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MINISTRY OF HEALTH

NATIONAL TUBERCULOSIS, LEPROSY AND LUNG DISEASE PROGRAM

TUBERCULOSIS (TB) ISOLATION POLICY

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The Ministry of Health through the National Tuberculosis, Leprosy and Lung Disease Program (NTLD-P), continue to provide the necessary technical assistance as well as developing policy guidelines documents for TB prevention, treatment and care. As part of giving policy direction on treatment of patients who interrupt or refuse to take medication, the Ministry of health has developed TB isolation policy guidelines for admission of TB patients as part of promoting and protecting the human right and the dignity of the patients. The realization of development this document was due consorted effort of various stakeholders' contribution and determination to ensure that we end TB transmission emitting from those who refuse to take medication or interrupt the treatment.

The ministry of health through NTLD-P wishes to acknowledge the immerse contribution of various organization listed below and the entire writing team see the attached list. I take note of the following and appreciate their contributions.

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- And appreciate the TB isolation consultant

Thank you all.

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FOREWORD

Tuberculosis (TB) remains a major public health problem despite it being a preventable, treatable and curable disease. It remains the leading killer of people living with HIV. TB is a contagious airborne disease, and just like the common cold, it spreads through the air. Only people who are sick with active TB in their lungs (pulmonary TB) are infectious. When people with active pulmonary TB cough, sneeze, talk or spit, they propel TB germs, known as bacilli, into the air. A person who needs only to inhale a small number of these bacilli to be infected.

Apart from implementation of TB infection Prevention and Control measures, treatment of those with active TB of the lungs is key in preventing the spread of the TB bacilli. The Public Health Act CAP 242, section 17 classify TB as notifiable infectious disease and under section 26 as part of prevention and control of infectious diseases, those exposed or suffer from the notifiable infectious diseases should be isolated in designated place and detained while taking medication until in the assessment of the Medical officer of health confirm that the person is free from infection or able to be discharged without danger to public health. Previous the TB patients who refused to take medication by the order of the magistrates there being confined in prison while under taking their treatment. TB patients were being confined in prison and not in the health facilities.

The High Court of Kenya, however on 24th March 2016 annulled the detention in prisons of patients who default on anti-TB medication. Due to this, the court gave directive to the Ministry of Health to issue a circular on confining of infectious patients in health facilities other than prisons. In order to comply with this directive, the Tuberculosis Interagency Coordinating Committee (TBICC) appointed and mandated a taskforce to spearhead the development of TB isolation policy.

The taskforce developed the road map for the policy and clearly outlined the key milestones and deliverables required to realize development of isolation policy and its implementation. Among the activities which were undertaken included Key informant Interview (KII) with CECs, COH, CDHs, selected health care workers and Focused Group Discussions (FGDs) with the County Health management teams, TB patients, Prisoners and Prison wardens in the five selected Counties namely Nairobi, Nandi, Homabay, Mombasa & Kirinyaga.

The isolation policy outline the procedures to be followed in isolation and admission of TB patients who interrupt TB treatment and refusing to take anti-TB medicine. The TB isolation policy offered two type of isolation, voluntary and involuntary isolation. In both, the isolation of TB patient will follow the laid down procedures as well as promoting human right and protecting the dignity of the patient and also protecting the public from the infectious disease.

The isolation policy therefore is a milestone in TB prevention, treatment and care. Failure to adherence to anti TB medication, the patient will continue spreading tuberculosis among the healthy part of Kenya population. This TB isolation policy document will give the basis under which those who interrupt treatment (default) in taking anti-TB medication will be admitted in designated isolation rooms in the health facilities both public and private.

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TABLE OF CONTENT

1. BACKGROUND 6
   1.1. Introduction 6
   1.2. Justification for the policy development 7
   1.3. Broad objective 8
   1.4. Scope of policy 9
   1.5. Links to other policies 11
2. GOVERNANCE 12
   2.2 National Level 12
   2.3 Training Institutions and Regulatory Bodies 12
   2.4 County and Sub County Levels 12
   2.5 Health Care Facility 12
   2.6 Health Care Providers (HCP) 12
   2.7 Community and Community Representatives 13
3 APPLICATION OF TB IPC IN THE ISOLATION FACILITIES 14
   3.1 Principles of infection control measures 14
   3.2 Standard/specification/location of isolation rooms to be followed 14
4. MANAGEMENT AND CARE OF PATIENTS AT ISOLATION FACILITIES 17
   4.1 Isolation 17
   4.2 Transmission risk assessment 17
   4.3 Criteria for Isolation 17
   4.4 Patient Education/Counselling 18
   4.5 Nutritional services 18
   4.6 Clinical management 19
   4.7 Contact Tracing 19
   4.8 Visitors to Patients in Isolation 19
5. LEGAL REQUIREMENT, PATIENT RIGHTS AND RESPONSIBILITIES 20
   5.1 Legal and Policy framework 20
   5.2 International and regional legal and policy framework 20
   5.3 Domestic Legal and Policy Framework 21
   5.4 The Health Act 2017 23
   5.5 Justification for TB Isolation 24
   5.6 Patients' Rights And Responsibilities 25
6. REVIEW PLAN AND MONITORING AND EVALUATION FOR THIS POLICY DOCUMENT 29
7. ANNEXES 30
   7.1 Annex 1: Key Informant Interview and Focus group discussion guides 30
   7.2 Annex 2: Key Informant interview report 32
   7.3 Annex 3: Focus Group Discussion report 37
   7.4 Annex 4: Sample designs 41
   7.5 Annex 5: Sample designs 44
   7.6 Annex 6: MOH Circular 46

1. BACKGROUND

1.1. Introduction

Tuberculosis (TB) remains a major public health problem despite it being a preventable, treatable and curable disease. It remains the leading killer of people living with HIV. TB is a contagious airborne disease, and just like the common cold, it spreads through the air. Only people who are sick with active TB in their lungs (pulmonary TB) are infectious. When people with active pulmonary TB cough, sneeze, talk or spit, they propel TB germs, known as bacilli, into the air. A person needs only to inhale a small number of these bacilli to be infected.

TB is caused by a bacterium called *Mycobacterium tuberculosis* that can affect all parts of the body except teeth, hair and nails. TB is transmitted from one person to another through the air when a person with TB of the lungs coughs sneezes or sings. TB affects those with low body defense systems e.g. those suffering from chronic illnesses like diabetes, cancers or those living with HIV and amongst people who abuse drugs . TB attacks people of all age groups but mostly those aged between 15-49 years. However, TB of the lungs, i.e., pulmonary TB, is the most common form. The common symptoms of TB include persistent cough lasting for more than one week or more, loss of weight, fever, excessive night sweats, tiredness and loss of appetite.

The World Health Organization (WHO) estimates that 9 million people develop tuberculosis (TB) annually, a sixth of who die as a result. In 2014, this translated to 1.6 million deaths, of which more than 90% were in developing countries.

In 2016, Kenya reported 75,896 cases of all forms of TB with 8.7 % of all cases notified being children below 15 years of age. The case notification rate is 170/100,000 population. In the last 5 years, Kenya has reported an annual decline in the number of reported TB cases at a rate of 1%. There has been a general increase in the proportion of bacteriologically confirmed cases with the advent of increasing utilization of MTB/RIF assay (gene Xpert) testing in the country.

Drug-resistant TB (DR-TB) continues to be a major public health challenge in Kenya with an increasing case notification of different forms of drug resistance TB cases every year. Globally, it is estimated that 480,000 cases developed multidrug-resistant (MDR-TB) in 2014, i.e., TB that is resistant to first-line medicines isoniazid and rifampicin. This is approximately 5% of all TB cases. In 2016, a total of 445 DR TB cases were diagnosed and enrolled on treatment. Surveillance of DR TB has continued to be strengthened with the use of gene Xpert testing to diagnose tuberculosis and identify Rifampicin resistance.

In Kenya, TB is among the notifiable diseases under the public health Act cap 242. During the course of treatment about 5% of TB cases interrupt treatment, wherein a health care worker may seek the court's intervention to ensure that the patient complete their TB treatment.

A policy on isolation of persons suffering from infectious diseases is the last resort and will provide a framework within which persons with an infectious disease may be isolated in a manner that respects their human rights. Further, the policy would serve the public health purpose of protecting the public while using a patient-centered and rights-based approach to TB prevention, treatment and management. The policy will also guide health care workers to ensure that there is proper handling of TB patients. This policy will also properly guide the health care worker on instances where isolation would be recommended and the steps to take. This policy outlines the two models of isolation in Kenya: voluntary and involuntary.

Isolation should never be implemented as a form of punishment. Isolation should always be implemented in an ethical, non-discriminatory way that conforms to patients' human rights. Patients who decline treatment and who pose a risk to others should be made aware in advance that their continued refusal may result in compulsory isolation. An individual that is deemed to require isolation has the right to appeal the decision in an appropriate adjudicatory setting, including before an administrative, judicial or quasi-judicial body.

Patients who are in isolation should receive treatment and all the clinical and social supports necessary to minimize the burden of isolation in their lives to the greatest extent possible. If isolated patients refuse treatment, their informed refusal should be respected, as they no longer present a public health risk. Forcing these patients to undergo treatment would require a repeated invasion of bodily integrity, however, the right to health of other members of society cannot be ignored. The state has a responsibility to protect the public from unnecessary risks of contracting airborne diseases and thus must balance involuntary confinement of people lost-to-follow up with public health protection of the wider population.

1.2. Justification for the policy development

The High Court of Kenya on 24th March 2016 annulled the confinement of TB patients who interrupt their anti-TB medication in prison and declared that it is unlawful and unconstitutional, to confine TB patients in prisons. The court directed the Ministry of Health to take the following measures, which should be applied with immediate effect:

1. Confinement of patients suffering from infectious diseases for the purposes of treatment shall not be done in prison facilities.
2. Where despite all reasonable efforts, patients with infectious disease are unwilling or unable to comply with treatment; court orders may be sought to

compel isolation, confinement or detention as referred to in section 27 of the Public Health Act, CAP 242 or any other law in place at the time to address this issue.

3. The isolation can be done at a health facility in adherence to infection control measures and for the purpose of ensuring that patients adhere to the course of treatment for the public interest and their own interest.
4. The Ministry of Health in consultation with county governments, shall in due course issue further policy direction on the involuntary confinement of persons with TB and other infectious diseases.

WHO suggests that interfering with freedom of movement when instituting quarantine or isolation for a communicable disease such as TB could be legitimate, but involuntary isolation should only be used as a last resort. Countries have a responsibility to develop an isolation policy, which aligns with their constitution and international instruments on human rights law. In Kenya, 5% (2015) of the loss-to-follow up among drug susceptible is attributed to adherence issues. Treatment interruption is the cause of continuous TB transmission and results in increase in incidence of drug resistant TB cases. These challenges will be addressed in this policy. As such, it is essential that TB patients receive adequate information to ensure they understand the health implications of non-adherence, are aware of potential side effects of TB medication, and have adequate nutritional, psycho-social and other support to promote treatment adherence.

1.3. Broad objective

This policy document provides details of the standards required for isolation care of TB patients who interrupt their anti TB medicine or those patients who cannot be treated using ambulatory or community based models due to their infectious conditions and provide rationale for the use of isolation facilities. The policy includes guidelines on indication for isolation procedures and procedures for the infection control management of patients in isolation facility.

1.3.1. Specific objectives

The objectives of this policy are

1. To ensure the rights of TB patients are protected and to encourage their continuation of treatment in an appropriate medical setting.
2. To ensure that the spread of TB disease is contained by application of infection control measures
3. To outline the structural requirement of designing, renovating and constructing isolation facility

1.4. Scope of policy

The policy is based on the following core values; leadership and integrity; good governance; public participation and ownership; respect of human rights and social justice; sustainability of benefits; and advocacy. This is in line with the values and principles laid out in article 10 of the Constitution of Kenya 2010.

1.4.1. Purpose

The policy describes a set of elements that will guide the health management teams at National and County levels to provide an isolation facility for eligible TB patients. The policy will focus on activities at the health facility level and will be used as a reference to guide the design, renovation and construction of TB isolation facilities.

1.4.2. Financing

The TB isolation policy makes it clear that sustained political, institutional and financial commitment is crucial. This therefore necessitates that discussions on isolation should feature during development of various activities including but not limited to county work plans, strategic plans, public participation forums and development of county budgets.

1.4.3. Roles and responsibilities

- ***Ministry of Health officials*** – ensure active participation of all stakeholders in TB control during development of the policy, perform oversight role and facilitate implementation of the policy (Printing, dissemination, communication and advocacy, technical assistance, monitoring and evaluation and policy review).
- ***County Governments*** – these include County Health Management Team (CHMT), Sub County Health Management Team (SCHMT) and Health Management Team (HMT). Budgetary allocation for development and sustainability of isolation facilities, Document printing skilled staffing requirements, support supervision, monitoring and evaluation, human rights trainings and capacity building to ensure strict adherence to the policy.
- ***Stakeholders*** – These include Civil Society Organizations (CSOs), implementing partners, development partners, Community Based Organizations (CBOs), patients' groups, Faith Based Organizations (FBOs), and human right groups. They facilitate the implementation of the policy, dissemination, printing, support construction/renovation of isolation facilities, monitoring and evaluation, oversight role, advocacy and communication.
- ***Health facilities*** – These include HMT and health care workers. Their main role is on infrastructure or space for construction of isolation facilities; provide health services, strict adherence to treatment, resource mobilization. Collaboration with development partners is encouraged to support future review of the policies.

1.4.4. Phases of policy cycle

- Development of the policy- the policy will be developed by the collaborative efforts of Ministry of Health officials and all Stakeholders who are involved in

TB control. This will also entail communication and advocacy to create awareness on the existence and scope of the policy.

- Enforcement - The Ministry of Health and the County Governments are responsible for the enforcement of the TB policy.
- Implementation - Health care providers in close collaboration with the Health management teams (HMT, SCHMT, and CHMT) will be responsible for prompt identification of patients (according to the criteria for isolation) and instituting appropriate measures.
- Monitoring, evaluation and feedback - This will happen at all levels; hospital management, sub-county, county and national level.

1.4.5. Criteria for isolation of patients

A patient centred approach should be advocated for during the entire course of treatment. This can be complemented by the community where treatment supporters are roped in to assist the patient in drug adherence and provide holistic care (psychological, spiritual and social support).

Isolation for TB may be applied in the following situations, however in all cases voluntary isolation is preferable and patients should be counselled and given adequate information and support and community-based care should be attempted first:

- A known TB patient who has refused effective treatment and all reasonable measures (counselling, health education, community support) to ensure adherence have been attempted and proven unsuccessful
- A known TB patient who has agreed to ambulatory treatment but lacks the capacity to institute infection control at home. This includes TB patients who are infectious.
- A known TB patient who has other comorbidities and/or severe health condition that require in-patient care. This includes MTR TB, pre-XDR-TB and XDR-TB and drug users

1.4.6. Policy Review

The isolation policy will be reviewed every three years or earlier if there is law reform before then, by the isolation taskforce to assess progress, utilization and implementation of the policy. It will also incorporate best practices across different settings and build on new evidence. This process will be ratified by the TB ICC.

1.4.7. Structure of the policy

The details of this policy are presented in a number of chapters as follows: (i) Introduction (ii) Governance (iii) Principles: Application of isolation facilities (iv) Management and care of patients at Isolation facilities (v) Legal requirements, patient rights/responsibility and statutory notification (vi) Review plan for the policy document and annexes are attached to this policy.

1.5. Links to other policies

The policy will be hinged on existing policies such as:

- National TB treatment guideline
- DR-TB guidelines
- National TB IPC policy – the three principles of infection control will be the backbone of designing the isolation facilities
- Public Health Act Cap 242: which was established as an act of parliament to make provision for securing and maintaining health and explicitly section 27 focuses on isolation of persons who have been exposed to infection. This section however lacks clear grounds that isolation should be enforced and does not provide guidance on the next steps.
- Bill of Rights which is enshrined in the constitution of Kenya which outlines the human rights whose purpose is to preserve dignity of individuals and communities and to promote social justice
- Ethics guidance for the implementation of END TB strategy – defines the ethically acceptable circumstances when TB patients should be confined
- Health Act 2017
- The Patients' Charter for TB Care

2. GOVERNANCE

2.1 Responsibility and Authority in Isolation

There are various levels of responsibility and authority for IPC and isolation in health care facilities and settings.

2.2 National Level

At the national level, the Ministry of Health has the ultimate responsibility and authority for ensuring the availability, dissemination and use of IPC and Isolation policies and guidelines. The National Infection Prevention and Control Committee (NIPCC) within the Ministry of health in collaboration with relevant departments and stakeholders shall be responsible for monitoring, reviewing, and updating the IPC and isolation guidelines.

2.3 Training Institutions and Regulatory Bodies

Training institutions and regulatory bodies, such as the Medical and Dental Practitioners Board, the Nursing Council, the Clinical Officers Council, and other Allied Health Professional regulatory bodies, are responsible for ensuring that each respective pre- and in-service curriculum reflects adequate and appropriate content on IPC.

2.4 County and Sub County Levels

The County and Sub-county health management teams (C/SCHMTs) shall be responsible for monitoring the facilities under their control for use of and compliance with Isolation practices. The CHMT is also responsible for ensuring that adequate and appropriate resources are available for support of IPC and Isolation practices within these facilities. In coordination with the community representatives, the county and sub-county levels should raise awareness in the communities about the isolation policy.

2.5 Health Care Facility

At the individual health care facility level, the implementation of Isolation is linked to the general IPC and TB IPC guidelines initiatives. The Facility IPC Committee through the leadership of the IPC focal person should monitor, coordinate, and evaluate its implementation. The IPC Focal person should ensure: adequate supply of IPC equipment and commodities, on-the-job training of other HCWs in the health care facility, Monitoring IPC practices and reporting IPC activities to the Sub-County.

2.6 Health Care Providers (HCP)

Each HCP at the individual level is responsible and accountable for effective and efficient implementation of the IPC and Isolation policies and guidelines at all times in her/ his duty station. Health care providers should collaborate in the timely and

appropriate application of isolation. Nursing personnel should be responsible for the following:

- Informing the patient's clinician when a patient's condition warrants isolation
- Verifying the clinician's order to institute isolation
- Explaining procedures and the need for isolation to the patient and family
- Preparing a well-ventilated room or area for isolation with all the necessary equipment
- Notifying the IPC lead person of the patient in isolation within 24 hours of the suspicion or confirmation of an infectious disease
- Displaying a STOP sign clearly in the patient's isolation area
- The clinician is the one responsible for instituting isolation. In the absence of a clinician, the nurse-in-charge institutes isolation

2.7 Community and Community Representatives

Individual members of communities have a responsibility for complying with IPC practices and TB community dialogues at the community level. Community representatives should collaborate with relevant departments to enhance compliance through identification and referral of patients in need of isolation.

3 APPLICATION OF TB IPC IN THE ISOLATION FACILITIES

3.1 Principles of infection control measures

The World Health Organization defines Tuberculosis infection prevention and control (IPC) as a combination of measures aimed at minimizing the risk of TB transmission within populations. There are three levels of TB infection control measures:

1. Administrative (Managerial) control measures
2. Environmental control measures
3. Personal protective equipment (respiratory protection)

Administrative control measures are the most important among the three levels. Environmental control measures and personal protective equipment (respiratory protection) will not work in the absence of solid administrative controls.

3.1.1. Administrative control measures

It is the managerial or work practices (e.g., early diagnosis, prompt separation of presumptive TB patients, prompt initiation of appropriate anti-tuberculosis treatment and diagnosis to minimize aerosol-generating procedures) to significantly reduce the risk of TB transmission by preventing the generation of and limiting exposure to droplet nuclei.

3.1.2. Environmental Control Measures

Environmental control measures refer to the use of engineering technologies to help prevent and reduce the concentration of infectious droplet nuclei in the air.
The following are the four main principles of environmental control measures

1. Dilution (e.g. Ventilation systems)
2. Filtration (e.g. HEPA filters)
3. Purification (e.g. UVGI Systems)
4. Disinfection (e.g. chemical, thermal.)

3.1.3. Personal Protective Equipment (PPE)

PPE includes surgical mask for the patients and respirators (N95) for visitors and health care workers. Gowns are provided for health care workers who manage the patient.

3.2 Standard/specification/location of isolation rooms to be followed

There are two types of isolation rooms both classified as AIA-Airborne infection Isolation room; 1) Atmospheric type-naturally ventilated and 2) Negative pressure isolation room-mechanically ventilated.

3.2.1 Standard

The structural standards are from NUFURT Architectural data
General configuration

1. single patient rooms without ante room-not self-contained (recommended size 12 m squared)

2. single patient room with ante room-self-contained (recommended size13 M square)
3. single patient room with ante room- has assisted bath (22m square)

Room Fittings and finishes

1. Medical Wash hand basin recommended
2. Medical gases, Oxygen and vacuum
3. Recommended non-porous glazed floor for ease of cleaning and decontamination
4. Walls smooth and non-porous for ease of cleaning and decontamination
5. Recommended ceilings should be non-porous to avoid fungal growth
6. Recommended windows should be double glazed for temperature and noise control
7. Recommended to use antifungal and antibacterial paints

Ventilation

Ventilation recommended should be of 12 air changes per hour (ACH) or better
The standard is ASHRAE/CDC/OSHA-American Standards for heat refrigeration and air-conditioning

Negative Pressure Isolation Rooms

a) Air Flow Volume differentials -minimum requirement is 50 CFM/cubic feet per minute or 10% of supply air whichever is the greater
b) Negative pressure differentials - 0.001"/inches of water gauge
c) Negative pressure monitoring should be continuous
d) Ante room pressurization to be positive to Isolation room
e) Ante room ventilation at least 10 ACH
f) Minimum air velocity under the door is 100FPM/feet per minute
g) Air distribution- recommended supply from ceiling (clean air) and exhausted near the floor the floor (dirt air)
h) Exhaust discharge is recommended to be on roof 25ft from air supplies and openings or to be HEPA filtered
    - HEPA filters are recommended for both supply and exhaust

3.2.2 Specification

3.2.3 Location

i. Atmospheric type-naturally ventilated
    - Should be standalone-detached from the other buildings
    - Distance between the isolation rooms from the neighbouring structure should be not less than the height of the tallest neighbouring structure
    - Openable windows not less than 20% of floor area
    - Openable windows should be aligned to the prevailing wind flow

ii. Negative pressure isolation room-mechanically ventilated

- Can be located in any part of the facility
- key thing is patient flow patterns are put in place to avoid cross infections, nosocomial transmission including to HCW and visitors and overcrowding and assisting segregation of patients.

iii. Standards for Ultraviolet germicidal irradiation (UVGI) fittings

UVGI is recommended for both natural and mechanical ventilated but not to replace ventilation

- Upper Room UVGI
  - ✓ To be fitted at least not less than 12 ft from the floor
  - ✓ Ceiling to have special paint non-reflective to UVGI (reflectivity <10%)
  - ✓ Air humidity <65%
  - ✓ UVGI fittings to have parabolic mirrors or shields to avoid scattering
  - ✓ UVGI lamp fittings to have OZONE filter at 185 nanometres
  - ✓ The lamp to produce 254 nanometre UVC intensities approximately 50 microwatts per centimetre square at one metre
- Lower Room UVGI
  - ✓ To be fitted not more than 2 feet from floor level
  - ✓ All the above apply except for the paint
- Induct UVGI
  - ✓ Recommended for both supply and exhaust
  - ✓ To be the unshielded type

Note: Adequate safety notices to be placed at appropriate places

4. MANAGEMENT AND CARE OF PATIENTS AT ISOLATION FACILITIES

4.1 Isolation

Isolation is the creation of a barrier—mechanical or spatial—to prevent the transmission of infectious diseases to or from a patient and to reduce the risk of transmission to other patients, HCWs, and visitors. Isolation is used to prevent the transmission of infectious diseases that are spread by both contact and airborne routes.

Types of Isolation

Protective Isolation (reverse barrier nursing)*:* This is where the patient requires protection i.e. they are immunocompromised

Source isolation: This is designed to prevent the spread of pathogens from an infected patient to other patients, hospital personnel and visitors. The need for isolation is determined by the way the organism or disease is transmitted. Examples of organisms requiring source isolation includes Pulmonary Tuberculosis, Certain specific organisms will require negative pressure side rooms or specialized care from the Infectious Disease Unit i.e. Drug resistant pulmonary tuberculosis.

4.2 Transmission risk assessment

Risk assessment is the assessment of the factors that influence the transmission of a pathogen and its impact. It enables staff to prioritize the use of isolation facilities

4.3 Criteria for Isolation

The use of isolation should be strictly limited to the infectious period; once patients are on effective treatment and are no longer infectious, there is no need for isolation. Before isolation is sort, all other means including community based interventions should be utilized first.

Patients who qualify for isolation include the following;

a) Involuntary

In rare circumstances, efforts to persuade and enable patients to accept voluntary isolation may fail. If this is the case, based on WHO ethical guidelines, involuntary isolation may be considered where ALL of the following conditions are met including:

I. Isolation is necessary to prevent the spread of TB AND
II. There is evidence that isolation is likely to be effective in this case AND
III. The patient refuses to remain in isolation despite being adequately informed of the risks, the meaning of being isolated, and the reasons for isolation AND
IV. The patient's refusal puts others at risk AND
V. All less restrictive measures have been attempted prior to forcing isolation, AND

VI. all other rights and freedoms (such as basic civil liberties) besides that of movement are protected AND
VII. Due process and all relevant appeal mechanisms are in place AND
VIII. Patient has, at least, basic needs met AND
IX. The isolation time given is the minimum necessary to achieve its goals AND

If the nine listed conditions are met, the following groups of patients may be isolated involuntarily:

- Non-adherence patient despite counselling intervention
- Uncontrolled mental illness without family support
- Religious faith who don't take medications

b) Voluntary Isolation based on medical/social conditions

- Patients with multiple comorbidities who require specialized inpatient care
- Patient with adverse drug reaction from TB treatment who require specialized care
- Homeless (Street populations)
- Inmates with pulmonary TB
- Patients without social support
- Extensively and Total drug resistance TB patients

4.4 Patient Education/Counselling

All TB patients and caregivers should receive focused education about TB care and prevention to empower them to succeed in management of the infection. Self-management is critical to the successful treatment of TB. Key messages for TB education and adherence counselling are described below;

- Patient and caregiver must be adequately informed on the rationale for isolation
- Patient rights and responsibilities
- Infection Prevention Control (IPC) practices
- Treatment adherence counselling
- The detail of Adverse Drug Reactions (ADRs) and what actions to take if they encounter.
- Psychological and wellbeing of patient should be evaluated daily
- Family counselling is important for the patients to successfully complete the treatment

4.5 Nutritional services

All Patients admitted in Isolation facility should be assessed for nutritional needs, counselling provided and appropriate interventions given.

4.6 Clinical management

All TB patients placed in isolation should be managed in line with the National treatment guidelines. DOTS should be provided by the Health Care providers. Systems should be in place to ensure prompt identification and reporting of ADRs as per laid down Pharmacovigilance procedures. The isolation facility will be linked to the TB clinic for notification and follow up of patients. Patients requiring other disease condition management for example HIV and other conditions may benefit from treatment in the isolation wards.

4.7 Contact Tracing

All efforts should be made to identify and screen all contacts for TB if contact tracing was not done. All identified contacts must be recorded in the facility TB contacts register. The following contact will be initiated on Isoniazid Preventive Therapy (IPT); Children under 5 years screening negative for TB irrespective of HIV status.

4.8 Visitors to Patients in Isolation

Classification of Patients;

a. Infectious patients - No visitors will be allowed.
b. Non- infectious patients - one visitor at a time. Maximum visitation is one hour.

The following rules and guidelines apply to visitors of patients in isolation:

- Visitors must report to the Health care provider (HCP)-in-charge prior to entering the isolation area
- Only one person at a time is allowed to visit for one hour and only during visiting hours
- Where applicable, the visitor can meet the patient in a designated open area
- Visitors must wear PPE (N95 respirators)

5. LEGAL REQUIREMENT, PATIENT RIGHTS AND RESPONSIBILITIES

5.1 Legal and Policy framework

An increasing amount of evidence suggests that individual vulnerability to TB is determined by risk factors that are often related to a person's social and economic position. This association has led some commentators to label TB as "traditionally a disease of the poor."

TB is associated with being malnourished, smoking, alcohol abuse, exposure to indoor air pollution, and living or working in crowded and poorly ventilated conditions. TB prevalence is also high among individuals confined in prisons. There is considerable evidence that people in lower socioeconomic groups are, on average, more likely to possess these risk factors or determinants, including those living in developed countries. Consequently, although context-specific differences may exist, overall, TB is more common in developing countries, where poverty, poor housing conditions, and indoor air pollution are more frequent, and expenditure on health is low.

Incarceration and detention approaches to patients who interrupt their treatment curtail the rights to health, informed consent, privacy, and freedom from non-consensual treatment, freedom from inhumane and degrading treatment, and freedom of movement of people lost to follow-up. Detention could also worsen social inequalities and lead to a paradoxical increase in TB incidence.

The solution is incorporation of less intrusive solutions in legislation and policies. These include strengthening health systems to reduce dependency on prisons as isolation spaces, decentralizing TB treatment to communities, enhancing treatment education, Community education and dialogues, implementing infection prevention and control measures and addressing socioeconomic and structural determinants associated with TB incidence and loss to follow-up.

On 24 March 2016, the High Court declared that the practice of confining TB patients in prisons for purposes of treatment is unconstitutional. Justice Mumbi Ngugi, in a judgment delivered on the said date, ruled that such incarceration of TB patients is unlawful, unconstitutional and a violation of their fundamental human rights. The court ordered an immediate stop to this practice.

The court therefore ordered the Cabinet Secretary for Health to develop a policy on the involuntary confinement of individuals with tuberculosis that is compliant with the Constitution and that incorporates principles from the international guidance on the involuntary confinement of individuals with TB. The judgment has set precedence in the region, setting stage for the first judicial interpretation on involuntary confinement of TB patients.

5.2 International and regional legal and policy framework

TB 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. By virtue of Article 2 (6) of the Constitution of Kenya, 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.

5.3 Domestic Legal and Policy Framework

5.3.1 The Constitution of Kenya

The Constitution is the supreme law of the Republic and binds all persons and all State organs at both levels of government. It sets out the standards that all laws, policies, guidelines, operational standards and programs must conform with.

The Constitution of Kenya has an expansive and progressive Bill of Rights that sets out the stage for the promotion and protection of the rights of all persons, including persons with TB.

5.3.2 Importance of Bill of Rights

The importance of the bill of rights cannot be understated. 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.* The rights and fundamental freedoms in the Bill of Rights further belong to each individual and are not granted by the State.

Some of the relevant rights, as contained in various international legislative instruments, that closely affect the TB response, and should be relied upon in the protection of TB patients, include:

(i) Right to Life: The argument is that people with TB have the right to access lifesaving diagnostics and treatment.

In the event that such treatment is denied then the right to life is threatened. In Kenya, the practice of incarceration of TB patients (that was declared unconstitutional and unlawful) potentially infringed on this right where the required medical attention is not given while in prison. The right to life is defined internationally by the International Covenant on Civil and Political Rights (ICCPR) (Article 6(1).

(ii) Right to the highest attainable standard of health: People with TB have the right to enjoy the highest attainable standard of health encompassing availability, acceptability, accessibility and quality of diagnostics and treatment. The right imposes an obligation on governments to prevent, treat, and control epidemic, endemic, occupational and other diseases.

It is defined by Article 12(1) of International Covenant on Economic, Social and Cultural Rights (ICESCR).

(iii) Right to Non-Discrimination and Equality: This right provides a framework for equal protection before the law.

Therefore, this right protects persons with TB from discrimination in both public and private settings, including but not limited to, health care, employment, education and access to social and religious services. This may also be relied upon to address the issues of stigma and discrimination.

It is defined by International Covenant on Civil and Political Rights ICCPR (Article 26), Convention on the Rights of People with Disabilities (CRPD) (Article 5(2)), and International Convention on the Elimination of All Forms of Racial Discrimination (ICERD) (Article 5(e)(iv))

(iv) Right to privacy: This is critical in the protection of information related to an individual's TB status, and privacy in treatment of TB patients. The right is exercised considering a delicate balance of individual rights versus protection of the public interest.

(v) Right to be free from torture or cruel, inhuman or degrading treatment or punishment: This right is specifically relevant for persons with TB in an institutional setting such as hospital, prison or isolation facility and would be relied upon to ensure there is appropriate TB testing, treatment, and good sanitary and hygienic conditions. It is defined by the Convention against Torture and other Cruel, Inhuman or Degrading Treatment or Punishment CAT (Article 16(1)).

(vi) Right to informed consent: (verbal and/or written) prior to treatment of persons, including those with TB, and to be free from non-consensual, compulsory treatment under all circumstances.

(vii) Right to freedom of movement: that would protect people with TB from travel restrictions within and outside their countries. It is provided for by Article 12 of ICCPR.

(viii) Right to information: that would guarantee persons with TB the right to access information about the nature of the disease, preventive measures, transmission and treatment. This is as provided by ICCPR Art. 19(2); and **WHO Guidance on Ethics of TB prevention, care and control**

(ix) Right to freedom from arbitrary arrest and detention: that is relied upon to protect persons with TB against arbitrary detention or involuntary isolation unless as provided by law – and respecting the Siracusa Principles. The United Nations Economic and Social Council has issued Principles on the Limitation and Derogation.

Provisions in the International Covenant on Civil and Political Rights (the Siracusa Principles), which are the leading international framework for determining whether involuntary confinement for public health purposes is justified under the International Covenant on Civil and Political Rights (to which Kenya is a State Party). They provide that involuntary confinement for public health purposes will be legitimate only where:

(a) The restriction is provided for and carried out in accordance with the law

(b) The restriction is in the interest of a legitimate objective of general interest

(c) The restriction is strictly necessary in a democratic society to achieve the objective

(d) There are no less intrusive and restrictive means available to reach the same objective, and

(e) The restriction is based on scientific evidence and not drafted or imposed arbitrarily or in an unreasonable or otherwise discriminatory manner.

The African Charter on Human and Peoples' Rights is important at the regional level. Article 16 of the African Charter on Human and Peoples' Rights provides:

a) Every individual shall have the right to enjoy the best attainable state of physical and mental health
b) State Parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick

5.4 The Health Act 2017

The Health Act 2017 was enacted primarily to align the health sector to the Constitution. The Act aims to:

- Establish a national health system that facilitates a progressive and equitable manner the highest attainable standard of health services
- Protect, respect, promote and fulfil the health rights of all persons in Kenya including rights of children to basic nutrition and health care services, and rights of vulnerable groups as defined in Article 21(3) of the Constitution

The Act is important in the TB response as it affirms the Constitutional duty of the State to observe, respect, protect, promote and fulfil the right to the highest attainable standard of health. The Act further provides that the right to heath includes:

(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

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 Health Care Workers in the TB response. The affirmation of the rights in this Act makes it fairly progressive.

5.5 Justification for TB Isolation

A summary of ethical guidance on TB isolation is provided in the World Health Organization (WHO) Ethics Guidance for the Implementation of the End TB Strategy, which is fully aligned with that of the framework for the Sustainable Development Goals (SDGs).

The TB isolation policy ensures that the implementation adheres to ethical and legal standards that protect the rights of all infected and non-infected individuals. The state has a legal and ethical obligation to ensure that non-infected and infected persons living with TB are only involuntarily isolated when all other treatment and voluntary isolation efforts have been exhausted. Involuntary isolation shall not become a routine part of TB programmes and will be used when interests of the public justify efforts to isolate the patient involuntarily.

The policy is transparent in explanation of when and how involuntary isolation is allowed. Involuntary isolation should be limited and programs that encounter frequent refusals of treatment or significant treatment adherence issues should review and evaluate its implementation and application of a patient-centred approach in an effort to avoid involuntary isolation of patients.

The following are guidelines for implementation in policy concerning prevention and justification of TB isolation:

5.5.1 It is ethical to ask persons with active TB to voluntary isolate themselves.

The least restrictive isolation measures should be taken at all times. Basic respiratory, voluntary isolation measures include asking a patient with active TB to wear a mask, to remain at home or in the hospital when contagious with active TB.

5.5.2 Isolation of TB patients is necessary only after all measures have been exhausted.

The Harm principle states that all persons are free to act as they choose as long it does not affect another non-consenting person, the principle also justifies involuntary isolation. This policy includes conditions necessary to justify involuntary isolation. Conditions that must be met before involuntary isolation include:

a. Isolation is necessary to prevent the spread of TB
b. Evidence supports isolation will be effective
c. Patient refuses to remain in voluntary isolation despite being informed of risks, the reasons and meaning for isolation
d. Patients refusal to be in isolated places and puts others and the public at risk
e. Less restrictive measures have been attempted before forcing isolation
f. Rights and freedoms, besides movement, are protected
g. Due process and relevant appeal mechanisms are in place

h. Patient has the basic needs met
i. Isolation time given is the minimum needed to achieve goals

5.5.3 The state must protect the rights and interests of any persons with TB who are subject to voluntary or involuntary isolation.

Their dignity and respect should be ensured, and they should receive all necessary clinical and social support to minimize burdens due to isolation. Patients who refuse treatment, must be made aware, in advance, that continued refusal may result in compulsory isolation. National policy shall contain safeguards for implementing involuntary isolation. Involuntary isolation shall be a last resort and applied within a medical setting in a least restrictive manner. The right to an appeal in a judicatory setting shall be provided.

5.5.4 The state must prevent the unethical isolation of persons with TB.

It is unethical to isolate if:

- The individual is not infectious
- Isolation does not provide clear medical benefits
- Isolation of individuals where treatment is inaccessible or unavailable, efficient infection control measures and humane living conditions (shelter, sanitation, food water or communication) are not met
- Involuntary detention in a non-medical setting, like a prison cell or general prison population is also unethical
- Isolation is being implemented as a form of punishment

It is also unethical to compel treatment of involuntary isolated patients. Patients shall still be offered opportunity to receive treatments, but their informed refusal shall be respected. However, efforts to convince the patient to engage in treatment should not be abandoned.

5.6 Patients' Rights And Responsibilities

5.6.1 The Patients' Charter for TB Care (2006)

The Patients' Charter, was informed by the need for patients in Kenya to be aware of their rights and responsibilities. It enumerates the rights of patients, including, the right to access health care, the highest attainable standard of health services, the right to information, right to informed consent, and right to confidentiality, among others.

It provides guidance on rights and responsibilities of patients and would be critical in expounding on Constitutional rights. It is useful in protection of the rights of TB patients in a health care setting as most of the rights contained therein are in line with the Constitution and International Framework.

According to The International Standards for TB Care (ISTC) also known as the Patients' charter the patients' have the following rights.

5.6.1.1 The right to care

- The right to free and equitable access to tuberculosis care, from diagnosis through treatment completion, regardless of resources, race, gender, age, language, legal status, religious beliefs, sexual orientation, culture, or having another illness
- The right to receive medical advice and treatment which fully meets the new International Standards for Tuberculosis care, focused on patient needs, including those with multidrug-resistant tuberculosis (MDR-TB) or tuberculosis-human immunodeficiency virus (HIV) coinfections and preventative treatment for young children and others considered to be at high risk
- The right to benefit from proactive health sector community outreach, education, and prevention campaigns as part of comprehensive care programs

5.6.1.2 The right to dignity

- The right to be treated with respect and dignity, including the delivery of services without stigma, prejudice, or discrimination by health providers and authorities
- The right to quality healthcare in a dignified environment, with moral support from family, friends, and the community

5.6.1.3 The right to information

- The right to information about what healthcare services are available for tuberculosis and what responsibilities, engagements, and direct or indirect costs are involved
- The right to receive a timely, concise, and clear description of the medical condition, with diagnosis, prognosis (an opinion as to the likely future course of the illness), and treatment proposed, with communication of common risks and appropriate alternatives
- The right to know the names and dosages of any medication or intervention to be prescribed, its normal actions and potential side-effects, and its possible impact on other conditions or treatments
- The right of access to medical information which relates to the patient's condition and treatment and to a copy of the medical record if requested by the patient or a person authorized by the patient
- The right to meet, share experiences with peers and other patients and to voluntary counselling at any time from diagnosis through treatment completion

5.6.1.4 The right to choice

- The right to a second medical opinion, with access to previous medical records
- The right to accept or refuse surgical interventions if chemotherapy is possible and to be informed of the likely medical and statutory consequences within the context of a communicable disease
- The right to choose whether or not to take part in research programs without compromising care

5.6.1.5 The right to confidence

- The right to have personal privacy, dignity, religious beliefs, and culture respected
- The right to have information relating to the medical condition kept confidential and released to other authorities contingent upon the patient's consent

5.6.1.6 The right to justice

- The right to make a complaint through channels provided for this purpose by the health authority and to have any complaint dealt with promptly and fairly
- The right to appeal to a higher authority if the above is not respected and to be informed in writing of the outcome

5.6.1.7 The right to organization

- The right to join, or to establish, organizations of people with or affected by tuberculosis and to seek support for the development of these clubs and community-based associations through the health providers, authorities, and civil society
- The right to participate as "stakeholders" in the development, implementation, monitoring, and evaluation of tuberculosis policies and programs with local, national, and international health authorities.

5.6.1.8 The right to security

- The right to job security after diagnosis or appropriate rehabilitation upon completion of treatment
- The right to nutritional security or food supplements if needed to meet treatment requirements

5.6.1.9 Patients' Responsibilities

A patient has the responsibility to:

a) Share Information

- The responsibility to provide the healthcare giver as much information as possible about present health, past illnesses, any allergies, and any other relevant details
- The responsibility to provide information to the health provider about contacts with immediate family, friends, and others who may be vulnerable to tuberculosis or may have been infected by contact

b) Follow Treatment

- The responsibility to follow the prescribed and agreed treatment plan and to conscientiously comply with the instructions given to protect the patient's health, and that of others
- The responsibility to inform the health provider of any difficulties or problems with following treatment or if any part of the treatment is not clearly understood

c) Contribute to Community Health

- The responsibility to contribute to community well-being by encouraging others to seek medical advice if they exhibit the symptoms of tuberculosis
- The responsibility to show consideration for the rights of other patients and healthcare providers, understanding that this is the dignified basis and respectful foundation of the tuberculosis community

d) Show Solidarity

- The moral responsibility of showing solidarity with other patients, marching together towards cure
- The moral responsibility to share information and knowledge gained during treatment and to pass this expertise to others in the community, making empowerment contagious
- The moral responsibility to join in efforts to make the community tuberculosis free.

6. REVIEW PLAN AND MONITORING AND EVALUATION FOR THIS POLICY DOCUMENT

The isolation policy will be reviewed every three years or earlier as need be, by the isolation taskforce to assess progress, utilization and implementation of the policy. It will also incorporate best practices across different settings and build on new evidence. This process will as mentioned will be ratified by the TB ICC.

Periodical monitoring and evaluation of the implementation shall be undertaken by all interested parties and the findings shall be presented to TB isolation task force and TB ICC ratification and onwards transmission to County government.

7. ANNEXES

7.1 Annex 1: Key Informant Interview and Focus group discussion guides

NATIONAL TUBERCULOSIS, LEPROSY AND LUNG DISEASE PROGRAM
TUBERCULOSIS (TB) ISOLATION POLICY
KEY INFORMANT INTERVIEW GUIDE

Introduction

The National TB Program is currently developing the TB isolation policy. The TB program is interviewing Key Stakeholders to collect their views on the isolation policy. The following key informants will be interviewed:

- ✓ County officials-Chief Officer for Health (COH), County Director for Health (CDH), /County Executive Committee Member for Health (CEC)
- ✓ Planning-CEC, COH, CDH
- ✓ Patients with adherence issues
- ✓ TB ambassadors- former patient
- ✓ Prison commandant
- ✓ International Organization of Migration (IOM)
- ✓ MSF France

Please allow us to ask you a few questions

1.	**In your view, do you think TB is a public health problem? And why?** **Probe:** do you think the problem is because of its mode of transmission or identification of signs and symptoms for TB or both? Please explain
2.	**What is your understanding of isolation in the context of TB?** **Probe 1:** in your view are there different types of isolation? **Probe 2:** is TB isolation feasible in Kenya? Please explain
3.	**Have you heard about the court ruling on TB isolation that occurred on 24th march 2016?** **Probe:** please expound on your understanding of the ruling
4.	**In view of the court ruling what are your thoughts on creating isolation facilities?** **Probe 1:** what do you think of the isolation policy that is being created? **Probe 2:** would you be willing to include isolation facilities in future plans and how? **Probe 3:** are there plans now, to create isolation facilities?
5.	**As a patient, or healthcare worker what would be the ideal conditions for an isolation ward?** **Probe 1:** what do you think about the duration of visitation? **Probe 2:** what do you think about the distance from other health facilities/wards etc **Probe 3:** what else can be done to improve the environment?
6.	**What do you think of the isolation policy that is being created?** **Probe 1:** in your view, what kind of patients should be eligible for isolation? **Probe 2:** how will the rights of those patients who get isolated be protected **Probe 3:** what practical and ethical ways can be implemented in your setting- county/health facility - to provide isolation for TB patients for both voluntary and in-voluntary isolation?
7.	**What do you think are the benefits of isolation?**
8.	**What do you foresee as the challenges of isolation** **Probe:** what are the possible solutions to these challenges?
END	

NATIONAL TUBERCULOSIS, LEPROSY AND LUNG DISEASE PROGRAM
TUBERCULOSIS (TB) ISOLATION POLICY
FOCUS GROUPS (FGDS) INTERVIEW GUIDE

Introduction

The National TB Program is currently developing the TB isolation policy. The TB program is interviewing Key Stakeholders in a form of focus group discussion (FGD) to collect their views on the isolation policy. The following will be the stakeholders who will form the FGD groups:

- ✓ Heath care workers – doctors, nurses, clinicians, PHOs
- ✓ Patients: TB and DR TB patients
- ✓ Prisoners
- ✓ Community Units

The following counties will participate in the FGDs. The criteria for selecting counties was based on High TB burden, high rates of detention in prisons, low adherence levels, high treatment interrupters, High TB/HIV burden, presence of isolation facility and the county where the court ruling took place.

- ✓ Homabay: Community units and DR TB patients
- ✓ Mombasa: Community units and prisoners
- ✓ Kirinyaga: healthcare workers and DS TB patients
- ✓ Nandi: Prisoners and Healthcare workers
- ✓ Nairobi: DR TB patients and DS TB patients

Please allow us to ask you a few questions

1.	**What do you think about TB care that is offered by the ministry of health** **Probe 1:** what is your view on the duration of treatment? **Probe 2:** what is your view on prevention measures in relation to the mode of transmission of TB? **Probe 3:** can the community play a role? Please explain
2.	**Taking TB medication as required can be difficult. What are some of the challenges that make adhering to TB medication difficult?** **Probe:** what practical ways do you suggest to keep TB patients adherent on treatment?
3.	**Have you heard about the court ruling on TB isolation that occurred on 24th march 2016?** **Probe 1:** please expound on your understanding of the ruling **Probe 2:** what is your understanding of TB isolation
4.	**As a patient, or healthcare worker what would be the ideal conditions for an isolation ward?** **Probe 1:** what do you think about the duration of visitation? **Probe 2:** what do you think about the distance from other health facilities/wards etc **Probe 2:** what else can be done to improve the environment?
5.	**What do you think of the isolation policy that is being created?** **Probe 1:** in your view, what kind of patients should be eligible for isolation? **Probe 2:** how will the rights of those patients who get isolated be protected? **Probe 3:** what practical and ethical ways can be implemented in your setting- county/health facility - to provide isolation for TB patients for both voluntary and in-voluntary isolation?

END

7.2 Annex 2: Key Informant interview report

The report is summarised per question.

i. In your view, do you think TB is a public health problem? And why?

All respondents agreed that TB is a public health problem that is made worse by malnutrition and poverty. It therefore becomes a social problem if looked at from this perspective. Since it is airborne it can be spread easily and resources should be spent to reduce transmission. Treatment has been shortened from 8 months to 6 months.

ii. What is your understanding of isolation in the context of TB?

Understanding

Previously it meant incarceration but, it now seeks to protect patient rights. The goal of isolation is to avoid transmission, improve adherence and TB management.

Types of isolation

The following were listed by the respondents as types of isolation

- Confinement: separated from the rest of the population
- Voluntary: the patient consents to be isolated
- Smear positive TB patients
- MDR TB patients
- Ordinary patients, for first few weeks of treatment
- Newly confirmed

Feasibility in Kenya

It was largely felt that it will be feasible in Kenya since there is good will. Sensitization however is key to its success. There is also need to understand ways and means of isolating different types of patients

iii. Have you heard about the court ruling on TB isolation that occurred on 24th march 2016?

Most had heard. Those who had heard were happy with the recommendation for isolation. Counselling will be needed to make the patients why isolation would be important. They found an isolation ward more humane than prison. Despite patient rights, those with MDR should be isolated to protect the public. Health care workers should be part of the team of court user's forums- a meeting where the prisons department and judiciary usually meet. Nutrition and psychosocial support should be part of the isolation program. Community gatekeepers like local administration on the importance of isolation and handling TB cases should be engaged in all processes.

iv. In view of the court ruling what are your thoughts on creating isolation facilities?

Some counties have already set aside some money to build TB isolation wards eg. Kirinyanga County have set 10M 2017/2018 for isolation ward in Kerugoya. In the next 5 years they want to set up 3 isolation facilities in 3 hospital. It will be a 15-20 bed facility.

Shimolatewa maximum prison has been implementing isolation for TB patients within the facility and it is an example of best practices within a prison setting. Those who are also drug abusers are treated for both TB and drug abuse. The prisons have written to the courts to allow TB patients complete treatment before they are sentenced to make sure incarceration does not affect their treatment. Health workers are screened annually for TB. Infection prevention is observed. Some are of the view that the prisons department should have isolation wards as well to avoid moving prisoners.

Some partners like International Organization of Migration are willing to partner to help build isolation wards.

It was strongly recommended that regional based isolation facilities to be created to reduce cost of construction and operation.

v. As a patient, or healthcare worker what would be the ideal conditions for an isolation ward?

The following were suggested as the ideal conditions for isolation wards:

- There should be a distance from other wards
- Rooms should be well ventilated and spacious
- Should be fenced, with open air circulation and grounds where patients can relax
- Should have a separate open bay for visitations
- Provide biological respiratory masks for health workers who visit the patients often
- Should have negative pressure, expose to UV light, inpatients should have time to rest outside the ward
- Provide protective gear of the health workers and visitors
- Should observe infection prevention practices
- Should have high level isolation equipment to accommodate other communicable diseases that require isolation such as Cholera, Ebola, SARS.
- Health care providers should be trained to manage the isolation ward
- Should have nutrition support
- Visiting hours should be short, one hour or two (other said 5 minutes others 20 others 30 minutes), and should not be everyday

- Should have sporting and entertainment provisions
- Sensitize and educate the community
- Unstable patients should be separated from stable patients
- Should be 20-30 meters from other facilities/wards
- Should be able to categorize patients with their resistance patterns to avoid cross infection
- Every patient should have their own room

The following were suggested as ways to improve the environment:

- Spacious
- A lot of windows
- Air filters
- Patients visited with IPC guidelines for about 30 minutes
- About 50 meters from other buildings
- Clean toilets and bathroom facilities

vi. What do you think of the isolation policy that is being created?

The following were suggested as eligibility for isolation:

a. Non-compliant patients
b. Non-adherent patients
c. TB patients who don't not have adequate nutritional, economic or psycho-social support
d. Patients with psychosocial issues e.g. alcoholics, drug addicts
e. Patients with co-morbidities
f. TB patients who are prisoners
g. Confirmed MDR patients
h. Newly diagnosed in the 1st month of treatment when they are infectious
i. Defaulters
j. DR TB patients
k. Other contagious diseases
l. Critically ill patients
m. Smear unstable positive patients
n. Patients whose sputum has not converted at month 2

The following were suggested as ways to Protect patient rights during isolation:

a. Isolation is protection of human rights in itself
b. Counselling
c. Education
d. Allow movement in a restricted area e.g. They can bath in the sun or play a sport
e. Informed consent
f. Use trained health care providers
g. A clinician should not see more than 20 patients a day

h. Patients should be allowed to continue with their activities in the isolation area
i. Relatives to be allowed to bring home made food and groom their patients
j. Collaboration with law makers, human rights groups and health care workers
k. Approved court orders

vii. What do you think are the benefits of isolation?

The following were suggested as benefits of isolation:

a) The public is protected from infectious disease
b) Quality of treatment will improve
c) It's a win win both from a public health and human rights perspective
d) Will help reduce transmission of disease
e) Will improve adherence
f) Nutritional support can be provided
g) Protect the public
h) Ultimately it will reduce cost

viii. What do you foresee as the challenges of isolation

The following were suggested as challenges of isolation:

a) Patients will feel discriminated against
b) Resistance from staff to work in the isolation facilities
c) Stigma
d) Lack of resources to built infrastructure and human resources for health
e) Lack of trained personnel
f) Lack of policy and guidelines
g) Lack of political will
h) Community resistance to isolation
i) Negative attitudes towards isolation
j) May not be feasible in cases where the individual is a bread winner
k) Lack of political will
l) Defaulting by those who are substance abusers due to withdrawal symptoms
m) Having isolation in prisons may be a challenge

The following were suggested as ways to mitigate challenges:

a) Sensitization and awareness
b) Advocacy at high level with stakeholders and partners
c) Adequate human resource for health
d) Budget for the isolation units
e) Advocacy from policy makers for sustained funding

f) Training and mentorship of health care providers
g) Policy to be put in place
h) Involve human rights groups

7.3 Annex 3: Focus Group Discussion report

The report is summarised per question.

i. **What do you think about TB care that is offered by the ministry of health**

Most thought TB care offered by the ministry of health is good. The shortcomings noted were limited laboratory follow up, inconsistent availability of nutritional supplements, small consolation rooms and that TB in children still remain a big challenge.

Most thought that adherence is good since most of them turn sputum negative after 2 months. They however recommended giving incentives to those who complete treatment like branded T shirts. Some treatment centres were applauded for being friendly, making adherence even easier.

On duration of treatment, most appreciate that its now 6 months for drug sensitive TB which is relatively shorter. They however wished that it can even be made shorter. They think that MDR TB treatment takes too long with very severe side effects.

On clinic visits, most suggested a reduction of the number of visits during the intensive pause from the current weekly to biweekly, because its a challenge for those with formal employment.

On transmission of Tb, they all agreed it is a public health problem that is preventable. There is a need for sensitization, awareness and contact tracing. Ventilation in the wards and all clinical areas is wanting and urgent improvement needed. Infection prevention practices should be observed by patients, care givers and health care providers. Infection prevention practices should also be implemented in public transport vehicles.

The following were the suggested role of the community:

- Sensitization and awareness
- Prevent stigmatization
- Assist in cases of emergencies
- CHVs should have knowledge on early screening
- Community gate keepers like chiefs should be utilized
- Involve community health workers for contact tracing
- Strengthen community strategy

ii. Taking TB medication as required can be difficult. What are some of the challenges that make adhering to TB medication difficult?

The following were suggested causes of non-adherence to treatment

- **a.** Treatment takes long
- **b.** The side effects are horrible
- **c.** Going to hospital daily is tedious, once a week refills would be preferable
- **d.** Poor nutrition
- **e.** Stigma
- **f.** Some special groups like alcoholics need tailor-made follow up since they may forget to take their medications
- **g.** Inadequate counseling
- **h.** Some follow up clinics for refills fall in public holidays or weekends when the clinics are closed
- **i.** Psychosocial problems like alcoholics and drug addicts
- **j.** Poor socio-economic status e.g. those residing in informal settlements
- **k.** Pill burden

The following were suggested ways to improve adherence

- **a.** Monitoring and follow up by CHV's
- **b.** Nutritional support
- **c.** Psycho-social support from peers and families
- **d.** Counseling
- **e.** Follow-up visits using Locator forms by CHV's
- **f.** Give enough medication, and not isoaltion

iii. Have you heard about the court ruling on TB isolation that occurred on 24th march 2016?

Some had heard about the ruling, but not aware of the ruling. Those who had heard were positive about the idea of not being jailed. They were however worried that isolation will restrict freedom of movement and socialization but at the same time not isolating leads to transmission. It was suggested that there is a need of a delicate balance here that may include home based treatment, where its more friendly, familiar, has psycho-social support and reduces stigma. There was a worry that isolation can lead to depression.

iv. As a patient, or healthcare worker what would be the ideal conditions for an isolation ward?

The following were suggested as ideal conditions for an isolation ward

a) Visiting hours up to one hour
b) Detached from other wards but should be in the same setting as the facility to avoid stigma. Others thought that it should be in a place that's equidistant from all other TB facilities in the County. Hence one per county
c) Well equipped with diagnostics
d) Good, tasty nutritious meals
e) Homely environment
f) Entertainment units- TV, Radio, Music
g) Protective gear
h) Visitors allowed to bring food
i) Comfortable with clean beddings
j) Well ventilated
k) Not congested
l) Stipend for patients, because they are care givers
m) Educate visitors on infection prevention practices
n) Community involvement is key to avoid resistance

v. What do you think of the isolation policy that is being created?

Most thought that it is a good policy, it will improve adherence, nutritional status and reduce transmission.

***The following were suggestions on patients eligible for* isolation**

a) Non-adherent patients
b) Infectious patients
c) Defaulters
d) Those with side effects of medication
e) Those in need of nutritional support
f) MDR not responding to medication
g) Very sick patients
h) Alcoholics

i) Those from low income families e.g. homeless or residing in informal settlements, street children
j) Patients who offer themselves voluntarily for isolation

The following were suggestions on how rights of patients will be protected

a) Allow access for human rights organizations to monitor
b) Sensitize patients on their rights
c) Should not be forced of coerced
d) Give the patients the right information
e) Provide treatment, healthy conditions and basic utilities
f) Should not be discriminated up on or stigmatized
g) Should be treated like any other patient
h) Train health care providers
i) Involve the family and community
j) Educate patients
k) Ensure confidentiality

The following were suggestions on what should be included as the policy is being implemented

a) Counselling
b) Voluntary
c) Meet eligibility criteria
d) Sensitization
e) Create isolation wards in prisons
f) Have nutritional support
g) Consumer education
h) Community engagement and linkages

7.4 Annex 4: STANDARDS FOR AIRBORNE INFECTION ISOLATION ROOMS (AI/AIR) ROOMS

A) TYPES

1) Atmospheric Isolation or Natural Ventilation AI Rooms

These employ natural ventilation or natural ventilation assisted with air propeller fans.

2) Negative pressure or mechanical ventilation AI Rooms

These employ mechanical air-moving equipment to generate and maintain ventilation in the Isolation Rooms.

B) SIZES

The following are minimum recommended sizes for various configurations or designs of Isolation Rooms.

1) Basic AI Room without ante-room, not self-contained. (Without dedicated bathroom) $10m^2$ plinth area.

2) Basic AI Room without anteroom, self-contained (with dedicated bathroom) $12m^2$ plinth area.

3) AI Room self-contained (with dedicated bathroom) with ante room – $22m^2$

C) VENTILATION RATE

Minimum total air-changes per hour (ACH) $\geq$ 12

D) MINIMUM NEGATIVE PRESSURE AI STANDARDS

1) ROOM PRESSURE DIFFERENTIAL

Minimum $\geq$ 0.01" W.G (water gauge)

2) MINIMUM EXHAUST AIR EXCESS AIRFLOW (OFFSET)

Recommended air volume flow differentials exhaust is to be 10% more than supply. Air Minimum differential to be 50 CFM.

3) TOTAL ACH SHOULD NOT INCLUDE HEPA RE-CIRCULATION

4) UPPER-ROOM OR IN-DUCT UVGI

This can be employed but not in lieu of ventilation.

5) AIR DISTRIBUTION

Supply air from clean (High, ceiling) and exhaust from less clean (low, near floor)

6) HEPA FILTERED RE-CIRCULATION

To other areas not recommended

7) EXHAUST DISCHARGE

Recommended to be on roof minimum 25 feet (8meters) high away from openings and fresh air intakes.

8) MONITORING OF NEGATIVE PRESSURE

Recommended to be continuous and alarmed.

Minimum, check daily when Room is in use.

9) ANTE-ROOM ACH

Recommended 10 ACH.

10) ANTE-ROOM PRESSURISATION

Positive to Isolation Room, negative to Corridor.

11) VARIABLE AIR-VOLUME ((VAV) VENTILLATION)

May be employed but maintain minimum code ACH and pressurizations.

E) UVGI INSTALLATIONS:

1) Recommended fittings to be installed 12 feet high from floor for upper room UVGI and 2 feet high from floor for lower room UVGI.
   Minimum Installation Height for upper room UVGI $\geq$ 9 ft.

2) UVGI to be shielded type for room installations, but un-shielded type for in-duct installations.
3) Ceiling Reflectivity to UVGI not more than 10%.

4) Recommended regular monitoring with a Radiometer to maintain dosage levels and control exposure.

F) MEDICAL GASES:

It is recommended AI rooms to be installed with oxygen and vacuum medical gases installations.

G) SAMPLE ROOMS:

Attached are sample A1 Room configurations/drawings.

REFERENCES:

ASHRAE -American Society of Heating, Refrigeration and air-conditioning Engineers'

AIA -American Institute of Architects

CDC -Centre for Disease Control

TERMS

ACH -Air Changes per hour

CFM -Cubic Feet per minute

FPM -Feet per minute

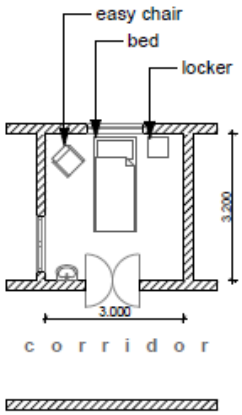
HEPA -High efficiency Particulate air filters

UVGI -Ultraviolet germicidal irradiation

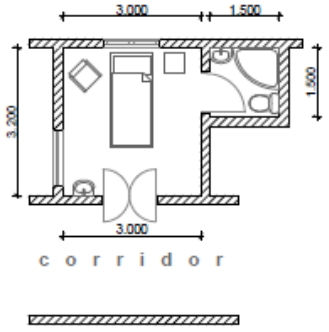
VAV -Variable air volume

"W.G." -Water gauge

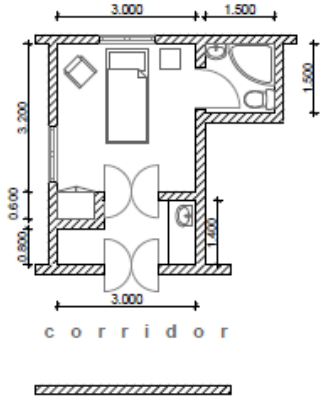
7.5 Annex 5: Sample designs



1 bed cubicle



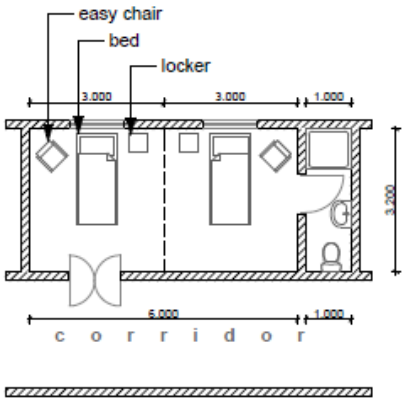
1 bed cubicle
with Shower & WC



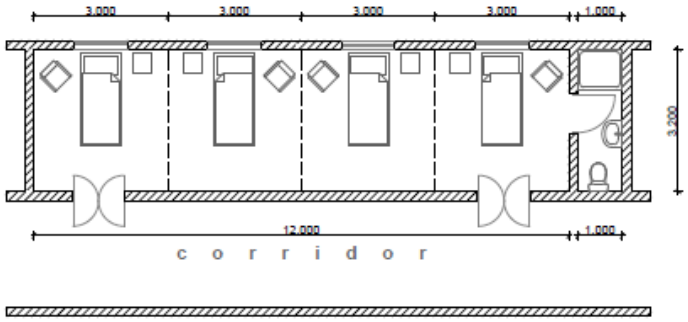
1 bed cubicle
with shower/WC,
Closet & AnteRoom

nb;
recommended;
-floors, walls & ceilings to be non-porous
-floor to be glazed tiles
-minimum medical gas supply to oxygen & vacuum

PATIENT AIRBOURNE INFECTION ISOLATION ROOM



2 bed cubicle with shower & WC



4 bed cubicle with shower & WC

nb;
recommended;
-floors, walls & ceilings to be non-porous
-floor to be glazed tiles
-minimum medical gas supply to oxygen & vacuum

PATIENT AIRBOURNE INFECTION ISOLATION ROOM

7.6 Annex 6: MOH circular

MINISTRY OF HEALTH
OFFICE OF THE PRINCIPAL SECRETARY

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AFYA HOUSE
CATHEDRAL ROAD
P. O Box 30016-00100
NAIROBI

When replying please quote:

Ref: MOH/ADM/1/1/2

Date: 12 May 2016

County Executive Committee Members for Health
Chief Officers of Health
County Directors of Health

Thro:

The Chairman
Council of Governors
Delta Plaza
Westlands

RE: IMPLEMENTATION OF THE HIGH COURT JUDGEMENT CHALLENGING THE IMPRISONMENT OF TB PATIENTS

Following the High Court ruling issued on March 24th 2016 that found the confinement of TB patients in prisons unlawful and unconstitutional, the following measures are to be applied with immediate effect:

1. Confinement of patients suffering from infectious diseases for the purposes of treatment shall not be done in prison facilities

2. Where despite all reasonable efforts, patients with infectious disease are unwilling or unable to comply with treatment; court orders shall be sought to compel isolation, confinement or detention as referred to in section 27 of the Public Health Act, CAP 242

3. The isolation can be done at a health facility in adherence to; infection control measures and for the purpose of ensuring that patients adhere to the course of treatment for the public interest and their own interest

4. The Ministry of Health in consultation with county governments, shall in due course issue further policy direction on the involuntary confinement of persons with TB and other infectious diseases.

Dr. Nicholas Muraguri
PRINCIPAL SECRETARY

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