



Ministry of Public Health and Sanitation

Standard Operating Procedures for Programmatic Management of Drug Resistant Tuberculosis – (PMDT) Kenya

August 2012



DLTLD

Division of Leprosy, Tuberculosis, and Lung Diseases



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STANDARD OPERATING PROCEDURES

PROGRAMMATIC MANAGEMENT OF DRUG
RESISTANT TUBERCULOSIS – (PMDT)

KENYA

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Preface

Drug Resistant TB has been on the increase in Sub-Saharan Africa and the world at large. Management of this public health threat has posed a major challenge to health care workers.

According to WHO, Kenya had an estimated 2,016 MDR TB cases in 2007, with an estimated prevalence of MDR TB of 1.7% among new TB cases and 7.9% among retreatment cases. Kenya initiated drug resistant TB surveillance in 2003 after the Central TB Reference Laboratory was refurbished. Kenya applied to the Green Light Committee for approval to treat MDR TB cases identified through this surveillance. Approval to treat was granted in 2004, and the country applied for Global Fund Round 5 the following year to cater for treatment and isolation of the diagnosed cases.

Treatment of DR TB in Kenya started in 2006 in the private sector and in April 2008 in public sector. Many challenges have been experienced in the management of these cases. By the end of 2011, Kenya had diagnosed 695 MDR TB cases and treated 389 by June 2012. Currently, all diagnosed patients have been treated. The treatment success rate of the 2008 cohort was 71% and a cure rate of 69%. Better outcomes are expected as the program grows. Newer diagnostic methods such as the Xpert MTB/RIF Assay, Line probe Assay (HAIN), and liquid cultures have been adopted to increase the number of cases diagnosed and improve turnaround time of laboratory results. Decentralization of DR TB surveillance is ongoing with the aim of ensuring universal access to diagnosis, care and treatment.

With the expansion of diagnosis and treatment of drug resistant TB, gaps have been identified, The program decided to come up with interventions to meet this gap. Lessons drawn from the existing program and other programs such as the Rwanda and Lesotho were used to develop standard operating procedures in the care and treatment of drug resistant TB cases to address and mitigate these gaps.

These standard operating procedures are aimed at improving programmatic and clinical management of DR TB. Program officers, health care workers, researchers, and medical students will use them as reference material. It targets both the private and public sector in improving the public private partnership



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List of Abbreviations

ART	Antiretroviral Therapy
CDC	Centres for Disease Control and Prevention.
CHEW	Community Health Extension Worker
CRL	Central Reference Laboratory
DLTLD	Division of Leprosy, Tuberculosis, and Lung Disease
DOTS	Directly Observed Therapy Short course
DR	Drug resistant
DST	Drug Susceptibility Testing
DTLC	District Tuberculosis and Leprosy Coordinator
EPTB	Extra-Pulmonary Tuberculosis
HIV	Human Immunodeficiency Virus.
INH	Isoniazid
IPC	Infection Prevention and Control
IUATLD	International Union against Tuberculosis and Lung Disease
KAPTLD	Kenya Association for Prevention of Tuberculosis and Lung Disease
KNH	Kenyatta National Hospital.
MDRTB	Multi-Drug Resistant Tuberculosis
PPM	Private Public Mix
PTB	Pulmonary Tuberculosis
PTLC	Provincial Tuberculosis and Leprosy Coordinator
R	Rifampicin
TB	Tuberculosis.
UV	Ultraviolet light
WHO	World Health Organization
XDRTB	Extensively Drug Resistant Tuberculosis
ZN	Ziehl-Neelsen

Introduction

1.1 Definitions

- **Mono resistance**
 - Documented resistance to only one drug
- **Poly resistance (PDR)**
 - Documented resistance to at least 2 drugs but not to both Isoniazid and Rifampicin
- **Multi-drug resistant (MDR)**
 - Documented resistance to at least INH and RIF
- **Extensively Drug Resistant TB (XDR TB) :**
 - Documented MDR TB and resistance to a Quinolone and at least one injectable

1.2 Classification of Patients

The classification of patients below are based on the WHO definitions.

- **New.** Patients who have never received anti-tuberculosis treatment, or who have received anti-tuberculosis treatment for less than one month. This group includes patients who had DST done before or within one month of the initiation of category 1 treatment and contacts that have never been treated for TB before.
- **Relapse.** Patients previously treated for tuberculosis that were declared cured or treatment completed, and then diagnosed with MDR TB. Sputum for DST for these patients should be collected prior to initiation of retreatment regimen.

- **Return after default.** A patient who returns to treatment, bacteriologically positive by sputum smear microscopy or culture, following interruption of treatment for two or more consecutive months.
- **Failure of Category I treatment (failure of first line treatment (FLT)).** A patient who has received Category I treatment for TB and in whom treatment has failed. Failure is defined as sputum smear positive at five months or later during treatment.
- **Failure of Category II treatment (failure of re-treatment-(FRT)).** A patient who has received Category II treatment for TB and in whom treatment has failed. For these patients, failure is defined as sputum smear positive at three months or later during treatment.
- **Transfer in.** Patients who have been transferred from another register for treatment of drug-resistant TB to continue Category IV treatment. Their outcomes should be reported to the transferring unit (where the patient was originally) so that it can report their outcomes in the cohort in which they originally started MDR-TB treatment.
- **Other.** Patients who do not fit the above definition. This group includes previously treated pulmonary patients without known outcome status and all previously treated extra pulmonary patients.

1.3 Causes of Drug Resistant TB

- Health care providers:
 - Inadequate regimen
 - Inappropriate guidelines
 - Non compliance with guidelines e.g poor DOT
 - Absence of guidelines
 - Poor training
 - No monitoring of treatment
 - Poorly organized or funded TB control programs

- Drugs:
 - Inadequate or inconsistent supply
 - Poor storage conditions
 - Wrong dose or combinations

- Patients:
 - Inadequate drug intake
 - Poor adherence (or poor DOT)
 - Lack of information
 - Lack of money
 - Lack of transportation
 - Adverse effects
 - Social barriers
 - Malabsorption
 - Substance dependency disorder

1.4 DR TB Diagnosis

People at high risk of getting drug resistant TB(When to suspect drug resistant TB-Case finding)

- Close contact of known MDR-TB case
- Smear positive after 2-3 months of treatment
- Failure of Category I treatment
- Failure of retreatment/chronic disease
- Failure of treatment in private sector
- Relapse or return after default
- History of exposure to anti-TB drugs of unproven quality
- Treatment in programs that operate poorly (with drug stock outs) or no program
- Medicines (history or concomitant) and co morbidities that affect metabolism, absorption of TB drugs
- Institutional exposure (HCW)
- Resident of high resistance-prevalence area

Drug Resistant surveillance target group:

- All retreatment cases:
 - Failures
 - Relapses
 - Return after default
- DR TB contacts
- Health Care workers
- Smear positive refugees

When sputum should be collected for XPERT MTB/RIF/, Culture & DST?

Contacts

- Immediately a history of contact with a DRTB patient is elicited
- One found to have TB symptoms during contact tracing of a DR TB patient
- Before initiation of CAT 1 treatment

New Smear positive

- Before initiation of CAT 1 treatment if:
 - A contact
 - A Refugee
 - Patient on IPT who develops TB
- At month 3, 4, 5 of treatment if still smear positive

New Smear Negative

- A contact
- HIV positive

Relapse

- Prior to initiation of retreatment regimen

Retreatment case

- Prior to initiation of retreatment regimen
- At month 3 of treatment or after if the sputum prior to treatment was not taken
- Return after default should have their samples collected prior to initiation of CAT 11

All patients found to have MDR TB should have Second Line DST done to rule out XDR TB

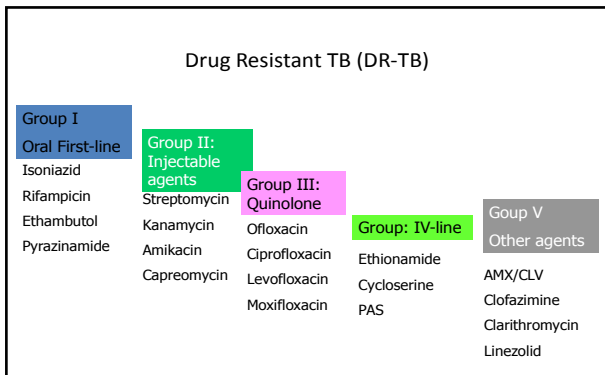
2 TREATMENT

All patients diagnosed to have drug resistant TB should be initiated on second line treatment.

2.1 Classification of Anti Tuberculosis Drugs

Drugs used in treatment of Drug Resistant TB

The drugs are divided into 5 groups: Group as I, II, III, IV, V



PIH curriculum

What to do when you get a drug resistant TB patient

Steps to follow you have identified an MDR TB patient

1. Inform the DTLC
2. Carry out thorough medical examination

i. Patient History

Take a detailed history of the patient including:

- Demographic data (name, age, sex, marital status)
- Residence (where the patient lives), including the village, Assistant chief, location, sub-location and district
- Telephone number of the patient and next of kin
- How the patient could have developed MDR TB
 - New patient
 - Number of times previously treated
 - Regimen previously used
 - History of defaulting
 - Current treatment
- HIV status
- History of drug allergies, smoking, alcohol or any other drug use
- History of any other disease

b. Physical examination

c. Systemic exam

Look out for signs of any other concurrent illness

3. Provide health education to the patient

The patient needs to know:

- Cough etiquette
- How TB is transmitted
- How to protect others from TB
- Treatment options available
- Treatment outcomes (prognosis)
- Infection control measures
- The importance of spending more time outside than in an enclosed area
- The side effects of drugs

4. Prepare the patient for HIV testing if status unknown

- Counsel the patient on the need to know his/her status
- Test the patient in line with the existing protocols
- Provide Cotrimoxazole if HIV positive and refer to CCC for ART

5. Refer the patient to a site offering MDR TB treatment

6. Carry out contact tracing

7. Home Visit

- Prepare to visit the patient at home
- Assess the residence, number of rooms, number of people in the house, ventilation in the house

- Assess patient's physical movements e.g. to church, market and other congregate setting
- Screen the household contacts for TB using symptom screen
- Refer any symptomatic contacts to the nearest health facility for further screening
- Provide health education to household members
- Encourage them to spend more time outside than in an enclosed area

At the MDR TB Treatment Facility

A. Prepare patient for MDR TB treatment

a. Laboratory preparation

The following tests should be done:

- i. Full hemogram
- ii. Liver function test
- iii. Renal function tests
- iv. Pregnancy test
- v. HIV test
- vi. Thyroid function test
- vii. CD4 count if HIV positive
- viii. Sputum test
 - i. Microscopy
 - ii. Culture and sensitivity tests

b. Clinical test

- i. Audiometry (hearing test)
- ii. Chest XR

c. Psycho-social assessment (Assess the patient's knowledge of the disease)

- i. The patient should identify a treatment supporter
 - ii. Ensure the patient understands the length of treatment
 - iii. Prepare the patient for possibility of adverse effects
 - iv. Ensure the patient understands the need of adherence
 - v. Discourage smoking, alcohol or any other drug abuse
 - vi. Discuss nutritional support
 - vii. If HIV positive, discuss the consequence of co infection and transmission prevention e.g. cough etiquette and use of condoms.
- d. Take consent of treatment prior to initiation of treatment after explaining to the patient all the above i.e. what to expect during treatment, adherence, side effects and length of treatment.

2.2 Drug Resistant TB Treatment Regimen

2.2.1 Treatment of MDR TB

Intensive phase:

8 months: Kanamycin /Levofloxacin /Cycloserine /
Prothionamide /Pyrazinamide (**Km/Lfx/Cs/Pto/Pza**)

Continuation phase

12 months: Levofloxacin /Cycloserine /Prothionamide /
Pyrazinamide (Lfx/Cs/Pto/Pza)

2.2.2 Treatment of PDR TB & Mono-resistance

Table 3 Patterns of drug resistance and recommended treatment

Pattern of drug resistance	Regimen	Duration of treatment
H (± S)	R/Z/E/LFX	9 months
H, E, Z (± S)	3Km-Lfx-R-Z/ -Lfx-R—Z**	15 18 months
H and Z	3Km-Lfx-R-Z/ -Lfx-R—Z**	15 18 months
H and E	3Km-Lfx-R-Z/ -Lfx-R—Z**	15 18 months
R	8 Km-Pto-Lfx-Cs-Z / Pto-Lfx-Cs-Z*	12 20 months
R and E (± S)	8Km-Pto-Lfx-Cs-Z/* Pto-Lfx-Cs-Z	12 20months
R and Z (± S)	8Km-Pto-Lfx-Cs-Z/ Pto-Lfx-Cs-Z*	12 20 months

- * The patient should be started on MDR regimen and another sample collected for DST
- ** Consider a patient's previous drug history between the time of sample collection and results being received before starting the patient on the recommended regimen.

2.2.3 Management of XDR TB

- XDR TB should be managed by using an individualized regimen based on the DST results and patient drug history.
- The patient should use at least an injectable, high generation Quinolone, Cycloserine, Prothionamide, Pyrazinamide and add at least two drugs from group 5.
- Injectable should be at least 12 months.
- For every culture positive after month 3 of treatment, add 3 months of injections after the 12th month of injectable.
- After the patient becomes culture positive after a period of negative cultures, repeat the culture.
- If still culture positive, count the first culture positive as the first month of treatment and restart treatment

Points to note

- For Quinolones the daily dose should be given in a single dose once a day. Maximum dose of Quinolone for weight should be administered.
- For Ethionamide, Cycloserine and PAS, the daily dose is divided into morning and evening doses for better tolerance
- All patients should receive pyridoxine. The recommended daily dose is 50mg for every 250 mg of Cycloserine/Terizidone
 - 50mg daily if receiving Cycloserine 250mg daily
 - 100mg daily if receiving Cycloserine 500mg daily
 - 150mg daily if receiving Cycloserine 750mg daily
 - 200mg daily if receiving Cycloserine 1000mg daily.

NB. 200mg of pyridoxine is the maximum dose per day.

- PAS should be used to replace Cycloserine or Prothionamide where the patient cannot tolerate them
- Capreomycin should be used in Pregnancy, children and to replace Kanamycin in case of ototoxicity.

NB: REFER TO THE ANNEX FOR DOSAGE WHERE NECESSARY

2.3 Management of a contact

- Contact tracing and invitation should be carried out for all DR TB patients by visiting the patient home
- Contacts should be screened for TB signs and symptoms such as cough, night sweats, and weight loss among others.
- If symptomatic the following tests should be performed:
- Sputum smear for microscopy, Xpert MTB/RIF (Xpert MTB/RIF Algorithm)
- Chest XR
- For contacts without symptoms: perform a chest XR
- The findings should be recorded in the contact registration form and the contact register (Annex)
- Symptomatic contacts should be managed as per the results
- Asymptomatic patients should be followed up for 24 months with visits carried out during month 0, 3, 6, 12 and 24.

2.4 Management of DR TB in patients with HIV

- All DR TB patients should be tested for HIV
- Partner and child(ren) testing should be encouraged for those found to have HIV
- All DR TB patients with HIV should be initiated on ART within 2-4 weeks after initiating of Cat IV treatment.
- If patient is already on ART , the same regimen should be continued
- If a patient is not on ART, the following regimen is preferred AZT/3TC/EFZ (Zidovudine, Lamivudine, Efavirenz)
- Monitor renal performance for patients on Tenofovir and Cat IV injectables.

The drugs are given as follows:

Morning	Evening
DR TB regimen	DR TB regimen
AZT-3TC: 1 tablet	AZT-3TC: 1 tablet
Cotrimoxazole: 1 tablet (960 mg)	EFX: 1 tablet

2.5 MDR TB in Pregnancy

- All women should have a pregnancy test done before treatment initiation
- Pregnancy is not a contraindication to MDR TB treatment.

- Health care workers should discuss the risks and benefits of the treatment to the mother.
- It is recommended that treatment be initiated in the second trimester. It can be started sooner if the condition of the patient is severe.
- Capreomycin is the recommended injectable in pregnancy. Avoid the other injectable due to the risk of ototoxicity to the fetal ear.
- Avoid Ethionamide during pregnancy

Contraceptive use in Management of DR TB

- *All mothers of childbearing age on Category IV treatment should be on a reliable contraceptive method*
- Perform a pregnancy test
- Counsel patient on reproductive choices and contraceptive options
- Injectable contraceptives are preferred
- DR TB HIV Co infected patients should use dual protection i.e. should use a condom

2.5 MDR TB in Children

Consider DR-TB TB in Children

- If the child is a contact of
 - An adult with infectious DR tuberculosis; or
 - A source case who is a retreatment case (especially treatment after failure) with unknown drug susceptibility, or who is a contact of DR-TB

- If the child, while adhering to treatment;
 - Responds unsatisfactorily or deteriorates, or
 - Relapses shortly after completing
- If the community in which the child resides (or had resided) has a high prevalence of drug-resistant tuberculosis
- All children with drug resistant TB should be initiated on category 4 regimens.
- Drug dosage should be based on the patient's weight.
- The same regimen as the adult should be given

NB: *Refer to dosing chart at the annex.*

Directly Observed Treatment in Drug Resistant TB

- Treatment and care of patients should be agreed between the DOT provider and the patient.
- The DOT provider should ensure that the drugs to be given to the patient are correct.
- The DOT provider should observe the patient swallow all the drugs
- DOT providers should record on the patient treatment card/ log book each time the patient swallows drugs
- The DOT provider should take note of side-effects or clinical worsening and refer to the facility as needed.
- The DOT provider should provide psychosocial support to encourage the patient to finish treatment

- In case a patient does not turn up for treatment, visit the patient's home within 24 hours. Find out the reason why the patient failed to turn up and give treatment. Defaulter tracing should be carried out until the patient has been found

2.6 Laboratory and Clinical Follow – up

Month	Baseline	1	2	3	4	5	6	7	8	9	10	11	12	15	18	21
Clinical review	X	Every 2 weeks	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Audiometry	X	X	X	X	X	X	X	X	X							
Weight	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Height	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Smear	X	X	X	X	X	X	X	X	X	X	X	X	X		Monthly till treatment completion	
Culture	X	X	X	X	X	X	X	X	X	X	X	X	X		Monthly till treatment completion	
DST	X						SLD DST									
LFTs (AST, ALT, Bilirubin)	X	X	X	X			X			X			X	X	X	
Creatinine Potassium	X	X	X	X	X	X	X	X	X							

Full Hemogram	X			X		X						X	X	
CD4	X					X						X	X	
CXR	X					X						X	X	
TSH	X		X			X						X		

Key:

- SLD DST: Second line DST, it should be done at the beginning of treatment. It should also be carried out if a culture negative patient turns positive.
- Liver function and renal function tests may be done at any time as clinically indicated
- Patient's height should be taken at baseline in adults and monthly in children. BMI should be calculated monthly
- The patients' HIV test should be done at baseline
- Hemogram (HB) in a patient on Zidovudine (AZT) should be carried out at baseline, 4, 8 and 12 months.

2.7: Side effects monitoring and management

Rational prescribing of and aggressive management of adverse effects of second-line anti-tuberculosis medicines facilitates the patient's adherence and favorable outcome of treatment

The health care worker attending the MDR TB patient or the DOT worker should be familiar with the common side effects of anti-tuberculosis therapy. Any patient that develops any adverse drug reaction effects should be referred to physicians as needed.

The table below lists the common side effects, the likely causative agents, and suggested management strategies.

THE COMMON SIDE EFFECTS, THE LIKELY AGENTS RESPONSIBLE, AND SUGGESTED MANAGEMENT

STRATEGIES

Side affect	Suspected agent(s)	Suggested management strategy	Comments
Seizures	Cs H FQ	<ul style="list-style-type: none"> • Suspend suspected agent pending resolution of seizures • Initiate anticonvulsant therapy (e.g., phenytoin, valproic acid) • Increasing pyridoxine to a maximum daily dose (200 mg per day) • Reinitiate suspected agent at lower dose, if essential to the regimen 	<ul style="list-style-type: none"> • Anticonvulsant is generally continued until MDR TB treatment is completed or suspected agent discontinued. • History of prior seizure disorder is not a contraindication to the use of agents listed here if a patient's seizures are well controlled and/or the patient is receiving anticonvulsant therapy. • Patients with history of prior seizures may be at increased risk for the development of seizures during MDR TB therapy.
Peripheral neuropathy	CS H FQ KM AMK CM E Ethio	<ul style="list-style-type: none"> • Increasing pyridoxine to a maximum daily dose (200 mg per day). • Change parenteral to CM if the patient has documented susceptibility to CM. • Initiate tricyclic antidepressants such as amitriptyline. NSAIDs or acetaminophen may help alleviate symptoms. • Lower dose of suspected agent, if this can be done without compromising regimen. 	<ul style="list-style-type: none"> • Patients with co-morbid disease (e.g., diabetes, HIV, alcoholism) may be more likely to develop peripheral neuropathy, but these conditions are not contraindications to the use of the agents listed here. • Neuropathy may be irreversible; however, some patients may experience improvement once offending agents are stopped

Hearing loss	S KM AMK CM	<ul style="list-style-type: none"> • Document hearing loss and compare to baseline Audiometry • Change parenteral to CM if patient has documented susceptibility to CM • Lower dose of suspected agent, if this can be done without compromising regimen. 	<ul style="list-style-type: none"> • Patients with prior exposure to amino glycosides may have a baseline hearing loss. In such patients, it may be helpful to obtain Audiometry at the initiation of MDR TB therapy. • The hearing loss is generally not reversible.
Psychotic symptoms	Cs, H, FQ, Ethio	<ul style="list-style-type: none"> • Usually caused by Cs. Withhold suspected agents until symptoms are brought under control. • Initiate anti-psychotic drugs e.g. Haloperidol • Start Cycloserine at 250mg per day, observe for 5 days, If stable increase to 250mg BD for 5 days. Increase the dose again to 750mg per day. If the patient cannot tolerate, reduce to where the patient can tolerate. NB. Cycloserine is given in divided doses. • In case of severe psychosis, replace with PAS 	<ul style="list-style-type: none"> • Some patients will need to continue anti-psychotic treatment throughout MDR TB therapy. • Prior history of psychiatric disease is not a contraindication to the use of agents listed here but may increase the likelihood of developing of psychotic symptoms. • Psychotic symptoms are generally reversible upon completion of MDR TB treatment or cessation of the offending agent

Depression	Socioeconomic Circumstances, Chronic disease, CS, FQ, H, Ethio	<ul style="list-style-type: none"> • Improve socioeconomic conditions. • Group or individual counselling. • Initiate antidepressant drugs. • Lower dose of suspected agent, if this can be done without compromising the regimen. • Withhold the suspected agent for a short period as symptoms subside (one to four weeks) and reinstate therapy 	<ul style="list-style-type: none"> • Socioeconomic conditions and chronic illness should not be underestimated as contributing factors to depression. • Depressive symptoms may fluctuate during therapy and may improve as illness is successfully treated. • History of prior depression is not a contraindication to the use of the agents listed here; however, these patients may be at increased risk for developing depression during MDR TB treatment
Hypothyroidism	PAS, Pto/Ethio, Especially when given in combination	<ul style="list-style-type: none"> • Initiate Thyroxin therapy • Thyroxin should be given for till one month after completion of treatment • Follow TSH and adjust thyroxin periodically 	<ul style="list-style-type: none"> • Completely reversible upon discontinuation of PAS or Ethio. • Generally, no need to suspend suspected agents
Nausea and vomiting	PAS, Pto, H, E, Z, CFZ	<ul style="list-style-type: none"> • Assess for dehydration. Initiate rehydration if indicated. • Initiate anti-emetic therapy. • Lower dose of suspected agent, if this can be done without compromising regimen. 	<ul style="list-style-type: none"> • Nausea and vomiting are ubiquitous in the early weeks of therapy and usually abate with time on treatment and supportive therapy. • Electrolytes should be monitored and repeated if vomiting is severe. • Reversible upon discontinuation of suspected agent. • Severe abdominal distress and acute abdomen have been reported with the use of clofazimine. Although these reports are rare, if this effect occurs, clofazimine should be suspended.

Gastritis	PAS Ethio H E Z CFZ	<ul style="list-style-type: none"> • Antacids (e.g., calcium carbonate, H2-blockers, proton-pump inhibitors). • Take medication after meals • Monitor electrolytes especially potassium and replace. 	<ul style="list-style-type: none"> • Severe gastritis, as manifested by hematemesis, melena, or hematechezia, is rare. • Dosing of antacids should be carefully timed So as to not interfere with the absorption of anti-TB drugs (take two hours before or after anti-TB medications).
Hepatitis	Z R H Ethio PAS E FQ	<ul style="list-style-type: none"> • Stop all therapy pending resolution of hepatitis. <i>(If the LFT results shows a >5 times more than the reference range)</i> • Rule out other potential causes of hepatitis. • Consider suspending most likely agent permanently. Re-introduce remaining drugs, one at a time with the LEAST suspected hepatotoxic agents first, while monitoring liver function 	
Renal failure	S KM AMK CM	<ul style="list-style-type: none"> • Consider using CM if an amino glycoside had been the prior parenteral in regimen. • Consider using intermittent dosing while monitoring the Creatinine clearance • Adjust all TB medications according to the Creatinine clearance 	<ul style="list-style-type: none"> • History of diabetes or renal disease is not a contraindication to the use of the agents listed here, although patients with these co-morbidities may be at increased risk for developing renal failure. • Renal impairment may be permanent

Electrolyte disturbance (Hypomagnesaemia & Hypokalemia)	CM KM AMK S	<ul style="list-style-type: none"> • Check potassium. • If potassium is low, also check magnesium (and calcium if hypocalcemia is suspected). • Replace electrolytes as needed 	<ul style="list-style-type: none"> • If severe Hypokalemia is present, consider hospitalization. • Amiloride 5-10 mg QD or spironolactone 25 mg QD may decrease potassium and magnesium wasting and is useful in refractory cases. • Electrolyte disturbances most commonly observed with Capreomycin
Optic neuritis	E	<ul style="list-style-type: none"> • Stop E. • Refer patient to an ophthalmologist 	<ul style="list-style-type: none"> • Usually reverses with cessation of E. • Rare case reports of optic neuritis have been attributed to streptomycin
Arthralgias	Z FQ	<ul style="list-style-type: none"> • Initiate therapy with non-steroidal anti-inflammatory drugs. • Initiate exercise regimen. • Lower dose of suspected agent, if this can be done without compromising regimen. 	<ul style="list-style-type: none"> • Symptoms of arthralgia generally diminish over time, even without intervention. • Uric acid levels may be elevated in patients on pyrazinamide. Allopurinol appears not to remediate uric acid levels.

Management of Hypokalemia

Hypokalemia is defined as serum potassium levels (K⁺) of < 3.5 mmol/l.

Causes:

- Malnutrition
- Diarrhoea
- Vomiting
- Renal electrolyte wasting (side effects of injectable)

Symptoms:

- Weakness
- Fatigue

- Palpitations
- Muscle cramps
- Muscle pains.
- Some patients present with no symptoms at all.

Oral Potassium Replacement

Serum K ⁺ (mmol/l)	Dose of slow release potassium (mg)
3.3 – 3.5	1200 mg TDS (6 tabs = 48mEq per day)
2.9 – 3.2	1800 mgs TDS (9 tabs = 72 mEq per day)
2.5 – 2.8	2400 mg TDS (12 = 96 mEq per day)
≤ 2.4	3000 mg TDS (15 tabs = 120mEq per day)

- For serum K⁺ ≤ 2.8 mmol/l, check potassium the next day.

Intravenous potassium replacement

Intravenous replacement of K⁺ should be done if:

- Serum potassium is < 2.0mmol/l
- Symptomatic Hypokalemia

Dose: potassium Chloride (KCL) 1500mg (2 ampoules = 20 ml = 40mEq) in 200ml of Normal saline over 2 – 4 hours.

DO not exceed infusion rate of 20 mEq per hour (100 ml/hr)

Recheck serum K⁺ 1 hour after infusion. Repeat I.V replacement until serum K⁺ > 2.8 mmol/l

NB: IV replacement should ideally be carried out as an in-patient.

REPLACEMENT OF MAGNESIUM

Patients on with Hypokalemia of $< 2.8\text{mmols/l}$ are likely to have hypomagnesaemia.

Giving potassium replacement alone will not correct their potassium deficit unless they receive concomitant magnesium replacement therapy.

Intravenous dose:

Magnesium sulphate (MgSo_4) 4g in 250ml of 5% dextrose over 90 min. Repeat until serum K^+ is 2.8ml/l

Oral dose: Magnesium gluconate 1g BD (give all patients with serum K^+ of $\leq \text{mmol/l}$)

NB: Patients with renal electrolyte imbalances due to injectable wasting will require regular magnesium and potassium supplements until the injectable has been discontinued.

Normal renal function should be confirmed prior to using the protocol, although even patients with renal failure receive smaller doses. Consult a physician.

Management of Hypocalcemia

- Symptomatic hypocalcaemia should be treated on an emergency basis with 2 grams of calcium gluconate (180 mg elemental calcium or 20 ml 10% calcium gluconate) IV over 10 minutes, followed by infusion of 6 grams calcium gluconate in 500 ml Dextrose 5% over 4–6 hrs. The IV infusion should be tapered. The initial oral dose during the transition from IV to oral therapy is 1–2 g elemental calcium three times a day.

- For long-term therapy, the typical dose is 0.5–1.0 g PO TID.
- Hypomagnesaemia must be treated if present.
- Total serum calcium levels need to be adjusted for low albumin (ionized levels of calcium do not need to be adjusted). The total serum calcium can be corrected by adding 0.8 mg/dl for every 1 g/dl decrease of serum albumin below 4 g/dl. By doing this calculation one can determine if true hypocalcaemia is present

FREQUENCY AND REPLACEMENT OF CALCIUM

Calcium level (total calcium adjusted for low albumin)	Dose of calcium	When to do next control
>8.5 mg/dl (>4.2 mEq/L)	None	
7.5 – 8.4	500 mg TID	Monthly
7.0 – 7.4	1000 mg TID	1–2 weeks
<7.0	Consider IV and taper to 1000 mg TID	1–4 days

NOTE: Corrected calcium for hypoalbuminemia = 0.8(4.0-measured albumin) + reported calcium

Management of Hypothyroidism

Since this is a slow process, both patient and clinician may not realize that there is something wrong.

Classical signs and symptoms:

- Patient is Slow
- Dry hair,
- Thick skin
- Deep voice
- Weight gain
- Cold intolerance
- Bradycardia
- Constipation

These are difficult to identify among the elderly.

Rule out:

- Hyponatremia
- Cumulative effect of Cycloserine
- Chronic illness
- Among HIV positive patients rule out HIV encephalopathy and other CNS opportunistic infections.
- Depression

Management

- Do TSH
- Replace Throxine, which should be continued throughout

the course of MDR TB therapy and may be extended until TSH has fallen to within normal.

- The dose will depend on the age and fitness of the patient, especially cardiac performance.
- Adequate replacement should be assessed clinically and by doing TSH at least every 6 weeks on a steady dose.
- Restore TSH to below 5m IU/ml.

Adults (>16 years)

- The typical dose is 2µg/Kg/day (150µg/day in a 75kg adult). The dose ranges from 50 to 200µg/day

Children (4 – 15 years old)

- 4mcg/kg/day (max. Dose is 200µg)

Infants (1 – 3 years old)

- 10 – 15 µg/kg/day (max. Dose is 200 µg)

Role of treatment centers

- **MDR TB Treatment Centre** (also the Referral Centre: PGH, D.H, Sub D.H & Big FBH)

- **Roles;**

- Overall Responsibility of the Pt
- MDR TB Team
- Plan pt treatment
- Monthly monitoring
- Daily monitoring if patient comes for DOT
- Receive Referred MDR TB cases
- Side effect management
- Microscopy, culture & DST
- DOT
- Ensure uninterrupted drug supply (order Drugs for the pts)
- Recording & reporting
 - Decentralize MDR TB pt
 - IPC
 - Adherence counseling
 - Family support

- **DOT Centre/facility** (also the treatment site: H.C, Dispensary, and Home/community)

- **Roles;**

- MDR TB surveillance
- Treatment initiation following MDR TB treatment plan by the MDR TB team
- Strict Daily DOT
- Contact tracing
- Daily monitoring
- Side effect identification
- Microscopy, culture & DST
- Ensure uninterrupted drug supply (order Drugs for the pts)
- Recording & reporting
- Referring patients for:
 - monthly follow up where necessary
 - Management of side effects
- Receive decentralized pt
- IPC
- Family support
- Adherence counseling

3. ROLE OF THE COMMUNITY IN CONTROL AND MANAGEMENT OF DR TB

RESPONSIBLE: Chews, Family Members, Patient,

- CHEWS Follow up the MDR TB patients
 - Carry out DOT
 - Monitor patient's management plan
 - Track defaulters and bring them back on treatment
- Active case finding:
 - Contact tracing
 - Screening of close contacts and other suspects for MDR TB and HIV
- Health Education
 - Educate family members on identification of side effects
 - Offer psycho-socio support to the patient and family members
 - Infection control measures at home and within the community
 - Help the community understand how MDR TB develops, its consequences and how to prevent it.
- Record and report significant findings in the community/home that could be risky to the patient or family
- Create awareness within the community to minimize stigma.
- Provide linkage to the CHWs

FAMILY MEMBERS

- Provide active DOT support.
- Open the windows to ensure adequate ventilation all the time
- Encourage the patient to observe cough etiquette i.e. use of surgical mask, tissue or handkerchief.
- As much as possible stay outdoors
- Observe proper sputum disposal procedures
- Ensure that the patient avoids crowded places as much as possible
- Provide nutritional support to the patient
- Provide a separate room for the patient especially during the intensive phase
- Offer social and economic support to the patient.
- Identify early signs of TB for early intervention

PATIENT

- Adhere to treatment
- Report any abnormal symptoms to family members or CHEWS
- Observe infection control measures to prevent infection transmission
- Ensure proper disposal of sputum
- Use sputum containers with disinfectant and tight fitting lid
- Adhere to clinical appointments and follow up investigations as required

4 Models of Drug Resistant TB Care and Treatment

- Isolation
- Facility based ambulatory
- Community based ambulatory
- Requirements
 - A dedicated team; Physician, Nurse, Pharmacist, PHO, Social worker/ counsellor, lab personnel
 - Identify someone to carry out DOT/ strict adherence
 - Patients Psychosocial and nutritional support
 - Management of side effects

Criteria for selecting the model of treatment

- Isolation:
 - Preferred for refugees
 - Complications necessitating admission e.g. for blood transfusion, electrolyte imbalance etc.
 - XDR-TB
 - Mobile populations / Nomadic
 - Non-adherence
- Facility based Ambulatory care
 - Patient preference
 - Distance home patient – health facility < 5 km
 - Time to reach the health facility is < 1-2 hours
 - General condition of the patient is stable

- Community based Care
 - Patient preference
 - Distance home patient – health facility > 5 km
 - Time to reach the health facility > 1-2 hours
 - General condition of the patient is stable

5 Nutritional Care and Management

The general objectives in Nutritional Care and management of MDR TB patients are to:

- Prevent and control body wasting and weakness
- Correct nutritional deficiencies, which may have occurred during the disease.
- Modify diets to the body's ability to metabolize nutrients during TB disease
- Improve immunity and accelerate the healing process.
- Maintain good nutrition status

5.1 Steps in nutrition management and support

- Carry out Nutritional assessment including
 - Anthropometric: weight, height/length
 - Biochemical (HB, Urea, electrolytes, Creatinine, blood sugar, TFT, LFT)
 - Clinic (wasting, hair change, pallor, etc.)
 - Dietary (History)
 - Economic/social
 - Medical history
- Prepare a nutrition care plan (diagnosis, intervention and follow-up plan)
- Conduct nutrition counselling /education
- Agrees on and carry out a follow up plan. Set target, timeline, return date and referrals)
- Refer the critically ill to specialized care if necessary

5.2 Actions point for the healthcare workers:

Provide health and nutrition education and counselling alongside DOTS guided by the following:

- Help the client set nutritional goals.
- Help clients understand how TB and HIV affect nutrition
- Assist clients understand malnutrition and the causes of poor nutrition
- Advise clients to eat a healthy and balanced diet from locally available foods, to cater for their increased energy and nutrient needs
- Conduct monthly nutrition assessments especially weight and height
- Use the standard cut off points for BMI and Z-scores to determine the patients that require nutrition interventions
- Refer severely malnourished clients for admission to a hospital. Consider provision of supplements and other nutritional support
- Advise clients maintain high levels of sanitation, food hygiene, and water safety at all times.
- Advise clients to practice positive living behaviour, including; safer sex, avoid use of alcohol and cigarettes, non-prescription drugs, moderation consuming junk foods.
- Advise clients to carry out physical activity or exercises
- Advise clients to drink safe, clean or boiled water
- Assist patients to manage symptoms, which may interfere with food intake, absorption, and utilization. Advise the patient on the use of locally available foods and natural spices that may alleviate the situation

- Manage food drug interactions and side effects and discourage the patient from using alternative medicine
- Provide multiple micronutrient supplements to all patients with BMI less 18.5.
- Give vitamin A every six months.
- Help the client come up with a food-drug plan, which specifies when the food is to be taken in relation to the drugs.
- Follow-up and closely monitor the patient and/or refer to a nutritionist
- Encourage the patients to ensure that they are food secure.

5.3 Key anthropometric cutoff points: BMI for adults

BMI level	Condition	Action
< 16	Severely malnourished	All patients need therapeutic nutrition management. Refer unstable patients for inpatient stabilization.
16.0–18.5	Moderate/mild	These patients require supplementary feeding. Conduct nutritional counselling. Continue with bi-monthly nutrition assessment
18.5–25.0	Normal/recommended	Conduct nutritional counselling to maintain the status. Continue with monthly nutritional assessments

25–30	Overweight	Nutritional counselling to attain healthy weight. Consider physical activity as tolerated.
30+	Obese	Nutritional counselling to attain healthy weight. Consider physical activity as tolerated.
<p>Note:- All of these patients should receive a monthly food basket for them and their families for food insecure households</p>		

5.4 Key anthropometric cut-off points: W/H for children

Weight/ Height level	Condition	Action in the Facility
<-2Z Score	Moderate acute malnutrition without medical complications	<ul style="list-style-type: none"> • Provide supplementary food every 2 weeks • Provide routine treatment according IMAM national guidelines e.g. de-worming • Give daily multiple micronutrients • Give vitamin A on registration and then every 6 months.

<-3Z Score	Severe acute malnutrition without medical complications	<ul style="list-style-type: none"> • Admit into the outpatient therapeutic feeding program • Administer routine treatment • Give daily multiple micronutrients
<-3Z Score	Severe acute malnutrition with medical complications	Admit/refer for inpatient stabilization and therapeutic nutrition management

6 Infection Control Measures

6.1 General Health Facility Measures

- Set up an infection control committee,
- Develop and display TB infection control plan Appoint TB IC focal person
- Educate clients on cough etiquette and respiratory hygiene
- Reduce TB suspects time in the facility through Triage, separation and express services
- Create a special open area for sputum collection
- Routinely screen patients/clients who are at high risk of TB infection e.g. in the CCC. Patients with chronic illness, in congregate settings etc.
- Provide adequate ventilation in patient waiting bays, and other high-risk rooms. For integrated TB/HIV program, give separate clinic days for TB/HIV co-infected from those with HIV only.
- Give regular health education e.g. during morning talks before clients are attended to
- Provide the sputum test results within 24hours. Start appropriate TB treatment promptly) and enforce DOT for treatment adherence
- Initiate TB defaulter tracing mechanisms
- Put all TB/HIV co infected patients on ART within the first 2 months.
- Train/sensitize all hospital Staff on infection control measures

Handle any TB relapse, return after default, failure, or resumed treatment cases while in the wards as potential MDR-TB patients

6.2 MDR-TB Specific Measures in Isolation Ward

- Make prior arrangement to reduce patient contact time with other clients either in the medical wards or outpatient departments
- Patients to spend much of their time Discourage relatives and caregivers from staying in the wards overnight to take care of the patients. In case they do they must wear an N95 mask
- All health care providers and other patient attendants in the wards must wear dust coats and N95 masks at all times
- Use disposable sputum containers with additional antiseptics for patients producing sputum
- Schedule date and time with the X-ray department for patients due for CXR during which other clients are blocked off)
- Adequately fit isolation rooms with functioning ventilators and UV lights where applicable.
- Make doors and windows wide enough to allow adequate movement of air and keep windows to outside wide open
- Collection and transportation of laboratory samples should be done by a provider trained on infection control and transportation of biohazards
- Organize for client discharged from hospital before sputum conversion to take great measures of infection control. Use of bicycles or motorcycle are best preferred options where possible

Health Care Workers

- Should undergo both baseline and routine screening for TB & HIV
- Who is HIV infected avoid deployment in areas of high risk of TB infection
- Should educate new DRTB patients on IC measures at in the facility to reduce emission of Mycobacterium into the environment
- Should wear a respirator when attending to a patient in an enclosed area
- The patient should wear a surgical mask while in the infectious phase
- Should ensure good ventilation, windows open
- The patient should wait in an open area
- Should prepare patient medication in advance to reduce contact time*
- Should determine your siting position verses the patient: The health care worker should ensure that the airflow is away from him/her to reduce transmission

Responsible: CHWs, CHEWs, family members, DOT supporters

6.3 Community (Home) Measures

People are encouraged to

- Attend an infection control session at the facility offering treatment
- Open windows and improve lighting at all times

- Spend as much time outdoors as possible.
- Educate on cough etiquette and respiratory hygiene (cover the mouth while coughing, spit in container with disinfectant solution, avoid spitting on the ground)
- Dispose cough products in a pit latrine, bury, burn or flush into a toilet
- Isolate patient in the intensive phase where possible
- Support patient with good nutrition, safe water and environmental hygiene
- In addition to the above roles, CHEW should:
 - Routinely screen all household contacts of MDR TB for TB
 - Issue IEC materials in the patient's preferred language if available

The patient should

- Use surgical masks during the intensive phase to reduce aerosol spread when on transit, talking or when close to family and non family members
- Adhere to prescribed treatment in order to control the infection
- Restrict movements as much as possible until sputum conversion is confirmed
- Avoid overcrowded social places e.g. church, bars until sputum conversion
- Reduce as much as possible close contact with children and other family members.

6.4 Community DOTS Providers Should

- Know your HIV status. If positive do not attend to TB patients
- Spend minimum time possible with the client if in an enclosed area
- Always wear N95 masks while providing services at home
- Always, (unless bed ridden) attend to the clients outdoors. Spend minimum time in the house.
- Observe aseptic techniques during injection or sample collection
- Sit in a way that ensures air from the patient flows away from you
- Dispose off all infectious material including sharps (Biohazard materials) either in a pit latrine or, in the case of non-liquid materials, in a safety box for incineration in the hospital
- Should routine HIV and TB screening
- In case of a cough not responding to treatment for more than one week. See a clinician for further evaluation and screening for TB.
- Always replace N95 masks every 3 weeks depending on how often you use and store it. If used more frequently, reduce the duration of use up to 1 week.
- Wear a N95 and ensure patients have a surgical mask on.
- Store your respirator in a clean, dry place

7 Monitoring and Evaluation

PMDT M&E (recording) tools include

- Patient Appointment card
- Patient treatment log book
- Referral forms
- Contact registration form
- Side effect monitoring tools
- Facility treatment Register
- Drug consumption tool
- Contact and suspect register
- District Register
- Laboratory request forms
 - AFB Microscopy form
 - Culture request forms

7.1 Reports from the facility to the division

Report	Frequency
DR TB register	Quarterly
DR TB case finding	Quarterly
Interim outcomes	Every 6 months, annually
Final outcomes (cohort)	3 months after the end of the cohort treatment to be send quarterly

Annex 1: Anti-TB Drug Dosing: Adults and adolescents

Drugs	Weight Class			
	Average daily dosing	33-50kg	51-70kg	>70kg
Isoniazid (H) (100,300 MG)	10-20 mg/kg daily	200 - 300 mg daily	300mg daily or	300mg
Rifampicin ® (150, 300m mg)	10-20 mg/kg daily	450-600 mg	600 mg	600 mg
Ethambutol (E) (100, 400 mg)	25 mg/kg daily	800-1200 mg	1200-1600 mg	1600-2000 mg
Pyrazinamide (Z) (500 mg)	30-40 mg/kg daily	1000-1750 mg	1750-2000 mg	2000-2500 mg
Streptomycin (S) (1 G vial)	15-20mg/kg daily	500-750 mg	1000 mg	1000 mg
Kanamycin Km (1G vial)	15-20mg/kg daily	500-750 mg	1000 mg	1000 mg
Amikacin (AM) (1G vial)	15-20mg/kg daily	500-750 mg	1000 mg	1000 mg
Capreomycin (CM) (1G vial)	15-20mg/kg daily	500-750 mg	1000 mg	1000 mg

Oxfloxacin (Ofx) (200,300,400mg)	The usual adult dose for MDR-TB is 800 mg	800 mg	800 mg	800-1000 mg
Levofloxacin (LFX) (250,500 mg)	The usual adult dose for MDR-TB is 750 mg	750 mg	750 mg	750-1000 mg
Moxifloxacin (Mfx)	The usual adult dose for MDR-TB is 400 mg	400 mg	400 mg	400 mg
Gatifloxacin (Gfx) (400 mg)	The usual adult dose for MDR-TB is 400 mg	400 mg	400 mg	400 mg
Ethionamide (Eto) (250 MG)	15-20 mg/kg daily	500 mg	750 mg	750-1000 mg
Prothionamide (Pto) (250 MG)	15-20 mg/kg daily	500 mg	750 mg	750-1000 mg
Cycloserine (Cs) (250 MG)	15-20 mg/kg daily	500 mg	750 mg	750-1000 mg
Terizidone (Trd) (300 MG)	15-20 mg/kg daily	500 mg	750 mg	750-1000 mg
PAS 4gm sachets	150mg/kg daily	8gm	8gm	8-12gm

Annex 2: Anti-TB Drug Dosing: Children

Medication	Dose	Maximum daily dose
Isoniazid(H)	10mg/kg daily	300mg
Rifampicin (R)	15mg/kg daily	600mg
Ethambutol (E)	25mg/kg daily	1200mg
Pyrazinamide (Z)	30 -40 mg/kg daily	1500mg
Streptomycin (S)	20 - 40mg/kg daily	1000mg
Kanamycin (K)	15 -30mg/kg daily	1000mg
Capreomycin (Km)	15 -30mg/kg daily	1000mg
Ofloxacin (Ofx)	15 - 20mg/kg daily	800mg
Levofloxacin (Lfx)	15 - 25mg/kg daily	1000mg
Moxifloxacin (Mfx)	7.5 -106mg/kg daily	400mg
Ethionamide (Eto)	15 – 20 mg/kg daily	1000mg
Cycloserine (Cs)	10 – 20mg/kg daily	1000mg
Terizidone(Trd)	10 – 20mg/kg daily	1000mg
Para – aminosalisyllic acid (PAS)	150mg/kg daily	8g(PASER)

MDR-TB DRUG SIDE-EFFECT MONITORING FORM												
Continuation phase (Adverse effect(indicate grading))												
Month of treatment	Month/date											
Date of collection												
Abdominal pain												
Constipation												
Decreased hearing												
Depression												
Diarrhea												
Dizziness												
Fatigue												
Fever												
Headache												
Joint pain												
Nausea												
Psychosis												
Rash												
Skin colorization												
Tinnitus												
Tremors												
Vision changes												
Vomiting												
Other (list)												

* Grading: 1 = mild, requiring no intervention; 2 = moderate, requiring palliative intervention; 3 = severe, requiring change in treatment

** Indicate in the last column the month of treatment that intensive phase ended

Annex 5 DR TB CONTACT REGISTRATION FORM

Facility Name		Region		County	
Date of Registration:			Site		
INDEX CASE District DR-TB registration No					
District CONTACT registration No.					
Contact's name(three names)					
Contact's Age					

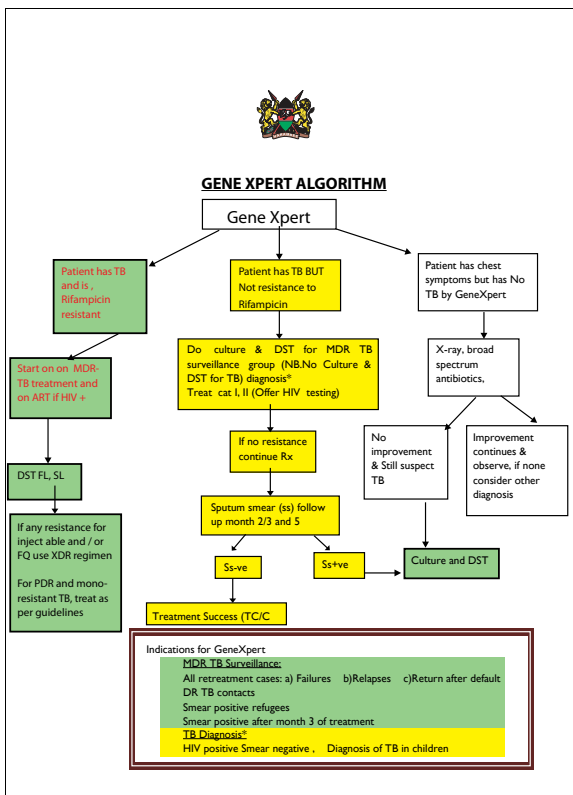
Physical address. Include nearest Church/School					
Contact's Phone:					
*Type of contact:					
Clinical History					
TB Symptoms (Check all that apply)					
	Follow Up				
Symptom	Month 0	Month 3	Month 6	Month 12	Month 24
Cough for ≥ 2 weeks (with or without hemoptysis)					
Fever for ≥ 2 weeks(or illness in children)					
Noticeable weight loss. (In children, Low weight for age or failure to thrive)					

Chest pain or breathlessness.					
Night sweats.					
Swelling in the neck, armpit, abdomen or groin(In children also Joint or spine)					
Additional Individual Risk for Infection: Check all that apply					
Immigrant	Yes				No
State from which country Resident/employee of congregate setting?	Yes				No
If yes, where:					
Previous TB Treatment	Yes			No	
Duration of TB treatment					
Second line drugs already received (Specify)					
Health care worker	Yes			No	

Homeless		Yes	No		
Individual Risk for Progression to Disease					
HIV Infected	Yes		No		
Medical conditions that increase risk(tick whichever is applicable)	Diabetes		Cancer		
	Immunosuppressive therapy (steroids, cancer		Low weight		
	Others(specify)				
Laboratory & Radiological Investigation(for symptomatic contacts)					
Follow Up					
	Month 0	Month 3	Month 6	Month 12	Month 24
Sputum Smear (Pos/Neg)					
Sputum culture (Pos/Neg)					

DST(drug Sensitivity Test)						
Chest XR						
XPRT MTB/RIF						
Action taken						
If no TB:	Review after three months					
If has TB:	Refer to MDR TB Clinic					
*Type of contact:	Household-HH					
	Workplace-WP					
	Health facility-HF					
	Others-O. This includes neighbours, school, Prisons,					

Annex 6: XPERT MTB/RIF (GENEXPERT) ALGORITHM



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