Ministry of Health

National Tuberculosis, Leprosy and Lung Diseases Unit

NLTD-Unit Operations Manual

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- The Government of Kenya
- National Tuberculosis, Leprosy and Lung Disease (NTLD) Unit
- County Governments
- World Health Organization (WHO)
- Centers for Disease Control and Prevention (CDC)
- Center for Health Solutions – Kenya (CHS)
- PATH
- National TB Reference Laboratory (NTRL)

PREFACE

Kenya is currently implementing the devolved system of government. This operational manual provides the framework for the management and engagement of all actors and stakeholders in the control of TB, leprosy and lung diseases.

This operational manual guides the coordinated country response to TB, leprosy and lung diseases. It is a practical guide to comprehensive control interventions that the country is currently undertaking. The objectives of this manual are:

- To outline the management process of TB, leprosy and lung disease control services
- To enhance the practical understanding of the TB, leprosy and lung disease programmatic reporting requirements at various tiers to improve desired targets
- To enhance practical understanding on management and monitoring tools used to improve performance
- To act as a reference manual for training and capacity building for healthcare workers and stakeholders at all tiers in the implementation TB, leprosy and lung disease activities.

The primary targets for this operation manual are

- National level policy makers and implementing health staff
- County health executive committee members
- County Health Management Team
- Program Implementers in the Ministry of Health
- County Health Staff at facility levels
- All partners supporting implementation of TB and leprosy in the country
- Development and funding partners
- Community members

The manual addresses the management and coordination at both national and county levels of government, managing for results and monitoring and evaluation in TB, Leprosy and Lung Disease control.

ACRONYMS AND ABBREVIATION

ACSM	Advocacy Communication Social Mobilization
AFB	Acid Fast Bacilli
AIDS	Acquired Immune-Deficiency Syndrome
ART	Anti-Retroviral Therapy
CBO	Community Based Organization
CBTB	
CDC	Centers for Disease Control
CDRR	Consumption Drug Requisition Report
CHEW	Community Health Extension Worker
CHMT	County Health Management Team
CHW	Community Health Worker
COPD	Chronic Obstructive Pulmonary Disease
CSO	Civil Society Organization
CTLC	County TB and Leprosy Coordinator
CU	Community Unit
DADR	Daily Activity Drug Register
DALY	Disability Adjusted Life Years
DHIS	District Health Information System
DOTS	Direct Observed Treatment Short Course Chemotherapy
DQA	Data Quality Audit
EQA	External Quality Assurance
FBO	Faith Based Organization
FIND	Foundation for Innovative New Diagnostics
GDF	Global Drug Facility
HIV	Human Immunodeficiency Virus
ICC	Interagency Coordinating Committee
INH	Isoniazid
IPC	Infection Prevention and Control
IPT	Isoniazid Preventive Therapy
ISTC	International Standard for TB Care
JICA	Japan International Cooperation Agency
KEMRI	Kenya Medical Research Institute
KAIS	Kenya Aids Indicator Survey
KAPTLD	Kenya Association for Prevention of TB And Lung Disease
KEMSA	Kenya Medical Supply Agency
KHSSP	Kenya Health Sector Strategic Plan
KNASP	Kenya National Aids Strategic Plan
KNCV	The Netherlands TB Foundation
LMIS	Logistic Management Information System
LTBI	Latent TB Infection
MDRTB	Multidrug Resistance TB
MOH	Ministry of Health
MSH	Management Sciences For Health
MTB	Mycobacterium Tuberculosis

NGO	Non-Governmental Organization
NSP	National Strategic Plan
NTLD	National TB, Leprosy and Lung Disease Unit
OSDV	On-Site Data Verification
PAL	Practical Approach to Lung Health
PMDT	Programmatic Management Drug Resistant TB
PPM	Public Private Mix
RIF	Rifampicin
SCTLC	Sub-County TB and Leprosy Coordinator
SHA	System for Health Account
SOP	Standard Operating Plan
TB	Tuberculosis
TIBU	Tuberculosis Electronic Surveillance System
USG	United State Government
WHO	World Health Organization

CHAPTER 1: INTRODUCTION

Kenya is currently implementing the devolved system of government. This calls for clear delineation of mandate and responsibilities between the national and county level of government. This operational manual provides the framework for the management and engagement of all actors and stakeholders in the control of TB, Leprosy and Lung Diseases.

Kenya is committed to the fight against TB, leprosy and chronic lung diseases. The Kenya Health Policy 2012 – 2030 has targeted the elimination of communicable disease conditions including TB and Leprosy and committed to halt and reverse the rising burden of non communicable conditions including chronic lung diseases[1].

Tuberculosis is a major public health problem in Kenya. Kenya is ranked 13th among the twenty-two high burden countries in the world that notifies the highest burden of TB disease[2]. Considerable progress has been made in the fight against TB with a declining trend in case notification, estimated incidence and prevalence. The mortality rate attributable to TB has remained unchanged over the last decade[3].

Leprosy control is in its post-elimination phase but the there are pockets of areas in which leprosy still remains endemic. These pockets include the coastal region and western regions including Nyanza[3].

The true burden of associated with chronic lung diseases (COPD) is unknown mainly due to lack of routine reporting and no national impact surveys undertaken. It is estimated the burden is on the rise with the associated increase in risk factors such as pollution, urbanization and early exposure to allergens.

The Ministry of Health has established the National TB, Leprosy and Lung Disease (NTLD) unit with the national mandate of coordinating the control of TB,

[1] Kenya Health Policy 2012-2030

[2] WHO TB Global report 2013

[3] NTLD Annual Report 2013

Leprosy and Lung Diseases. Tuberculosis control in Kenya has historically been linked to leprosy control. Since 1948, leprosy control services consisted of small "leper settlements" and these isolated projects were brought together under the National Leprosy Programme (NLP) in 1976 and subsequently absorbed by the NLTP, launched by the Government of Kenya in 1980 to integrate leprosy and tuberculosis control activities[4]. The mandate of NLTP was later expanded in July 2007 to address critical lung health concerns and ensure alignment of the program to international expectations leading to the establishment of the NTLD unit.

The NTLD operations are geared towards the realization of Kenya's vision 2030 of transforming the country into a globally competitive, prosperous and industrialized middle-income country by 2030[6]. The NTLD has aligned to the Kenya Health Policy goal of **'attaining the highest possible standard of health in a manner responsive to the needs of the population'**[1]. In its strategic plan 2015-2018, NTLD overall goal aims to **accelerate the reduction of TB, leprosy and lung disease burden** through provision of people-centered, universally accessible, acceptable and affordable quality services in Kenya[5]. NTLD has developed and actualize its vision: Kenya free of Leprosy, Tuberculosis and Lung Disease and mission: Sustaining and improving Tuberculosis, Leprosy and Lung Disease control gains in order to accelerate the reduction of tuberculosis incidence, achieve leprosy eradication and control lung disease

The core mandate of the NTLD is to formulate policies, set standards, develop capacity, identify and mobilize resources, ensure uninterrupted supply of commodities, provide technical assistance, coordinate, monitor and evaluate implementation of TB, Leprosy and Lung disease control interventions. The implementation of control intervention is executed through partnership with key actors:

- The county governments
- The community
- The patient

[4] DLTLD strategic plan 2011-2015

[5] NTLD National Strategic Plan 2015-2018

[6]. Kenya Vision 2030

- Technical partners
- Civil Society Organizations and Non-Governmental Organizations
- Faith Based Organizations
- Bilateral and Multi-lateral partners
- Media

This operational manual guides the coordinated country response to TB, Leprosy and Lung diseases. It is a practical guide to comprehensive control interventions that the country is currently undertaking. Its objectives are:

- To outline the management process of TB, leprosy and lung disease control services
- To enhance the practical understanding of the TB, Leprosy and Lung Disease programmatic reporting requirements at various tiers to improve desired targets
- To enhance practical understanding of the management and monitoring tools used to improve performance

  To act as a reference manual for training and capacity building for health workers and stakeholders at all tiers of the implementation TB, leprosy and lung disease activities

Target audience

While this operation manual is written for all stakeholders involved at all levels of TB, Leprosy, & Lung disease control services (from national, county and peripheral levels of healthcare), the primary targets are:

- The national level policy makers and implementing health staff
- The county health executive committee members
- County Health Management Team
- County Health Staff at facility level
- All the partners supporting implementation of TB and leprosy in the country
- Development and funding partners
- Community members

The manual addresses the management and coordination at both national and county levels of government, managing for results, and monitoring and evaluation in TB, Leprosy and Lung Disease control.

CHAPTER 2: OVERVIEW OF DISEASE; TUBERCULOSIS, TB/HIV, LEPROSY AND LUNG DISEASE BURDEN

2.1 Burden of TB and TB/HIV in Kenya

Tuberculosis remains a major cause of morbidity and mortality in Kenya. TB ranks 4th among the leading causes of death and 6th among the causes of DALY's in Kenya as shown in table 1 below:

Table 1: Leading causes of deaths and DALYs in Kenya

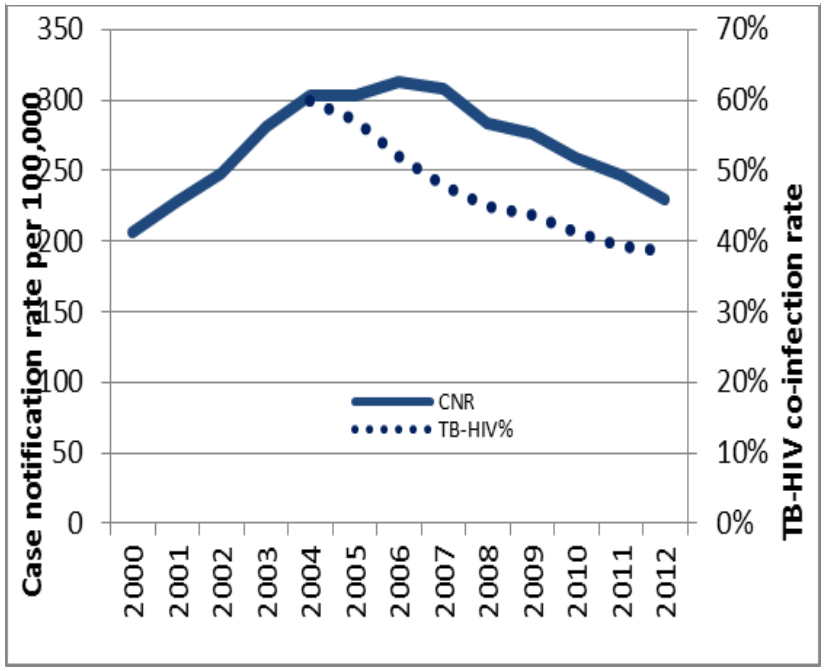
Causes of death			**Causes of DALY**		
No	**Disease or injury**	**% Total Deaths**	**No**	**Disease or injury**	**% Total DALYs**
1	HIV/AIDS	29.3	1	HIV/AIDS	24.2
2	Conditions arising during the peri-natal period	9.0	2	Conditions arising during the peri-natal period	10.7
3	Lower respiratory infections	8.1	3	Malaria	7.2
4	Tuberculosis	6.3	4	Lower respiratory infections	7.1
5	Diarrheal diseases	6.0	5	Diarrheal diseases	6.0
6	Malaria	5.8	6	Tuberculosis	4.8
7	Cerebral-vascular disease	3.3	7	Road traffic accidents	2.0
8	Ischemic heart disease	2.8	8	Congenital anomalies	1.7
9	Road traffic accidents	1.9	9	Violence	1.6
10	Violence	1.6	10	Uni-polar depressive disorders	1.5

Source : Kenya Health Policy 2012-2030

TB affects all age groups, with the greatest burden in the productive age group of 15 to 44 years. The biggest risk factor of TB disease in Kenya remains the HIV pandemic. Other factors include poverty and social deprivation that has resulted in the mushrooming of unplanned urban settlements (slums), congestion in prisons, and limited access to primary healthcare services. There is an increasing concern about the emergence of drug resistant TB, a threat that has the greatest potential of reversing the gains made over the decades in TB control.

Significant progress has been made in the fight against TB; the TB case notification rate is declining at annual average of 2-3% and there is a consistent reduction in the TB/HIV co-infection rate as shown in figure 1 below:

Figure 1: Trends of TB case notification rates & TB/HIV co-infection rates



Case finding for TB involves screening approximately 2 million individuals in the general population and among PLHIV in care and treatment. This translates to huge investment in human resources, commodities and time.

2.2 The burden and trend of leprosy in Kenya

Kenya is now at post-elimination phase on leprosy control. Since the introduction of Multi-Drug Therapy (MDT) in 1985, the registered prevalence decreased from 6,558 cases in 1986 to 122 cases by the end of 2011. The number of new leprosy cases detected decreased from 630 in 1986 to 134 in 2012. ([6])

2.3 Burden of Lung Disease

The country has no existing data on the true burden and magnitude of lung diseases. It can however be inferred, that with the rise in non-communicable disease conditions, the lung disease burden could be on the rise. Kenya purposes to establish the magnitude of lung disease burden at national and county level as elaborated in NTLD strategic plan 2015-2018[6]

2.4 Basic principles of TB and TB/HIV disease control

The goal of TB control is to reduce TB morbidity and mortality by:

- Preventing transmission from persons with contagious TB to uninfected persons through early diagnosis, effective treatment and addressing the risk factors of infection.
- Eliminating deaths and complications associated TB disease.

[6] NLTD strategic plan 2015-2018

- Preventing progression from latent TB infection (LTBI) to active TB disease among persons infected by addressing the risk factors for acquiring the disease.

The National and County levels of government shall implement the internationally recommended strategies for TB control. These are outlined the STOP TB strategy which consists of six components:

1. Pursue high-quality DOTS expansion and enhancement

a. Political commitment with increased and sustained financing

b. Case detection through quality-assured bacteriology

c. Standardized treatment, with supervision and patient support

d. An effective drug supply and management system

e. Monitoring and evaluation system, and impact measurement

2. Address TB/HIV, MDR-TB and other challenges

a. Implement collaborative TB/HIV activities

b. Prevent and control MDR-TB

c. Address prisoners, refugees and other high-risk groups and situations

3. Contribute to health system strengthening

a. Actively participate in efforts to improve system-wide policy, human resources, financing, management, service delivery, and information systems

b. Share innovations that strengthen systems, including the Practical Approach to Lung Health (PAL)

c. Adapt innovations from other fields.

4. Engage all care providers

a. Public–Public and Public–Private mix (PPM) approaches

b. International Standards for Tuberculosis Care (ISTC)

5. Empower people with TB and communities

a. Advocacy, communication and social mobilization

b. Community participation in TB care

c. Patients' Charter for Tuberculosis Care

6. Enable and promote research

a. Programme-based operational research

b. Research to develop new diagnostics, drugs and vaccines

The National government will provide guidelines on the implementation of the STOP TB strategies as applies to TB, Leprosy and Lung Disease control at the various tiers.

CHAPTER 3: COORDINATION AND MANAGEMENT AT NATIONAL LEVEL (NTLD-UNIT)

The control of TB, Leprosy and Lung diseases brings together different actors and stakeholders that require proper coordination at national level of government.

3.1 ***Mandate of the NTLD Unit***

The key mandate includes:

- National policy formulation for TB, Leprosy and lung disease control
- Mobilizing resources for disease control
- Ensuring commodity security for TB, Leprosy and lung disease -forecasting and quantification, procurement and storage at national level
- Formulating standards for TB and Leprosy diagnosis, care and treatment
- Standardizing health and non-health equipment and tests for TB control
- Monitoring and evaluation of control interventions and maintaining a responsive and effective TB, Leprosy and lung disease surveillance system
- Maintaining Quality assurance and Quality control of TB and Leprosy diagnostics and drugs
- Coordinating uptake and scale up of new technologies
- Providing technical assistance to counties on control services
- Coordinating partnerships

3.2 ***Roles and responsibilities***

Key roles and responsibilities of the NTLD Unit include:

- Develop, review and disseminate policy documents, treatment guidelines, operations manual and any other relevant documents related to TB, Leprosy and lung disease.
- Coordinate National Strategic planning
- Design and develop training curriculum and training content
- Develop standard data collection and reporting tools
- Conduct annual national forecasting and quantification of TB, Leprosy and lung disease commodities

- Establish standards for quality of all TB, Leprosy and lung disease services, commodities and equipment.
- Provide technical assistance on TB, Leprosy and lung disease services at all levels
- Collate national data, compile and disseminate reports to the relevant Ministries, partners and co-operating organizations
- Advocate for and mobilize resources for Tuberculosis control, Leprosy elimination and Lung disease control
- Identify and facilitate operational research and assessments
- Promote linkages and collaborate with County governments, programs and partners.
- Evaluate TB, Leprosy and Lung Disease interventions

3.3 ***TB, Leprosy and Lung Disease Surveillance system***

The NTLD Unit will maintain a national TB, Leprosy and Lung Disease monitoring and evaluation system. Key components include:-

1. A compendium of indicators, definitions and measurements
2. Routine TB, leprosy and Lung Disease surveillance system: Recording and Reporting
    a. TIBU system: http: pms.dltd.co.ke
    b. Data collection and reporting tools
3. Evaluation: Quarterly reviews, impact surveys, desktop reviews and special studies
4. Data quality assurance mechanisms: Data Quality Audit and On Site Data Verification
5. Technical assistance
6. M&E coordination: M&E and OR technical working group
7. Data and OR dissemination
    a. Quarterly bulletins
    b. Annual reports
    c. Kenya International Lung Health Conference
    d. Maintaining the program website: www.nltp.co.ke
8. Capacity building
9. M&E planning and budgeting

3.4 ***Planning for control***

The NTLD Unit will coordinate planning for TB, Leprosy and Lung disease control. This will be in collaboration with specific and will include stakeholder engagement, joint planning and a common M&E framework.

Some of the key plans will include, but will not be limited to:-

1. National strategic plans & its M&E plans
2. Biennial operation plans
3. National medium term plans (MTPs)
4. Annual Work Plans (AWPs)
5. Project plans

3.5 Programme Reviews and Evaluation

The Unit will facilitate review meetings at all levels;

a) Program review meeting

There shall be program mid/end term reviews for the national strategic plan.

b) Annual national review meetings;

There shall be annual intergovernmental review meetings between counties coordinated and supported by NTLD – Unit with the following objectives:

- Performance review
- Sharing best practices
- Sharing achievements and challenges
- Dissemination of information by the NTLD-Unit and partners

Participants

- Head directorate preventive and promotive services
- Head-division of communicable disease and control
- NTLD Unit programme officers,
- County health directors of health
- County and sub county TB, Leprosy coordinators
- County and sub county medical lab coordinators
- implementing and development Partners
- Academic institutions

Duration: Maximum 5 days

c) **Inter-governmental quarterly review meetings**

There shall be intergovernmental quarterly review meetings between counties with similar epidemiological profiles and geographical proximity. The objective of the meeting is as follows;

- Data verification, cleaning and presentation
- Sharing achievements and challenges
- Dissemination of information by the NTLD-Unit and partners

The participants include:

- County and sub county TB, Leprosy coordinators
- County and sub county medical lab coordinators
- County health directors
- Implementing partners
- NTLD-Unit program officers

Duration: maximum 4 days
Meeting Frequency: Quarterly

3.6 Coordination Structure

For effective coordination of TB, Leprosy and Lung Disease control interventions, the following structures have been established

a) TB Interagency Coordinating Committee - (TB ICC)

Its mandate is to coordinate, advocate and mobilize resources to run TB, Leprosy and Lung health interventions in the country. The chair is from the Government sector while the secretariat is housed at AMREF Kenya. Membership includes

- Private sector
- Multi-lateral and bilateral partners
- Technical partners-academic institutions
- CSOs
- FBOs
- Patient and community representatives

b) Technical Working Groups

The TB ICC is supported by 5 technical groups

- Monitoring and evaluation and operation research
- MDR TB and Lab
- Core TB and leprosy
- Practical approach to Lung Health (PAL) & public private partnership (PPP)
- ACSM/Community Based TB Care

c) Stop TB partnership

This consortium brings together all the TB stakeholders in the country to raise awareness and mobilize resources in different sectors. The secretariat is hosted by Centre for Health Solutions- Kenya (CHS).

CHAPTER 4: COUNTY COORDINATION AND MANAGEMENT

The new constitution mandates the implementation of health service provision including TB, Leprosy and Lung Diseases to the County governments.

4.1 The Mandate of County Governments

The mandate of the county governments in control of TB, Leprosy and Lung disease include:

- Coordination of control interventions at county level
- Planning and budgeting for control interventions
- Resource Mobilization at county level
- Ensuring un-interrupted supply of anti-TB, Leprosy and laboratory commodities in collaboration with County pharmacist
- Ensuring adherence to standards for TB, Leprosy and Lung Health diagnosis, care and treatment as outlined in the guidelines
- Acquisition and maintenance of health and non-health equipment
- Monitoring and evaluation of control interventions
- Recording and reporting for TB, Leprosy and Lung Disease surveillance
- Implementing Quality assurance and Quality control of TB diagnostics
- Ensuring uptake and scale up of new technologies
- Conducting supportive supervision and on-the-job training to health facilities
- Coordinating partnerships at county level
- Undertaking TB Infection Prevention and Control (IPC) activities
- Planning and carry out ACSM activities in the county

4.2 County control coordination

At the county level, the control interventions are coordinated and supervised by the County TB, Leprosy Coordinator (CTLC). These are medical officers or Clinical Officers trained in lung and skin diseases. They are members of the County Health Management Teams (CHMT).

The Roles and responsibilities of CTLCSs are:

- Supervising TB, leprosy and lung disease activities in the sub counties and peripheral health facilities within his/her jurisdiction. Each

sub county should be supervised at least once per month

- Planning and budgeting for TB, leprosy and lung disease activities in collaboration with the sub county TB, Leprosy coordinators
- Managing the TB, leprosy and lung disease finances at county and sub county levels
- Ensuring adequate transport facilities for the implementation of planned TB, leprosy and lung disease activities at county and sub county levels.
- Initiating, plan and implement various training programmes for county and sub county level healthcare staff in collaboration with the NTLD Unit
- Monitoring and evaluation of the TB, leprosy and lung disease activities carried out at the county and plan for targeted control interventions
- Initiating and participating in operational research
- Advocating for best practices in TB, leprosy and lung disease management among doctors and other healthcare workers in the county, NGOs, private health services and the community
- Collating reports, analyze and validate TB, leprosy and lung disease data from the sub counties and compile reports for sharing with the CHMT and forwarding to the national TB, leprosy and lung disease Unit
- Providing feedback to the CTLC, SCTLC and other partners on the analysis of data related to TB, Leprosy and lung disease activities within the county
- Participating in quarterly intergovernmental meetings and the bi-annual county meetings
- Advocacy of CHMT and other authorities at county level
- Co-operating/Coordinating with other programmes at county level
- Consolidating CTLCs and SCTLC clinic and supervision schedule and forward to the county director for health.
- Participating in the county TB/HIV technical groups meeting and activities
- Resource mobilization for TB/leprosy, and Lung disease activities within the sub county
- Convening and coordinating stakeholders' activities

The Roles and Responsibilities of County Medical Laboratory Technology

- Supervising TB laboratory activities in the sub counties and peripheral health facilities within

their jurisdiction. Each Sub County should be supervised at least once per month

- Planning and budgeting of TB diagnostic activities in collaboration with the Sub county TB, leprosy coordinators.
- Initiating, planning and implementing various laboratory-training programmes for county and sub county level health care staff in collaboration with NTLD Unit
- Monitoring and evaluation of the TB laboratory activities carried out at the county and plan the implementation of targeted control interventions
- Initiating and participating in operational research
- Undertaking of regular quality control and quality assurance in TB bacteriology methods
- Planning and carrying out ACSM activities in the county in collaboration with county TB, leprosy coordinators
- Conducting on job training of health care workers on TB IPC and other TB control activities in collaboration with the county TB, leprosy coordinators

The Roles and Responsibilities of County Pharmacist

- Forecast and quantify TB, leprosy and lung disease medicines and other health products
- Quarterly aggregation of orders from sub-county to KEMSA/Supply agents
- Ensure monthly reporting through LMIS
- Capacity building of county and sub-county health workers on commodity management
- Distribution, storage and inventory management
- Ensure rational use of medicines and coordinate pharmacovigilance activities
- Initiate and participate in operational research.

4.3 Sub county control coordination

Sub-county is the lowest coordination unit. TB, leprosy and lung disease activities are co-coordinated and supervised by the Sub-county TB and Leprosy Coordinator (SCTLC). Where the facilities have bigger workload or the sub county is vast, the sub county can have more than one coordinator for effective supportive supervision.

The Roles and Responsibilities of SCTLC

Their role involves working with the facility Health care providers to;

- Prepare an annual clinic and supervision schedule Carry out monthly support supervisory visits to all health facilities involved in the diagnosis and

treatment of tuberculosis, leprosy and lung disease

- Prepare reports on each supervisory visit, providing feedback on achievements and challenges to the facilities visited and filing copies
- Identify training needs and coordinate capacity building for skilled and unskilled staff including community health workers and the general public
- Provide technical assistance as needed
- Verify diagnosis and treatment regimen of cases identified during clinic visits and ward rounds
- Ensure referral of leprosy patients in need of reconstructive surgery
- Verify regular and appropriate treatment according to the treatment guidelines is delivered to patients
- Ensure effective defaulter tracing is conducted and recorded
- Ensure effective contact tracing, intensified case finding and infection control strategies are carried out

Provide on-the- job training during supervisory visits

- Initiate, plan and coordinate public awareness campaigns for the general public including public barazas (collaborate with the CHEWs), school visits, radio talks, theatre groups etc.
- Verify the clinic records and update the sub county register (TIBU)
- Provide quarterly progress reports to the CTLCS, NTLD Unit, and other partners based on the supervision reports and data analysis.
- Collect samples of slides quarterly for External Quality Assurance (EQA) from peripheral facilities and forward for EQA
- Liaise with pharmacist to assure sufficient stocks of drugs and other supplies at sub county level
- Prepare sub-county annual work plan

Initiate and participate in operational research.

- Participating in quarterly inter -governmental TB/Leprosy and lung disease review meetings
- Participate actively in the sub county health management team meetings and activities
- Convene and coordinate partnerships at sub county
- Mobilize resources for TB/ leprosy, and Lung disease activities within the sub county
- Plan and carry out ACSM activities in the sub county
-

The Roles and Responsibilities of sub-county medical laboratory technologist

- Supervise TB, laboratory activities at peripheral health facilities
- Plan and budget of TB diagnostic activities for the sub- county
- Initiate, design and implement various laboratory training programmes for laboratory health care providers
- Monitor and evaluate the TB laboratory activities carried out at the sub-county
- Initiate and participate in operational research.
- Undertake regular quality control and quality assurance in TB bacteriology methods
- Facilitate decentralization of TB diagnostic services
- Undertake TB IPC activities

The Roles and Responsibilities of Sub-County Pharmacist

- **Forecast and q**uantify TB, leprosy and lung disease medicines and other health products
- Quarterly aggregation of orders from health facility to KEMSA/Supply agents
- Ensure monthly reporting through LMIS
- Capacity building of sub-county health workers on commodity management
- Distribution, storage and inventory management at the sub county and facility level
- Ensure rational use of medicines and pharmacovigilance activities
- Initiate and participate in operational research.
- Undertake appropriate TB IPC measures

4.4 Organization of services at Health Facility level

The health facility nurse, clinician, laboratory and pharmacist are responsible for day-to-day TB, leprosy and lung disease control interventions.

The tasks of facility based Health Care Providers (HCP)

- Identify leprosy, tuberculosis and lung disease suspects and conduct appropriate diagnostic procedures
- Initiate and maintain patients diagnosed with TB, Leprosy or lung disease on appropriate management
- Notify confirmed cases in appropriate treatment registers
- Refer complicated cases appropriately for further evaluation and management
- carry out defaulter tracing for patients interrupting treatment in collaboration with

CHEWs and other community based health care providers

- Conduct intensified case finding at all patient entry points
- Carry out contact tracing for new leprosy and tuberculosis cases.
- Ensure adherence to TB IPC procedures for HCPs and patients
- Participate in advocacy, communication and social mobilization for TB, Leprosy and lung disease prevention and control.
- Provide patient education
- Ensure care tools and registers are complete and updated including patient-record cards, treatment registers and drug ledgers
- Ensure timely ordering of TB and Leprosy commodities to maintain sufficient stocks of drugs, health education materials, laboratory supplies and stationery (registers, forms, patient cards, etc) at the health facility
- Collaborate with partners working in the facility
- Participate and give feedback to facility health management team
- Provide diagnostic testing and counseling [DTC for HIV among TB and Leprosy patients

TB and Leprosy services should be provided by trained HCPs. Continuous training both formal and mentorship is needed

Health care providers with immunosuppressive diseases should be exempted from working in TB clinics.

4.5 Community Unit (CU)

The community unit services are provided by community health workers (CHW) under the supervision of community health extension worker (CHEW)

Roles and Responsibilities of Community Health Extension Worker (CHEW)

- Provide coordination of the CU
- Conduct community dialogue
- Ensure linkages between CUs and health facility
- Plan and budget for community interventions
- Ensure community based recording and reporting of control activities
- Support partnership with community based actors and stakeholders
- Plan and carry out ACSM activities in the community
- Conduct training of CHWs on TB IPC and community engagement

Roles and Responsibilities of Community Health Worker (CHW)

- Identify **and refer presumptive cases at communi**ty
- Carry out defaulter tracing
- Provide community based DOTS observation where needed
- Facilitate contact tracing and referral
- Carry out health education at community and household levels
- Provide linkages to community patient support groups
- Maintain community health records
- Participate in community dialogue

CHAPTER 5: MANAGING FOR RESULTS

5.1 Background

Managing for Results (MFR) is a strategic planning, performance measurement, and budgeting process that emphasizes use of resources to achieve measurable results, accountability, efficiency, and continuous improvement in line with the goals and objectives of the National TB Leprosy and Lung Disease Unit (NTLD-U). The MFR will facilitate **functional partnership and coordination of all stakeholders in the health sector at all the respective levels, representing the recognized health sector constituencies of:**

a. The Central and County government: Including the ministry responsible for health, and the other health related ministries functioning at the respective tiers of service delivery;
b. Development partners supporting health, and health related interventions;

c. Non state Implementing partners providing health services

This Chapter therefore describes the processes and systems that the NTLD-U has put in place to help it achieve maximum results within the available resources. These processes include:

- Planning for disease control
- Technical Assistance
- Monitoring and Evaluation (Recording, reporting and information dissemination for TB, Leprosy and Lung disease control)
- Key performance indicators
- Health financing
- Impact measurement
- Continues Quality Improvement (CQI)
- Other internal management systems

5.2 Planning for Disease control

5.2.1The National Government

The National TB, Leprosy and Lung Health Strategic Plan 2015-2018 (NSP) gives guidance on management of the three diseases. This also spells out operations and inter-linkages between the National and County Governments.

The NTLD Unit shall use the following national planning tools as references for effective coordination of its activities:

- Health policy 2013-2030
- National Health Sector Strategic Plan (NHSSP)
- Ministry of Health Medium Plan
- National TB, Leprosy and Lung Disease 5 year strategic plan
- Kenya National AIDS Strategic Plan (KNASP)
- Health System and Community System Strengthening strategies
- National annual operation plans
- Annual TB and Leprosy Quantification report
- Program review reports
- System for National Health Accounts (SHA)
- Kenya Demographic Health Surveys
- Kenya AIDS indicator Surveys (KAIS)
- Data Quality Audits/ On-Site- Data verification reports
- Quality of care surveys
- Routine surveillance and monitoring: DHIS-2 and TIBU
- Service Availability and Readiness Assessment reports (SARA)
- Kenya International Lung health conference reports

The County government and individual health facilities shall use the following NTLD-Unit treatment guidelines and Standard Operating Procedures (SOPs) to guide service delivery practices to ensure standard quality of care. These documents shall be available in hard copies availed to the facilities and downloadable softcopies in the NTLD-Unit website. The unit shall work in collaboration with the county government to ensure that each facility maintains a copy of each document.

- TB and Leprosy Management Guidelines
- PMDT guidelines and SOPs
- AFB microscopy and QA guidelines
- TB culture guidelines and QA

5.2.2County Government

In consultation with the national government, the county government shall undertake the following roles in ensuring effective control of the three diseases.

As part of political commitment to TB, Leprosy and Lung disease control, the county government shall mainstream the control activities of the three diseases into their county plans and reports. These plans and reports will include but not limited to the following:

- County integrated business development plan
- County health strategic plan
- Annual operation plans

  County annual and quarterly TB and Leprosy reports

- PAL guidelines (Asthma and COPD Guidelines)
- TB/HIV guidelines
- Childhood TB guidelines
- Relevant Diagnostic Algorithms
- National HTC guidelines
- TB IPC guidelines

Data quality shall be ensured through annual data quality audits and quarterly date review meetings

5.3.1 Recording

All the facilities shall use nationally approved reporting tools to record all TB, Leprosy and lung health services provided at the facility. These tools are as detailed in Chapter 6.

5.3.2 Reporting

The national government shall guide the facilities on the indicators that shall be reported on a monthly basis. This report shall be entered into DHIS-2 using the existing reporting system.

5.3 Monitoring and Evaluation (Recording, reporting and information dissemination for TB, Leprosy and Lung disease control)

All the counties shall prepare and report the TB, Leprosy and Lung Disease Core Indicators using a common Framework as specified by the National Government.

5.3.1 Case notification at County and National Level

The Sub county TB Leprosy Coordinator shall line list the patients from every TB treatment facilities in TB and Leprosy surveillance system (TIBU) that aggregates the cases for notification to the counties. The County TB and Leprosy Coordinators shall have access to the TIBU system for analysis and dissemination of County specific data for the three focus diseases.

At the national level, the Data Management Unit shall have the responsibility of analyzing and development of data sharing products for dissemination.

5.3.2 Sharing of data with partners and other stakeholders

Data shall be shared through TIBU and DHIS-2. For TIBU, the head of the NTLD Unit shall mandate the Data Management Unit to give partner's access limiting them to their areas of operations.

Partners and stakeholders wishing to access DHIS-2 data shall register through the web-based system. Any other request for extra data shall be done through the head of the NTLD Unit in writing.

5.3.3Reporting for TB commodities

Logistics management information system (LMIS) reports shall be generated on a monthly basis from the sub county level. The sub county aggregation tool shall aggregate data from all sites receiving medicines and laboratory commodities and send to logistic management unit that is housed at KEMSA. A TB supply chain information work book shall be generated and shared with the NTLD unit and that will form the basis of the re-supply decisions. Commodity data will also be collected through DHIS-2.

5.3.4Annual Report and Quarterly Bulletins

The annual report for the previous year shall be prepared by end of April and shared through the NTLD Unit website. A few copies shall be printed and shared with counties, partners, line ministries and programs.

Quarterly bulletins shall be prepared by the second month of the following quarter and shared through the website.

5.4 Key performance indicators

For effective TB, Leprosy and Lung Disease control in the county, the following indicators shall be monitored closely;

1. TB treatment success rate
2. Case Notification rate
3. Proportion of notified TB cases who are children <15 years
4. Proportion of children under five who are contacts of TB patients started on IPT.
5. TB/HIV indicators
    a. Proportion of TB patients tested for HIV
    b. Proportion of TB/HIV co-infected patients on Co-trimoxazole
    c. Proportion of TB/HIV co-infected patients on ART
    d. Proportion of HIV patients screened for TB
    e. Proportion of eligible HIV patients on IPT
6. Drug resistance Tuberculosis
    a. Proportion of eligible TB patients with culture and DST results
    b. Number of new drug resistance TB cases notified

7. Community Involvement in TB Disease control
    a. Proportion of notified TB patients referred by Community Health Workers
    b. Proportion of TB patients who are out of control
8. Diagnosis
    a. Proportion TB Labs performing External Quality Assurance (EQA)
    b. Proportion of laboratories showing adequate performance in EQA for smear microscopy.

5.5 Technical Assistance

Technical assistance will be provided both at the national and county levels. The TA needs will be identified through regular consultative meetings with key stakeholders. The NTLD Unit shall coordinate with the identified institutions to provide the necessary TA. These institutions include the following:

- WHO
- GDF
- KEMRI
- USAID
- CDC
- MSH
- FIND
- Green Light Committee (GLC)
- JICA

The types of TA that will be provided include:

- Development of guidelines and job aids
- Development of recording and reporting tools
- Development of supply chain management system
- Capacity building of staff at the national, county and facility level.

For in country trainings, a training curriculum will be used. The national program is expected to provide TA to each county at least once in a year while counties will provide direct TA to the facilities under their jurisdiction.

5.6 Health Financing

Financing of TB Leprosy and lung disease activities shall be based on all-inclusive and fully costed strategic plans and annual operation plans
Keys sources of funds are:

Internal Sources

- National government budgetary allocation
- County government budgetary allocation
- Local donor and well wishers

External funding sources include

- Global Fund
- USAID
- CDC

- GDF
- The World Bank
- WHO
- JICA
- UNITAID

5.7 Impact Measurement

The NTLD Unit shall on a regular basis conduct Impact assessment in collaboration with other partners. These assessments shall be in form of:

- TB prevalence surveys
- TB drug resistance survey
- Kenya Demographic Health survey
- Vital registration (TB Mortality)
- Periodic epidemiologic analysis
- Burden of Lung Disease (BOLD)

5.8 Continues Quality Improvement (CQI)

The NTLD unit will at least once in a year conduct CQI assessments in sample of facilities providing TB care in the country. This will involve the assessment of:

- Use of standard treatment regimens (for all treatment categories)
- Availability of drugs
- Availability and display of up dated IEC materials, SOPs and guidelines
- Time taken to diagnose and initiate TB treatment
- Patient retention in care/treatment success rates
- Surveillance rates among retreatment patients
- Patients receiving follow up sputum smears as appropriate
- DSTs done and received among Xpert RIF resistant samples (including TAT)
- PLHIV provided with IPT
- TB patients tested for HIV and initiated on ART

The NTLD Unit shall support the Counties and facilities to implement CQI as recommended in the Kenya Quality Health Model (KQHM) by sensitizing the leadership on its benefits, conducting trainings, championing the formation of Work Improvement Teams (WIT) to implement the 5S - CQI (Set, Sort, Shine, Standardize and Sustain) as well as the formation of Quality Improvement Teams (QIT) to develop and implement quality improvement plans and systems to monitor and evaluate the process.

NTLD unit will also participate in ISO 9001:2008 QMS certification processes and continue with internal and external audit for sustaining ISO certification. To do this all the systems will be

internally audited once every quarter and externally once every six months. To ensure continuous quality improvement the NTLD unit will also:

- Hold top management review meetings once every six months
- Review of QMS documents once every year
- Capacity building of program staff on ISO 9001:2008 QMS: Sensitize and train staff on QMS requirements every six months. The training will be on ISO implementation and auditing.
- Carry out quarterly internal quality management system audit in all the sections and aspects of QMS
- At the beginning of each year the head of unit in consultation with top management team shall appoint management representative (MR) responsible for ISO processes and the lead auditor responsible for internal Quality audit process
- Internal audit review and preparation meetings shall be held every quarter convened by the lead auditor
- The QMS certifying body shall carry out surveillance audits of NTLD Unit quality management system **every 6 (six) months** to determine its continued conformity to ISO 9001:2008 requirements.

5.9 Other internal management systems

The NTLD unit shall also maintain other internal management systems aimed at:

- Tracking of trainings, TA and other services provided by the unit
- Tracking of delivery and distribution of tools and other equipments
- Maintenance of all IT equipment at the NTLD unit offices. NTLD unit shall have a dedicated IT officer to ensure tagging, upgrade and storage of IT equipment and software.

CHAPTER 6: TB, LEPROSY AND LUNG DISEASE DATA RECORDING AND REPORTING TOOLS AND SYSTEMS

The NTLD unit is responsible for the development, formatting and design of standardized data recording and reporting tools meeting international standards. The Unit is also responsible for development of guidelines, SOPs, training material and IEC materials for use in the provision of TB Leprosy and Lung disease control services. Printing and distribution of the tools and the guidelines shall be coordinated at the national level in collaboration with the county government and other implementing partners. Review of the tools and the guidelines shall be done every two years or as need arises through the guidance of the respective technical working groups.

The NTLD unit shall support development and implementation of a nationally accepted electronic medical records system for both case recording and reporting. This system shall be linked to the other web based reporting systems supported by the ministry of health for reporting other diseases.
This chapter details all the tools, guidelines and the systems that will be used for data recording reporting and service provision.

6.1 Electronic Systems

- Electronic TB reporting system (TIBU)
- District Health Information system-2 (DHIS-2)

6.2 Technical assistance tools

The following tools shall be used for provision of TA at the various levels: National, County and Sub county TA/supervision checklists. These checklists will be integrated in to TIBU electronic system phase

6.3 Facility TB recording and reporting tools

The following tools will be used for First line TB and will be filled by the health care workers managing the patients

- TB Patient Appointment Card
- TB Patient Record Card
- TB Treatment Facility Register
- Referral Form to TB clinic
- Referral Form from TB Clinic to other care providers
- ICF/IPT forms

- IPT Register
- Presumptive/contact register
- Facility Based case reporting tools

For MDRTB the following tools will be used

- MDRTB Patient Appointment Card
- MDRTB Patient Record Card
- MDRTB Treatment Facility Register

Laboratory Tools

For the laboratory services the following tools will be used:

- TB Sputum-smear Examination Request Form
- Laboratory Register for Sputum-smear Examination
- TB Culture/sensitivity Request Form.
- Quarterly AFB Report Form
- Quarterly EQA forms
- MTB/RIF (gene expert) request Forms

Drugs and other supplies reporting tools

- Facility CDRR (Consumption Drug Report & Request) Form
- Sub County CDRR
- Bin Card.
- Daily Activity Drug Register (DADR)
- S11, S12,S13

Leprosy tools

- Leprosy registers
- Leprosy cohort tools
- Leprosy case-finding tools

Asthma tools

- Asthma facility register
- Asthma record Card
- Asthma appointment card

6.4 Community Tools

The following tools will be used for community TB control services.

- Loss to follow up tool
- Contact tracing tool
- Referral tool
- Screening tool
- CHW monthly reporting tools
- Lung health tools