

REPUBLIC OF KENYA



MINISTRY OF HEALTH

KENYA LATENT TUBERCULOSIS INFECTION POLICY 2020



**NATIONAL TUBERCULOSIS, LEPROSY
AND LUNG DISEASE PROGRAM**

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KENYA LATENT TUBERCULOSIS INFECTION POLICY 2020

March, 2020

Version 1

This policy is intended as a guide for the management of LTBI in Kenya
towards elimination of TB

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FOREWORD

Tuberculosis (TB) remains one of the top 10 causes of death worldwide. Globally, millions of people continue to fall sick from TB each year. In 2018, 10 million people fell ill from TB and of these, 1.5 million people lost their lives. It is estimated that one-quarter of the world's population (an estimated 1.7 billion people) is latently infected with the TB bacteria. Of these 5-10% are at risk of progressing to TB disease.

Latent TB infection occurs when a person is infected with the TB bacteria but does not have any symptoms. People with Latent TB infection pose a great threat in the community as they are the breeding ground for the TB epidemic. TB preventive therapy is offered to individuals who are considered at risk of developing TB disease in order to reduce that risk.

The National Strategic Plan (NSP) for Tuberculosis, Leprosy and Lung Health 2019-2023 targets to offer TB preventive therapy to approximately 900,000 persons who have Latent TB infections. These populations are as follows: adults, adolescents, children and infants living with HIV; HIV-negative household contacts of bacteriologically-confirmed TB patients, health care workers, prisoners and other HIV-negative at-risk groups like patients on immunosuppressive therapy, dialysis, those preparing for organ or haematological transplant and patients with silicosis.

This Latent TB policy aims at providing a framework to guide the management of Latent TB infections as a key strategy to ending TB by 2035 in Kenya. This will be achieved through the systematic implementation of evidence-based interventions on identifying the at-risk populations, screening them, offering a timely diagnosis and effective treatment options and monitoring them to treatment completion.

The policy is also aimed at offering guidance to all stakeholders on the management of Latent TB infections in Kenya, including Government ministries, County governments, Faith-based organizations, private sector players, patient groups, civil society organizations and non-governmental organizations among others towards a coordinated response.

The development of this policy has been a participatory process by all stakeholders and it is my belief that we all put efforts to ensure implementation and monitoring of the objectives in this policy. Let us all join hands to End TB in Kenya.



**Cabinet Secretary
Ministry of Health**



Hon. Mutahi Kagwe, EGH



Ms. Susan N. Mochache, CBS

PREFACE

Tuberculosis (TB) is the leading cause of death from an infectious agent globally. In 2018, an estimated 1.5 million people died due to TB. Globally, an approximate 1.7 billion people are infected with *Mycobacterium tuberculosis*, the causative agent of TB among humans. Treatment of latent tuberculosis infection (LTBI) in people at high risk for progression to active TB is a key principle strategy for eliminating TB.

Approximately 5-10% of people with LTBI develop active TB disease during their lifetime, usually within the first five years. However, this risk increases several fold in the presence of immunosuppressive conditions like HIV. Preventive treatment can avert the development of active TB disease with efficacy ranging from 60-90%.

The Ministry of Health, Kenya has reviewed its TB preventive treatment (TPT) policy to be in line with the recent World Health Organization guidelines including an expanded at-risk population, LTBI testing and more treatment options. The population to benefit from TPT include adults, adolescents, children and infants living with HIV; HIV-negative household contacts of bacteriologically confirmed TB patients, health care workers, prisoners and other HIV-negative at-risk groups like patients on immunosuppressive therapy, dialysis, those preparing for organ or haematological transplant and patients with silicosis.

TB disease among these at-risk populations will first be ruled out by screening for the cardinal symptoms of TB (For adults: current cough, fever, weight loss or night sweats. For children: current cough, failure to thrive/poor weight gain, hotness of the body, reduced playfulness). HIV negative at-risk populations who do NOT have any of the above symptoms will undergo testing for LTBI by either tuberculin skin testing (TST) or interferon-gamma release assay (IGRA). LTBI testing is not a requirement for initiating TPT in people living with HIV or child household contacts aged <5 years.

Older adolescents and adults living with HIV who screen negative for TB and HIV negative at-risk populations testing positive for LTBI will be provided a weekly combination of Isoniazid and Rifapentine for 3 months (3HP). Children and adolescents aged <15 years will be provided a daily dose of Rifampicin and Isoniazid for 3 months (3RH). Anyone with a contraindication to 3HP or 3RH will be provided a daily dose of Isoniazid for 6 months (6H). Other important considerations put in place include the monitoring of adverse events; enhanced adherence and ensuring completion of treatment; and adequate programmatic management, recording, reporting and evaluation.

The revision of this policy has been based on sound international guiding principles and review of the Kenyan situation. This process has been participatory involving multiple stakeholders in the country. It is based on patient-centered approach as envisioned in the END TB Strategy and with the main aim of ending TB in the country by 2035.

**Principal Secretary
Ministry of Health**

ACKNOWLEDGEMENT

The development of this Latent Tuberculosis infections (LTBI) policy document involved consultations with key stakeholders through conducting reviews and consultative meetings. It is heavily guided by the World Health Organization recommendations. The Ministry of Health wishes to acknowledge the immense contribution of various organizations and individuals listed below for their efforts in this process.

We take note of the support from the office of the Cabinet Secretary, the Principal Secretary, Head of Directorate of Medical Services / Preventive and Promotive Health and the Head, Department of National Strategic Public Health Programs.

Specifically, the Ministry would like to thank the following organizations: United States Agency for International Development (USAID), World Health Organization (WHO), Center for Disease Control and Prevention (CDC), Clinton Health Access Initiative (CHAI), Centre for Health Solutions (CHS), Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) and Respiratory Society of Kenya (RESOK) for their technical inputs and support.

We also recognize the stewardship and guidance provided by the Division of National Tuberculosis, Leprosy and Lung Disease led by Dr. Elizabeth Onyango. Special thanks to the LTBI team members particularly Rhoda Pola, Dr. Philip Owiti, Dr. Stephen K. Macharia, Samuel Misoi, Felix Mbetera and Dr. Muthoni Karanja (NASCOP).

In a special way, we wish to convey our gratitude to the expanded team that worked tirelessly to ensure the successful completion of this process.



Ag. Director General for Health



Dr. Patrick Amoth

Acronyms

3HP	Weekly dose of Rifapentine plus high dose of Isoniazid for 12 weeks
3RH	Three months of daily Rifampicin plus Isoniazid
6H	Six months of daily isoniazid monotherapy
ART	Antiretroviral Therapy
ARVs	Antiretroviral Drugs
BCG	Bacille Calmette-Guérin (vaccine)
CLHIV	Children living with HIV
FDC	Fixed-dose combination
HH	Household
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
IGRA	Interferon-gamma release assay
IPT	Isoniazid Preventive Treatment
KHP	Kenya Health Policy
LTBI	Latent Tuberculosis Infection
PLHIV	People living with HIV
TPT	Tuberculosis Preventive Treatment
TST	Tuberculin Skin Test
TB	Tuberculosis
UNHLM	United Nations High Level Meeting on Tuberculosis
WHO	World Health Organization

INTRODUCTION

1.1 Background

Tuberculosis (TB) is one of the leading causes of death from infectious diseases in the world, with an estimated 1.5 million deaths in 2018. Globally, approximately 1.7 billion people are estimated to be infected with *Mycobacterium tuberculosis*, the causative agent of TB among humans. Treatment of latent tuberculosis infection (LTBI) in people at high risk for progression to active TB is a principal strategy for controlling and eliminating TB.

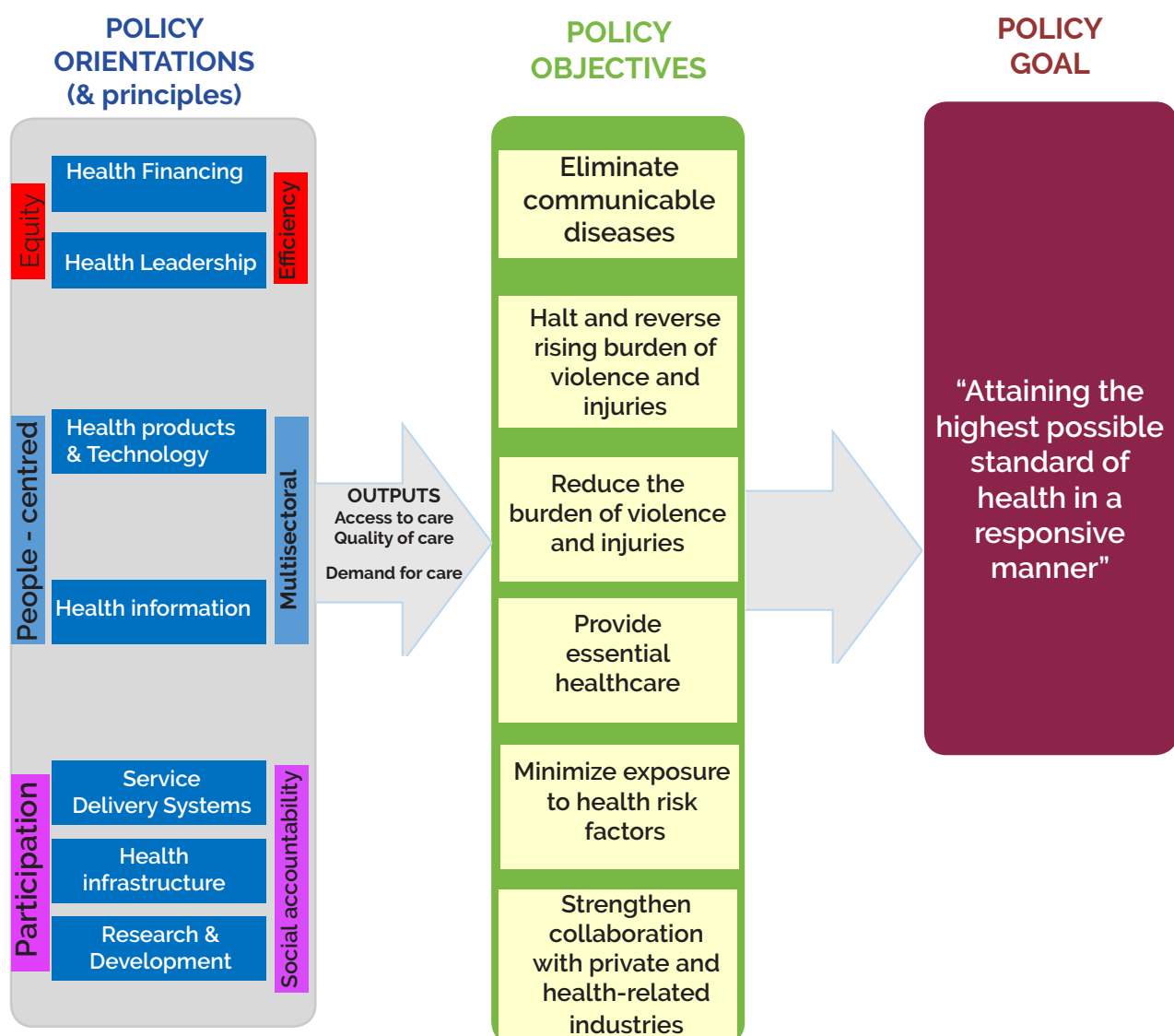
Approximately 5-10% of those with LTBI will develop active TB disease during their life usually within the first 5 years after initial infection. The risk for active TB disease after infection depends on several factors, the most important being immunological status such as HIV, severe malnutrition, patients on immunosuppressive therapy etc. Provision of preventive treatment has proven itself an effective intervention to avert the development of active TB disease, with efficacy ranging from 60% to 90%.

The Division of National Tuberculosis, Leprosy and Lung Disease (DNTLD) will be implementing the new WHO recommendations on treatment of Latent TB infection as per the strategic plan 2019-2023 with a target of offering TB Preventive Treatment (TPT) to 900,000 persons with Latent TB infection.

Successful implementation of management of Latent TB infection requires:

- Sound technical guideline
- Coordinated efforts from ministries of health, finance, justice, labor, public works and environment
- Coordination between different national disease-specific programs, especially HIV and TB programs
- Coordination between health authorities at national and subnational level
- Contributions from technical partners and civil society
- Advocacy mobilization to remove obstacles that impede wide implementation of activities
- Adequate funding at all levels.

Policy Framework for Health: Orientations, Principles, Objectives, and Goals



1.2 Purpose

The purpose of this policy document is to provide guidance on the implementation of management of Latent TB infection prevention control by all stakeholders in the country.

TB prevention therapy is a combination of measures aligned with “The End TB Strategy” and it is also in line with the vision of the National TB program which envisions Kenya free of tuberculosis—zero deaths, disease and suffering due to tuberculosis by 2035. The foundation of such infection prevention is early screening, rapid diagnosis, testing and treatment, and proper management.

This latent TB policy document will provide a structural framework that involves: - a comprehensive package of intervention which will include, identification and testing of individuals who are at risk of developing TB, offering them the right diagnostic options, delivering effective and safe treatment and lastly monitoring and evaluating the process. The policy will also be used as a reference to guide the screening, diagnosis, treatment, monitoring and evaluation of latent TB infections in the Country. Anyone who may be responsible for programmatic planning, budgeting and mobilizing resources for diagnostic services will benefit from this document.

1.3 Rationale

TB preventive therapy for management of Latent TB infection is growing in importance both globally and regionally and has already shown to be effective in preventing TB among the People Living with HIV. It is aimed at stopping progression from infection to TB disease as these cases are the seedbeds of TB in the community. To end the TB burden, therefore, there is need to scale up high quality diagnostics and effective treatment options for the management of LTBI. This document has been developed in response to WHO recommendation for countries to scale up TB preventive therapies to all other at-risk populations and also to prioritize TB preventive measures at the national and county levels. This policy document focuses on providing guidance on TB prevention for at-risk populations, because people in such settings have a higher incidence of TB than the general population.

1.4 Target audience

The policy document targets all managers of the National TB and HIV control programs and other decision-makers (stakeholders including research organization, developing and implementing partners) who set priorities to address the specific requirements for scaling up LTBI control.

This document is also helpful for those responsible for TB and HIV control both at the National and County level such as representatives from the civil society, community-based and faith-based organizations and the health care workers in both private and public sectors.

1.5 Scope of the Policy

The policy describes a set of elements that will help to reduce transmission of TB in health-care facilities, congregate settings, and in households.

1.6 Principle of the LTBI Policy

The policy is based on the following principles: leadership and integrity, good governance, public participation and ownership, respect of human rights and social justice, sustainability of benefits, and advocacy.

1.7 Situation analysis

This guidance includes four key areas: target risk groups, diagnosis of LTBI, treatment of LTBI, and monitoring and evaluation process for programmatic management of LTBI.

1.8 Target Risk groups

1.8.1 TB Contacts

Recent TB contacts regardless of age (persons with recent exposure to persons with infectious pulmonary TB) are considered to be at risk of progression to active TB. Effective investigation of TB contacts within National TB control programs and other services can result in the detection of a significant number of cases.

Children who are contacts of bacteriologically confirmed TB patients are more at risk of TB infection and also at higher risk of progressing to active disease with the major risk of the TB being severe (disseminated TB, TB Meningitis and others) with consequently higher risk of death. The prevalence of TB disease among children who are close contacts of a TB case is high.

Additionally, systematic reviews conducted by WHO in 2014-2016 revealed that the prevalence of LTBI was also high among children and adolescents aged > 15 years and adults.

Early identification means a better chance of cure and a reduction in further transmission. Furthermore, Contact investigation allows identification of people who are latently infected and at high risk for active TB.

1.8.2 Health care workers- (Technical and non-technical personnel)

The risk of progression to active disease is also documented in health care settings where health care workers or non- health care workers in hospital settings come in contact with people who have TB disease. Periodic testing of health care workers is recommended as part of a TB Control Plan requirement by the National TB program. TB screening and testing should include anyone working or volunteering in health-care settings. Persons (health care workers and non- health care workers) who come in contact with or potential exposure to TB through shared air or space with infectious patient(s) should be part of a TB screening, testing and treatment program.

1.8.3 Prisoners

Prisons are well established breeding sites for tuberculosis and HIV infection, especially in settings where no preventive measures are in place and where illicit drug use and drug equipment sharing are common among prisoners. Routine monitoring and evaluation will be needed to assess the coverage of TB among prisoners. The prevention, diagnosis and treatment of LTBI among prisoners have not been well implemented in the past and require immediate attention. Open dialogue on policy in this area should be encouraged, and a coordinated program response from stakeholders working in prisons and in harm reduction, HIV infection, hepatitis and tuberculosis services should be sought. Prisoners should be provided with evidence-based, integrated tuberculosis/ HIV, hepatitis and harm reduction services that fully respect basic human rights.

1.8.4 Clinical risk groups

People living with HIV and other groups who have compromised immune systems face a high risk of poor outcomes from TB treatment, including relapse and death. The risk is augmented when diagnosis is delayed. Systematic identification, screening and diagnosis can be particularly beneficial for these groups. However, the first essential action is to ensure that diagnostic procedures are optimal among people actively seeking care.

1.8.4.1 Adults and adolescent living with HIV

The spread of HIV in the past has been accompanied by increase in the numbers of TB cases. In Kenya, the HIV co-infection rate among patients with TB was 26 % in 2019, which was a drop from 35% before the introduction of TB preventive therapy. TB remains the leading cause of mortality and morbidity among HIV infected individuals in the country as HIV infection weakens a person's immunity to TB. Therefore, the main focus of action and efforts need to be intense in recognizing the increasing proportion of TB cases in this group and preventive TB therapy should be offered to this group.

1.8.4.2 Infants and children living with HIV

Children with TB are likely to represent a large proportion of the pool of undetected TB, but the size of the proportion is uncertain. This is particularly the case for young children, who are more at risk of TB infection and also at higher risk of progressing to active disease with the major risk of the TB being severe (disseminated, TBM and others) with consequently higher risk of death. The prevalence of TB disease among children who are close contacts of a TB case is high.

Children who are HIV infected may be at increased risk of developing TB just like adults. The diagnosis of TB in HIV-infected children is more complex, as many HIV-related lung diseases can easily be confused with TB. It is possible that a significant proportion of HIV infected children with pulmonary disease and treated as TB do not in fact have TB. Therefore, identification and screening children who are contacts is already widely recommended by WHO.

1.8.4.3 Persons receiving immunosuppressant's

TB is one of the significant infections in immunosuppressed patients. Early diagnosis and treatment of TB is essential to prevent its progression and preventing its transmission. Similarly, the clinical expression of TB in immunosuppressed patients is conditioned by patient's degree of immunosuppression. Therefore, it's very important not to delay diagnosis in these patients. This group includes people preparing for dialysis, organ transplant, those on chemotherapy and those with silicosis.

1.9 Diagnosis of LTBI

The diagnosis of LTBI can be carried out with Tuberculin Skin Test (TST) and Interferon-Gamma Release Assays (IGRAs) which are the tests currently available for the diagnosis of LTBI. Either TST or IGRAs can be used to identify candidates for LTBI treatment. These tests will highly depend on the availability and affordability of the tests in different regions of the country.

1.10 Treatment of LTBI

Use of treatment regimens that are effective and promote adherence and enhance completion by different target groups is highly recommended. Latent TB Infections can effectively be treated in order to prevent progression to active TB, thus resulting in a substantial benefit for both the individual and the community. The selection of LTBI treatment regimen can be based on age and other comorbidities e.g. HIV and Hepatic conditions. Currently available treatment options recommended by WHO for the treatment of LTBI are;

- 6-month isoniazid daily (6H),
- 3-month rifapentine plus isoniazid weekly (3HP),
- 3-month isoniazid plus rifampicin daily(3RH),

3HP is the preferred treatment option for LTBI management in individual above 15 years of age in Kenya. However it is contraindicated for People living with HIV on Nevirapine and PI - based ARVs.

3RH is the preferred treatment option for LTBI management in children below the age of 15 years. However it is contraindicated for Children Living with HIV on PIs and Nevirapine based - ARVs

6H is the preferred treatment option for anyone with a contraindication to the above two regimens.

CHAPTER TWO:

POLICY DIRECTION

2.1 Policy statement

TB continues to affect vulnerable populations and requires a robust public health infrastructure to maintain adequate elimination and control measures. The national TB control Program mission is to ensure provision of quality care and prevention services for all people in Kenya with TB. This can be achieved by intensifying efforts to eliminate the reservoir of disease because many TB cases may originate from reactivation of infection. Success in achieving elimination will depend on a number of factors including adequate resource to allow state and local county health departments to maintain core public health activities (TB surveillance and contact investigations) while increasing targeted testing and treatment for LTBI by primary care providers.

2.2 Policy goal

The policy document has been developed in line with the national TB program's vision to reduce the burden of lung disease in Kenya and render Kenya free of tuberculosis and leprosy and also it is in line with the National Strategic Plan 2019 - 2023 vision to have a Kenya free of TB with a target of initiating 900,000 people at risk of TB on TB preventive treatment by 2023. The policy goal is, therefore, to prevent active TB, encourage treatment of Latent TB infection, effective engagement of and support for community-based providers, and policies that ensure universal access and reduce financial barriers to screening, testing, and treating TB infection in primary care.

2.3 Policy objective

The aim of the policy is to provide guidance on management of Latent TB Infections towards a common goal of eliminating TB by 2035 in healthcare facilities, households and in prisons and in Kenya at large.

CHAPTER THREE:

POLICY IMPLEMENTATION

3.1 Implementation approach

All entities that have a role in the implementation of this policy shall be expected to develop action plans for the realization of the objective of this policy.

3.2 Implementation

The coordination of implementation of the policy will be done through technical working group and national validation steering committee who shall act as a national link between the global and regional validation committees as well as domesticate international and national policy directions. They shall also strengthen national ownership coordination and harmonization among partners and stakeholders.

The Ministry of Health and technical working groups shall be ultimately responsible for providing platforms to inform programming and to develop guideline and standards required for implementation of this policy and shall facilitate any regulation required for successful implementation of this policy.

Both National and County Governments shall be expected to mobilize resources required for successful implementation of this policy through budget allocation. Other source of funding may include donors, grants or others sources directed to support the objective of this project

Human capacity development will be key component in the successful implementation of this policy and will involve all stakeholders. Diagnostic industry and other stakeholders in collaboration with government will play a key role in training health care workers. Development partners and others may also contribute to continuous training through CMEs and other form of training to all health care workers.

CHAPTER FOUR:

MONITORING AND EVALUATION

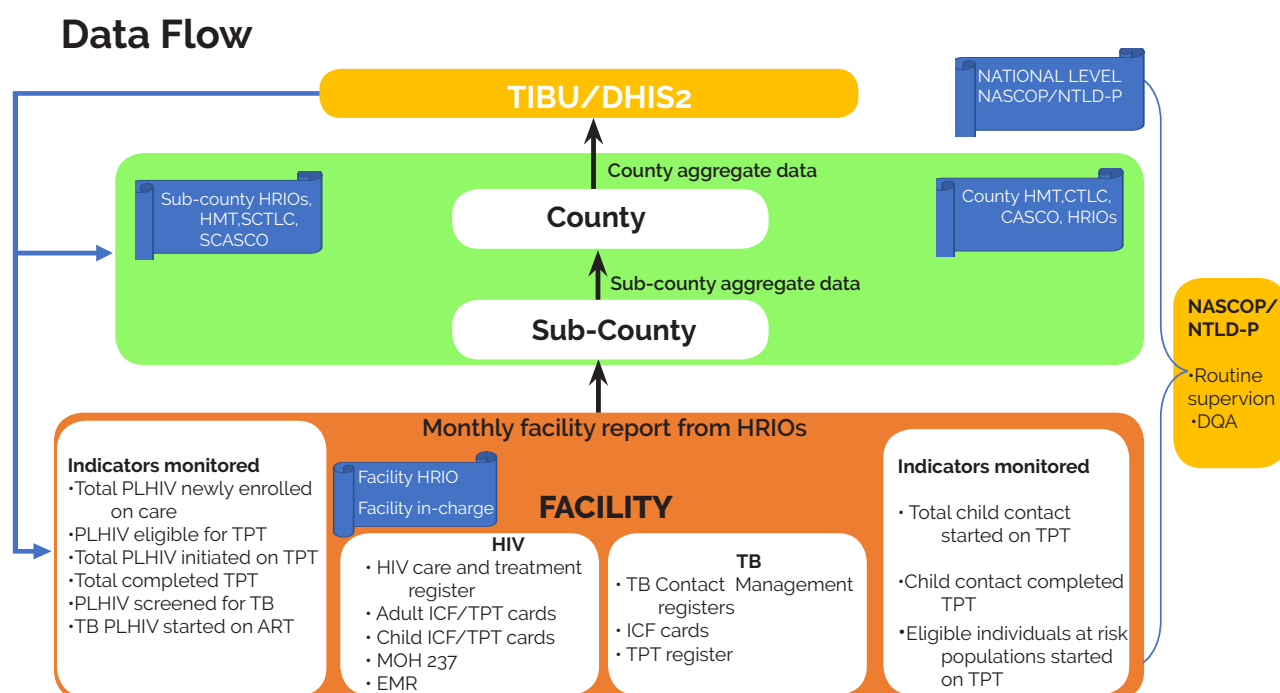
4.1 Monitoring and evaluation frame work

Policy statement: All people put on TB or LTBI treatment should be notified to the national authorities both in public, private and faith-based health facilities including prisons

Purpose: To guide effective documentation, reporting and evaluation of LTBI interventions in Kenya

Objective: To monitor and evaluate progress towards achievement of the policy implementation

Coverage Indicators	Outcome Indicators	Evaluation
Proportion of TB contacts who are eligible for TPT and have been put on treatment	Proportion of TB contacts who completed the course of TPT	Operation Research
Proportion of eligible people living with HIV, newly enrolled on HIV care and started on TPT	Proportion of eligible people living with HIV who completed the course of TPT	Periodic Reviews (Mid Term review of the strategic plan
Proportion of eligible individuals at-risk populations (HCWs, prisoners, on immunosuppressant therapy) who are started on TPT	Proportion of eligible individuals at-risk populations (HCWs, prisoners, on immunosuppressant therapy) who completed the course of TPT	



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