTGlobal FundGlobal FundKEMSAKEMSAKITMOHMOHMOHMOHMOHMOH
Christy Hanson Casey Selwyn Peter Ihmin Kimuu John Ochero Soukeyna Sylla Fiona Muhiri Heather Njuguna Lucie Blok Ente Rood Joseph Mugo Njinju Emilly Vuguza Dr Joseph Sitienei Samuel Githui Kimaru Njoki Kimani	Gates FoundationGates FoundationGF-NTGlobal FundGlobal FundKEMSAKEMSAKITMOH

Josephine Wahogo	МОН
Dickson Nyakundi	MOH-CHU
Diane Kamar	MOH-CHU
Richard Kiplimo	MOH-TB
Elizabeth Onyango	NTLD-P
Aiban Rono	NTLD-P
Martin Githiomi	NTLD-P
Josphat Mutua	NTLD-P
Jeremiah Okari	NTLD-P
Elvis Muriithi	NTLD-P
Mary Nyagah	NTLD-P
Lucy Njeru	NTLD-P
Samuel Misoi	NTLD-P
Eunice Mailu	NTLD-P
Lilian Kerubo	NTLD-P
Victor Kimathi	NTLD-P
John Mueke	NTLD-P
Wesley Tomno	NTLD-P
Polly Kiende	NTLD-P
Wandia Rose	NTLD-P
Nkirote Mwirigi	NTLD-P
Evans Kituzi	NTLD-P
Philip Owiti	NTLD-P
Moses Kigen	NTLD-P
Nduta Waweru	NTLD-P
Kiogora Gatimbu	NTLD-P
Dickson Kirathe	NTLD-P
Mercy Nyangaresi	NTLD-P
Nellie Mukiri	NTRL
Peterson Njenza	Planning, MOP
Preston Izulla	PWC Kenya
Miriam Faid	Stop TB

Evaline Kibuchi	Stop TB	Nobuyuki Nishikiori	WHO
Karen Kuria	STP-K	Kawuma H. Joseph	WHO T.A.
Maurice Maina	USAID	Michael Gasana	WHO/AFRO
Cicilia Gita Parwati	WHO	Renee Ridzon	CDC
Debora Pedrazzoli	WHO	Dr Jack Irungu	NTLDP
Annabey Baddeley	WHO	Phyllis Munywa	NTDU-MOH
Wilfred Nkhoma	WHO	Judy Kabathi	МОН

COUNTY CONSULTATIVE FORUM - JULY 02, 2018					
County	Name	Designation			
Bungoma	Dr Atieno Dinah	СР			
Busia	Betty Olonyi	CMLT			
Elgeyo Marakwet	Kiprono Chepkok	CEC			
Garissa	Dr. Idris Abdi	СР			
Homa Bay	Judith Niver Atieno	CMLT			
Isiolo	Abdi Ibrahim	CEC			
Kajiado	Ezekiel Kapkoni	CDH			
Kakamega	Dr Misiani Ayub W	СР			
Kericho	Johana Too	CMLT			
Kirinyaga	Dr Eve W.Thiongo	СР			
Kisii	Richard Moronge Ongeri	CMLT			
Kitui	Allan Owino	CDH			
Kwale	Dr Bernard Makenzi	СР			
Laikipia	Gachuhi Samuel Gutu	CMLT			
Machakos	Ruth Mutua	CEC			
Makueni	Dr Mwaka Mwango	СР			
Mandera	Abdikadir Khalif Ibrahim	CMLT			
Marsabit	Adano Kochi	CDH			
Meru	Eunice Nkirote	CEC			
Migori	Dr Michael Nyachae	СР			
Mombasa	Thani Suleimani	CMLT			
Mombasa	Hezekiah Koitaba	CEC			
Nairobi North	Dr. Ogaro	CDH			
Nakuru	Beatrice Kariuki Gathii	CMLT			
Narok	Vivian Sereti Mpeti	CEC			
Nyamira	Dr George Otieno	СР			
Nyandarua	Evelyne Macharia	CMLT			
Nyeri	Nelson Muriu	CDH			
Pokot	Noah Atudonyang	CEC			
-----------------	---------------------	------			
Samburu	Dr Alex Mungai	СР			
Siaya	Alfred J. O. Obiero	CMLT			
Taita Taveta	Frank Mwangemi	CEC			
Tharaka Nithi	Kimathi Mbaka	СР			
Trans Nzoia	Daniel Wekesa	CMLT			
Uasin Gishu	Wenselaus Kuria	CDH			
Vihiga	Dr Kaitany Benjamin	СР			
Wajir	Siyad Kulow	CMLT			
Uasin Gishu	Hillary Ndiema	CTLC			
Trans Nzoia	Jayne Alenga	CTLC			
Homabay	Carolly Migwambo	CTLC			
Nandi	Sammy Rop	CTLC			
Nandi	Joseph Kanhor				
Meru	Eunice Kanana	CTLC			
Laikipia	David K Mureithi	CTLC			
Nandi	Nathaniel Rotich				
Elgeyo Marakwet	Bernard Sawe	CTLC			
Baringo	Felix Kibet				
West Pokot	Michael Lotekori	CTLC			
Muranga	Lucy Irungu	CTLC			
Samburu	Peter Lekaite	CTLC			
Nyeri	Hiram Mathenge	CTLC			
Machakos	Joseph Mukoma	CTLC			
Taita Taveta	Suleiman Mwalenga				
Nakuru	Winnie Migwi				

COUNTY STAKEHOLDERS FORUM - AUGUST 20, 2018				
County	Name	Designation		
Baringo	Dr Kipsang Marachi	CDH		
Bomet	Joseph Sitonik	CEC		
Bungoma	Dr Sylvester Mutoro	CDH		
Bungoma	Paul Lodi	CTLC/Leprosy		
Busia	Phaustine Barasa	CEC		
Elgeyo Marakwet	William Kendagor	CDH		
Embu	Jamleck Muturi	CEC		
Garissa	Mohamed Salat Dagane	CDH		
Homa Bay	Prof Richard Muga	CEC		
Isiolo	Dima Oge	CDH		

Kajiado	Esther Somoire	CEC
Kakamega	Dr Arthur Andere	CDH
Kericho	Shadrack Mutai	CEC
Kiambu	Teresa Wanjiku	CDH
Kilifi	Dr Anisa Omar	CEC
Kirinyaga	George Karoki	CDH
Kisii	Sarah Omache	CEC
Kisumu	Dr Lawrence Otieno	CDH
Kisumu	Timothy Malika	CTLC
Kitui	Dr Rabut Grace	CDH
Kwale	Dr Hajara El-busaidy	CDH
Laikipia	John Mwaniki	CEC
Lamu	Crispin Lado	CDH
Machakos	Ruth Muthama	CDH
Makueni	Andrew Mulwa	CEC
Mandera	Dr Mohamed Adaw	CDH
Marsabit	David Timado	CEC
Migori	Iscar Oluoch	CEC
Mombasa	Shem Patta	CDH
Murang'a	Joseph Mbai	CEC
Nairobi	Elizabeth Mueni	CTLC
Nairobi North	Dr Thomas Ogaro	CDH
Nakuru	Dr Lenai JK	CDH
Nandi	Ruth Koech	CEC
Narok	Dr Francis Kiio	CDH
Nyamira	Douglas Bosire	CEC
Nyandarua	Zakayo Kariuki	CDH
Nyeri	Dr Rachel Kamau	CEC
Samburu	Martin Thuranira	CDH
Siaya	Mary Omondi Olute	CEC
Taita taveta	Christine Andeyo Kalema	CDH
Tana River	Dr Oscar Endekwa	CDH
Tharaka Nithi	Dr Gichuya Nthuraku	CEC
Trans Nzoia	Dr Gilbert Sowon	CDH
Turkana	Jane Ajele	CEC
Uasin Gishu	Everline C. Rotich	CEC
Vihiga	Dr Amos Kutwa	CEC
Wajir	Abdihakim Billow	CEC
West Pokot	Nobert Abuya	CDH

COUNTY ENGAGEMENT FORUM - FEBRUARY 14, 2019				
County	Name	Designation		
Baringo	Robert Kiplangat Rono	COUNTY REP.		
Baringo	Mary Chebet Panga	COUNTY REP		
Bomet	Louis Mwaniki Kibathi	СОН		
Bungoma	Mathias - Mathias	SCP		
Bungoma	Patrick Wechuli Wandili	COUNTY REP.		
Bungoma	Moses Wambusi Wanyonyi	COUNTY REP.		
Busia	Melsa Machio Lutomia	CDH		
Busia	Janerose Amoit Ambuchi	COH REP.		
Busia	Dorah Wandawa Mutonyi	CEC REP.		
Elgeyo Marakwet	Kimaile Benjamin Muisyo	COUNTY REP.		
Elgeyo Marakwet	Kiprono Chepkok Kiprono	COUNTY REP.		
Elgeyo Marakwet	William Kendagor Cheruiyot Kendagor	CDH		
Garissa	Abdullahi Daud Mohammed Daud Mohammed	COUNTY REP.		
Garissa	Aden Hussein Ibrahim	COUNTY REP.		
Homa Bay	Richard Otieno Muga	CEC		
Isiolo	Abubakar Abdallah Hussein	COUNTY REP.		
Isiolo	Asha Diba Dima Diba	CDH		
Kajiado	Mildred Wambui Macharia	COUNTY REP.		
Kajiado	Ezekiel Kibelion Kapkoni	СDH		
Kakamega	Rose Karevera Idanyuku	COUNTY REP.		
Kericho	Betty Chepngeno Langat	СDH		
Kiambu	Maxwell Murage Maina	COUNTY REP.		
Kirinyaga	Dickson Kimathi Mbaka	СР		
Kirinyaga	George N Karoki	СDH		
Kisii	Dr Richard Onkware Seme Onkware	CDH		
Kisii	Judith Bochaberi Nyangau	COUNTY REP.		
Kisumu	Kennedy Ochieng Otieno	COUNTY REP.		
Kitui	Grace Atieno Rabut	CDH		
Kwale	Hajara El Busaidy	CDH		
Laikipia	Josephine Atieno Ohas	CDH		
Lamu	Ann Gathoni Kabii	CEC		
Lamu	Victor Tole Mwakio	CDH		
Makueni	Pius Nthwao Mutuku	CTLC		
Mandera	Rahma Abdullahi Mahmud	СОН		
Mandera	Abdullahi Mohamed Madey	COUNTY REP.		
Marsabit	Adano Diba Kochi	CDH		
Meru	Lilian Karoki Bruno	CDH		
Meru	Sammy Githu Wachira	COUNTY REP.		

Meru	Muthuri Geoffrey Koome	СР
Migori	Jonathan Billis	COUNTY REP
Migori	Elizabeth Adhiambo Mgamb	CDH
Mombasa	Shem Onyango Patta	CDH
Muranga	Winnie Wambui Kanyi	CDH
Nairobi North	Martin Maithya Mulonzi	CTLC
Nandi	Ruth Cherotich Koech	CEC
Narok	Benard Sananka Reson	COUNTY REP.
Narok	Dan Frederick Onyango Ngere	СР
Nyamira	David Motaroki Osumo	COUNTY REP.
Nyandarua	Joram Kabui Muraya	СОН
Nyeri	Nelson Mwangi Muriu	CDH
Nyeri	Lydiah Wambui Warui	COUNTY REP.
Nyeri	Virginia Wambui Mwatha	COUNTY REP.
Nyeri	David Kathurima Mituru	COUNTY REP.
Pokot	Onyango Peter Oduor	СР
Siaya	Dorothy Akinyi Owino	CEC
Taita Taveta	Mariam Ndamu Kalela	COUNTY REP.
Taita Taveta	Christine Mawondo Mwakera	СОН
Taita Taveta	David Muthui Musya	CTLC
Tana River	Frederick Mokano Nyamori	COUNTY REP.
Tharaka Nithi	Fridah Muthoni Murungi	СОН
Tharaka Nithi	Cornellius Musembi Muendo	COUNTY REP.
Trans Nzoia	Sowon Kibet Gilbert	CEC
Turkana	Okemwa Job	CTLC
Turkana	Roberts Eloto Abok	СОН
Turkana	Jane Auru Ajele	CEC
Uasin Gishu	Hillary Kigai Ndiema	CTLC
Uasin Gishu	Faith Tarus Jeruto	COUNTY REP.
Uasin Gishu	Charles K C Makwila	CDH
Uasin Gishu	Everlyne Chepkemoi Nyangwaria	COUNTY REP.
Vihiga	Bernardus Quido Ahindukha	CDH
Vihiga	Arnold Kimiya Mamadi	COH REP.
Wajir	Dahir Ibrahim Somow	CDH
Wajir	Ahmed Guhad Omar	СОН

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NATIONAL TUBERCULOSIS, LEPROSY AND LUNG DISEASE PROGRAM

National Tuberculosis, Leprosy and Lung Disease Program,

Afya House Annex 1st Floor | Kenyatta National Hospital Grounds P.O. Box 20781-00202 Nairobi, Kenya | **Cell:** 0773 977 440 **Website:** www.nltp.co.ke | **Facebook:** NTLDKenya | **Twitter:** @NTLDKenya