REPUBLIC OF KENYA

MINISTRY OF HEALTH

Treatment of Drug Resistant Tuberculosis in Kenya

Introduction of the Injectable Free Regimens 2020

NATIONAL TUBERCULOSIS, LEPROSY AND LUNG DISEASE PROGRAM

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Treatment of Drug Resistant Tuberculosis in Kenya

Introduction of the Injectable Free Regimens 2020

March, 2020

Version 1

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

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FOREWORD

Hon. Mutahi Kagwe, EGH

Drug-resistant tuberculosis (DR TB) continues to be a major public threat worldwide with about half a million new cases annually. While only one-in-three of those with Multidrug Resistant TB (MDR-TB) are enrolled into treatment globally, even those started on treatment have a high likelihood of experiencing poor treatment outcomes: globally the treatment success is barely above half. This is partly because of the toxic nature of medications, the lower efficacy and long duration of treatment, ranging from 9 to 20 months.

Kenya is one of the 30 countries highly burdened by TB, TB/HIV and MDR-TB. The number of DR TB patients in the country has been rising consistently over the years. In 2017 the country adopted a shorter treatment option – lasting 9 months – but which still relied on daily injections for a minimum of 4 months. Besides the painful injections, these drugs could lead to permanent hearing loss and associated social challenges in up to one-fifth of the patients. In 2018, and further updated in 2019, the World Health Organization (WHO) released evidence-based guidelines recommending all-oral regimens for the treatment of DR TB. Injectable free regimens are associated with reduction in deaths, treatment failure and relapses. Moreover, there is no deafness associated with the new treatment regimens.

Through an extensive and all-inclusive stakeholder engagements, Kenya reviewed and adopted these regimens and developed a road map for the transition. Beginning January 2020, patients diagnosed with drug resistant tuberculosis in the country are to benefit from the injection-free regimens. We believe this will reduce the drug-related side effects, mainly hearing loss, while improving adherence to treatment and eventually the treatment outcomes.

Through this policy document, the Ministry of Health is committed to ensuring better welfare of all patients with TB, including those with drug resistant tuberculosis. This is in line with the commitment made by the head of state at the United Nation High Level Meeting on TB and the END TB Strategy to end the epidemic by 2035.

Cabinet Secretary
Ministry of Health

Ms. Susan N. Mochache, CBS

PREFACE

The emergence of drug resistant tuberculosis (TB) poses a major public health problem globally and in Kenya. The number of patients with drug resistant tuberculosis (DR TB) diagnosed in the country continues to increase significantly.

For over a decade, treatment of DR TB has heavily relied on the use of injectable agents like amikacin, capreomycin and kanamycin which have been shown to be less effective and are associated with significant side effects. These injectable agents are given for 4 to 8 months. Besides the daily painful injections, these drugs are associated with permanent hearing loss in up to 20% of patients. Deafness causes loss of independence, depressive illness, social difficulties and stigma, and learning and language development challenges for children. The overall treatment success rate remains as low as 66% in Kenya.

In August 2018, the World Health Organization (WHO) issued a rapid communication on major changes in the treatment of DR TB. This was later followed by a guideline released in early 2019. The updated recommendations were based on new evidence that the new TB drugs Bedaquiline and Delamanid and other repurposed medicines like Linezolid and the Flouroquinolones were associated with reduced deaths, treatment failure and relapses by up to 80%. These medicines are taken orally therefore avoiding the daily painful injections for months.

Following the 2018 WHO rapid communication, Kenya reviewed the recommendations and with extensive deliberations and discussions with stakeholders, the country decided to adopt and domesticate the WHO recommendations to the country's situation. A roadmap was developed for the country's transition to the new injection free regimens. The transition plan involved TB experts, the civil society, current and former DR TB patients, patients' advocates, the Pharmacy and Poisons Board (PPB), partners, academia, medical research institutions, counties and the Division of National Tuberculosis, Leprosy and Lung Disease.

The injectable free regimens are revolutionary and will improve the quality of life for our DR TB patients while avoiding the misery associated with hearing loss. The new recommendations put our DR TB patients' interests and rights at the center of our country's health policies.

Principal Secretary
Ministry of Health

ACKNOWLEDGEMENT

Dr. Patrick Amoth

The development of this policy involved extensive consultations and deliberations with various stakeholders through consultative meetings, interviews, and review of evidence on the best treatment strategies. The process is guided by the current WHO guidelines and best clinical practice.

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.

The Ministry of Health Kenya appreciates the team that coordinated the development of this policy. We recognize the leadership provided by the Division of Tuberculosis, Leprosy and Lung Disease (DNTLD) headed by Dr. Elizabeth Onyango. Special gratitude to the team that coordinated the guideline development particularly Dr. Kiogora Gatimbu, Dr. Stephen K. Macharia, George Oballa (Technical advisor - PMDT), Dr. Simon Wachira (CHS) and led by Dr. Irungu Karuga (PMDT coordinator).

We are also grateful to the Pharmacy and Poisons Board, Moi Teaching and Referral Hospital, Kenyatta National Hospital, County Governments, KEMRI, STOP TB partnership, USAID through TB ARC II, Clinton Health Access Initiative (CHAI), KANCO, KELIN, NASCOP and other the entire team that worked tirelessly to ensure the successful completion of this process.

Ag. Director General for Health

Abbreviations and Acronyms

aDSM	Active Drug Safety Monitoring and Management
CoE	Committee of Experts
CSOs	Civil Society Organizations
DHIS	District Health Information System
DNTLD	Division of National Tuberculosis, Leprosy and Lung Disease
DR TB	Drug Resistant Tuberculosis
DST	Drug Susceptibility Testing
FL LPA	First Line Line Probe Assay
HCW	Health Care Workers
HIV	Human Immunodeficiency Virus
IPC	Infection Prevention and Control
MDR TB	Multidrug Resistant Tuberculosis
MTBC	Mycobacterial Tuberculosis Complex
NSP	National Strategic Plan
PMDT	Programmatic Management of Drug Resistant Tuberculosis
Pre-XDR	Pre-Extensively Drug Resistant Tuberculosis
RR TB	Rifampicin Resistant Tuberculosis
SL LPA	Second Line Line Probe Assay
STR	Shorter term regimen
SLDs	Second Line Drugs
TB	Tuberculosis
TSR	Treatment Success Rate
WHO	World Health Organization
XDR TB	Extensively Drug Resistant Tuberculosis

Definition of terms

Drug-susceptibility testing (DST) refers to in-vitro testing using either phenotypic methods to determine susceptibility, or molecular techniques to detect resistance-conferring mutations to a medicine.

Isoniazid-resistant TB (Hr-TB), refers to Mycobacterium tuberculosis strains in which resistance to isoniazid and susceptibility to rifampicin has been confirmed in vitro.

Longer MDR-TB regimens are those used for the treatment of MDR/RR-TB given for at least 18 months or more, and may be standardized or individualized. These regimens are usually designed to include a minimum number of second-line TB medicines considered to be effective based on patient history or drug-resistance patterns. The term "conventional" was previously used to refer to such regimens but was discontinued in 2016. Conventional regimens were used until October 2017 in Kenya when the shorter term regimen was introduced for MDR/RR TB.

New case is defined as a newly registered episode of TB in a patient who has never been treated for TB or has taken anti-TB medicines for less than 1 month.

Previously treated refers to patients who have received 1 month or more of anti-TB medicines in the past either using first line or second line regimens.

Rifampicin-resistant TB (RR-TB) strains are considered not to be susceptible to rifampicin on the basis of DST and, as a result, are eligible for treatment with MDR-TB regimens. Rifampicin-resistant TB strains may be susceptible or resistant to isoniazid (i.e. MDR-TB), or resistant to other first-line TB medicines polyresistant) or second-line TB medicines (e.g. extensively drug-resistant [XDR]-TB). In this document MDR-TB and RR-TB cases are often grouped together as MDR/RR-TB.

Relapse patients have previously been treated for TB, were declared cured or treatment completed at the end of their most recent course of treatment, and are now diagnosed with a recurrent episode of TB

A second-line TB medicine (or drug) is an agent reserved for the treatment of drug-resistant TB. First-line TB medicines used to treat drug-susceptible TB – ethambutol, isoniazid and pyrazinamide – may also be used in MDR-TB regimens.

A shorter MDR-TB regimen refers to a course of treatment for MDR/RR-TB lasting 9–12 months, which is largely standardized, and whose composition and duration follows closely the one for which there is documented evidence from different settings.

The **treatment outcome** categories used in these guidelines and the term relapse were applied according to the definitions agreed for use by TB programmes, unless otherwise specified.

Outcome Definitions

Cure refers to treatment completion as recommended by the national policy without evidence of failure AND three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase

Treatment completion refers to treatment completed as recommended by the national policy without evidence of failure BUT no record that three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase

Treatment failure refers to treatment termination or need for permanent regimen change of at least two anti-TB drugs because of:

- lack of conversion by the end of the intensive phase, or
- bacteriological reversion in the continuation phase after conversion to negative, or
- evidence of additional acquired resistance to fluoroquinolones or second-line injectable drugs, or
- adverse drug reactions (ADRs)

Died refers to a patient who dies for any reason during the course of treatment

Lost to follow-up refers to a patient whose treatment was interrupted for 2 consecutive months or
more

Treatment success is the sum of those cure and those who completed treatment.

CHAPTER ONE:

INTRODUCTION

1.1 Background

Drug Resistant Tuberculosis (DR TB) poses a major public health threat globally. This form of TB occurs when the TB bacilli undergoes mutations enabling it to survive exposure to any of the anti TB drugs. The commonest forms are Multidrug resistant (MDR) TB and Rifampicin resistant (RR) TB. MDR TB refers to a form of TB where the germ is resistant to both isoniazid and rifampicin. Rifampicin resistant (RR) TB refers to resistance to rifampicin only. Rifampicin and isoniazid are the most important TB drugs. There exist other forms of DR TB depending on the medicines that the TB bacilli is resistant to.

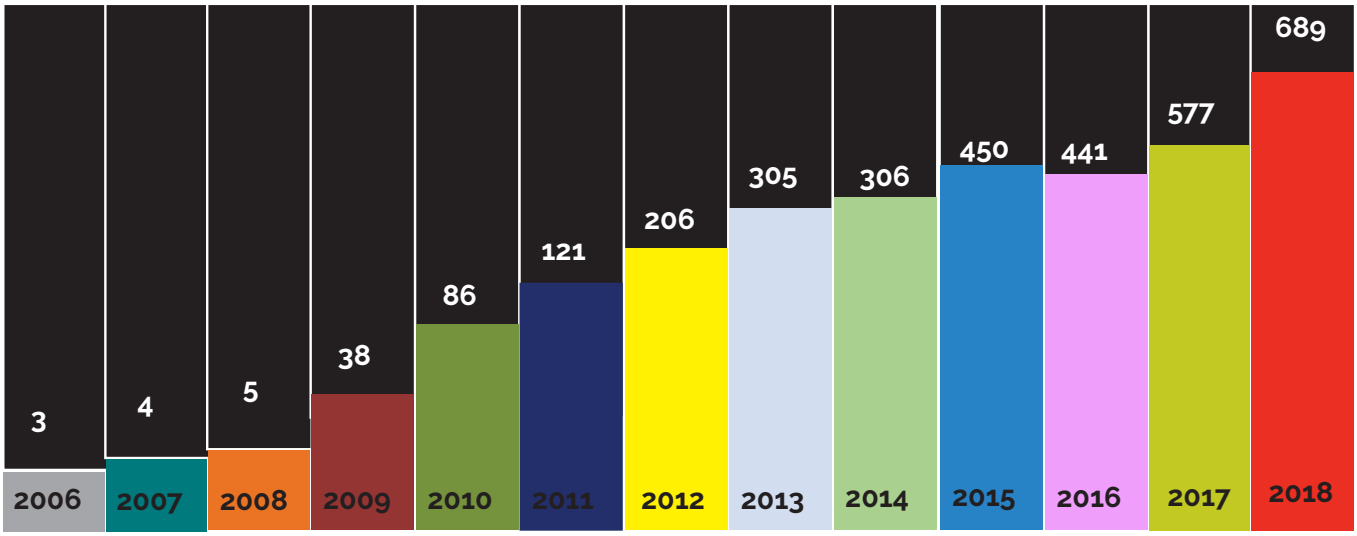
Detection of DR TB requires robust surveillance among patients diagnosed with TB. WHO recommends universal drugs susceptibility testing (DST) among TB patients for the detection of resistant TB. Globally in 2018 an estimated 3.4% of new TB cases and 18% of previously treated patients had MDR/RR TB. In the same year there were 484,000 MDR/RR TB cases notified worldwide. Isoniazid monoresistance is estimated to have occurred in 7.2% of new cases and 11.2% of previously treated cases. Among those with MDR/RR TB, 20.8% had resistance to flouroquinolones (pre-XDR TB). The global treatment success rate (TSR) for MDR/RR TB has remained relatively low globally at 56%.

Kenya is among the top 30 high burden countries for TB, MDR TB and TB-HIV. WHO estimates that 1.3% of new TB cases and 4.4% of previously treated TB cases have MDR/RR TB. According to Kenya drug resistance survey of 2014, the prevalence of isoniazid monoresistance among new patients was 5.5%.

GeneXpert testing is currently recommended as the initial test for diagnosis of TB and the detection of rifampicin resistance (where available) in Kenya. Patients who are at high risk of DR TB have been identified and are prioritized in receiving further DST beyond GeneXpert in the TB reference laboratories. This test include first line (FL) and second line (SL) probe assay (LPA), culture and phenotypic DST.

The number of DR TB cases has increased significantly over the years. Multidrug and rifampicin resistant (MDR/RR) TB contribute 70% of all DR TB cases notified in Kenya. Kenya is estimated to have had 2,300 incident MDR/RR TB cases in 2018, however the country notified 485 MDR/RR TB cases, missing the detection of 79% of the estimated incident cases. Cases of DR TB whom have never been treated for TB before signify transmission of DR TB, whether diagnosed or not. The proportion of DR TB cases due to transmission has also increased significantly from 17% in 2013 to 46% in 2018.

Figure 1: Number of drug resistant cases notified in Kenya, 2006 to 2018



Kenya started the implementation of the programmatic management of drug resistant TB (PMDT) in 2006. Treatment of DR TB has evolved with changing WHO guidelines over time. Flouroquinolones and injectable agents (amikacin, capreomycin and kanamycin) have been used as core drugs in the DR TB treatment since 2011. The longer conventional regimens for MDR/RR TB was administered for 20 months, where the intensive phase containing the injectable agent was given in the initial 8 months. Treatment of DR TB has been associated with a low treatment success rate. The 2016 DR TB treatment cohort had a TSR of 66%3. Death occurred in a fifth of the treatment cohort. In October 2017 the country launched the shorter term regimen (STR) administered for 9-11 months. The injectable medicines were given for 4 to 6 months.

1.2 Purpose

This policy document aims to guide the implementation of the new injectable free regimens for the treatment of DR TB in Kenya.

The new changes in DR TB treatment are based on new evidence, and past experience and shall be implemented in a patient centered approach. This document provides a framework for the roll out of the injectable free regimens for DR TB based on patient's resistance pattern and other clinical parameters, comprehensive baseline and follow up work up, and adverse drug safety and monitoring (aDSM).

1.3 Rationale

In Kenya, treatment regimens for MDR/RR TB containing injectable medicines have been the mainstay of DR TB treatment. Injectable medicines have been associated with permanent hearing loss, painful injections for months, and kidney injury and electrolyte imbalances. More so, administration of the injections requires qualified HCWs in addition to the consumables required to give these drugs.

In 2019, WHO released new guidelines for the treatment of DR TB. This was informed by new evidence following a Cochrane method of meta-analysis based on database of 12,000 individual patients. This meta-analysis informed landmark changes in the treatment of DR TB going forward. Key changes in the guideline were;

- Drug reclassification with preference for the use of new drugs and other repurposed medicines
- Preference for an all oral treatment regimens for 18-20 months
- Substantial changes in the priority ranking of medicines
- Based on benefit vs risk, preference for oral drugs, drug tolerability etc
- Injectable agents, Kanamycin and Capreomycin are no longer recommended due to;
    - Increased risk of treatment failure
    - Irreversible hearing loss
    - Need for careful and close monitoring using audiometry

NB: Amikacin did not show similar associations of treatment failure, relapse and death as other injectables. However, it had similar safety concerns as for the other injectables.

Drug reclassification was done using benefit vs risk analysis. The basis for drug reclassification was:

- Balance of effectiveness and harms
- Preference for oral over injectable agents
- Results of drug-susceptibility testing (DST)
- Reliability of existing DST methods
- Population drug resistance levels
- Drug tolerability, and
- Potential drug-drug interactions.

Figure 2: 2019 WHO drug reclassification

Group	Medicine	
Group A	Levofloxacin OR Moxifloxacin	Lfx Mfx
	Bedaquiline	Bdq
	Linezolid	Lzd
Group B	Clofazimine	Cfz
	Cycloserine OR Terizidone	Cs Trd

Group C	Ethambutol	E
	Delaminid	Dlm
	Pyrazinamide	Z
	Imipenem-cilastatin OR Meropenem	Lpm-Cln Mpm
	Amikacin OR Streptomycin	Am S
	Ethionamide OR Prothionamide	Eto Pto
	p-aminosalicylic acid	PAS

The meta-analysis reviewed data on likelihood of treatment failure, relapses and death. The newer drugs, in group A and B, reduced the likelihood of treatment failure, relapses and death by 40% to 80% (Figure 3).

Figure 3: The likelihood for treatment failure or relapse and death (versus treatment success)

Medicine		Treatment failure or relapse versus treatment success		Death versus treatment success	
		Number treated	Adjusted odds ratio (95% confidence limits)	Number treated	Adjusted odds ratio (95% confidence limits)
A	Levofloxacin *OR* moxifloxacin	3 143	0.3 (0.1–0.5)	3 551	0.2 (0.1–0.3)
	Bedaquiline	1 391	0.3 (0.2–0.4)	1 480	0.2 (0.2–0.3)
	Linezolid	1 216	0.3 (0.2–0.5)	1 286	0.3 (0.2–0.3)
B	Clofazimine	991	0.3 (0.2–0.5)	1 096	0.4 (0.3–0.6)
	Cycloserine *OR* terizidone	5 483	0.6 (0.4–0.9)	6 160	0.6 (0.5–0.8)
C	Ethambutol	1 163	0.4 (0.1–1.0)	1 245	0.5 (0.1–1.7)
	Delamanid	289	1.1 (0.4–2.8) *	290	1.2 (0.5–3.0) *
	Pyrazinamide	1 248	2.7 (0.7–10.9)	1 272	1.2 (0.1–15.7)
	Imipenem–cilastatin *OR* meropenem	206	0.4 (0.2–0.7)	204	0.2 (0.1–0.5)
	Amikacin	635	0.3 (0.1–0.8)	727	0.7 (0.4–1.2)
	Streptomycin	226	0.5 (0.1–2.1)	238	0.1 (0.0–0.4)
	Ethionamide *OR* prothionamide	2 582	1.6 (0.5–5.5)	2 750	2.0 (0.8–5.3)
	p-aminosalicylic acid	1 564	3.1 (1.1–8.9)	1 609	1.0 (0.6–1.6)
Other medicines	Kanamycin	2 946	1.9 (1.0–3.4)	3 269	1.1 (0.5–2.1)
	Capreomycin	777	2.0 (1.1–3.5)	826	1.4 (0.7–2.8)
	Amoxicillin–clavulanic acid	492	1.7 (1.0–3.0)	534	2.2 (1.3–3.6)

WHO consolidated guidelines on drug-resistant tuberculosis treatment - 2019

The likelihood of serious adverse effects from the meta-analysis is as shown below.

Figure 4: Serious adverse events (SAEs) in patients on longer MDR-TB regimens

Medicine	Absolute risk of SAE	
	Median (%)	95% credible interval
Bedaquiline	2.4	[0.7, 7.6]
Moxifloxacin	2.9	[1.4, 5.6]
Amoxicillin–clavulanic acid	3.0	[1.5, 5.8]
Clofazimine	3.6	[1.3, 8.6]
Ethambutol	4.0	[2.4, 6.8]
Levofloxacin	4.1	[1.9, 8.8]
Streptomycin	4.5	[2.3, 8.8]
Cycloserine/terizidone	7.8	[5.8, 10.9]
Capreomycin	8.4	[5.7, 12.2]
Pyrazinamide	8.8	[5.6, 13.2]
Ethionamide/prothionamide	9.5	[6.5, 14.5]
Amikacin	10.3	[6.6, 17.0]
Kanamycin	10.8	[7.2, 16.1]
p-aminosalicylic acid	14.3	[10.1, 20.7]
Thioacetazone	14.6	[4.9, 37.6]
Linezolid	17.2	[10.1, 27.0]

* From an "arm-based network" meta-analysis of a patient subset from the 2016 IPD for which AEs resulting in permanent discontinuation of a TB medicine (27 studies) or classified as Grade 3–5 (3 studies) were reported. There were insufficient records on delamanid, imipenem–cilastatin and meropenem to estimate risks. Agents that are not in Groups A, B or C are italicized.

WHO consolidated guidelines on drug-resistant tuberculosis treatment - 2019

The policy document targets policy makers at DNTLD, county governments the civil society such as advocacy groups, community and faith-based organizations, health care workers in both private and public sector and other stakeholders involved in TB control and PMDT.

1.5 Scope of the Policy

The policy describes treatment of DR TB, quality of care improvement in a patient centered approach as per the END TB strategy and the WHO consolidated guidelines on drug resistant (MDR) tuberculosis treatment, 2019.

1.6 Principle of the IFR 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 Transition timelines

Kenya transitioned to the injectable free regimens for DR TB on 1st January 2020. This also included the introduction of paediatric friendly medicines for children less than 6 years and less than 25kgs. Patients initiated on other treatment regimens before the transition date were continued with the regimens they were initiated on.

1.8 Diagnosis of DR TB

Diagnosis of DR TB shall be based on WHO approved DST laboratory methods. These include:

1. Rapid molecular methods
    a. Xpert® MTB/RIF (geneXpert)
    b. FL LPA
    c. SL LPA
    d. Other WHO approved rapid molecular methods
2. Phenotypic DST methods
    a. Culture and phenotypic DST to first line antiTB medicines
    b. Culture and phenotypic DST to second line antiTB medicines – flouroquinolones, injectables, Bedaquiline, Delamanid, clofazimine, linezolid and
    c. any other WHO approved phenotypic DST methods

Exemption for laboratory confirmation of DR TB shall be made for patients who are confirmed contacts of DR TB and are diagnosed with TB. The contacts shall be treated for the same resistance pattern as the index case.

CHAPTER TWO:

Treatment of DR TB

2. 1 Treatment of DR TB

Treatment of DR TB in Kenya shall conform to the WHO consolidated guidelines on drug resistant tuberculosis treatment 2019, Rapid Communication on key changes to the treatment of drug-resistant tuberculosis December 2019 and the Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis 2014.
Treatment regimen for DR TB shall be based on;

1. The resistance patterns
2. The clinical status of the patient
3. Availability of TB medicines (first and second line drugs)

2.1.1 Standard regimens

Standard regimens based on the patients' resistance shall be used as specified in the guidelines. The standard regimens are as shown below:

Figure 5 : Standard regimens

Drug Resistance Pattern	Regimen name	Intensive Phase		Continuation Phase	
		Standard Duration (Months)	Regimen	Standard Duration (Months)	Regimen
INH Mono Resistance	Inh Mono regimen (with FDC)	9	RHZE/Lfx		
RR	Standard injectable free regimen	6	Bdq/Lzd/Lfx/ Cfz/Cs	12	Lfx/Cfz/Cs
RR	Alternative IFR for MDR/RR	6	Bdq/Lfx/Cfz/ Cs/Z	12	Lfx/Cfz/Cs/Z
RR	Standard paediatric injectable free regimen	6	Mfx/Lzd/Cfz/ Cs	12	Mfx/Cfz/Cs
RR	Bedaquiline intolerance	6	Dlm/Lzd/Lfx/ Cfz/Cs	12	Lfx/Cfz/Cs
MDR	Standard injectable free regimen	6	Bdq/Lzd/Lfx/ Cfz/Cs	12	Lfx/Cfz/Cs
MDR	Alternative IFR for MDR/RR	6	Bdq/Lfx/Cfz/ Cs/Z	12	Lfx/Cfz/Cs/Z

MDR	Standard paediatric injectable free regimen	6	Mfx/Lzd/Cfz/Cs	12	Mfx/Cfz/Cs
MDR	Bedaquiline intolerance	6	Dlm/Lzd/Lfx/Cfz/Cs	12	Lfx/Cfz/Cs
Pre XDR Injectables Resistant	Standard injectable free regimen	6	BDQ/Lzd/Lfx/Cfz/Cs	14	Lfx/Cfz/Cs
Pre XDR Injectables Resistance (paediatric)	Standard paediatric injectable free regimen	6	Mfx/Lzd/Cfz/Cs	14	Mfx/Cfz/Cs
Pre XDR Flouroquinolone Resistant	Standard pre-XDR Regimen	6	Bdq/Dlm/Cfz/Cs/Lzd	14	Dlm/Cfz/Cs
Pre XDR Flouroquinolone Resistant (Paediatric)	Standard Paediatric Pre-XDR regimen	6	Bdq**/Dlm**/Lzd/Cfz/Cs	14	Dlm/Cfz/Cs
XDR	Individualized regimen	Individualized	Individualized - Select the individuals drugs	Individualized	Individualized - Select the individuals drugs
PDR	PDR oral regimen (With FDC)	9	RHZE/Lfx	N/A	N/A

Abbreviations	Drug		Abbreviations	Drug
Bdq	bedaquiline		Lfx	levofloxacin
Cfz	clofazimine		Lzd	linezolid
Cs	cycloserine		Mfx	moxifloxacin
Dlm	delamanid		RHZE	rifampicin,isoniazid,pyrazinamide,ethambutol

2.1.2 Individualized regimens

Individualized regimens shall be constructed for patients who cannot be on the standard regimens. Construction of these regimens shall use the drug as per the current WHO drug reclassification and any other new WHO approved drugs. The construction of the regimens shall be done in using the best practice and in conformity with the current guidelines or any other approved relevant guidelines

Treatment shall be offered through any of the following models of care

1. Community based
2. Facility based care
3. Isolation
    a. Voluntary isolation
    b. Involuntary isolation

The TB isolation policy shall guide the implementation of TB isolation.

CHAPTER THREE:

POLICY DIRECTION

3.1 Implementation approach

The DNTLD's mission is aimed at promoting quality of life by preventing, controlling, and eventually eliminating tuberculosis in Kenya. Treatment of DR TB is aimed at

1. Preventing death
2. Prevention of significant morbidity and TB complications
3. Reducing catastrophic costs associated with DR TB
4. Reduce transmission in the community
5. Prevention of development of further drug resistance

Successful implementation of the new regimens requires a multisectoral approach. Key players include;

1. DNTLD
2. County governments
3. Partners
4. Civil society
5. Patients
6. Patient advocates

Treatment of DR TB shall require improvement in quality of care through;

1. Baseline and follow up work up as per the guideline
2. Provision of holistic DR TB care – clinical, nutrition, patient education, psychosocial, screening for drug and substance abuse
3. Active drug safety monitoring
4. Palliative care as necessary
5. Management of TB complications during and after treatment
6. Linkage to social protection programs
7. Mandatory review by sub county and county clinical teams as per guidelines
8. Capacity building among HCWs
9. Adequate infection prevention and control (IPC)

3.2 Policy goal

The policy document has been developed in line with the National TB Program's and the 2019- 2023 national strategic plan's (NSP) vision which is, to have a Kenya free of TB. Kenya is expected to have detected and treated 5,412 DR TB cases by 2023. The policy's goal is to introduce better treatment regimens for the treatment of DR TB.

3.3 Policy objective

The objective of the policy is to provide the implementation framework of the injectable free regimens for the treatment of DR TB in Kenya.

CHAPTER FOUR:

POLICY IMPLEMENTATION

4.1 Implementation approach

Ministry of Health and county departments of health, partners and other stakeholders shall develop work plans for the implimentation of this policy.

4.2 Implementation

The DNTLD shall oversee the implementation of this policy. The PMDT Committee of Experts (CoE) shall provide technical guidance on its implementation and advising on tackling any challenges that may arise. The sub county and county clinical teams shall be responsible for;

- Confirmation of the diagnosis of DR TB
- Patient education and counselling
- Thorough clinical evaluation
- Obtaining informed consent before treatment initiation
- Conducting home visits and contact screening
- Timely ordering of DR TB medicines and timely treatment initiation (within 7 days from the date of diagnosis)
- Conducting baseline and follow up work ups
- Monthly and ad-hoc clinical reviews of patients by the sub county and county clinical teams
- Appropriate referral of patients
- Ensure appropriate recording and reporting as per national guidelines

CHAPTER FIVE:

MONITORING AND EVALUATION

5.1 Monitoring and evaluation frame work

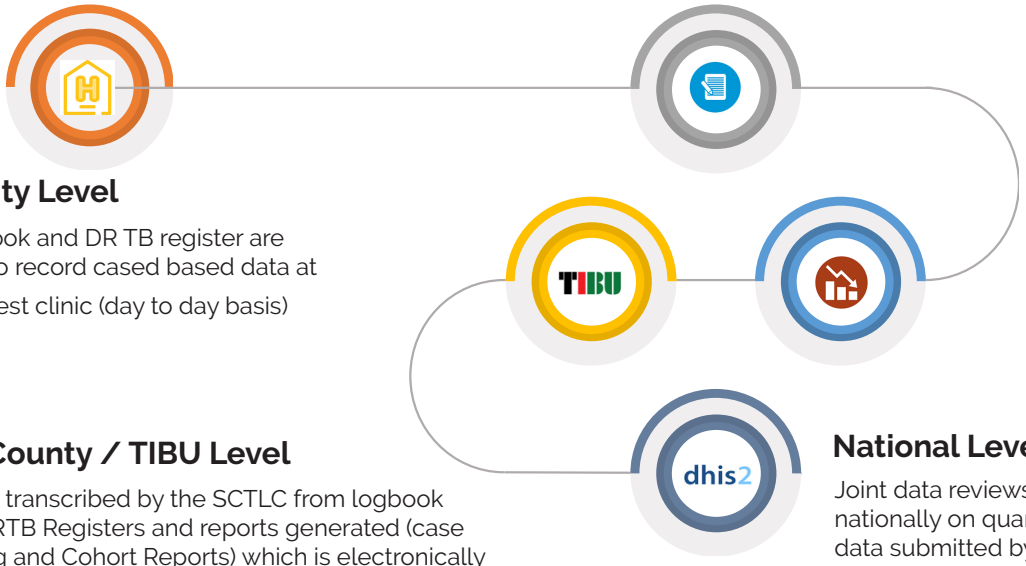
Policy statement: Monitoring and evaluation of uptake of Injectable Free Regimen follows the national guidelines on recording and reporting. All DRTB patients diagnosed should be notified to the National TB Program

Purpose: To guide effective documentation, reporting and evaluation of IFR roll-out in Kenya

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

Coverage Indicators	Outcome Indicators	Evaluation
Number of DR TB patients initiated on Injection Free Regimen	Proportion of DR TB patients enrolled on NHIF	Operation Research
Proportion of DR TB patients initiated on IFR and develops adverse drug reaction	Proportion of DRTB patients who died while on IFR treatment	Periodic Reviews (Mid Term review of the strategic plan
Proportion of DR TB patients enrolled on NHIF		Drug Utilization Reviews
		Cohort Event Monitoring

Data Flow



Facility Level

Log book and DR TB register are used to record cased based data at the chest clinic (day to day basis)

Facility Level

Facilities extracts data summaries from the logbook and DRTB Registers. Data is validated and discussed at the facility before submission to the SCHRIO

Sub County / TIBU Level

Data is transcribed by the SCTLC from logbook and DRTB Registers and reports generated (case Finding and Cohort Reports) which is electronically transmitted to National level. Data is then pushed to DHIS after validation . SCHRIOs will also enter summary data on DHIS on indicators not captured in TIBU

National Level

Joint data reviews are done nationally on quarterly basis for data submitted by SCTLCs and HRIOs. Data is synthesized for performance monitoring and policy formulation

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