



NATIONAL TUBERCULOSIS CONTROL PROGRAM

MANUAL OF PROCEDURES

6th edition



TB DOTS
CERTIFIED FACILITY

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**National Tuberculosis Control Program
Manual of Procedures 6th edition**

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ABBREVIATIONS

3HP	rifapentine plus isoniazid regimen (weekly for three months)
3HR	isoniazid rifampicin daily (for three months)
4P	Pantawid Pamilyang Pilipino Program (Conditional Cash Transfer)
4R	rifampicin daily (for four months)
6H	isoniazid daily (for 6 months)
AESI	adverse events of special interest
AFB	acid-fast bacillus
AI	artificial intelligence
ALT	alanine
AST	aspartate transaminase
ART	antiretroviral therapy
ARV	antiretroviral
ACF	active case finding
ADR	adverse drug reaction
aDSM	active drugs safety monitoring and management
BC	bacteriologically confirmed
BCG	bacille Calmette-Guerin
BCTB	bacteriologically confirmed tuberculosis
BPNS	brief peripheral neuropathy screen
CDTB	clinically diagnosed tuberculosis
CHD	Center for Health Development
CHO	city health office
CNS	central nervous system
DOT	directly observed treatment
DOTS	directly observed treatment, short course
DR-TB	drug-resistant tuberculosis
DST	drug-susceptibility test
DS-TB	drug-susceptible tuberculosis
DSWD	Department of Social Welfare and Development
ECC	Employees Compensation Commission
ECF	enhanced case finding
ECG	electrocardiogram
EFV	efavirenz
EPTB	extrapulmonary tuberculosis
FBS	fasting blood sugar
FLD	first-line drugs
FM	fluorescence microscopy
FQ	fluoroquinolone

FQ-S	fluoroquinolone susceptible
FQ-R	fluoroquinolone resistant
GSIS	Government Service Insurance System
HCW	health-care worker
ICF	intensified case finding
IGRA	interferon-gamma release assays
INH	isoniazid
IRIS	immune reconstitution inflammatory syndrome
ITIS	Integrated Tuberculosis Information System
ITR	individualized treatment regimen
KMITS	Knowledge Management and Information Technology Service
LFT	liver function test
LGU	local government unit
LPA	line probe assay
LPV/r	iopinavir/ritonavir
LTBI	latent tuberculosis infection
LTFU	lost to follow-up
MDR-TB	multidrug-resistant tuberculosis
MOP	Manual of Procedures
MTB	Mycobacterium tuberculosis
NDPCO	Drug Policy Compliance Officer
NTP	National Tuberculosis Control Program
NVP	nevirapine
OIF	oil immersion field
PA	posteroanterior
PCC	patient-centered care
PhilSTEP1	2017–2022 Philippine Strategic TB Elimination Plan: Phase 1
PHO	provincial health office
PICT	provider-initiated counseling and testing
PLHIV	people living with HIV
PMDT	programmatic management of drug-resistant tuberculosis
PPD	purified protein derivative
PTB	pulmonary tuberculosis
PViMS	Pharmacovigilance Information Management System
R	rifampicin
RDT	rapid diagnostic test
RR-TB	rifampicin-resistant tuberculosis
SAE	serious adverse event
SLD	second-line drugs
SLI	second-line injectable
SLOR	standard long all oral regimen
SM	smear microscopy
SMS	short message service

SRF	service request form
SSOR	Standard Short All Oral Regimen
SSS	Social Security System
TAT	turnaround time
TB	tuberculosis
TB LAMP	loop-mediated isothermal amplification
TB MAC	Tuberculosis Medical Advisory Committee
TNF	anti-tumor necrosis factor
TPT	tuberculosis preventive treatment
TST	tuberculin skin test
ULN	upper limit of normal
WHO	World Health Organization
XDR-TB	extensively drug-resistant tuberculosis

FOREWORD

In September 2018, the United Nations General Assembly held the first-ever High-level Meeting on Tuberculosis, where countries committed to the goal of ending tuberculosis (TB) globally. The Philippines committed to finding and treating 2.5 million tuberculosis patients, as reiterated in our 2017–2022 Philippine Strategic TB Elimination Plan, Phase 1. The UN meeting emphasized the shift in strategy from TB control to TB elimination, which had been launched three years earlier through the global *End TB Strategy*. This strategy shift requires new tools and approaches in screening, diagnosis, treatment and prevention.

It is with distinct honor that I introduce to all frontline health workers the revised National Tuberculosis Control Program Manual of Procedures, 6th edition (NTP MOP). Since its last update five years ago, many breakthroughs and innovations in TB control were developed. In this revised MOP, we introduce the mainstreaming of Chest X-rays as a screening tool, and the adoption of a new rapid diagnostic tool with better accuracy to detect TB and the additional advantage of detecting drug resistance. We also have new regimens for drug resistant TB without the use of painful injectables. The approach to prevention by treating latent TB infection has also been expanded. Most importantly, we emphasized the importance of patient-centered care in the revised NTP MOP.

In the past, we have looked at patients as mere recipients of our services. But in these new policies and procedures, we treat patients as active partners in health care, capable of making well-informed and appropriate decisions for prompt diagnosis and effective treatment. This is not a new concept to us. Responsiveness has always been a core principle in our national health objectives, as well as in PhilSTEP1. We emphasize this in the revised MOP as it is a priority program policy that encompasses all technical procedures on screening, diagnosis, treatment and prevention.

Given the global political support on TB elimination, we take advantage of this momentum to further strengthen the fight against TB. We as a country shall match that commitment and zeal to end TB. This revised MOP with its bold and radical shift in policies and procedures shall serve as a statement that the Philippines is prepared to implement better strategies to contribute towards ending TB.

Together, let us all work for a TB-free Philippines.



FRANCISCO T. DUQUE, III
SECRETARY OF HEALTH

PREFACE

The *National Tuberculosis Control Program Manual of Procedures* (MOP) was last updated in 2014 (5th edition). In the past five years, various new strategies, laboratory tools and treatment regimens have been introduced globally as part of *The End TB Strategy*. The Philippines has adopted some of these changes with the issuance of various technical policies on case finding and case holding through administrative orders and department memoranda that aimed to update the 5th edition. In the recently revised 6th edition, the National Tuberculosis Control Program (NTP) has consolidated all new policies and procedures on tuberculosis (TB) case finding and case holding and also introduces a shift in the program approach towards “patient-centered care”.

The major changes in this revised edition are:

- The guidelines are focused on a **technical approach to patient care** – screening, diagnosing, treatment and preventive treatment for TB. With the exception of recording and reporting, which is also an important task of frontline health workers, all other previous MOP content for program managers (e.g. monitoring and supervision, health promotion, infection control, drug supply management) is not included in this revision, and program managers should follow the prevailing policies until a separate manual/course for them is developed.
- There is an emphasis on **patient-centered care** (PCC), with the integration of policies and procedures that are patient-centered in all chapters. In addition, there is a separate chapter on PCC to emphasize and clearly define this new paradigm that the program will adopt.
- The revised edition includes **guidelines for both drug-susceptible tuberculosis (DS-TB) and drug-resistant tuberculosis (DR-TB)**, not just in case finding but also in treatment.
- The **contents are focused on policies (what to do) and procedures (how to do)**. A more detailed explanation of the rationale for the policies and procedures (why to do it) are in the annexes and/or will be included in the training course.

The intended primary users of the MOP are the **frontline health-care workers (HCWs) who are directly involved in patient care**. This includes physicians, nurses, medical technologists and other allied health workers who encounter patients face-to-face and take care of them throughout the entire cascade of care, both for TB as well as for other illnesses and health needs. This is intended for both private and public HCWs although specific procedures on recording and reporting are mainly for health facilities with TB services.

Secondary users of this Manual are program managers at all administrative levels, development partners, other government agencies and other stakeholders who are not directly involved in service delivery but participate in planning, implementation and monitoring of the program.

With the rapid advances in TB diagnostics and treatment, the MOP is expected to be revised more rapidly to cope with new evidence and to enable the program to offer the most up-to-date, evidence-based, feasible and patient-centered alternatives for TB patients.



CHAPTER 1.

PATIENT-CENTERED TUBERCULOSIS CARE



INTRODUCTION

The patient-centered approach to tuberculosis (TB) care recognizes and respects the patient's rights and values, and considers the patient as an important partner who actively participates in decisions on diagnosis and treatment. The institution of patient-centeredness in TB services is a significant catalyst in the delivery of quality health care at all levels. This important holistic approach is designated as pillar one by the World Health Organization (WHO) in its *End TB Strategy*, capitalizing on the trust-based relationship between the patient and the provider. TB care should move beyond the aspect of merely the clinical service delivery and towards effectively addressing the patient's social and economic conditions that underly the occurrence of TB disease. Furthermore, there should be a purposive integration of the TB delivery services into the general health-care system in mitigating the prevailing stigma and discrimination being experienced by patients.

This chapter describes the approaches to patient-centered TB treatment and care aimed at customizing health services to be more patient-centric across the TB care continuum in health facilities.

OBJECTIVE

To provide care which is respectful of and responsive to individual patient preferences, needs and values, and to ensure that the patient's values guide all clinical decisions

DEFINITION OF TERMS

1. **Individualized treatment and care plan** – a personalized treatment plan to be completed and mutually agreed upon by both the health-care provider and the patient throughout the course of treatment, encompassing: (1) literacy competency of the patient; (2) nutritional support; (3) co-morbid condition management; (4) psycho-emotional support; (5) familial and social support; and (6) financial support.
2. **Treatment supporter** – a person nominated by the patient and/or health-care provider to supervise the treatment of the patient in home-, community- or facility-based treatment settings, including facilitating follow-up laboratory diagnostic monitoring and the provision of counseling and motivational support for adherence.
3. **Nutritional support** – the provision of nutritional sustenance to patients on treatment to enhance rapid healing and recovery, or the rendering of nutritional advice to identify appropriate food for the patient's condition, as well as fostering healthy eating habits and practices.
4. **Co-morbid physical condition** – a concomitant medical condition that may compromise or aggravate TB treatment, and requiring similar attention to treatment and management. These co-morbid conditions can be in the form of other immunocompromised medical conditions, such as HIV, diabetes or cancer.
5. **Palliative care** – care provided to patients commonly in severe distress from their illness that includes affirming life and alleviating their suffering by emphasizing improved quality of life through physical, psychosocial and spiritual aspects of care.
6. **Stigma** – a disapproving renown or distinction commonly perpetuated from misconception and scant knowledge on TB disease and treatment.
7. **Discrimination** – prejudicial perception of TB patients leading to unjust distribution or deprivation of services and non-acknowledgement of their rights.

POLICIES

1. Throughout the continuum of TB care, health-care workers (HCWs) shall respect patient autonomy and support self-efficacy.
2. The patient's physical comfort, safety and wellness shall be maximized by providing evidence-based integrated care for TB and other co-morbidities.
3. Psycho-emotional support and protection from social isolation or discrimination shall be provided to all TB patients.
4. The impact of poverty and food insecurity on TB diagnosis and treatment shall be recognized and addressed by linking TB patients to social protection measures.

PROCEDURES

A. Respecting patient autonomy and supporting self-efficacy

1. Develop a comprehensive patient assessment and individualized treatment and care plan.
 - a. Use a standardized patient assessment and care plan.
 - b. Review and update plan monthly based on both clinical and non-medical needs of patient (social, psychological, economic).
 - c. Prioritize patients with high risk of loss to follow-up for supportive care.
 - d. Ensure confidentiality of patient information.
2. Provide patient and family education on drug-susceptible tuberculosis (DS-TB) and drug-resistant tuberculosis (DR-TB) disease and latent tuberculosis infection (LTBI), including pertinent information on early diagnosis, disease transmissibility and infectiousness highlighting its impact on public safety and the stigma associated with the disease.
3. Provisions to assist patients complying with diagnostic testing, such as specimen transport.
4. Provisions to treat patients at an appropriate location and timing of their choice.
 - a. Location of treatment can be at the home, community-based facility, workplace or health facility.
 - b. Treatment supporter can be an oriented family member, lay volunteer, community health worker or health-care worker.
 - c. Use of technology – video for directly observed treatment (DOT) and missed call/short message service (SMS) DOT to assist self-administered treatment – may be considered.

B. Maximize physical comfort, safety and wellness

1. Regularly monitor and promptly treat side effects and adverse drug reactions (ADRs).
2. Nutritional support as needed to speed healing and reduce the side effects of medications.
 - a. Conduct baseline and periodic nutritional assessment (height, weight, body mass index).
 - b. Provide general nutrition advice and, among patients with co-morbidities or requiring nutritional build-up, refer to nutritionist for appropriate nutritional rehabilitation.

3. Monitor, treat and refer for co-morbid physical conditions that affect the patient's ability to reach cure.
 - a. HIV and diabetes screening.
 - b. Counseling on pregnancy during treatment for women of reproductive age and testing, as needed.
 - c. Assess for excess alcohol use, illicit drug use, mental deficits or physical disabilities, and refer as necessary. (*Annex 1A. CAGE questionnaire to assess alcohol use*)
 - d. Link people with TB to smoking cessation programs like counseling and pharmacotherapy.
4. Organize physical rehabilitation after cure. Patients who develop permanent physical disabilities (e.g. hearing loss, vision impairments) as a result of treatment will require physical rehabilitation after cure.
5. Offer palliative care for patients who cannot be cured or who refused treatment. When all treatment alternatives fail and there is no possible cure, as confirmed by the TB Medical Advisory Committee, a treating physician should consider palliative care or end-of-life care as an option for the DR-TB case management. (*Annex 1B. Palliative care for TB Patients*)

C. Provide psycho-emotional support and protection from social isolation and discrimination

1. Maintain respectful and compassionate communication and counseling between providers and patients throughout care.
 - a. Provide interpersonal communication and counseling to empower patients to participate in decision-making in their own treatment.
 - b. Conduct periodic patient-satisfaction surveys.
2. Regularly monitor and treat mental health conditions that affect the patient's ability to reach cure.
 - a. Conduct baseline and periodic assessment of the patient's mental health condition and refer as necessary.
 - b. Make available ancillary medications to treat depression and other mental health conditions.
3. Provide emotional support and encouragement to the patient to reduce social isolation and improve treatment adherence.
 - a. Assign a treatment supporter that is acceptable to the patient.
 - b. Elicit support of peer and patient support groups, including patient support hotlines and digital support groups.
 - c. Link patients and families with community-based organizations providing treatment adherence support services.
 - d. Hold periodic celebrations of milestone accomplishments for the patient toward cure.
4. Protection of the patient and family from stigma and discrimination in access to health-care services, employment and community life, and facilitation of social rehabilitation.
 - a. Educate patients who experience workplace discrimination on the TB in workplace policy (DOLE Order 05-73) and refer to the Department of Labor and Employment, if necessary.
 - b. Introduce community outreach and education strategies aimed at reducing stigma against people with TB in the community.

D. Financial assistance to DS-TB and DR-TB patients to support diagnosis and treatment adherence

Provide financial assistance as needed, directly, indirectly, or both as appropriate, including patients belonging to the indigent population, and not simply from Pantawid Pamilyang Pilipino Program, known as the 4Ps, households. Options include support for the transport of specimens during diagnostic testing, conditional cash transfers provided to patients contingent upon treatment adherence, unconditional cash transfers not linked to treatment adherence, microfinance schemes, support for transportation costs, food packages and support for income-generating activities.

These interventions require coordination with other government agencies as well as nongovernmental partners. Refer patients to the appropriate national or local agency for benefits whenever available.

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CHAPTER 2.

SCREENING AND DIAGNOSIS OF TUBERCULOSIS



INTRODUCTION

Case finding is the identification of presumptive TB, either by clinical signs and symptoms or chest X-ray, followed by the diagnosis of active TB disease through bacteriological testing or clinical diagnosis.

Presumptive TB can be identified through systematic screening in health facilities, or among targeted populations in congregate settings, the community or workplaces by using either symptom-based screening, chest X-ray or both. The bacteriological test recommended is a rapid diagnostic test (e.g. Xpert MTB/RIF).

This chapter is divided into two sections: i) systematic screening to identify presumptive TB; and ii) diagnosis of active TB.

OBJECTIVE

Early identification of presumptive TB and prompt diagnosis of TB cases

SECTION 2.1. SYSTEMATIC SCREENING

DEFINITION OF TERMS

1. **Systematic screening for active TB** – refers to the systematic identification of presumptive TB in a predetermined target group, using examinations or other procedures that can be applied rapidly.
 - a. **Active case finding (ACF)** – systematic screening implemented outside health facilities (i.e. high-risk populations or settings) by bringing the screening examination/procedures such as chest X-ray to the community.^{1,2}
 - b. **Intensified case finding (ICF)** – systematic screening in health facilities among all consults. In the program context, ICF will also utilize chest X-ray screening.
 - c. **Enhanced case finding (ECF)** – systematic screening in the community using symptoms screening, such as house-to-house visits by community workers.
2. **Presumptive pulmonary tuberculosis** – refers to any person having: i) two weeks or longer of any of the following – cough, unexplained fever, unexplained weight loss, night sweats; or ii) chest X-ray finding suggestive of TB.^{1,2,3}
3. **Presumptive extrapulmonary tuberculosis** – refers to anyone having signs and symptoms specific to the suspected extrapulmonary site with or without general constitutional signs and symptoms such as unexplained fever or weight loss, night sweats, fatigue and loss of appetite.³
4. **Symptom-based screening** – refers to screening using any of the four cardinal TB signs and symptoms.^{1,2} The four cardinal signs and symptoms of TB are at least two weeks duration of cough, unexplained fever, unexplained weight loss and night sweats.
5. **Screening by chest X-ray** – refers to using chest X-ray to identify presumptive pulmonary TB (PTB) which will manifest with common abnormalities that are suggestive of PTB.^{1,2}
6. **Primary screening tool** – refers to the test or tool that is used initially to detect presumptive TB in the systematic screening of TB. It may be symptom-based or chest X-ray.^{1,2}
7. **Health facility with TB services** – a health-care facility, whether public or private, that provides the entire spectrum of TB services in accordance with the policies and guidelines of the National Tuberculosis Control Program (NTP), Department of Health (DOH). This was formerly referred to as directly observed treatment, short course (DOTS) facility.
8. **Close contact** – a person who shared an enclosed space, such as the household, a social gathering place, workplace or facility, for extended periods within the day with the index case during the three months before diagnosis of TB.³
9. **Index case** – the initially identified TB case of any age in a specific household or other comparable setting in which others may have been exposed.³
10. **Children** – any person who is less than 15 years old.

POLICIES

1. Systematic screening for TB shall be implemented in all health facilities.
2. Symptom screening using any of the four cardinal signs and symptoms (at least two weeks of cough, unexplained fever, unexplained weight loss and night sweats) shall be the primary screening tool for systematic screening in health facilities among all consults including for immunization, maternal health and child health. Accompanying persons will also be screened by asking for TB signs and symptoms.
3. Screening by chest X-ray shall be recommended annually among all health facility consults.
4. Active case finding shall be implemented in congregate settings, targeted communities and workplaces using chest X-ray as the primary screening tool and Xpert as the diagnostic test.
5. All people living with HIV (PLHIV) shall be screened for the TB co-infection.
6. All health facilities shall screen its workers for TB annually using both symptom and chest X-ray screening.
7. Household and close contacts of all ages of a diagnosed TB case shall be screened for TB using symptoms and chest X-ray.

PROCEDURES

The screening strategies shall consider the adequacy and efficiency of specimen transport systems, the capacity of laboratory and clinical services to offer diagnosis and treatment, the availability of drugs, and the characteristics (risk groups) of the populations being served. Screening may be done in health facilities, in communities or congregate settings, and among health workers and TB contacts.

A. Systemic screening in health facilities (intensified case finding)

Systematic screening in facilities shall be done for all clients visiting the facility regardless of reason for consult. If the patient consults due to any of the four cardinal signs/symptoms (i.e. at least two weeks of cough, unexplained fever, unexplained weight loss and night sweats), simply follow the guidelines below and in Fig. 1. If patient consults for other reasons, also ask for the four cardinal signs/symptoms as stated below.

1. The following steps are involved in screening for pulmonary TB (PTB) **in adults ≥ 15 years old** (Fig. 1):
 - 1.1 Record the patient's demographic and contact information in a register of consults.
 - 1.2 Ask all patients consulting the health facility, if they have the following cardinal signs and symptoms that are lasting for ≥ 2 weeks: (*Annex 2A. Sample Screening Form*)
 - a. cough
 - b. unexplained fever
 - c. unexplained weight loss
 - d. night sweats.
 - 1.3 If any of the above signs/symptoms are present for at least two weeks, identify as a **presumptive TB**.
 - 1.4 For those who do not have any of the cardinal signs/symptoms above or experienced it for less than two weeks, offer chest X-ray screening if one has not been conducted in the past year.⁹

A chest X-ray posteroanterior (PA) upright view should be requested and previous chest X-rays should be brought for comparison. For pregnant women, a written consent shall be taken and abdominal protective shield shall be used by the X-ray facility.

The National TB Prevalence Survey in 2016 showed that “screening for TB cases using symptoms alone would have missed one-third to two-thirds of bacteriologically confirmed pulmonary TB cases.”

If resources are limited, you have the option to prioritize those with TB risk factors as primary clients for chest X-ray screening. Risk factors¹⁻⁸ include:

- a. contacts of TB patients;
- b. those ever treated for TB (i.e. with history of previous TB treatment);
- c. people living with HIV (PLHIV);
- d. elderly (> 60 years old);
- e. diabetics;
- f. smokers;
- g. health-care workers;
- h. urban and rural poor (indigents); and
- i. those with other immune-suppressive medical conditions (silicosis, solid organ transplant, connective tissue or autoimmune disorder, end-stage renal disease, chronic corticosteroid use, alcohol or substance abuse, chemotherapy or other forms of medical treatment for cancer).

If a chest X-ray is not available and these high-risk patients have signs and symptoms lasting less than two weeks, the physician may decide whether to consider the patient a presumptive TB case.

- 1.5 All patients with chest X-ray findings suggestive of TB should be identified as presumptive TB. Screening by chest X-ray may be done once a year.
- 1.6 For PLHIV, screening by both chest X-ray and symptoms should be done at the time of diagnosis of HIV/AIDS and annually, thereafter. Symptom-based screening should be done at every visit (Fig. 2). Note that signs and symptom for PLHIV (cough, unexplained fever, unexplained weight loss and night sweats) can be of any duration, not necessarily two weeks.^{11,12} In the presence of one or more TB signs and symptoms and/or a chest X-ray suggestive of TB, identify as presumptive TB in PLHIV.
- 1.7 For all presumptive TB identified, ask about previous history of treatment and exposure to TB cases to determine the risk for DR-TB. Presumptive DR-TB cases are those with previous history of TB treatment, close contacts of a known DR-TB case or a non-converter of DS-TB regimen.
- 1.8 Record the patient in Form 1. Presumptive TB Master List and follow the diagnostic algorithm as outlined in the diagnosis section (*pages 27, Fig. 7*). Record also on a monthly basis the total number of clients who underwent chest X-ray screening from ICF in the assigned portion of Form 1.

Fig. 1. Systematic screening for pulmonary PTB in adults ≥ 15 years old with unknown HIV infection status in health facilities

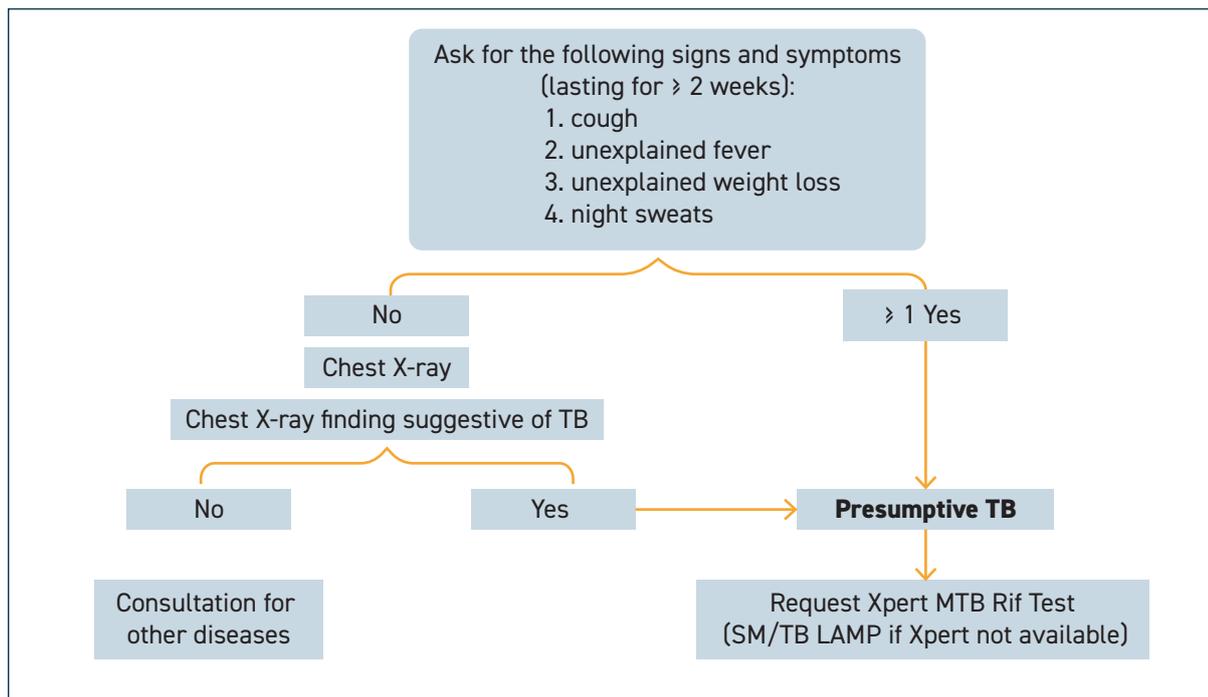
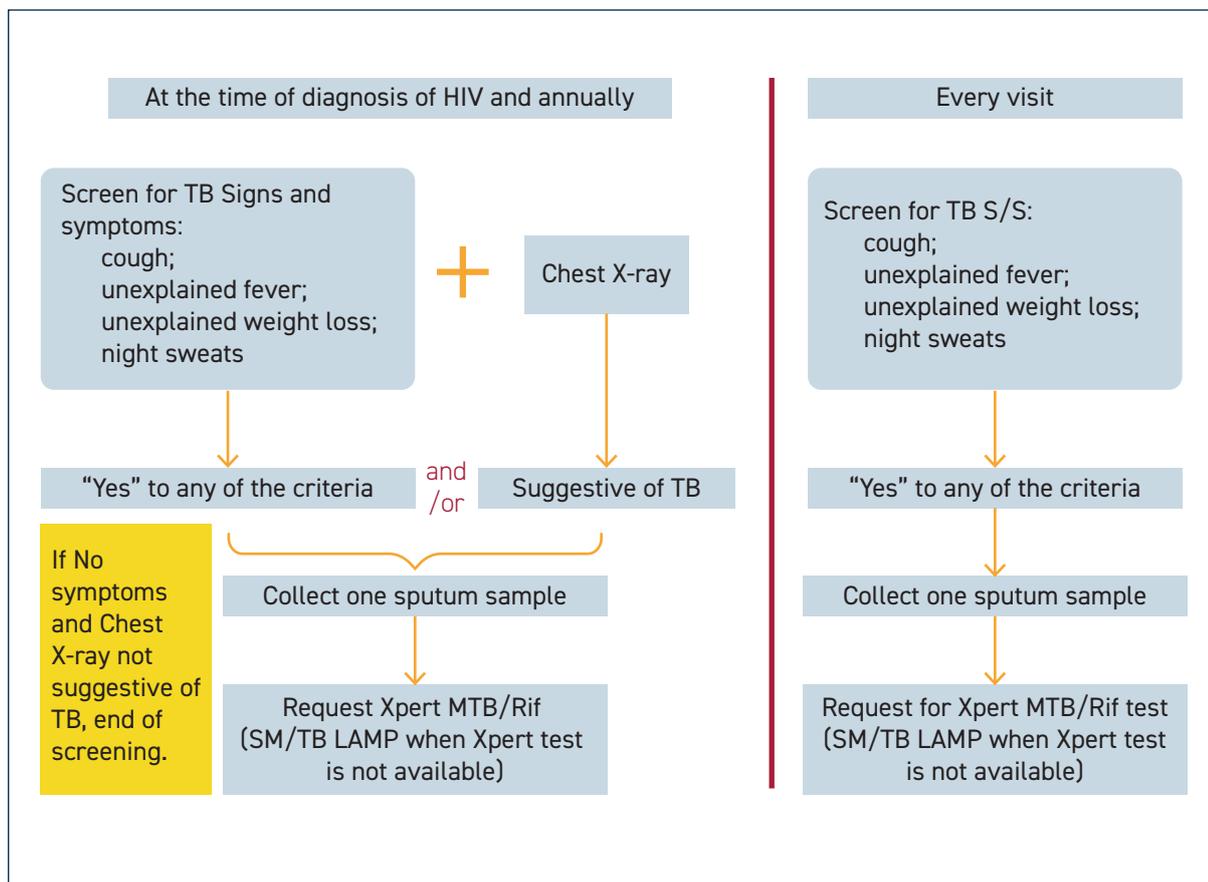


Fig. 2. Systematic screening for the diagnosis of active PTB disease in PLHIV



2. The following steps are involved in the screening for pulmonary TB (PTB) **in children < 15 years old:**

- 2.1 Ask if the child has TB signs and symptoms. Identify as **presumptive TB** if the child has at least one of the three main signs and symptoms suggestive of TB:^{13,14}
- coughing/wheezing of two weeks or more, especially if unexplained (e.g. not responding to antibiotic or bronchodilator treatment);
 - unexplained fever of two weeks or more after common causes such as malaria or pneumonia have been excluded; and
 - unexplained weight loss or failure to thrive not responding to nutrition therapy.
- 2.2 Ask if the child is a close contact of a known TB case. If the child is a contact, the presence of fatigue, reduced playfulness, decreased activity, not eating well or anorexia that lasted for two weeks or more should also be considered and identify them as a presumptive TB.
- 2.3 If the child already has a chest X-ray, review the results. If chest X-ray findings are suggestive of PTB, identify as presumptive TB.

Screening by chest X-ray is not routinely recommended for children, except for TB household contacts who are 5 years old and above.^{1, 35}

- 2.4 For all PTB identified, ask about previous history of treatment and exposure to TB case to determine risk for DR-TB.
- 2.5 Record the patient in Form 1. Presumptive TB Master List and follow the diagnostic algorithm as outlined in the diagnostic section (Fig. 5).

3. The following steps are involved in the screening **for extrapulmonary TB (EPTB), all ages**¹³:

- 3.1 Note any of the following to identify presumptive EPTB:
- gibbus deformity, especially of recent onset (resulting from vertebral TB);
 - non-painful enlarged cervical lymphadenopathy with or without fistula formation;
 - neck stiffness (or nuchal rigidity) and/or drowsiness suggestive of meningitis, with a sub-acute onset or raised intracranial pressure;
 - pleural effusion;
 - pericardial effusion;
 - distended abdomen (i.e. big liver and spleen) with ascites;
 - non-painful enlarged joint; and
 - signs of tuberculin hypersensitivity (e.g. phlyctenular conjunctivitis, erythema nodosum).
- 3.2 For all presumptive TB identified, ask about previous history of treatment and exposure to TB case to determine risk for DRTB.
- 3.3 Record the patient in **Form 1. Presumptive TB Master List** and follow the diagnostic algorithm as outlined in the diagnostic section (*page 27*).

B. Active case finding in targeted community, workplace and congregate settings

The priority target population groups in the community are urban and rural poor. In the workplace setting, the priority includes miners, construction workers, public transport drivers and garment factory workers. They are considered priority due to their exposure

to industrial dust (e.g. silicon), pollutant particles and fumes, or enclosed and crowded working condition.^{1,2,5,7,9}

Congregate settings include jails, detention centers, and residential homes or residential care facilities for the elderly, disabled and orphans, as well as crowded living places (e.g. evacuation centers for internally displaced population).^{1,2,5}

1. Screening, using “**chest X-ray for ALL**” regardless of TB signs and symptoms, shall be conducted annually (*Fig. 3*). This is specifically for adults (i.e. ages 15 years old and above). For children, only symptom screening as described in section A.2 (*page 13*) is recommended.

The target populations are already high-risk settings and all individuals are eligible for chest X-rays. However, depending on available resources and manpower (i.e. presence of health staff who can do risk screening), you may consider implementing an initial risk factor and symptom screening to prioritize chest X-rays among those with risk factors or symptoms.

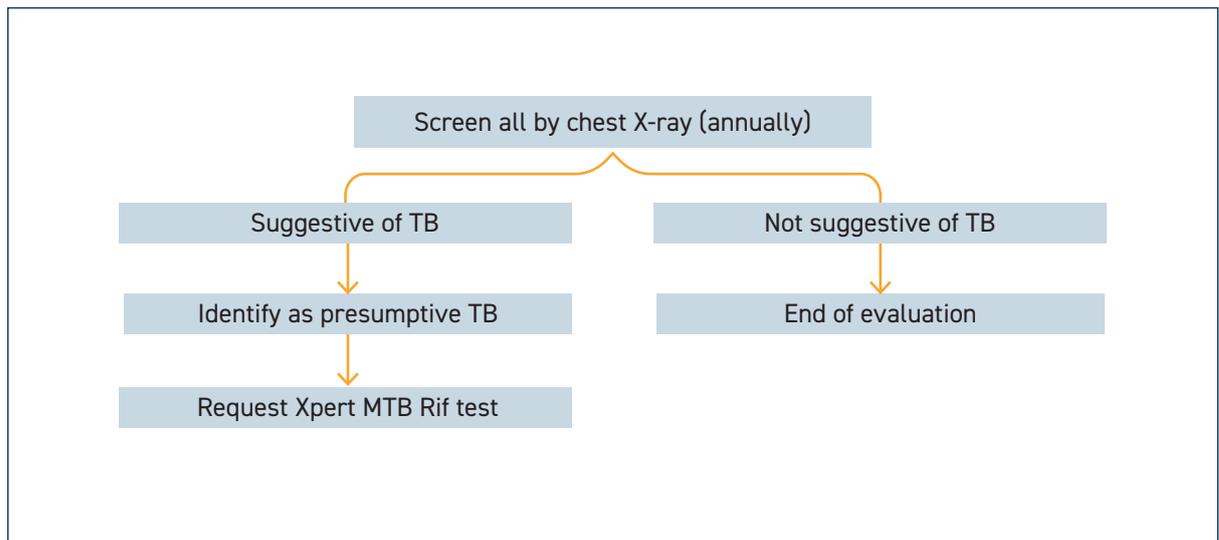
2. Estimate the required logistics for the screening activity and plan with all stakeholders. Ensure the availability of sufficient supply, especially of Xpert cartridges and drugs. (*Annex 2B. Planning logistics and Estimation of presumptive TB yield*).
3. Orient and sensitize the people in the community, workplace or congregate settings.
4. During the actual screening day, inform patients of the purpose of screening and the next steps in the event their chest X-ray is positive. For pregnant women, obtain written consent and use protective shield when taking a chest X-ray.
5. All patients with chest X-ray findings suggestive of TB should be identified as **presumptive TB**. Sputum should be collected for an Xpert MTB/RIF test.

Using smear microscopy (SM) in ACF will not be as cost-effective as Xpert MTB/RIF because of the expected lower yield of bacteriologically confirmed TB cases since SM is less sensitive than Xpert. Further, there is higher chance of clinical diagnosis and, hence, the risk of false positive diagnosis.¹⁶⁻²⁷

6. For all presumptive TB identified, ask about a patient’s previous history of treatment and exposure to a TB case to determine risk for DR-TB.
7. Record the patient in **Form 1. Presumptive TB Master List** and follow the diagnostic algorithm as outlined in the diagnosis section (*Fig. 7*). Record also the total number of clients who underwent chest X-ray screening during the ACF activity in the assigned portion of **Form 1**.

Between ACF activities, **enhanced case finding** (i.e. surveillance for presence of TB signs and symptoms) should be installed and maintained. This is especially applicable to high-risk populations and congregate settings. All those who have any of the cardinal signs and symptoms of TB (i.e. at least two weeks of cough, unexplained fever, unexplained weight loss and night sweats) should be identified as presumptive TB and referred to the health facility.

Fig. 3. Screening for PTB in targeted community, workplace and congregate settings

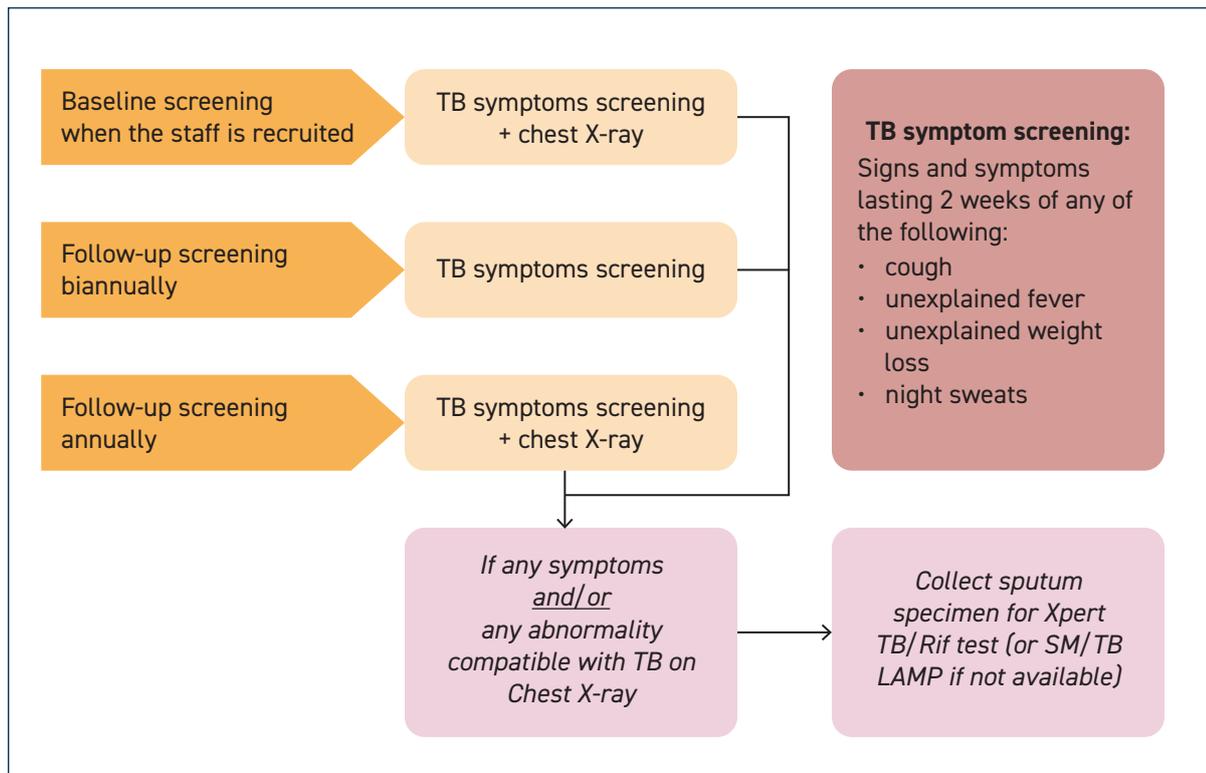


C. Screening among health-care workers

Health-care workers (HCWs) are considered high-risk groups for TB because of occupational exposure. In this context, HCWs include all those present in the health facility, whether medical, paramedical or ancillary staff. These include those who provide janitorial, logistics, maintenance and ambulance services.¹⁵

1. Symptom surveillance shall be implemented in all health facilities (*Fig. 4*). All health workers with any of the four cardinal signs and symptoms (Two weeks of any of cough, unexplained fever, unexplained weight loss or night sweats) should be identified as **presumptive TB**.
2. Baseline chest X-ray screening followed by annual chest X-ray shall be done for all HCWs. Those with findings suggestive of tuberculosis or with progression of lesions compared to a previous chest X-ray shall be identified as **presumptive TB**.
3. Orient and sensitize the activity to the HCWs. Reassure HCWs on the entitlement of medical benefits, sick leave and job safety if they are found to have TB.
4. For all presumptive TB identified, ask about previous history of treatment and exposure to TB case to determine risk for DR-TB.
5. Record the patient in **Form 1. Presumptive TB Master List** and follow the diagnostic algorithm as outlined in the diagnosis section (*Fig. 7*).

Fig. 4. Screening among health-care workers



D. Contact tracing

1. Screening household contacts of DS-TB cases^{13,35} (Table 1)
 - a. Instruct index case to bring all household members to the health facility or use trained barangay health workers or community health workers to do community-based contact screening. Household contacts should be evaluated within seven days from treatment initiation of the index case to ensure prompt diagnosis.
 - b. If chest X-ray is available and accessible, perform chest X-ray on all household contacts who are 5 years old and above. If not, perform symptom screening including those under 5 years of age.
 - c. All household contacts identified to be a presumptive TB based on a chest X-ray or symptom screening should undergo diagnostic testing.
 - d. Consider latent tuberculosis infection (LTBI) if not a presumptive TB or after exclusion of active TB disease (refer to Chapter 4. TB Preventive Treatment, page 65).³⁵
 - e. Advise contacts to follow-up every six months for the next two years. Do symptom screening every six months and chest X-ray screening annually.
 - f. Educate about TB signs and symptoms and advise to consult immediately if signs and symptoms of TB develop.

Table 1. Comparison of procedures for screening DS-TB and DR-TB household contacts

	DS-TB contacts	DR-TB contacts
Chest X-ray screening	<ul style="list-style-type: none"> All 5 years old and above (symptom screening only for < 5 years old) If chest X-ray not available, do symptom screening 	<ul style="list-style-type: none"> All contacts If chest X-ray not available, do Xpert test directly for <u>all</u> contacts.
Diagnostic test	Xpert, if not available SM/loop mediated isothermal amplification (TB LAMP)	Xpert
If active TB ruled-out	Consider TB preventive treatment (TPT)	TPT currently not recommended
Follow-up contacts	Every six months for two years (Symptom screen every six months, chest X-ray every year)	Every six months for two years (Symptom screen every six months, chest X-ray every year. If chest X-ray not available, do Xpert test directly.)

2. Screening household contacts of DR-TB cases^{13,35} (*Table 1*)

- a. Evaluate all household contacts of diagnosed DR-TB cases by screening with signs and symptoms and chest X-ray. Those with signs and symptoms or a positive chest X-ray result should be identified as presumptive TB.
If it is not feasible to do chest X-ray screening, proceed directly to do Xpert test for DR-TB contact (irrespective of symptoms).
- b. Refer all household contacts identified as presumptive TB to Xpert MTB/RIF testing.
- c. All household contacts who have no signs and symptoms or with chest X-ray findings not suggestive of TB should be educated about TB signs and symptoms and advised to immediately return to the health facility if signs and symptoms of TB develop.
- d. Follow-up contacts every six months for the next two years. Do symptom screening every six months and chest X-ray annually. If it is not feasible to do a chest X-ray, directly do Xpert MTB/RIF test annually.

SECTION 2.2. DIAGNOSIS OF TUBERCULOSIS DISEASE

DEFINITION OF TERMS

1. **Active TB disease** – a presumptive TB case that is either bacteriologically confirmed or clinically diagnosed by the attending physician.
2. **Pulmonary TB (PTB)** – refers to a case of tuberculosis involving the lung parenchyma. A patient with both pulmonary and extrapulmonary tuberculosis should be classified as a case of pulmonary TB.
3. **Extrapulmonary TB (EPTB)** – refers to a case of tuberculosis involving organs other than the lungs (e.g. larynx, pleura, lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, meninges).
4. **Bacteriologically confirmed TB (BCTB)** – refers to a patient from whom a biological specimen, either sputum or non-sputum sample, is positive for TB by smear microscopy, culture or rapid diagnostic tests (such as Xpert MTB/RIF, line probe assay for TB, TB LAMP).
5. **Clinically diagnosed TB (CDTB)** – refers to a patient for which the criterion for bacteriological confirmation is not fulfilled but diagnosis is made by the attending physicians on the basis of clinical findings, X-ray abnormalities, suggestive histology and/or other biochemistry or imaging tests.
6. **New** – refers to a patient who has never had treatment for TB or who has taken anti-TB drugs for less than one month. Preventive treatment is not considered as previous TB treatment.
7. **Previously treated for TB** – refers to a patient who had received one month or more of anti-TB drugs in the past. Also referred to as **Retreatment**.
8. **High risk for multidrug-resistant tuberculosis (MDR-TB)** – previously treated for TB, new TB cases that are contacts of confirmed DR-TB cases or non-converter among patients on DS-TB regimens.
9. **Rifampicin-resistant TB (RR-TB)** – resistance to rifampicin detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs. It includes any resistance to rifampicin, whether monoresistance, multidrug resistance, polydrug resistance or extensive drug resistance.
10. **Turnaround time (TAT)** – the time from collection of first sputum sample to initiation of treatment for TB. The desired turnaround time is five working days (also referred to as Program TAT).

POLICIES

1. A rapid diagnostic test (RDT), such as Xpert MTB/RIF, shall be the primary diagnostic test for PTB and EPTB in adults and children.^{29,32}
2. All presumptive TB patients who are at high risk for MDR-TB shall be referred for Xpert MTB/RIF testing. If not accessible, a sputum transport system shall be used or patient shall be referred to the nearest health facility with DR-TB services for screening.
3. For presumptive EPTB cases, the body fluid or biopsy samples that are appropriate for Xpert MTB/RIF testing shall be obtained.
4. Smear microscopy (whether brightfield or fluorescence microscopy) or loop mediated isothermal amplification (TB LAMP) shall be the alternative diagnostic test if Xpert is not accessible. Unavailability of Xpert MTB/RIF test shall not be a deterrent to diagnose TB disease bacteriologically.
5. TB LAMP may be utilized to process large sample loads especially in ACF activities, but not for children, PLHIV and MDR-TB risk groups.³³
6. If bacteriologic testing is negative or not available/accessible, patients shall be evaluated by the health facility physician who shall decide on clinical diagnosis based on best clinical judgment.
7. Tuberculin skin test (TST), also known as purified protein derivative (PPD) test or Mantoux test, shall be used only as an adjuvant when there is doubt in making a clinical diagnosis of TB in children. Either 5-TU or 2-TU strength may be used.
8. Trained health workers shall do the testing and reading of TST. An induration of at least 10 mm regardless of bacille Calmette-Guerin (BCG) vaccination status or 5 mm in immunocompromised children (e.g. severely malnourished) is considered a positive TST reaction.¹³
9. Health facilities with TB services, whether public or private, are encouraged to establish their own in-house TB diagnostic laboratory such as Xpert MTB/RIF, SM and TB LAMP. In cases where it is not possible, access to an officially NTP-linked TB diagnostic laboratory would be acceptable.
10. All laboratories providing TB diagnostic tests, whether public or private, shall participate in the quality assurance system of the NTP.
11. A Tuberculosis Medical Advisory Committee (TB MAC) shall be established at least per region to provide clinical expertise and guidance in the diagnosis of clinically diagnosed DR-TB and management of difficult DS-TB and DR-TB cases.

PROCEDURES

Once a presumptive TB case is identified, diagnosis through bacteriologic confirmation must be conducted. This requires collection of the necessary specimens for testing, performing the test (Xpert, SM or TB LAMP), and making a diagnosis based on the results. (*Annex 2C. Different TB Diagnostic Tools*)

A. Collection and transport of sputum specimens

The only contraindication to collecting sputum for bacteriological diagnosis of TB is massive hemoptysis, which is expectoration of large volumes of blood from the respiratory tract. Blood-streaked sputum can still be examined.

1. Prepare a sputum cup or 50 ml conical tube and accomplish **Form 2a. Laboratory Request and Result Form**.
2. Instruct patient to expectorate one sputum sample on the spot for diagnostic testing with Xpert (if not available, SM or TB LAMP). Collect 1ml for Xpert MTB/RIF and TB LAMP and 3–5 ml for SM.
 - 2.1 Collect specimen in a well-ventilated designated sputum collection area, or outside the health facility.
 - 2.2 Instruct the patient on how to expectorate:
 - a. clean mouth by thoroughly rinsing with water
 - b. breathe deeply, hold breath for a second or two, and then exhale slowly. Repeat the entire sequence two more times;
 - c. cough strongly after inhaling deeply for the third time and try to bring up sputum from deep within the lungs; and
 - d. expectorate the sputum in the sputum cup or conical tube.
 - 2.3 Sputum induction for individuals unable to expectorate should be done only in facilities where the staff is trained, supplies and equipment are available, and infection control measures are in place.
 - 2.4 If the child cannot expectorate (especially < 5 years old), nasopharyngeal aspirate or gastric lavage may be performed in facilities where trained staff, supply and equipment are available.
3. Label the body of the sputum cup/conical tube, indicating patient's complete name and indicating the specimen for Xpert (or SM/TB LAMP).
4. Check quality of the sputum.
 - 4.1 For Xpert, testing should be performed on any collected spot sputum sample (i.e. a coughed-out sample) regardless whether it is sputum or saliva.
 - 4.2 For SM, examine the specimen to see that it is not just saliva. Mucus from the nose and throat, and saliva from the mouth are not good specimens. Repeat the process if necessary.
5. For SM, instruct to collect a second sample one hour later or an early-morning sputum sample the following day. Follow-up within three days if patient fails to submit a second specimen unless the first specimen already tests positive for acid-fast bacillus (AFB) in which case the second specimen will not be necessary.

6. Seal the sputum cup or conical tube and transport it to an Xpert site, TB microscopy laboratory or TB LAMP site together with the completed **Form 2a. Laboratory Request and Result Form**.
7. If the laboratory is in another facility, use the triple packaging system. (Reference: Manual on Collection, Storage and Transport of Specimens for TB testing, <http://bit.ly/CSTSMannual>)
 - 7.1 Place the primary container in individual plastic bags.
 - 7.2 Place each in a durable, leak-proof, water-tight and properly sealed container (i.e. biological bottles or plastic jars as secondary containers).
 - 7.3 Enclose in the sputum transport box (tertiary container).
 - 7.4 Transport at cold temperature by placing cold packs inside the tertiary container.
 - 7.5 Accomplish a dispatch list.
8. Specimens for SM can also be smeared immediately by trained volunteers and then stored appropriately before transport to the TB microscopy laboratory.
9. For diagnosis of EPTB, facilities with the necessary capability can collect body fluid samples or tissue biopsy sample from the suspicious site. Refer if necessary. Table 2 lists the specimens and required volume which may be tested using Xpert. Ask presumptive EPTB to also submit sputum for SM or Xpert testing if they can expectorate.

Table 2. Extrapulmonary specimens that may be submitted for Xpert MTB/RIF test and corresponding volume required

Specimen type	Volume
Respiratory specimens other than sputum	
Tracheal aspirate, endotracheal aspirate, bronchial washing, bronchial alveolar lavage fluid, and nasopharyngeal aspirate	1–4 mL
Non-respiratory specimens	
Gastric aspirate	1–4 mL
Cerebrospinal fluid	0.5–4 mL
Other fluid aspirates, and body fluids (e.g., peritoneal, synovial fluid)	1–4 mL
Tissues and fine needle aspiration biopsy specimens	Immersed in 1–4 mL Normal Saline Solution

The last two types of specimens in Table 2 (other fluid aspirates and biopsy specimens) can only be submitted to specifically designated RTD laboratories equipped with certified biosafety cabinets such as in TB culture laboratories. Blood, urine and stools are currently not accepted specimens for Xpert MTB/RIF testing.

10. Inform the patient when to return for follow-up consultation regarding the results. If necessary, contact the patient by phone call, SMS or other means once results are available.

B. Procedure for Xpert MTB/RIF

1. Record the patient information in **Form 3a. Laboratory Register for Xpert**.
2. Prepare the Xpert MTB/RIF cartridge, process the sputum/specimen sample and load it in the Xpert MTB/RIF machine. Start the test.
3. When the test is finished, view test result. Xpert MTB/RIF results are reported as follows (*Table 3*):

Table 3. Xpert MTB/RIF results and interpretation

Notation	Interpretation
T	Mycobacterium tuberculosis (MTB) detected, rifampicin resistance not detected.
RR	MTB detected, rifampicin resistance detected.
TI	MTB detected, rifampicin resistance indeterminate.
N	MTB not detected.
I	Invalid/no result/error.

4. Interpret the result and write the final laboratory diagnosis in the lower portion of **Form 2a. Laboratory Request and Result Form** and in **Form 3a. Laboratory Register for Xpert**.
5. Send the request form with its corresponding results back to the requesting unit within three working days from receipt of specimen. The result may also be sent by SMS/text, email or other means especially those with MTB detected while the paper form of the result is being delivered. Ensure that confidential information about the patient is protected.

C. Procedure for smear microscopy

SM may be performed using either brightfield microscopy (Ziehl-Neelsen technique) or fluorescence microscopy (FM). Fluorescence microscopy using light-emitting diodes (LED) as the microscope light source is also known as LED-FM. Fluorescence microscopy has increased sensitivity and can be five times faster.

1. Record the patient information in **Form 3b. Laboratory Register for Smear Microscopy and TB LAMP**.
2. Smear, fix and stain each slide.
3. Read each slide and interpret the result (*Table 4*).

Table 4. Interpretation of results for both brightfield and fluorescence microscopy

IUATLD/ WHO Scale	Brightfield Microscopy	Fluorescence Microscopy	
		200x magnification (1 length = 30 fields)	400x magnification (1 length = 40 fields)
0	No AFB seen in 300 oil immersion field (OIF)	No AFB observed / 1 length	No AFB observed / 1 length
Confirmation required		1-4 AFB in one length (150 OIF)	1-2 AFB / 1 length + n 1-9
+n	n AFB seen in 1 length	5-49 AFB/ 1 length	3-24 AFB / 1 length
1+	10-99 AFB in 1 length	3-24 AFB / 1 Field	1-6 AFB / 1 field
2+	1-10 AFB /OIF, at least 50 fields	25-250 / 1 field	7-60 / 1 field
3+	> 10 AFB / OIF, at least 20 OIF	> 250 / 1 field	> 60 / 1 field

4. Interpret the results of the two specimens. Write the reading (IUATLD/WHO Scale) and final laboratory diagnosis in the lower portion of **Form 2a. Laboratory Request and Result Form** and on the remarks column of **Form 3b. Laboratory Register for Smear Microscopy and TB LAMP**. Final laboratory diagnoses are reported as follows:
 - Positive = at least one sputum smear is positive for AFB (+n, 1+, 2+, 3+)
 - Negative = both sputum smears are negative for AFB.
5. Send the request form with its corresponding results back to the requesting unit within three working days from receipt of specimen. The result may also be sent by SMS/text, email or other means especially positive results while the paper form of the result is being delivered. Ensure that confidential information about the patient is protected.

D. Decision on diagnosis based on laboratory results

1. If sputum or non-sputum specimen tested by Xpert MTB/RIF, SM or TB LAMP shows MTB detected or positive result, classify as **bacteriologically confirmed PTB or EPTB**.
2. **For patients who are at least 15 years old** with negative Xpert MTB/RIF, SM, TB LAMP results (or not done), retrieve the chest X-ray result or refer the patient for chest X-ray if not yet done. A chest X-ray PA upright view should be requested for adults.
 - 2.1 If the chest radiograph indicates shadows in the lung fields consistent with pulmonary disease, a course of broad-spectrum antibiotics (without anti-TB activity) may be prescribed. If signs and symptom suggestive of TB are not resolved after antibiotic treatment, the attending physician will use best clinical judgment to decide whether to treat for active TB. If the physician decides to treat as active TB, classify as **clinically diagnosed PTB**.

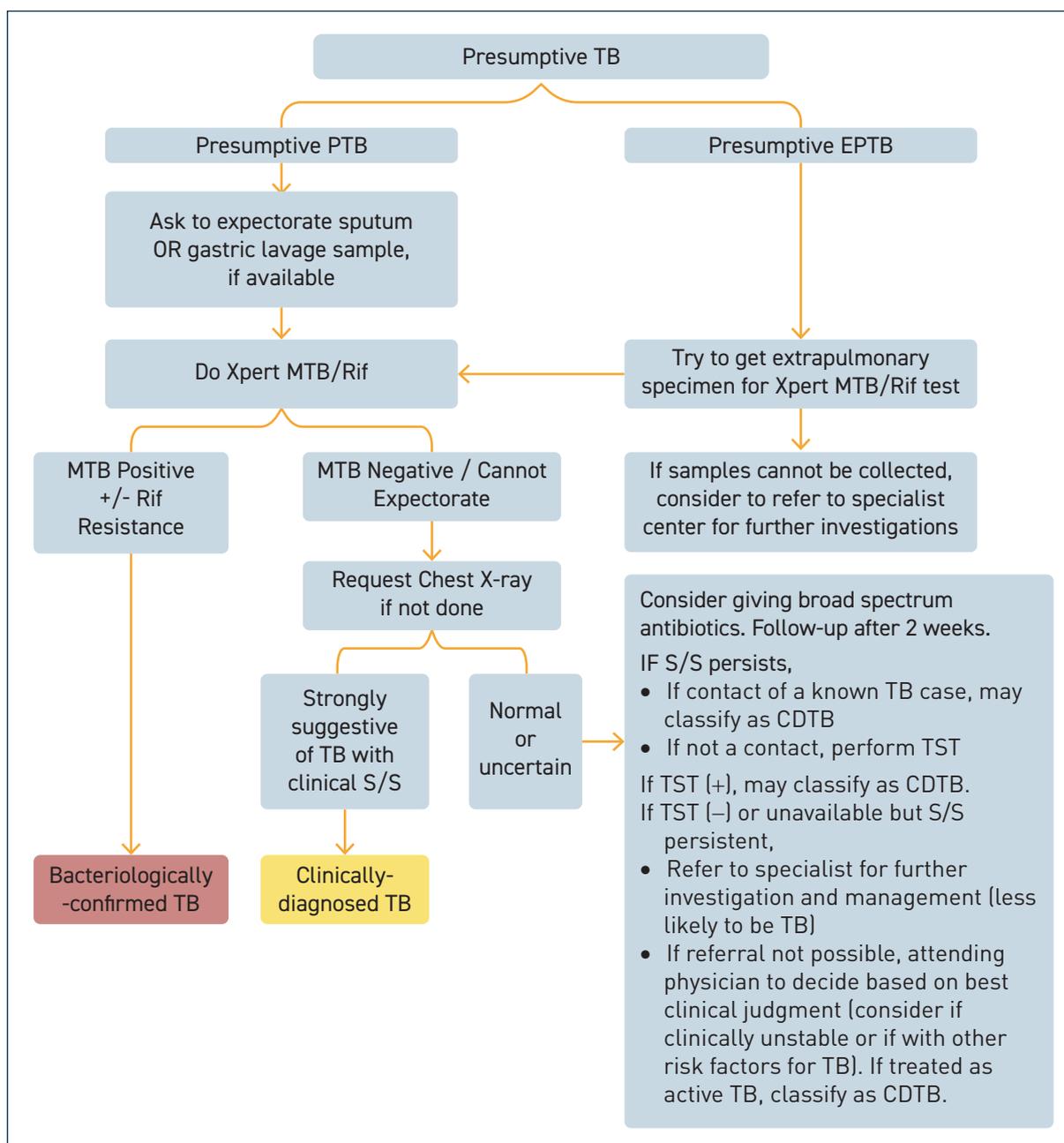
Guide for clinical diagnosis in adults

- If a chest X-ray was done before, a comparison of serial chest X-ray findings is useful to guide diagnosis.
 - Only a small proportion (10–20%) of TB patients will have a negative Xpert test and is expected to be clinically diagnosed PTB by chest X-ray and clinical signs and symptoms.
 - Ninety-two percent (92%) of culture-positive PTB and > 80% of SM negative PTB will be detected by a single test of Xpert MTB/RIF provided that the sputum quality is good.²⁸
 - Take caution with over- and under-diagnosis by chest X-ray as it depends on the quality of chest X-ray image/film, and there is inter- or intra-observer variation in reading.
 - Even broad-spectrum antibiotics should be reserved for treating a clear indication by ruling out other possible causes of the symptoms. Trial treatment with antibiotics is particularly discouraged in children.
 - Referral to a specialist may be done if reasonably accessible or able to render a decision within two weeks.
 - If the patient has no symptoms and has a negative Xpert test, strongly consider doing surveillance with repeat chest X-rays instead of treating the case as TB.
- 2.2 If the chest X-ray is normal or not suggestive of TB, investigate for other morbidities or refer to a specialist.

For PLHIV, TB is not immediately ruled out, especially if symptoms are present. Evaluate the clinical response after general antibiotic treatment. If clinical worsening or no improvement, TB is likely. If there is clinical improvement, TB is unlikely but is not ruled out, especially if the PLHIV is seriously ill or have CD4 count less than or equal to 100 cells/microliter. Conduct additional investigations or discuss with the physician managing the PLHIV.

3. **For patients below 15 years old** with negative Xpert MTB/RIF, SM results (or not done), but with persistent signs and symptoms, retrieve the chest X-ray result or refer the patient for a chest X-ray if not yet done.^{13,14} A chest X-ray PA upright and lateral view should be requested. For children who cannot stand, request for a chest X-ray anteroposterior and lateral view. (Fig. 5)

Fig. 5. Approach to diagnosis of TB in children (< 15 years old)

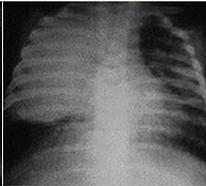
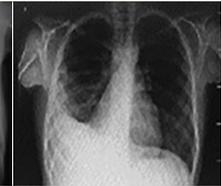


3.1 If chest X-ray finding is strongly suggestive of TB based on the following (Fig. 6), classify as **clinically diagnosed TB**.

- Markedly enlarged unequal hilar lymph gland (i.e. > 2 cm in size) with or without opacification
- Miliary mottling
- Large pleural effusion ($\geq 1/3$ of pleural cavity, usually common in children > 5 years old)
- Apical opacification with cavitation (rare in younger children, common in adolescents).

There may be other chest X-ray findings which are likely suggestive of TB such as atelectasis, consolidation, reticular or nodular infiltrates, and pericardial effusion. The physician should exercise his best clinical judgment in correlation with history of exposure and clinical signs and symptoms.

Fig. 6. Chest X-ray findings strongly suggestive of PTB in children and adolescents

Aspect	Pediatric patients				
	< 10 years of age			10–18 years of age	
Signs and symptoms	Persistent fever, weight loss, cough, and irritability			Persistent fever, adynamia, and expectoration (bloody sputum)	
Chest X-ray					
Finding	Right hilar lymphadenopathy	Chronic pneumonia	Miliary pattern	Pulmonary cavitations	Pleural effusion

SOURCE: Carvalho CCA, et. AL.2018. JBL

*View the chest X-ray film and read full report to identify above features rather than just reading final impression.

- 3.2 If chest X-ray finding is normal or uncertain and the child is in stable clinical condition, follow up the child in two weeks. Consider giving one week of broad-spectrum antibiotics, if not given before.
- 3.3 If the child still has persistent signs and symptoms during follow-up, may **classify as clinically diagnosed TB** if a contact of a known TB case.
- 3.4 If not a contact of a TB case, perform TST.
- If TST is positive, may classify as **clinically diagnosed TB**.
 - If TST is negative or not available, even if clinical signs and symptoms remain unresolved, it is less likely to be TB (chest X-ray is not suggestive of TB). Hence, refer to specialist center for further investigation and management.
- 3.5 When referral to specialist center cannot be made, the decision to **clinically diagnose** and treat TB can be made by the physician if the clinical condition is unstable (e.g. having severe respiratory signs and symptoms) or child has other TB risk factors. If clinically stable and no other risk factors, may follow up in two weeks or one month

- 3.6 If **clinically diagnosed DR-TB** is being considered, present the case to TB MAC and follow the advice of TB MAC for the regimen decision.
4. Diagnose **EPTB** either bacteriologically or clinically.
 - 4.1 EPTB can be **confirmed bacteriologically** using Xpert MTB/RIF.
 - 4.2 For presumptive EPTB cases where it is not possible to get body fluid or tissue sample, give an antibiotic trial and follow-up after one to two weeks.
 - 4.3 EPTB can be assessed as **clinically diagnosed TB** by the health facility physician based on signs and symptoms, imaging studies, histology or other laboratory tests.
 - 4.4 As necessary, refer presumptive EPTB to health facilities capable of performing appropriate diagnostic procedures.
5. If a presumptive TB is assessed as **not TB** after diagnostic testing, evaluate for other differential diagnoses. If not symptomatic, assure the patient and advise to follow-up anytime if symptoms develop.
6. All patients diagnosed with active TB, whether bacteriologically confirmed or clinically diagnosed, should be notified, and a **Form 4a. TB Notification** should be accomplished. Register patients in **Form 6a. DSTB Register** or **6b. DRTB Register** – Integrated Tuberculosis Information System (ITIS) – regardless of whether or not treatment has been initiated.

E. Decision on further testing based on result of Xpert MTB/RIF

1. For patients with Xpert result: MTB without rifampicin resistance, classify as **drug-susceptible TB (DS-TB)**. (*Fig. 7*)
2. For MDR-TB risk groups (retreatment, contact of DR-TB, non-converter of DS-TB regimen) with Xpert result: MTB detected with rifampicin resistance, classify as **drug-resistant TB (DR-TB)**.
 - a. Collect a fresh sputum sample for baseline culture, phenotypic DST and first- and second-line probe assay (LPA) drug-susceptibility test (DST).
 - b. If LPA testing shows MTB not detected or indeterminate, repeat LPA testing.³⁴
 - c. Further classify the TB disease by bacteriologic status of DR-TB cases for recording and reporting purposes (*Table 5*).
3. For those who are at low risk for MDR-TB (i.e. new TB cases who are not DR-TB contacts) but with an Xpert result: MTB detected with rifampicin resistance, the patient can be classified as **bacteriologically confirmed TB (BCTB)**, but recollect a fresh sputum sample for repeat the Xpert MTB/RIF test and follow the second result on Rifampicin resistance for the treatment decision.

However, in PLHIV in which mortality from the TB co-infection is high, there is no need to repeat the Xpert test as it will result in significantly delaying initiation of treatment. The patient may be treated based on the result of the initial test.

4. For indeterminate, invalid or error results, recollect a fresh sputum sample, **repeat the Xpert MTB/RIF test** and follow the second test result for the treatment decision.
5. If SM or TB LAMP testing was done and tested positive, yet Xpert does not detect MTB, consider as **bacteriologically confirmed DS-TB**.

Fig. 7. Diagnosis and clinical application of Xpert/MTB RIF

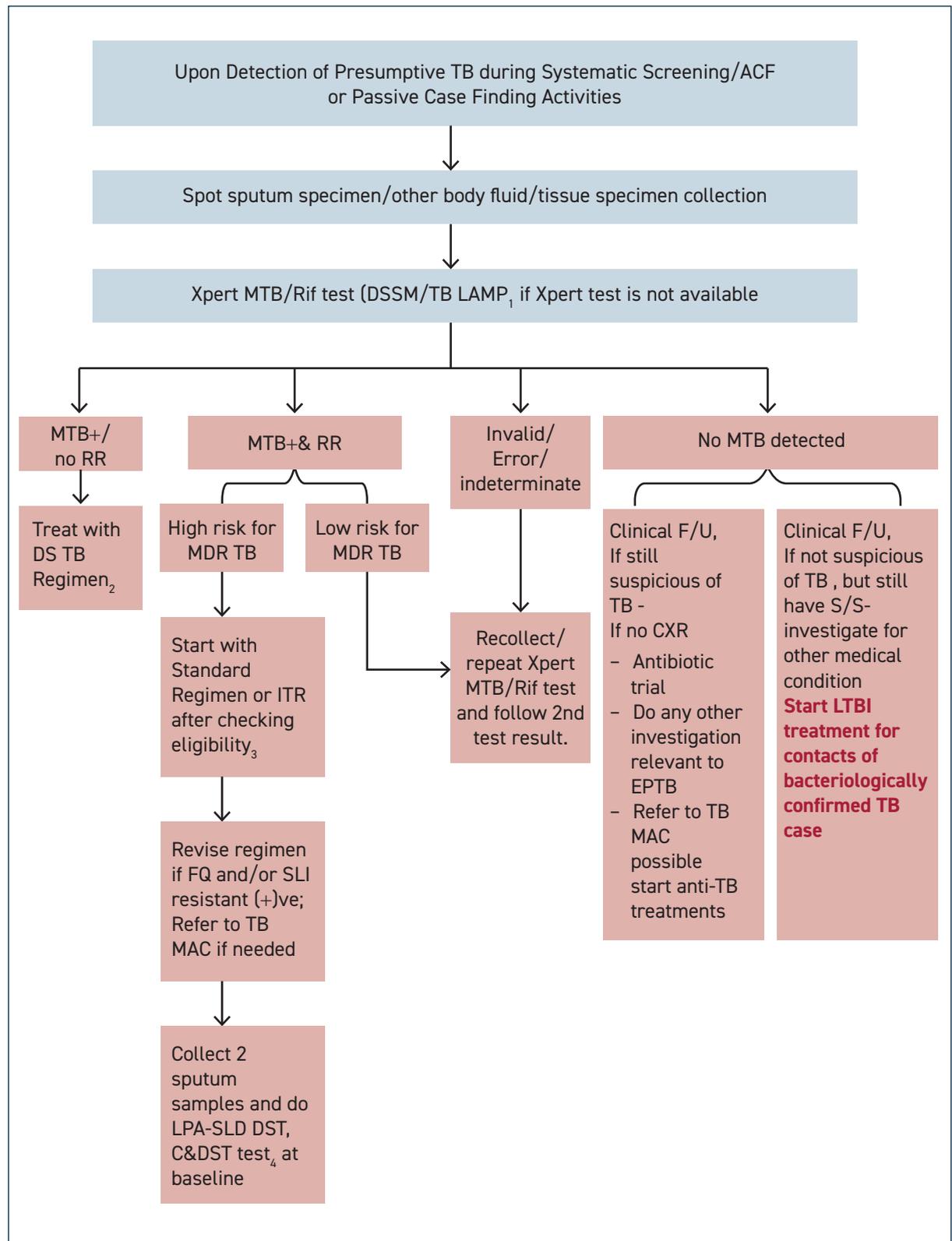


Table 5. Specific DR-TB classification based on bacteriological status for recording and reporting purposes

Bacteriological status categories	Definition
1. Bacteriologically confirmed rifampicin-resistant TB (BC RR-TB)	Positive for MTB using rapid diagnostic modalities (i.e. Xpert MTB/RIF) with resistance to rifampicin. (If patient had previous successful treatment, resistance should be from specimen collected after successful treatment.)
2. Bacteriologically confirmed multidrug-resistant TB (BC MDR-TB)	Positive for MTB complex with resistance to at least both isoniazid and rifampicin from an NTP-recognized laboratory. (If patient had previous successful treatment, resistance should be from specimen collected after successful treatment.)
3. Bacteriologically confirmed extensively drug-resistant TB (XDR-TB) (BC XDR-TB)	Positive for MTB complex with resistance to any fluoroquinolone (FQ) and to at least one second-line injectable drug (e.g. amikacin, streptomycin), in addition to multidrug resistance from an NTP-recognized laboratory. (If patient had previous successful treatment, resistance should be from a specimen collected after successful treatment.)
4. Clinically diagnosed multidrug-resistant TB (CD MDR-TB)	<p>A patient with at least one of the following:</p> <ul style="list-style-type: none"> • specimens tested in an NTP-recognized laboratory that is negative for MTB complex but with clinical deterioration and/or radiographic findings consistent with active TB; or • specimen/s with other resistance pattern (i.e. mono DR-TB or poly DR-TB) with clinical deterioration and/or radiographic findings consistent with active TB; or • laboratory diagnosis not done due to specified conditions but with clinical deterioration and/or radiographic findings consistent with active TB; or • diagnosis showing resistance to both isoniazid and rifampicin in a non-NTP-recognized laboratory; <p>and there has been no response to a course of empiric antibiotics and/or symptomatic medications; and</p> <p>who has been decided by the TB Medical Advisory Committee (TB MAC) to have TB disease requiring a full course of second-line anti-TB chemotherapy similar to BC MDR-TB.</p>
5. Other DR-TB: a. monoresistant TB	A patient with resistance to one first-line anti-TB drug, except rifampicin whether bacteriologically confirmed (regardless of the date of collection, with or without radiographic abnormalities) or clinically diagnosed (i.e. severe adverse drug reaction (ADR) to anti-TB drugs except rifampicin) and who has been decided by the Medical Advisory Group (<i>consilium</i>) to have TB disease requiring a course on mono drug-resistant TB regimen.
5. Other DR-TB: b. polydrug-resistant TB	A patient with resistance to more than one first-line anti-TB drug, other than both isoniazid and rifampicin, whether bacteriologically confirmed (regardless of date of collection, with or without radiographic abnormalities) or clinically diagnosed (i.e. severe ADR to anti-TB drugs except rifampicin) and who has been decided by the Medical Advisory Group (<i>consilium</i>) to have TB disease requiring a course on polydrug-resistant TB regimen.
5. Other DR-TB: c. serious adverse drug reaction to rifampicin	A patient who is positive for MTB complex, but no resistance to any anti-TB drugs, or negative for MTB complex, but has been decided (either by the physician and/or TB MAC) to have TB disease and has serious ADR to rifampicin, thereby requiring a full course of second-line anti-TB treatment similar to BC MDR-TB.

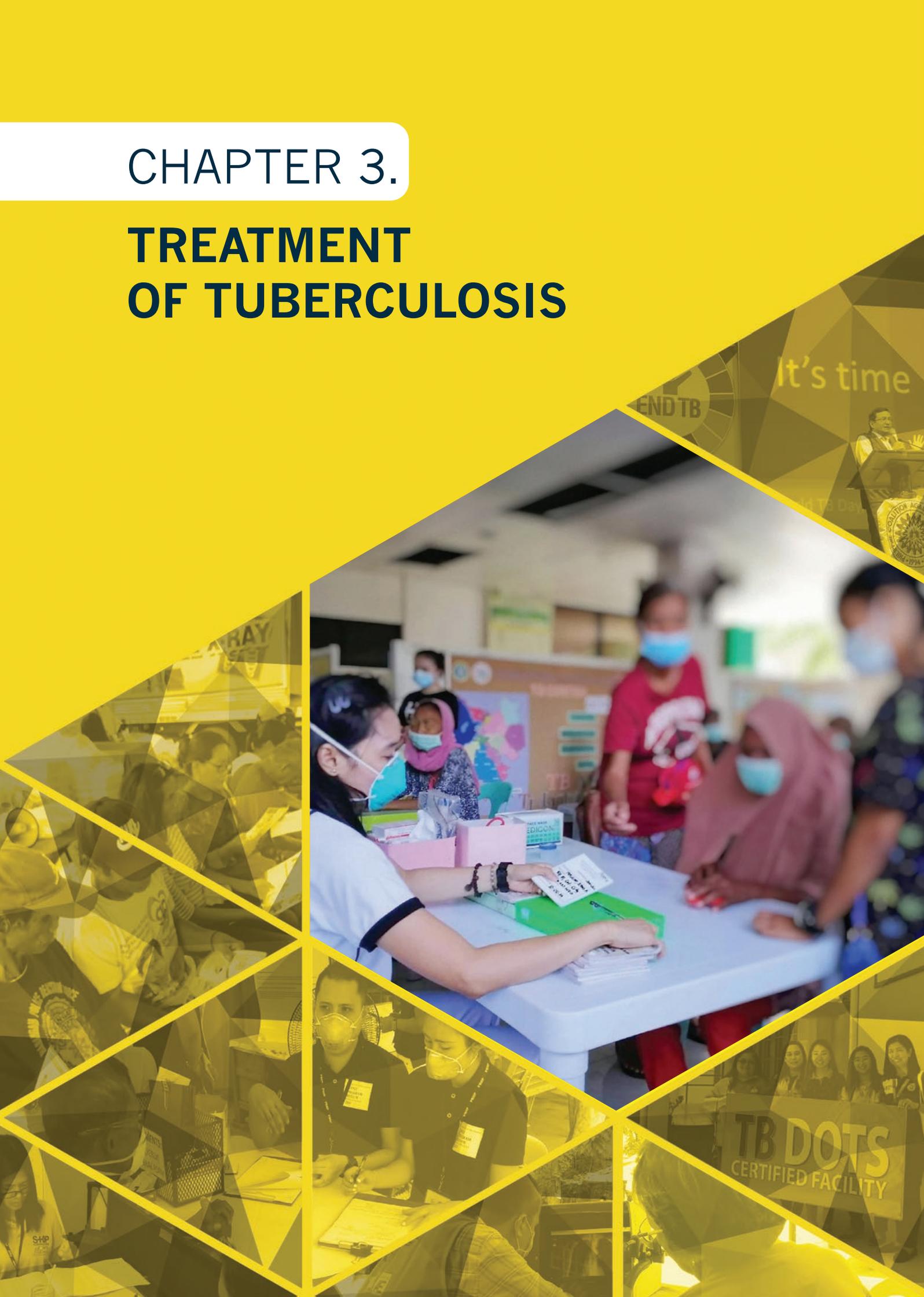
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CHAPTER 3.

TREATMENT OF TUBERCULOSIS



INTRODUCTION

Case holding is the set of procedures that begins at diagnosis and continues to initiation of treatment and then throughout the treatment duration. Activities include treatment education for the patient, family members and treatment supporters, regular adherence to counselling, provision of psychosocial support and medical management.

Medical management consists of: (1) assignment of the appropriate treatment regimen; (2) monitoring of treatment response; and (3) monitoring and management of adverse events. Uninterrupted intake of anti-TB medication by patients coupled with provision of a comprehensive patient-centered care by health-care workers are essential to achieve cure for TB and MDR-TB patients.

This chapter is divided into two sections: i) treatment of drug-susceptible tuberculosis (DS-TB); and ii) treatment of drug-resistant tuberculosis (DR-TB).

OBJECTIVES

To cure or successfully treat DS-TB and DR-TB patients

To achieve treatment success rates of $\geq 90\%$ for DS-TB and $> 85\%$ for DR-TB patients

DEFINITION OF TERMS

1. **TB Disease Registration Group** – refers to the classification of TB cases based on history of previous treatment.¹
 - **New** – has never had treatment for TB or has taken anti-TB drugs for less than one month
 - **Retreatment** – has been treated before with anti-TB drugs for at least one month. This includes the following:
 - i. **Relapse** – previously treated for TB and declared cured or treatment completed, but is presently diagnosed with active TB disease
 - ii. **Treatment after failure** – previously treated for TB but failed most recent course based on a positive SM follow-up at five months or later, or a clinically diagnosed TB patient who does not show clinical improvement anytime during treatment
 - iii. **Treatment after lost to follow-up** – previously treated for TB but did not complete treatment and lost to follow-up for at least two months in the most recent course
 - iv. **Previous treatment outcome unknown** – previously treated for TB but whose outcome in the most recent course is unknown
 - v. **Patients with unknown previous TB treatment history** – patients who do not fit any of the categories listed above or previous treatment history is unknown (this group will be considered as previously treated also)
2. **Treatment adherence interventions** – includes social support such as material support (e.g. food, incentives, transportation); psychological support; tracers such as home visit or digital health communication; medication monitoring; and staff education that collectively aims to ensure completion of treatment.²

3. **Provider-initiated counseling and testing (PICT)** – refers to HIV counseling and testing which is recommended by health-care providers to people attending health facilities as a standard component of medical care.³
4. **Medical Advisory Committee (MAC)** – is a case management committee composed of health-care providers with expertise in managing DR-TB who reviews and approves the cases presented for empiric treatment, and provides recommendations on difficult cases.^{1,5}
5. **Standardized treatment** – refers to a treatment regimen that all patients in a defined group or category will receive. The design of the treatment regimens is based on drug-resistance surveillance data from the representative population. However, presumptive MDR-TB should be confirmed by DST, whenever possible.^{4,5}
6. **Individualized treatment regimen (ITR)** – refers to a treatment regimen that is designed for an individual patient based on previous TB treatment history, individual DST results and history of contact with DR-TB patients.^{4,5}
7. **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.^{1,4,6}
8. **Intensive phase** – in the context of the NTP, this refers to the initial part of a standardized regimen which usually consists of four or more anti-TB drugs. Once some of the drugs are discontinued according to the schedule of the standard regimen, this is now referred to as **continuation phase**.
9. **Isoniazid-resistant TB** – refers to mycobacterium tuberculosis (MTB) strains in which resistance to isoniazid and susceptibility to rifampicin has been confirmed in vitro.⁶
10. **Polyresistance** – refers to resistance to more than one first-line anti-TB drug, other than isoniazid and rifampicin together.⁶
11. **Rifampicin-resistant TB (RR-TB)** – refers to MTB strains that are not susceptible to rifampicin on the basis of DST and, as a result, are eligible for treatment with MDR-TB regimens.⁴ Rifampicin-resistant TB strains may be resistant to isoniazid (i.e. MDR-TB), resistant to other first-line TB medicines (poly-resistant), or resistant to second-line TB medicines (e.g. XDR-TB). In these guidelines and elsewhere, MDR-TB and RR-TB cases are often grouped together as MDR-TB and RR-TB.⁶
12. **Multidrug-resistant TB (MDR-TB)** – refers to MTB strains in which resistance to both isoniazid and rifampicin has been confirmed in vitro.^{1,4,5}
13. **Second-line TB drug (SLD)** – refers to an agent reserved for the treatment of drug-resistant TB.⁶
14. **First-line TB drugs (FLD)** – refer to the agents used to treat drug-susceptible TB – ethambutol, isoniazid, pyrazinamide and rifampicin. Streptomycin is now considered a second-line TB medicine.⁶

SECTION 3.1. TREATMENT OF DRUG-SUSCEPTIBLE TUBERCULOSIS

POLICIES

1. All diagnosed drug-susceptible tuberculosis (DS-TB) cases shall be provided with appropriate anti-TB treatment within five working days from collection of sputum.
2. Standard treatment for DS-TB shall be given based on results of Xpert MTB/RIF. If Xpert MTB/RIF test or any other DST is not done, history of treatment will be used as basis for the regimen.
3. Quality of anti-TB drugs shall be ensured by ordering from a source with a track record of producing first-line drugs according to national standards of quality as set by the Food and Drug Administration (FDA).
4. Treatment adherence shall be ensured through patient-centered approaches. Treatment support shall be provided by health workers, community volunteers or family members.
5. Treatment response shall be monitored through follow-up smear microscopy and clinical assessment.
6. All adverse drug reactions (ADRs) shall be reported using the official reporting form of the FDA and managed accordingly.
7. All TB patients aged 15 years old and above shall be offered provider-initiated HIV counselling and testing, according to the phased implementation of the TB-HIV collaboration.
8. All TB patients aged 25 years old and above shall be screened for diabetes.

PROCEDURES

A. Initiation of treatment

1. Inform the patient that they have TB disease. Provide key messages for TB patients and families:
 - Basic information about TB disease covering: cause, transmission, clinical signs and symptoms; how TB is diagnosed; and how to prevent TB
 - Duration of treatment: six months for DS-TB, 12 months for severe drug susceptible EPTB, and 9–20 months for DR-TB cases
 - The schedule of regular clinical and laboratory follow-up for treatment monitoring
 - Potential adverse events during treatment and how to address them
 - The relevance of contact investigation and TB preventive treatment (TPT)
 - Tracing mechanism in case of treatment interruption (missed dose)
 - Availability of free-of-charge services for TB diagnosis and treatment and TPT
 - Discuss with patients their social and financial needs and offer possible sources of social support to enable adherence to treatment (e.g. Department of Social Welfare and Development, Social Security System, Government Service Insurance System, Employees Compensation Commission, local government units (LGUs), etc.)

2. Determine baseline weight and record baseline clinical findings (TB signs and symptoms)
3. Assign the appropriate DS-TB regimen based on results of DST (Xpert) or, if not available, based on history of treatment (Table 6).^{2,8,9}

Table 6. Treatment Regimens for DS-TB

REGIMEN	Eligible TB patients
Regimen 1 2HRZE/4HR	<ul style="list-style-type: none"> • PTB or EPTB (except central nervous system [CNS], bones, joints) whether new or retreatment, with final Xpert result: <ul style="list-style-type: none"> ◦ MTB, RIF sensitive ◦ MTB, RIF indeterminate • New PTB or new EPTB (except CNS, bones, joints), with positive SM/TB LAMP or clinically diagnosed, and: <ul style="list-style-type: none"> ◦ Xpert not done* ◦ Xpert result is MTB not detected
Regimen 2 2HRZE/10HR	<ul style="list-style-type: none"> • EPTB of CNS, bones, joints whether new or retreatment, with final Xpert result: <ul style="list-style-type: none"> ◦ MTB, RIF sensitive ◦ MTB, RIF indeterminate • New EPTB of CNS, bones, joints, with positive SM/TB LAMP or clinically diagnosed, and: <ul style="list-style-type: none"> ◦ Xpert not done* ◦ Xpert result is MTB not detected

*All efforts shall be exerted to ensure that all retreatment cases are tested with Xpert MTB/RIF.

4. Instruct on proper dosage based on weight (Table 7 for adults and Tables 8 and 9 for children).

Table 7. Standard regimens for DS-TB: dosing for adults

Body Weight (Kg)	Intensive Phase, 2 RHZE (150/75/400/275 mg)	Continuation Phase, 4 RH (150/75 mg)
	No. of Tablets per day	
25–37	2	2
38–54	3	3
55–70	4	4
70	5	5

Table 8. Standard regimens for DS-TB: dosing for children using Fixed-dose combination

Weight band	Numbers of tablets		
	Intensive phase: RHZ 75/50/150	Intensive Phase: Etham 100mg/tab	Continuation phase: RH 75/50
4–7 kg	1	1	1
8–11 kg	2	2	2
12–15 kg	3	3	3
16–24 kg	4	4	4
25+ kg	Adult dosages recommended		

Table 9. Standard Regimen for DS-TB: dosing for children using single-dose formulations

Body Weight (kgs)	Isoniazid (200 mg/5ml)	Rifampicin (200 mg/5ml)	Pyrazinamide (250 mg/5ml)	Ethambutol (100 or 400 mg/tab)
	10 mg/kg	15 mg/kg	30 mg/kg	20 mg/kg
	ml.	ml.	ml.	Tablet
3	0.75	1.00	1.75	(50 mg)
4	1.00	1.50	2.50	(100 mg)
5	1.25	2.00	3.00	
6	1.50	2.25	3.50	
7	1.75	2.50	4.25	
8	2.00	3.00	4.75	(200 mg)
9	2.25	3.50	5.50	
10	2.50	3.75	6.00	
11	2.75	4.00	6.50	
12	3.00	4.50	7.25	(300 mg)
13	3.25	5.00	7.75	
14	3.50	5.25	8.50	
15	3.75	5.50	9.00	
16	4.00	6.00	9.50	
17	4.25	6.50	10.25	
18	4.50	6.75	10.75	(400 mg)
19	4.75	7.00	11.50	
20	5.00	7.50	12.00	
21	5.25	8.00	12.50	
22	5.50	8.25	13.25	
23	5.75	8.50	13.75	
24	6.00	9.00	14.50	

5. Compute for total drug requirements based on dosage, regimen and 28 calendar days per month (*Table 10 and 11*). Allocate and secure the required supply for entire duration of patient's treatment.

Table 10. Matrix for number of tablets required (adults)

Body Weight	DSTB Regimen 1		DSTB Regimen 2	
	4 fixed-dose combination (FDC) (No. tablets*)	2 FDC (No. tablets)	4 FDC (No. tablets)	2 FDC (No. tablets)
25-37kg	112 tablets	224 tablets	112 tablets	560 tablets
38-54kg	168 tablets	336 tablets	168 tablets	840 tablets
55-70kg	224 tablets	448 tablets	224 tablets	1,120 tablets
More than 70kg	280 tablets	560 tablets	280 tablets	1,400 tablets

*number of blister packs = number of tablets required/number of tablets per blister pack

Table 11. Matrix for number of tablets required (children)

Body Weight	DSTB Regimen 1			DSTB Regimen 2		
	HRZ (No. tablets*)	Etham 100mg (No. of tablets)	HR (No. tablets)	HRZ (No. tablets)	Etham 100mg (No. of tablets)	HR (No. tablets)
4–7 kg	56	56	112	56	56	280
8–11 kg	112	112	224	112	112	560
12–15 kg	168	168	336	168	168	840
16–24 kg	224	224	448	224	224	1,120
25+ kg	Follow computation for Adults in Table 8					

*number of blister packs = number of tablets required/number of tablets per blister pack

- Determine other co-morbidities, such as diabetes, HIV and malnutrition, and note other medications that patient is taking; manage or refer accordingly. Adjust the regimen if needed based on presence of any co-morbidity (*Annex 3A. Management of DS-TB in special situations*)¹⁰ or any possible drug–drug interaction (*Annex 3B. Drug–drug interactions of TB medications*).¹¹
- If not a known diabetic, screen all TB patients ≥ 25 years old for diabetes using a fasting or random plasma blood glucose test (Cut-off level ≥ 7 mmol/L or 126 mg/dl for fasting; 11.1 mmol/L or 200 mg/dl for random).¹²
- If the health facility staff are already trained in the TB–HIV collaboration, offer **provider-initiated HIV counseling and testing (PICT)** to all TB patients 15 years old and above. If a child with TB has an HIV- positive mother or has signs and symptoms suggestive of HIV (e.g. oral thrush, recurrent chronic infections severe wasting and persistent diarrhea), offer testing also and secure consent of mother.

Trained health-care worker (doctors, nurses, medical technologists and midwives) are allowed to perform HIV screening through finger-pricking using DOH-FDA registered HIV testing kits (DOH Administrative Order 2017-0019: Policies and Guidelines in the Conduct of HIV Testing Services in Health Facilities.)

Complete the corresponding **Form 2b. HIV Result Form**, as applicable.

- Discuss the appropriate treatment adherence mechanism with the patient. Consider the most suitable location of drug intake and treatment supporter based on patient's condition. Options include:
 - location: can be at home, community, workplace or health facility
 - treatment supporter: can be oriented family member, trained lay volunteer or health worker.

The choice should be mutually agreed upon between the patient and the provider.

If daily intake is not in the health facility, the health worker can provide initially a one-week supply to the treatment supporter and adjust the supply later to a maximum of monthly dispensing, depending on the situation. Ensure that health workers or trained volunteers regularly communicate with patient at least every two weeks as part of psychosocial support.

Other modes of treatment supervision such as self-administered treatment assisted by technology (e.g. Video DOT, call or SMS-based DOT) may also be done. (*Annex 3C. Other modes of Treatment Supervision*)

10. Complete **Form 4b. DS-TB Treatment Card** and register in **Form 6a. DS-TB Register** (ITIS) if not yet done previously upon diagnosis. If already done, update the records to reflect initiation of treatment. Determine and record the treatment registration group.

Complete also **Form 5. TB and TPT Patient Card** for the patient/treatment supporter.

11. Ask if the patient is a member of the Philippine Health Insurance Corporation, known as PhilHealth, or a qualified dependent of a member and file for reimbursement, as applicable.
12. Ask if the patient requires any further social or financial support. Refer accordingly to other programs providing social protection, for example, Social Security System (SSS), Government Service Insurance System (GSIS), Employees Compensation Commission (ECC), Department of Social Welfare and Development (DSWD) and LGU programs.

B. Approach to TB patients initiated treatment by a provider outside a DOTS facility

There are many patients whose treatment was initiated by a private clinic, hospital or other health facility not according to NTP policies, including those who initiated treatment outside the country. Either they are walk-ins or with a referral for continuation of treatment. Approach them as follows:

1. Get a detailed clinical history following the same procedures as with any presumptive TB. Record the patient in **Form 1. Presumptive TB Master List** if not previously encoded.
2. Ask for copies of supporting documents of TB diagnosis, evidence of disease activity or history of treatment. With the patient's consent, contact the attending physician and/or health-care facility.
3. Assess the patient's willingness and commitment to continue treatment under the program.
4. Do Xpert/SM, if not yet done or done by a non-NTP recognized TB microscopy unit (for SM). Record in **Form 3a. Laboratory Register for Xpert** (or Form 3b, if Xpert not available).
5. The health facility physician shall exercise their best clinical judgement on deciding whether to continue, modify, restart or discontinue treatment considering history of exposure, adherence to treatment, symptoms and clinical assessment, and SM results, among other things.
6. Assign the appropriate treatment regimen if decision to treat or continue treatment was made.
7. Complete **Form 4b. DS-TB Treatment Card** and register in **Form 6a. DS-TB Register** (ITIS) if not yet done by referring provider. Assign a registration group to the patient based on NTP policies; this is not a "transfer-in".
8. Provide feedback to the previous attending physician or facility of the patient.

C. TB treatment in HIV co-infection

Antiretroviral treatment (ART) should be started in all TB patients living with HIV, regardless of CD4 cell count. TB treatment should be initiated first, followed by ART as soon as possible within the first eight weeks of treatment. If with profound immunosuppression (e.g. CD4 counts less than 50 cells/mm³), HIV-positive TB patients should receive ART within the first two weeks of initiating TB treatment.

Patients with the TB-HIV co-infection should also receive co-trimoxazole as prophylaxis for other infections. People with HIV infection who, after careful evaluation, do not have active

TB should be given TB preventive treatment for presumed latent tuberculosis infection (see Chapter 4).

D. Monitoring treatment

1. Ask patient to follow up at the health facility two weeks after initiation of treatment and then at least monthly thereafter.
2. Update **Form 4b. DS-TB Treatment Card** during every visit. If with missed doses, discuss with the patient and treatment supporter the interventions to improve treatment adherence.

Wherever the agreed location of treatment and whoever the treatment supporter, ensure that the health worker or trained volunteer regularly communicates with patient at least every two weeks as part of psychosocial support.

3. Perform clinical assessment during follow-up visits.
 - Get the weight monthly and adjust dosage accordingly. Get additional tablets from stock if adjustment upward is needed.
 - Ask about resolution of TB signs and symptoms.
 - Manage any ADRs or refer if needed (*Table 12. Management of ADRs to anti-TB drugs*).
 - Continue management of co-morbid conditions, and refer if necessary.

Table 12. Management of adverse drug reactions (first-line TB drugs)

Adverse reactions	Drug(s) probably responsible	Management
Minor		
1. Gastrointestinal intolerance	Rifampicin, isoniazid, pyrazinamide	Give drugs at bedtime or with small meals
2. Mild or localized skin reactions	Any of the drugs	Give antihistamines
3. Orange-colored urine	Rifampicin	Reassure the patient
4. Burning sensation in the feet due to peripheral neuropathy	Isoniazid	Give pyridoxine (Vit B6) 50–100 mg daily for treatment; it can also be given 10 mg daily for prevention
5. Arthralgia due to hyperuricemia	Pyrazinamide	Give aspirin or NSAID; if persistent, consider gout and request uric acid determination, manage accordingly or refer
6. Flu-like symptoms (fever, muscle pains, inflammation of the respiratory tract)	Rifampicin	Give antipyretics
Major		
1. Severe skin rash due to hypersensitivity	Any of the drugs	Stop anti-TB drugs and refer to specialist
2. Jaundice due to hepatitis	Any of the drugs (especially isoniazid, rifampicin, pyrazinamide)	Stop anti-TB drugs and refer to specialist; if symptoms subside, resume treatment and monitor clinically
3. Impairment of visual acuity and color vision due to optic neuritis	Ethambutol	Stop ethambutol and refer to ophthalmologist
4. Oliguria or albuminuria due to renal disorder	Rifampicin	Stop anti-TB drugs and refer to specialist
5. Psychosis and convulsion	Isoniazid	Stop isoniazid and refer to specialist
6. Thrombocytopenia, anemia, shock	Rifampicin	Stop anti-TB drugs and refer to specialist

- If there is a need to discontinue anti-TB drugs due to major ADRs, consider reintroducing using single dose formulations once the ADR has resolved following the schedule below (Table 13). If the drug responsible for the ADR is identified (i.e. occurrence of a reaction after adding that drug), consider replacing that drug. Refer as needed.

Table 13. Reintroduction of anti-TB drugs following drug reaction¹³

Drug	Likelihood of causing a reaction	Challenge Doses		
		Day 1	Day 2	Day 3
Isoniazid	Least likely to most likely	50 mg	300 mg	Full dose
Rifampicin		75 mg	300 mg	Full dose
Pyrazinamide		250 mg	1000 mg	Full dose
Ethambutol		100 mg	500 mg	Full dose

If the initial reaction is severe, smaller initial challenge should be given (approx. 1/10 of the doses given for Day 1)

A similar approach may be used for children wherein you compute for full dosage based on weight (Table 14), and proceed to give increments of the dosage adding each drug successively.

Table 14. Drug dosage per kg body weight, adults and children

Drug	Adults ¹⁰	Children ⁹
Isoniazid (INH)	5 (4–6) mg/kg, Not to exceed 400 mg daily	10 (715) mg/kg, Not to exceed 300 mg daily
Rifampicin (R)	10 (8–12) mg/kg, Not to exceed 600mg daily	15 (10–20) mg/kg, Not to exceed 600 mg daily
Pyrazinamide (Z)	25 (20–30) mg/kg, Not to exceed 2g daily	35 (30–40) mg/kg
Ethambutol (E)	15 (15–20) mg/kg, Not to exceed 1.2 g daily	20 (15–25) mg/kg

- Request for follow-up SM among pulmonary TB based on the schedule below (Table 15).¹⁰

Table 15. Schedule of sputum follow-up examinations for PTB on DS-TB regimen

Type of PTB	Ff-up 1	Ff-up 2	Ff-up 3
• New, CDTB	End of Intensive Phase (2 nd month)	ONLY IF positive at end of intensive phase	
		End of 5 th month	End of treatment (6 th month)
• New, BCTB • Retreatment	End of Intensive Phase (2 nd month)	End of 5 th month	End of treatment (6 th month)

Xpert MTB/RIF test is not used for follow-up examination to monitor treatment because current-generation PCR-based tests are unable to determine MTB viability and may test positive even with nonviable or dead bacilli.

6. Decide on appropriate action based on follow-up SM results:
 - a. Proceed with treatment if SM follow-up results are negative.
 - b. If SM is positive at the end of the intensive phase (2nd month), request Xpert MTB/RIF. Proceed to continuation phase while awaiting results.
 - If Xpert result is RIF resistant, shift to DR-TB regimen (page 43, Section 3.2).
 - If Xpert result is MTB not detected, or RIF sensitive, or RIF indeterminate, continue treatment. Request for culture/DST if feasible.

Once the NTP laboratory network has capacity for rapid molecular tests for first-line DST (e.g. LPA), a request for First Line-LPA should be done for non-converters of DS-TB regimens who are still rifampicin susceptible on an Xpert test. Guidance for isoniazid mono-resistant regimens will be issued accordingly.

- c. If positive SM after the fifth or sixth month, stop treatment and declare as treatment failure. Do or repeat Xpert MTB/RIF and refer the patient to a Programmatic Management of Drug-resistant tuberculosis (PMDT) Treatment Center.
7. Explain the results of any baseline or follow-up tests conducted. For any positive sputum follow-up results, review the treatment adherence and discuss with the patient on how to improve adherence, if necessary.
8. Inform patient if already cleared for school/work based on non-infectiousness.¹⁴
 - After one week of uninterrupted treatment for clinically diagnosed TB cases.
 - After a negative follow-up SM for bacteriologically confirmed TB cases. If patient wishes to return to work sooner, SM may be repeated (outside of the regular schedule) at least two weeks after treatment initiation.
9. Record the visit, drug intake and all findings in **Form 4b. DS-TB Treatment Card**.

E. Management of patients who interrupted treatment

1. Make sure to have regular contact or communication with patient every two weeks, even if treatment is done at home by a family treatment supporter.
2. Any interruptions in treatment should be discussed with the patient and treatment supporter, and interventions to address problems should be instituted. Assess again if patient needs psychological, emotional, financial or social support and act or refer accordingly (Chapter 1. Patient Centered Care).
3. For patients who interrupt treatment for less than one month, continue the treatment and just prolong it to compensate for missed doses.
4. If interruption is more than one month but less than two months, perform a SM and decide on continuation of treatment based on results (*Table 16. Management of cases who interrupted treatment*).¹⁵

Table 16. Management of cases who interrupted treatment

Length of interruption	SM result (if > 1-month interruption)	How long has patient been treated?	Disposition
Less than 1 month	Continue treatment and prolong to compensate for missed doses		
More than 1 month but less than 2 months	Negative SM	Continue treatment and prolong to compensate for missed doses	
	Positive SM	Less than 5 months	Continue treatment and prolong to compensate for missed doses
		5 months or more	Assign outcome as "Treatment Failed"
More than 2 months	Assign outcome as "lost to follow-up"		

- If interruption is at least two months, declare "lost to follow-up". Exert all efforts to trace patient, perform Xpert MTB/RIF test and refer to DR-TB treatment center if needed.

F. Assigning treatment outcome

- Assign a treatment outcome based on completion of treatment, SM follow-up results and clinical improvement (*Table 17. Treatment outcomes for DS-TB*)
- Record the outcome in **Form 4b. DS-TB Treatment Card** and **Form 6a. DS-TB Register (ITIS)**. If applicable, issue the certificate of treatment completion found in **Form 5. TB and TPT Patient Card**.

Table 17. Treatment outcomes for DS-TB

Outcome	Definition
Cured	A patient with bacteriologically confirmed TB at the beginning of treatment and who was smear- or culture-negative in the last month of treatment and on at least one previous occasion in the continuation phase.
Treatment completed	A patient who completes treatment without evidence of failure but with no sputum smear negative results in the last month of treatment and on at least one previous occasion, either because tests were not done or because results are unavailable. This group includes clinically diagnosed patients who completed treatment.
Treatment failed	<ul style="list-style-type: none"> A patient whose sputum smear or culture is positive at five months or later during treatment. Treatment terminated because of evidence of additional acquired resistance (e.g. RIF resistance on Xpert at 2nd month) A patient for whom follow-up sputum examination was not done (e.g. child or EPTB) and who does not show clinical improvement anytime during treatment. Severe uncontrolled adverse drug reaction
Died	A patient who dies for any reason during the course of treatment.
Lost to follow-up (LTFU)	A patient whose treatment was interrupted for at least two consecutive months. A patient diagnosed with active TB but was not started on treatment (i.e., initial LTFU).
Not Evaluated	A patient for whom no treatment outcome is assigned. This includes patients transferred to another facility for continuation of treatment but the final outcome was not determined.

SECTION 3.2. TREATMENT OF DRUG-RESISTANT TUBERCULOSIS

POLICIES

1. MDR-TB and RR-TB treatment shall be started within seven days from diagnosis.
2. Standard treatment regimens for MDR-TB and RR-TB shall be given based on patient eligibility and exclusion criteria. Individualized treatment shall be given to patients who are not eligible for any of the standard regimens.
3. First- and second-line LPA test shall be done prior to MDR-TB and RR-TB, pre-XDR-TB and XDR-TB treatments. Results should be available within 14 days from submission and prompt adaptation of treatment shall be done if with resistance to fluoroquinolones (FQ), or both high-dose isoniazid and prothionamide.
4. Regular adherence counselling shall begin before treatment and continue two weeks after treatment, as well as monthly throughout treatment. All health facilities with TB services shall establish a responsive treatment adherence mechanism that allows for prompt follow-up of patients who interrupt treatment.
5. Patients shall be provided with support to enhance treatment adherence. This includes, but is not limited to, community-based care, transportation allowance and conditional cash transfers.
6. Each patient shall be assigned a treatment supporter – either a health worker, a trained lay volunteer or a family member – who shall ensure daily intake at home, designated community area, workplace or health facility. Use of digital adherence technologies (e.g. video-based treatment, 99 DOTS or artificial intelligence (AI) to aide self-administered treatment but reinforced with proper and regular adherence counselling and support may be applied, if feasible.
7. Treatment monitoring shall be undertaken by clinical, microbiological (SM and culture) and laboratory investigation according to recommended schedules and as needed.
8. Prompt management of adverse events shall be undertaken. Modification of treatment shall be done in case of intolerance to drugs (e.g. persistent nausea and vomiting). Prompt referral shall be made for patients who need hospital care for severe adverse events or other co-morbidities.
9. All severe adverse events and adverse events of special interest shall be recorded and reported through the Pharmacovigilance Information Management System (PViMS) or through the paper form using FDA standard report form for ADRs.
10. Treatment education, including infection prevention education, shall be given to patients and family members prior to and during treatment.
11. Prompt discussion of the cases with TB Medical Advisory Committee shall be done for patients whenever indicated.

PROCEDURES

A. Education, counselling and support to patients and family members prior to treatment

1. Inform the patient that they have MDR-TB or RR-TB disease.
2. Educate about TB and MDR-TB or RR-TB disease and the nature of treatment and motivate them to undergo treatment. For patients less than 18 years old, talk to the parent/guardian regarding the need for treatment. Provide, as necessary, the following key messages for TB patients and their families:
 - basic information about TB disease covering cause, mode of transmission, clinical signs and symptoms suggestive of TB, how TB disease is diagnosed and how to prevent TB;
 - duration of treatment: nine to 20 months for MDR-TB and RR-TB cases;
 - the schedule of regular clinical and laboratory follow-up for treatment monitoring;
 - potential adverse events during treatment and how to address them;
 - the relevance of contact investigation;
 - tracing mechanism in case of treatment interruption (missed dose); and
 - availability of free of charge services for TB and DR-TB diagnosis and treatment, and LTBI treatment for contacts.
3. Discuss with patients their social and financial needs and offer possible sources of support to enable adherence to treatment, for example SSS, GSIS, ECC, DSWD, LGUs, etc.

B. Pretreatment evaluation

1. Determine other co-morbidities (HIV, Diabetes, renal disease) and other health issues (tobacco, alcohol, illicit drug use and abuse) and manage them accordingly. Referral to specialist, if needed. (*Annex 3D. Special Situations in DR-TB Treatment*)
2. Do pretreatment evaluation including the following baseline tests:
 - clinical examination including body weight and height;
 - smear microscopy (SM);
 - TB culture (and DST);
 - first- and second-line LPA test ;
 - chest X-ray;
 - electrocardiogram (ECG);
 - visual acuity and color vision test;
 - potassium, Blood Urea Nitrogen (BUN), creatinine, aspartate transaminase (AST), alanine (ALT), fasting blood sugar (FBS);
 - complete blood count (CBC);
 - HIV rapid antibody test (with written consent);
 - pregnancy test;
 - thyroid stimulating hormone (TSH);
 - mental health screening;³⁵
 - brief peripheral neuropathy screen (BPNS); and
 - baseline tests required for specific regimens:
 - i. albumin, if regimen contains delamanid (Standard Long All Oral Regimen [SLOR] Fluoroquinolone Resistance [FQ-R])
 - ii. Audiometry, if regimen will contain amikacin or streptomycin (individualized treatment regimen [ITR]).

For Baseline Mental Health Screening, a simple questionnaire may be used (*Annex 3E. PHQ9 Questionnaire*) or routinely ask five simple questions:

1. Any mood changes? (easy irritation, agitation, challenge to concentration)
2. Any change in sleeping pattern? (insomnia, oversleep)
3. Any feeling of sadness?
4. Any feeling of hopelessness?
5. Any thought of hurting themselves? (suicidal ideation)

Refer to a psychologist or psychiatrist if any of the above is present.

C. Assigning the appropriate DR-TB treatment regimen

Assignment of the appropriate DR-TB regimen will depend on standard eligibility criteria set by the program and results of DST (Xpert, first- and second-line LPA and phenotypic DST). See Table 18 and Fig. 8 for different DR-TB regimens.

Table 18. Type of MDR-TB and RR-TB treatment regimens

Regimen name	Type of DR-TB	Regimen*	Remarks
Regimen 3: Standard Short All Oral Regimen (SSOR)	MDR-TB and RR-TB eligible to SSOR	4–6 months: Lfx-Bdq(6)-Cfz-Pto-E-Z-HdH <i>(Bdq shall always be given for 6 months)</i> 5 months: Lfx-Cfz-Z-E	
Regimen 4: Standard Long All Oral Regimen for FQ Susceptible (SLOR FQ-S)	MDR-TB and RR-TB eligible to SLOR (no FQ resistance)	6 Months: Lfx-Bdq-Lzd-Cfz 12–14 months: Lfx-Lzd-Cfz	Request for “off-label” use at TB MAC if extending use of Bdq beyond 6 months.
Regimen 5: Standard Long All Oral Regimen for FQ Resistance (SLOR FQ-R)	MDR-TB and RR-TB eligible to SLOR (with FQ resistance)	6 Months: Lzd-Bdq-Dlm-Cfz-Cs 12–14 months: Lzd-Cfz-Cs	Request for “off-label” use of Bdq and Dlm combination at TB MAC.
Individualized treatment regimen (ITR)	Retreatment MDR-TB and RR-TB cases (not eligible to SSOR nor SLOR)	Construct to have at least 4–5 likely effective drugs	Present the case at TB MAC and follow their advice for the regimen design

* Z=Pyrazinamide, E=Ethambutol, Bdq=Bedaquiline, Dlm= Delamanid, Lfx=Levofloxacin, Cfz=Clofazamine, Lzd=Linezolid, Cs=Cycloserine, Pto=Prothionamide, HdH=high dose isoniazid

1. Children (< 15 years old) diagnosed with MDR-TB and RR-TB shall be evaluated for eligibility to standard all oral regimens recommended for children (*page 54, Section E*).
2. The standard treatment regimens shall only be offered to patients if all of the drugs in the regimen are available and accessible. Patients who are pregnant and contacts of patients who failed on MDR-TB treatment shall be referred to the TB Medical Advisory Committee (TB MAC) for design of an individualized treatment regimen (ITR).
3. Patients who are adults (15 years old or above), not pregnant and not a contact of a patient who failed MDR-TB treatment are eligible to receive standard short all oral regimen (SSOR) if they do not have any of the following exclusion criteria:

Exclusion Criteria for SSOR (If YES to any of the following exclusion criteria, DO NOT GIVE SSOR)

1. Disseminated TB or severe/intractable EPTB (e.g. TB meningitis, bone/joint TB)
 2. Confirmed resistance to fluoroquinolone (levofloxacin/moxifloxacin)
 3. Exposure to levofloxacin(Lfx)/moxifloxacin (Mfx), bedaquiline (Bdq), clofazimine (Cfz), prothionamide (Pto) for > 1month
 4. Risk of toxicity or intolerance to any drugs in SSOR as manifested by:*
- History of heart disease (heart failure, myocardial infarction, cardiac conduction abnormality, arrhythmia)
 - QTcF > 500 ms
 - History of chronic active hepatitis (AST/ALT > 5 times elevated)
 - History of chronic renal insufficiency (creatinine clearance < 20 ml/min)

** For patients who are clinically unstable or have severe disease, eligibility may be determined using clinical history and whatever laboratory results are immediately available so as not to cause delay in start of treatment.*

4. If all of the exclusion criteria are absent, start treatment with SSOR (Regimen 3 in Table 18).
5. If not eligible to SSOR, check eligibility to Standard Long All Oral Regimen (SLOR) for Fluoroquinolone Susceptible (SLOR FQ-S).

Exclusion criteria for SLOR FQ-S (If YES to any of the following, DO NOT GIVE SLOR FQ-S)

1. Confirmed resistance to fluoroquinolone-levofloxacin (Lfx)/moxifloxacin (Mfx)
 2. Exposure to levofloxacin (Lfx)/moxifloxacin (Mfx), bedaquiline (Bdq), linezolid (Lzd), or clofazimine (Cfz) for > 1 month
 3. Risk of toxicity or intolerance to any drugs in SLOR FQ-S as manifested by:
- History of heart disease (heart failure, myocardial infarction, cardiac conduction abnormality, arrhythmia)
 - QTcF > 500 ms
 - History of chronic active hepatitis (AST/ALT > 5 times elevated)
 - History of chronic renal insufficiency (CrCl < 20ml/min)
 - Severe anemia (Hgb <8mg/dl)

6. If all of the exclusion criteria are absent, start treatment with SLOR FQ-S (Regimen 4 in Table 18).
7. If not eligible to SLOR FQ-S, check eligibility to standard long All Oral Regimen for Fluoroquinolone Resistance (SLOR FQ-R).

Exclusion Criteria SLOR FQ-R (YES to any of the following, DO NOT GIVE SLOR FQ-R)

1. Exposure to bedaquiline (Bdq), linezolid (Lzd), cycloserine (Cs), clofazimine (Cfz) or delamanid (Dlm) for > 1 month
 2. Risk of toxicity or intolerance to any drugs in SLOR FQ-R as manifested by:
- History of heart disease (heart failure, myocardial infarction, cardiac conduction abnormality, arrhythmia)
 - QTcF > 500 ms
 - History of chronic active hepatitis (AST/ALT > 5 times elevated)
 - History of chronic renal insufficiency (CrCl < 20 ml/min)
 - Severe anemia (Hgb < 8 mg/dl)

8. If all of the exclusion criteria are absent, start treatment with SLOR FQ-R (*Regimen 5 in Table 18*).
9. If not eligible to SLOR FQ-R, refer to TB MAC for composition of individualized treatment regimen (ITR). For composition of ITR, see guide in Annex 3F.
 - 9.1 Usually the cases that are not eligible to both SSOR and SLOR are MDR-TB and RR-TB patients with previous exposure to second-line drugs for more than one month (i.e., second-line retreatment cases – relapse, failure, LTFU from previous DRTB regimens) or who are contacts of an index case who failed MDR-TB treatment.
 - 9.2 In patients for whom design of an effective regimen based on existing recommendations is not possible, bedaquiline-pretomanid-linezolid regimen may be considered as a last resort under prevailing ethical standards, with strict implementation of active drug safety monitoring and management (aDSM) and after consultation with TB MAC.
10. Follow recommended regimen from the TB MAC.
11. Perform the following for off-label use of anti-TB drugs:
 - 11.1 Any situation that requires the off-label use of an anti-TB drug should be presented to TB MAC. These situations include the following:²⁰
 - Use of bedaquiline and delamanid in combination
 - Extended use of bedaquiline and/or delamanid for more than 24 weeks (six months)
 - Use of bedaquiline and delamanid in EPTB
 - Use of bedaquiline in children less than 6 years old and pregnant patients
 - Use of delamanid in children less than 3 years old and pregnant patients.

In general, informed consent form is required for patients who will be enrolled under Regimen 5
 - 11.2 (SLOR FQ-R) and patients who need extension of Bdq and Dlm.
 - 11.3 Once approved by the TB MAC, explain to the patient and/or significant others the benefits and risks involved with off-label use.
 - 11.4 Once a patient agrees to the use of anti-TB drugs off-label, ask the patient to sign the informed consent form (*Annex 3G*). For patients who cannot be fully informed (e.g. less than 18 years old, mentally incapacitated), seek consent from the parent(s) or legal guardian.
12. After determining treatment regimen, follow the dosing in Table 20 (adults) and Table 21 (children).
 - 12.1 For regimens containing prothionamide (Pto), start Pto in two divided dosage (morning and evening) for the first two weeks of treatment if total daily dose is > 250 mg.
 - 12.2 Advise patients to only take Pto after light meals.
 - 12.3 Once tolerance has improved, change Pto dosing to once daily after two weeks.
13. Upon receipt of first- and second-line DST results of LPA and phenotypic DST test, revise the regimen accordingly (*Fig. 8*).

- 13.1 Check the result of LPA for the presence of fluoroquinolone (FQ) resistance, high-dose isoniazid (H) resistance and Prothionamide (Pto) resistance (which also refers to low-dose H resistance). Results of the LPA will be reported for each drug/drug group as follows:

MTB detected	
Resistance detected	R
Resistance not detected	S
Resistance indeterminate	I
Resistance detected – low level	R _{Low}
Resistance Detected – high level	R _{High}
MTB not detected	
Not done/invalid/error	ND

- 13.2 Take appropriate action based on LPA results (*Table 19*)

Table 19. Guide on deciding appropriate treatment regimen based on LPA results

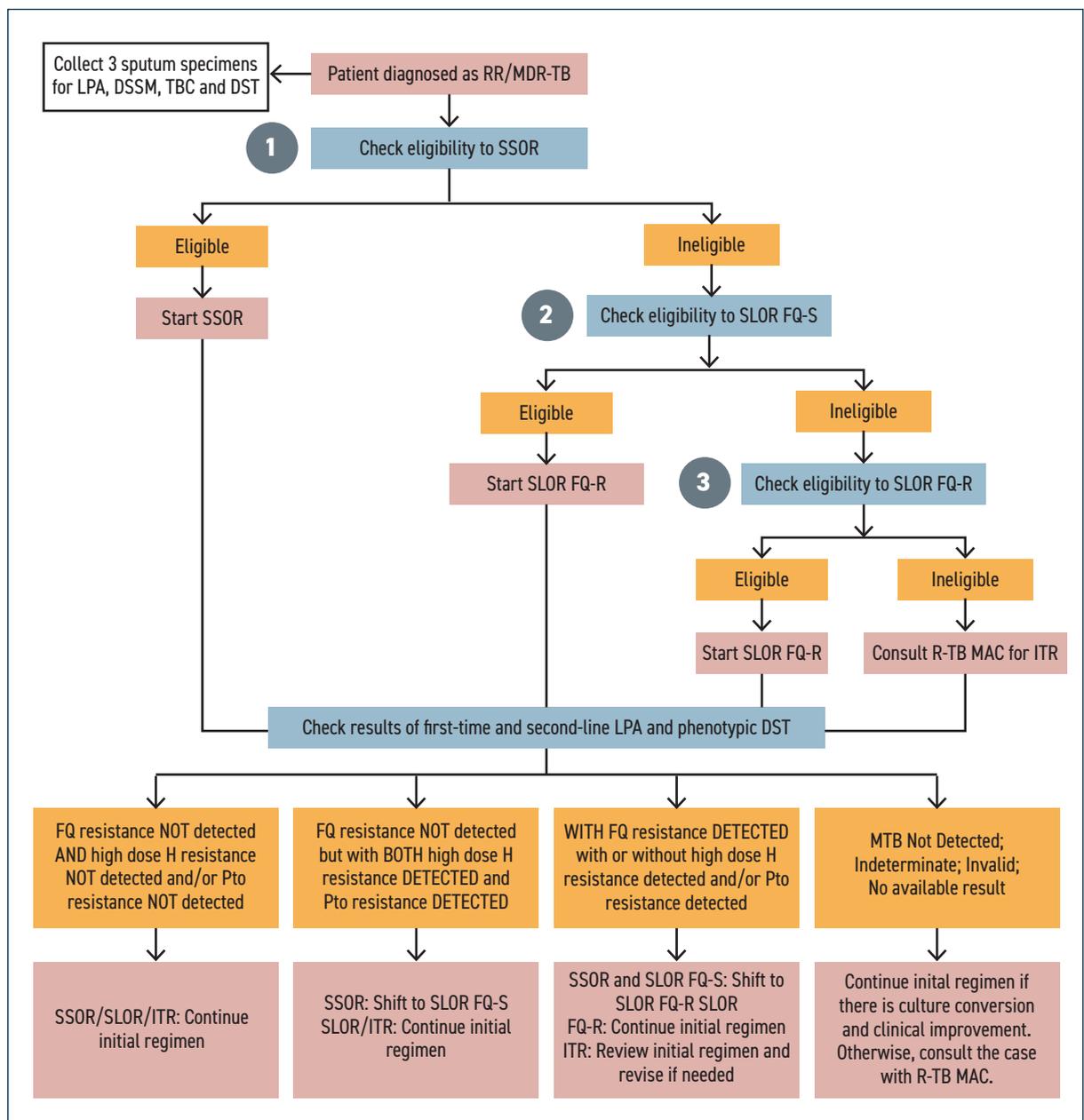
Initial regimen	Baseline LPA Result			Clinical and programmatic action
	FQ resistance detected	High-dose H (HdH) resistance detected	Pto resistance detected	
SSOR	-	-	-	Continue SSOR
	-	+	-	Continue SSOR
	-	-	+	Continue SSOR
	-	+	+	Shift to SLOR FQ-S. Continue dose count if within 1 month from treatment initiation
	+	+/-	+/-	Shift to SLOR FQ-R Restart dose count
SLOR FQ-S	-	+/-	+/-	Continue SLOR FQ-S
	+	+/-	+/-	Shift to SLOR FQ-R Restart dose count
SLOR FQ-R	+/-	+/-	+/-	Continue SLOR FQ-R
ITR	+/-	+/-	+/-	Review initial regimen and revise if needed in consultation with TB MAC

- 13.3 If LPA result is MTB not detected, invalid for MTB detection, or indeterminate resistance for any drug, and result is received before treatment or within two weeks from start of treatment, recollect sputum specimen for repeat LPA testing and continue initial regimen. If treatment is already more than two weeks, just continue initial regimen and wait for the phenotypic DST result.
- 13.4 If LPA results (whether initial or repeat) are received within two months of treatment, adjust the regimen according to guidelines above (*Table 19*).
- 13.5 If LPA result is delayed for more than two months or not available, correlate results with patient's clinical condition, sputum smear and culture results.

- If there is sputum culture conversion and clinical improvement, continue the initial regimen.
- If there is no culture conversion at the fourth month of treatment, or no clinical improvement, or with recurrence of TB signs and symptoms, repeat DST (both LPA and phenotypic) and consult the case with TB MAC.

13.6 Follow the same procedures above upon receipt of phenotypic DST results. In case of discordant result between LPA and phenotypic DST, follow the worse result (i.e. that with more drug resistance) and consult the case with TB MAC for regimen revision, if needed. Moreover, if phenotypic DST or other molecular DST from a quality-assured reference laboratory showed resistance to pyrazinamide (Z) and/or ethambutol (E), discuss the case with TB MAC.

Fig. 8. Assignment of DR-TB treatment regimens and revision of the regimen upon receipt of LPA and phenotypic DST results



D. MDR-TB and RR-TB treatment in HIV co-infected

1. Antiretroviral treatment (ART) should be started in all MDR-TB patients living with HIV, regardless of CD4 cell count. TB treatment should be initiated first, followed by ART as soon as possible within the first eight weeks of treatment. If with profound immunosuppression (e.g. CD4 counts less than 50 cells/mm³), HIV-positive MDR-TB patients should receive ART within the first two weeks of initiating treatment, except for those who are suspected to have TB meningitis for whom ART initiation should be deferred due to the risk of developing potentially fatal immune reconstitution inflammatory syndrome (IRIS).^{6, 25, 26}
2. For co-administration of bedaquiline and antiretroviral drugs (ARVs);
 - Replace efavirenz (EFV) with nevirapine (NVP) if still susceptible because EFV decreases Bdq blood concentration level by 52%. Allow five days for washout (i.e. substitute NVP then start MDR-TB treatment five days later). However, if patient is critically ill, no need to wait for a washout period just start MDR-TB treatment immediately.^{25,26}
 - Use Bdq with lopinavir/ritonavir (LPV/r) only when other options are not available because LPV/r increases Bdq concentration threefold. The better option is to substitute with an integrase inhibitor such as raltegravir or dolutegravir together with dual nucleoside reverse-transcriptase.^{25,26} But if the co-administration of Bdq and LPV/r is really needed, use with extreme caution and closely monitor ECG every two weeks.
 - Be aware of potential risk of an additive adverse event when using with linezolid-containing treatment regimen:^{25,26} i) HIV-related neuropathy when co-administered with stavudine; and ii) bone marrow dysfunction, particularly anemia when co-administered with zidovudine
 - Dolutegravir, which is now becoming widely used globally in first-line ART, has no significant interactions with Bdq, Dlm or Lzd.^{25,26}

Table 20. Dosing of medicine used in second-line MDR-TB and RR-TB regimens by weight band in patients 15 years old and above6

Group	Medicine	Weight-based daily dose	Formulation	Weight bands for patients older than 14 years old					Usual upper daily dose	Comments
				30-35 kg	36-45kg	46-55kg	56-70kg	> 70kg		
A	Fluoroquinolones									
	Levofloxacin		250 mg tab	3	3	4	4	4	1.5 g	
			500 mg tab	1.5	1.5	2	2	2		
	Moxifloxacin	Standard dose	400 mg tab	1	1	1	1	1	400 mg	As used in the standardized shorter MDR/TB Regimen
		High dose	400 mg tab	1 or 1.5	1.5	1.5 or 2	2	2	800 mg	
			100 mg tab	4 tabs OD for 2 weeks; then 2 tabs OD M/W/F for 22 weeks					400 mg	
B	Linezolid		600 mg tab	(< 15 y)	(< 15 y)	1	1	1	1.2 g	
	Clofazimine		50 mg cap	2	2	2	2	2	100 mg	
			100 mg cap	1	1	1	1	1	100 mg	
	Cycloserine or Terizidone	10-15 mg/kg	250 mg cap	2	2	3	3	3	1 g	
	Ethambutol	15-25 mg/kg	400 mg tab	2	2	3	3	3		
	Delamanid		50 mg tab	2 BID	2 BID	2 BID	2 BID	2 BID	200 mg	
	Pyrazinamide	20-30 mg/kg	500 mg tab	2	3	3	3	4		
	Impipinem-Cilastatin		0.5 g + 0.5 g vial	2 vials (1g + 1g) BID						To be used with clavulanic acid
	Meropenem		1g vial (20 ml)	1 vials 3x/day or 2 vials BID						To be used with clavulanic acid
	Amikacin	15-20 mg/kg	500 mg/2ml vial	2.5 ml	3ml	3 to 4 ml	4ml	4ml	1 g	
Streptomycin	12-18 mg/kg	1 gm vial	Calculate according to the dilution used					1 g		
Ethionamide or Prothionamide	15-20 mg/kg	250 mg tab	2	2	3	3	4	1 g	Once daily dose advised but can start with 2 divided doses until tolerance improves	
p-aminosalicylic acid (PAS)	8-12 g/day in 2 to 3 divided doses	PAS Acid (4 gm) sachet	1 BID	1 BID	1 BID	1 BID	1 to 1.5 BID	12 g		
Others	Isoniazid	Standard dose: 4-6 mg/kg	300 mg tab	2/3	1	1	1	1	100 mg isoniazid tablet can facilitate the administration of certain dosages	
		High dose: 10-15 mg/kg	300 mg tab	1.5	1.5	2	2	2	Pyridoxine is given with isoniazid in patients at risk (such as dose with HIV and malnutrition)	
	Clavulanic acid		125 mg tab	1 BID	1 BID	1 BID	1 BID	1 BID	To be used only with carbapenems (such as imipenem and meropenem)	

* (<15 y) = follow the separate dose schedule for patients younger than 15 years of age

Note: BID = twice a day, OD = once a day

Table 21. Dosing of medicine used in second-line MDR-TB and RR-TB regimens by weight band in patients under 15 years6

Group	Medicine	Weight-based daily dose	Formulation	Weight bands for patients older than 14 years old						Usual Upper Daily Dose	Comments		
				5-6 kg	7-9 kg	10-15 kg	16-23 kg	24-30 kg	31-34 kg			> 34 kg	
Fluoroquinolones													
A	Levofloxacin	15-20 mg/kg	250 mg tab	0.5	0.5	1 to 1.5	1.5 to 2	2	3	(>14 y)	1.5 g		
	Moxifloxacin	10-15 mg/kg	400 mg tab ^C	2 ml	3 ml	5 ml	0.5 or 0.75	1	1	(>14 y)	400 mg	Use 10 mg/kg in <6months	
	Bedaquiline		100 mg tab									Only in patients > 5 years old (lower dose from 15-29 kg, higher dose from > 29 kg)	
	Linezolid	10 mg/kg OD in < 16 kg 10-12 mg/kg OD in > 15 kg		600 mg tab ^C	0.25	0.25	0.25	0.5	0.5	0.5	0.75 ^d	600 mg	
B	Clofazimine	2-5 mg/kg											
			50 mg cap	1 alt days	1 alt days	1 alt days	1	2	2	(> 14 y)	100 mg		
			100 mg cap	M/W/F	M/W/F	1 alt days	1 alt days	1	1	(> 14 y)	100 mg	Give on alternate days if dose in mg/kg/day is too high	
	Cycloserine or Terizidone	15-20 mg/kg		250 mg cap ^C	4 to 5 ml ^C	5 to 6 ml ^C	7 to 10 ml ^C	2	2	(> 14 y)	1 g		
C	Ethambutol	15-25 mg/kg		400 mg tab ^C	3ml ^C	4ml ^C	6 ml ^C	1	1 or 1.5	2	2	200 mg	Only in patients > 2 years old (25 mg BID in 3-5 years; 50 mg BID in 6-11 years 100 mg in 12- 17 years
	Delamanid			50 mg tab	-	-	-	-	1 BID	1 BID	2 BID		
	Pyrazinamide	30-40 mg/kg		500 mg tab	0.5	0.5	0.75 or 1	1.5	2	2.5	(> 14 y)	-	
	Imipinim-Cilastatin			0.5 g + 0.5 g vial	-	-	-	-	-	-	-	-	Cannot be used in patients <15 years (use meropenem
C	Meropenem	20-40 mg/kg IV q 8 hours		1g vial (20 ml)	2 ml	4 ml	6 ml	8-9ml	11ml	(> 14 y)	(>14 y)		To be used with clavulanic acid
	Amikacin	15-20 mg/kg		500 mg/2 ml vial	0.4 ml	0.6 ml	0.8-1.0 ml	1.2 - 1.5 ml	2.0 ml	(> 14 y)	1 g		
	Streptomycin	20-40 mg/kg		1 gm vial	Calculate according to dilution used						1 g		
	Ethionamide or Prothionamide	15-20 mg/kg		250 mg tab	0.5	0.5	1	2	2	2	(> 14 y)	1 g	
p-aminosalicylic acid	200-300 mg/kg in 2 divided doses		PAS Acid (4 gm) sachet	0.5 to 0.75 g BID	0.75 to 1 g BID	1-2 g BID	2-3 g BID	3 to 3.5 g BID	(> 14 y)	(> 14 y)		Full dose can be given daily if tolerated	

Table 21. Dosing of medicine used in second-line MDR-TB and RR-TB regimens by weight band in patients under 15 years⁶ (Cont.)

Group	Medicine	Weight-based daily dose	Formulation	Weight bands for patients older than 14 years old						Usual Upper Daily Dose	Comments
				5-6 kg	7-9 kg	10-15 kg	16-23 kg	24-30 kg	31-34 kg		
Others	Isoniazid	15-20 mg/kg (high dose)	300 mg tab	1	1.5	2	3	4	4		300 mg isoniazid tablet be used in patients > 20 kg. Pyridoxine is always given with high dose isoniazid in children (12.5 mg OD in < 5yrs old and 25 mg OD in > 4 years old
	Clavulanic acid		25 mg Amx/62.5 mg Clv 5 ml susp	2ml BID	3 ml BID	5 ml BID	8 ml BID	10 ml BID	(> 14 y)		Only to be used with carapenems

(> 14 y) – follow the separate dose for patients older than 14 years of age

c Dissolving in 10 ml distilled water may facilitate administration in patients in lower weight-bands and avoids fractioning of solid formulation, although bioavailability is uncertain (use of dispersible tablet is preferred if available)

Note: BID = twice a day, OD = once a day

E. MDR-TB and RR-TB treatment in children

- Design a regimen consisting of four to five drugs for the entire treatment duration (Table 22).
 - Consult with TB MAC. Initiation of treatment should be in accordance with the regimen and dosage advised by TB MAC.
 - Avoid injectable drugs as much as possible to avoid hearing loss, which will affect child's language development and social skills.
 - The following regimens should be considered, especially those who have disseminated TB and bacteriologically confirmed, FQ-resistant MDR-TB and RR-TB.^{6,23,24}

Table 22. DR-TB treatment regimens for children

Age	Regimen 6: FQ-susceptible MDR-TB	Regimen 7: FQ-resistant MDR-TB
< 3 years	(6a) Lfx-Lzd-Cfz-Cs (PAS/Eto)	(7a) Lzd-Cfz-Cs-PAS (Eto/Dlm)
3–6 Years	(6b) Lfx-Lzd-Cfz-Cs (Dlm/PAS)	(7b) Lzd-Cfz-Cs-Dlm (PAS/Eto)
> 6 years	(6c) Bdq-Lfx-Lzd-Cfz (Cs/Dlm)	(7c) Bdq-Lzd-Cfz-Cs (Dlm/PAS)

- Determine the severity of the disease.^{6,23,24} Severity of TB in children is usually defined by presence of:
 - positive TB bacteriology (smear, Xpert MTB/RIF, culture);
 - cavities or bilateral disease on chest radiography or smear-positivity;
 - extrapulmonary forms of disease other than lymphadenopathy (peripheral nodes or isolated mediastinal mass without compression); and
 - presence of co-morbid condition or disease such as severe malnutrition or advanced immunosuppression.
- Give treatment accordingly:
 - nine to 12 months for non-severe disease depending on the clinical progress as assessed by physician
 - 15–18 months for severe or extensive disease.
- Monitoring of treatment

For children with no bacteriologic confirmation at baseline (e.g. children who cannot expectorate), monitor clinically:

- resolution of TB signs and symptoms;
- monthly weight gain and growth (weight and height chart for children < 5 years old);
- baseline chest X-ray and follow-up chest X-ray at six months to check resolution of lesions in case of thoracic TB;
- follow-up CT scan/MRI scan at six months for intrathoracic or EPTB diagnosed with this imaging tests; and
- healing of other EPTB lesions (e.g. cold abscess).

For children who have bacteriologic confirmation:

- monitor clinically as above; and
- follow the bacteriological monitoring schedule for sputum and culture tests (Table 23 and 24).

F. Initiation of treatment

1. Accomplish **Form 4c. DR-TB Treatment Card** and **Form 5. TB and TPT Patient Card** and assign case number.
2. Record patient details in **Form 6b. DR-TB Register** (ITIS).
3. Discuss and finalize the appropriate treatment adherence mechanism with patient. Consider the most suitable location of drug intake and treatment supporter based on the patient's condition. Options include:
 - location: can be at home, community, workplace or health facility; and
 - treatment supporter: can be family member, trained lay volunteer and health worker.
4. If daily intake is not in the health facility, the health worker can provide initially a one-week supply to the treatment supporter and adjust later to a maximum of monthly dispensing depending on the situation. Ensure that health workers or trained volunteers regularly communicate with patient at least every two weeks as part of psychosocial support.

Other modes of treatment supervision such as self-administered treatment assisted by technology (e.g. video DOT, call- or SMS-based DOT, AI-based therapy) may also be done. (*Annex 3C. Other modes of Treatment Supervision*)

G. Monitoring treatment

1. Record successful intake of daily dose in **Form 4c. DR-TB Treatment Card** and **Form 5. TB and TPT Patient Card** by affixing the initials of the health staff or treatment supporter.
2. Conduct treatment monitoring clinically, microbiologically and by laboratory investigation as per schedule (*Table 23 for SSOR and Table 24 for SLOR*). Check the following and manage accordingly:
 - general well-being, weight and height in children, resolution of symptoms and mental health screening;
 - identify any occurrence of adverse events and provide prompt and appropriate management; and
 - remind patient to submit sputum specimen and have other laboratory examinations done according to schedule.
3. Weigh the patient monthly and adjust dosage accordingly based on weight.
4. Give positive feedback on the patient's treatment (e.g. weight gain and/or resolution of other symptoms as good signs of clinical response). Record the interaction in the individual treatment record or patient's chart.
5. Manage any adverse events appropriately (*Annex 3H. Clinical Management of Some Adverse Events*). Report serious adverse events (SAE) or adverse events of special interest (AESI) using **FDA Suspected Adverse Reaction Form** (*page 59, Section H. aDSM*).
6. For patients who cannot tolerate any of the drugs in the regimen (e.g. hearing loss, intolerable pain to amikacin, persistent vomiting) consider modification of treatment (*page 60, Section I. Modification of Treatment Regimen*). Discuss the case with TB MAC for possible shift of SSOR to other regimens if it is necessary to replace more than one drug.

7. Revise the regimens based on first- and second-line LPA and phenotypic DST test results (*Fig. 8 and Table 19*).
8. Adjust the SSOR regimen based on results of follow-up SM.
 - If the is smear negative at the fourth month, shift to continuation phase (i.e. discontinue HdH and Pto). If smear positive, extend intensive phase for one month.
 - If intensive phase extended to five months and SM is still positive, extend intensive phase for another month. If negative, shift to continuation phase (i.e. discontinue HdH and Pto).
 - If the intensive phase is extended to six months and SM is still positive, refer to the TB MAC. If negative, shift to continuation phase (i.e. discontinue HdH and Pto). Discontinue Bdq at month six.
9. If there is no culture conversion (for all regimens) at month four of treatment or if there is culture reversion, collect one sputum sample from patients and request for repeat LPA, DST and culture/phenotypic second-line DST.
 - If there is any drug resistance amplification detected from the repeat DST tests, declare the case as failure.
 - When failure is declared or in any other situation when failure is suspected, consult with TB MAC for the possible causes, patient management strategy and registration of outcome.

Table 23. Schedule of baseline and follow-up clinical, laboratory and bacteriologic examination for patients on standard short all-oral regimen (SSOR)16

Test/Examination – Baseline (BL), Month (M)	Intensive phase: 4 months, may be extended up to 6 months					Continuation phase: 5 months					Post-treatment follow-up	
	BL	M1	M2	M3	M4	M5	M6	M7	M8	M9	M15	M21
Clinical Evaluation by the PMDT Physician including weight for all and height for children	/	/	/	/	/	/	/	/	/	/	/	/
Mycobacteriological Tests												
Smear Microscopy	/	/	/	/	/	/	/	/	/	/	/	/
TB Culture (TBC)	/	/	/	/	/	/	/	/	/	/	/	/
Drug Susceptibility Testing (DST)	/	If culture remains positive at month 4 of treatment, in case of culture reversion or culture positive during post-treatment follow-up										
First-line and Second-line Line Probe Assay (LPA)	/											
Diagnostic Tests												
Chest X-ray (Chest X-ray)	/						/				/	/
Electrocardiogram (ECG)	/	/	/	/	/	/	/	/	/	/		
Visual Acuity and Color Vision	/	/	/	/	/	/	/	/	/	/		
Brief Peripheral Neuropathy Screening (BPNS)	/	/	/	/	/							
Mental health screening	/	Monthly if regimen contains Cycloserine (Patient Health Questionnaire-9 or short screening tool may be used)										
Blood Chemistry/Hematology/Immunological Tests												
Alanine and Aspartate Transaminase (ALT/AST)*	/	/	/	/	/	/	/	/	/	/		
Complete Blood Count (CBC)	/	Monthly if regimen contains Linezolid										
Urea Nitrogen, Creatinine, Fasting Blood Sugar (FBS), Potassium (K),	/											
Thyroid Stimulating Hormone (TSH)	/						/					
HIV Rapid Antibody Test	/											
Pregnancy Test	/											

*If ALT and AST are higher than upper limit of normal value, consider doing total bilirubin test.

Table 24. Schedule of baseline and follow-up clinical, laboratory and bacteriologic examinations for patients on 18–20 months treatment regimens^{4,16}

	Intensive phase: 6 months										Continuation phase: 12–14 months										Post-treatment Follow-up			
	BL	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	6m	12m	
Test/Examination – Baseline (BL), Month (M)	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/
Clinical Evaluation	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/
Mycobacteriological Tests																								
Smear Microscopy	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/
TB Culture (TBC)	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/	/
DST	/	If culture remains positive at month 4 of treatment, in case of culture reversion or culture positive during post-treatment follow-up																						
LPA	/																							
Diagnostic Tests																								
Chest X-ray	/																							
ECG [#]	/	Monthly if regimen contains Bedaquiline, Delamanid, Clofazimine and/or Moxifloxacin																						
Visual Acuity and Color Vision	/	Monthly if regimen contains Linezolid and/or Ethambutol																						
BPNS	/	Monthly if regimen contains Linezolid, Cycloserine and/or High Dose Isoniazid																						
Audiometry	Baseline and Monthly if regimen contains Amikacin or Streptomycin																							
Mental health screening	Baseline and Monthly if regimen contains Cycloserine (Patient Health Questionnaire-9 or short screening tool may be used)																							
Blood Chemistry/Hematology/Immunological Tests																								
ALT/AST*	/	Monthly if regimen contains Bedaquiline and/or Pyrazinamide																						
CBC	/	Monthly if regimen contains Linezolid																						
FBS,																								
Urea Nitrogen, Creatinine, K	/	Monthly if regimen contains Amikacin or Streptomycin																						
TSH	/	Every 6 months if regimen contains Prothionamide or Para-aminosalicylic Acid (PAS) Every 3 months if regimen contains both Prothionamide and Para-aminosalicylic Acid (PAS)																						
Albumin	Baseline if regimen contains Delamanid																							
HIV Rapid Antibody Test																								
Pregnancy Test	/																							

* If ALT and AST are higher than upper limit of normal value, consider doing total bilirubin test. If regimen contain Bdq+Dlm and/or Mfx+Clz, more frequent ECG monitoring, every other week for initial 3 months is recommended.

10. Do adherence counseling regularly:
 - assess compliance to treatment;
 - explore any potential issues or constraints related to adherence to drug intake, treatment follow-up schedule or continuation of treatment;
 - provide psychological support and refer to psychologist or psychiatrist if necessary; and
 - refer to any relevant department for social support needed (e.g. rehabilitation center for drug/alcohol issue, conditional cash transfer for DSWD, etc.).
11. If patient is interrupting treatment, immediately make a phone call upon missing one dose and follow up in person if a patient missed does doses. Do adherence counselling.
12. If patient finishes their treatment, congratulate the patient and instruct to follow up every six months for the next year.
13. Record and update the necessary forms during every follow-up visit – **Form 4c. DR-TB Treatment Card** and **Form 5. TB and TPT Patient Card**

H. Active drug safety monitoring and management (aDSM)

Active drug safety monitoring and management (aDSM) is an essential component in treating DR-TB. One of the key activities in aDSM is the reporting of all serious adverse events (SAE) and adverse events of special interests (AESI).³³ But it should be noted that active clinical and laboratory monitoring of patients for surveillance of any adverse events and prompt and appropriate management of adverse events, regardless of severity, are equally important.

1. Report all SAEs or AESIs (*Table 25*) through the prescribed reporting form or system.
2. Complete the report through the Pharmacovigilance Monitoring System (PViMS).
3. In case PViMS is not accessible, complete the FDA Suspected Adverse Reaction Form (aDSM reporting form). The paper report shall be submitted to Center for Health Development (CHD) NTP Coordinator and National Drug Policy Compliance Officer (NDPCO). This shall be later entered into PViMS by NDPCO.
4. Through PViMS or paper format, submit the report within two working days from occurrence of event or immediately upon receipt of information.
5. Manage all adverse events accordingly (*Annex 3H. Clinical Management of some Adverse Events*)

Table 25. Serious adverse events (SAE) and adverse events of special interest (AESI)

<p>Serious adverse events³³</p> <p>SAE refers to any untoward medical occurrence that at any dose:</p> <ul style="list-style-type: none"> • results in death; • is life threatening; • requires inpatient hospitalization or results in prolongation of existing hospitalization; • results in persistent disability/incapacity; • is a congenital anomaly/birth defect; or • does not immediately result in one of the above outcomes, but which require an intervention to prevent a serious outcome.

Adverse events of special interests³³

AESI refers to an adverse event documented to have occurred during clinical trials and for which the monitoring program is specifically sensitized to report **regardless of its seriousness, severity or causal relationship** to the TB treatment. These are the following:

- acute kidney injury (acute renal failure);
- hepatitis, defined as increases in alanine aminotransferase (ALT) or aspartate aminotransferase (AST) $\geq 5x$ the upper limit of normal (ULN), or increases in ALT or AST $\geq 3x$ ULN with clinical manifestations, or increases in ALT or AST $\geq 3x$ ULN with concomitant increase in bilirubin $\geq 1.5x$ ULN;
- hypokalemia;
- myelosuppression (manifested as anemia, thrombocytopenia, neutropenia or leucopenia);
- optic nerve disorder (optic neuritis) or retinopathy;
- ototoxicity (hearing impairment, hearing loss of any degree);
- pancreatitis;
- peripheral neuropathy (paresthesia);
- prolonged QT interval (Fridericia correction) of > 500 ms or > 60 ms increased from baseline; and
- psychiatric disorders and central nervous system toxicity (e.g. depression, psychosis, suicidal intention, seizures).

I. Modification of treatment regimen

Modification of a treatment regimen can be done if an anti-TB drug needs to be replaced due to intolerance or toxicity that may lead to the negative consequences to patients such as permanent disability, life-threatening complications, death or loss-to-follow-up.

1. **For patients started on SSOR**, modification of the same regimen is allowed, as follows:⁵
 - If complete cessation of Bdq or Lfx is required, consult the case with TB MAC.
 - In case of toxicity or intolerance to Pto, quickly shift Pto to cycloserine (or linezolid if there is contraindication to use cycloserine) if splitting the dose for the first two weeks did not prevent vomiting, or tolerance to Pto did not improve. (Note: Exclude other causes of vomiting such as hepatitis, food poisoning, etc. and treat accordingly.)
 - For clofazimine (Cfz) intolerance, replace with cycloserine (or linezolid if there is contraindication to use cycloserine) and give for the entire treatment duration. If patient has underlying seizure or mental health condition (e.g. depression, psychosis), Lzd is preferred over Cs. If it happens after intensive phase, Bdq may be continued for entire duration without replacement of Cfz with Cs or Lzd.
 - For ethambutol, pyrazinamide and isoniazid, discontinue the suspected culprit drug related to an adverse drug event without replacement. Treatment duration is nine to 11 months based on smear conversion.
 - If modification requires replacement or premature discontinuation of two or more drugs, or complete discontinuation of SSOR, shift to ITR in consultation with TB MAC.
2. **For patients on SLOR**, modification of regimen is allowed in case an anti-TB drug needs to be replaced due to severe intolerance or toxicity.⁶ The following may be considered:
 - Delamanid is the first choice to replace bedaquiline, levofloxacin or linezolid.
 - Cycloserine (if never used before) may be used to replace clofazimine.
 - PAS, prothionamide and ethambutol (if never used before) are the last option to choose for replacement.
 - If patient needs to stop Lzd after six months of treatment – when Bdq has been stopped – replace Lzd with Cs as long as the reason for stopping Lzd is not due to peripheral neuropathy.
 - Other alternative if Cs cannot be used are:

- ethionamide/prothionamide or p-aminosalicylic acid;
- ethambutol or pyrazinamide may be considered to replace Cfz or Cs if there is DST confirming susceptibility to ethambutol and pyrazinamide; and
- if the oral anti-TB drugs cannot be used due to previous use in a failing regimen, confirmed resistance or intolerance, consider imipenem-cilastatin or amikacin (or streptomycin) if susceptible to Amikacin/Streptomycin.

J. Assigning treatment outcome

1. After completion of treatment or if patient is discharged from the program, assign the appropriate treatment outcomes for DR-TB patients based on definitions in *Table 26* for SSOR and *Table 27* for SLOR.
2. Record the treatment outcome in the **Form 4c. DR-TB Treatment Card** and update **Form 6c. TB Register for DR-TB Treatment (ITS)**.
3. Issue the certificate of completion of treatment found in **Form 5b. DRTB Patient Card** and advise patient on post-treatment follow-up.

Table 26. Treatment outcome definitions for SSOR5, 16

Outcome	Definition
Cure	A patient with bacteriologically confirmed MDR-TB or RR-TB who has completed treatment as recommended by the national policy, without evidence of failure and with three or more consecutive cultures taken at least 30 days apart negative after the intensive phase.
Treatment completed	Treatment completed as recommended by the national policy without evidence of failure but no record that the three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase.
Failed	Any one of the following: <ul style="list-style-type: none"> - treatment terminated or need for permanent regimen change; - lack of evidence of at least two negative cultures (and not followed by a positive culture) by the end of an extended intensive phase (six months) of the shorter regimen; or - positive sputum smear (confirmed by two consecutive samples) after > 6 months of treatment, - culture reversion* in the continuation phase after conversion to negative; - evidence of additional acquired resistance to a FQ or a second-line injectable (SLI) drugs; and - adverse drug reaction resulting to switching to a new regimen.
Died	A patient who dies for any reason during the course of treatment
Lost to follow-up**	A patient whose treatment was interrupted for > 2 consecutive months
Not evaluated	A patient for whom no treatment outcomes is assigned. (This includes cases "transferred out" to another treatment unit and whose treatment outcome is unknown.)

* Culture reversion (to positive) after an initial conversion; two consecutive cultures taken at least 30 days apart, are found to be positive during continuation phase.

Remark: In all other situations when failure is suspected, the possible causes, patient management strategy and registration of outcome will be discussed by the expert committee

** If a patient has received the SSOR for more than a month, and returns for treatment after an interruption of two consecutive months or more, he is not restarted on the SSOR but on a longer MDR-TB regimen which is individualized based on the medicines most likely to be effective. If the interruption is less than two months, e.g. medical indication in case of adverse events), or patient's decision, then the SSOR can be continued and the missed doses added to the rest of the treatment.

Table 27. Treatment outcome definitions for SLOR and ITR34

Treatment outcome	Definition
Cured	Treatment completed 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 eight months of treatment (for SLOR) or after the intensive phase (for ITR with SLI).
Treatment completed	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 eight months of treatment (for SLOR) or after the intensive phase (for ITR with SLI).
Treatment success	The sum of <i>Cured</i> and <i>Treatment completed</i>
Treatment failed	Treatment terminated or need for permanent regimen change of at least two anti-TB drugs because of: <ul style="list-style-type: none"> • lack of culture conversion by the end of month eight from the start of treatment; or • bacteriological culture reversion after the conversion to negative in the initial eight months of treatment; or • evidence of additional acquired resistance to fluoroquinolones or other second-line drugs in the regimen; or • adverse drug reaction that necessitated completely stopping MDR-TB or RR-TB treatment.
Died	A patient who dies for any reason during the course of treatment.
Lost to follow-up	A patient whose treatment was interrupted for two consecutive months or more.
Not evaluated	A patient for whom no treatment outcome is assigned (this includes cases “transferred out” to another treatment unit and whose treatment outcome is unknown)

Culture conversion (to negative); two consecutive cultures taken at least 30 days apart, are found to be negative, the specimen collection date of the first culture is taken as culture conversion date.

Culture reversion (to positive) after an initial conversion; two consecutive cultures taken at least 30 days apart, are found to be positive, for the purpose of defining “Treatment Failed,” culture reversion is considered only when it occurs after eight months of treatment.

K. Post treatment follow-up

1. Do post-treatment follow-up at month six and 12 after successful completion of treatment (cure or completed).^{5, 16} Follow-up procedures include:
 - clinical evaluation of TB signs and symptoms
 - chest X-ray
 - SM and culture.
2. Define the outcomes of post-treatment follow-up below:^{5, 16}
 - Non-relapsing cure: a successfully treated individual who remains culture-negative within six to 12 months post-treatment.
 - Relapse: recurrent TB disease in a successfully treated individual who becomes culture-positive within six to 12 months after cure or treatment completion.
 - Died: a patient who dies for any reason during the 12 months following treatment.
 - Lost to follow-up after treatment completion: individuals who had an outcome recorded but cannot be traced in the 12 months following treatment outcome.
3. Record the outcome of post-treatment follow-up in **Form 4c. DR-TB Treatment Card.**

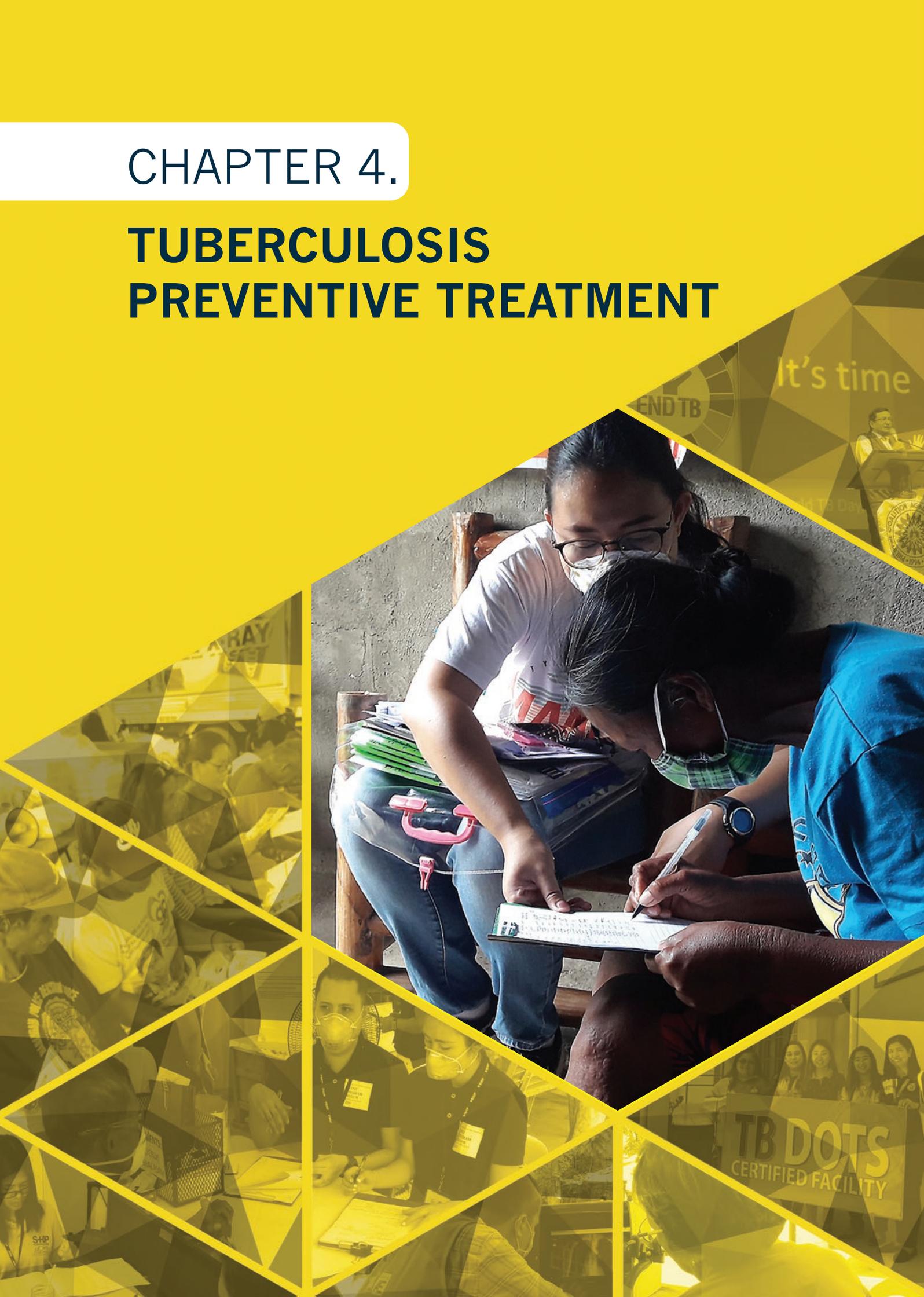
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CHAPTER 4.

TUBERCULOSIS PREVENTIVE TREATMENT



INTRODUCTION

The provision of tuberculosis preventive treatment (TPT) in populations most at risk of developing TB is critical to end the epidemic of TB as stated by the World Health Organization (WHO) *End TB Strategy*. People living with HIV and child household contacts less than 5 years old have been primary targets for isoniazid preventive treatment globally. Accordingly, coverage of preventive treatment is one of the core program indicators measured in the *2017–2022 Philippine Strategic TB Elimination Plan: Phase 1* (PhilSTEP1).

In March 2018, WHO issued new guidelines on the programmatic management of LTBI, which recommended the adoption of shorter regimens such as a three-month weekly rifapentine plus isoniazid regimen (3HP). Furthermore, the guidelines also recommended expansion of the target groups to all household contacts (including aged 5 years and older) of bacteriologically confirmed PTB. The adoption of the shorter regimens is expected to facilitate scaling up preventive treatment.

OBJECTIVE

To prevent development of active TB by providing TB preventive treatment to eligible high-risk individuals.

DEFINITION OF TERMS

1. **Contact investigation** – a systematic process for identifying people with previously undiagnosed TB among the contacts of an index person with TB. The investigation includes identification of the source person with TB if the index person with TB is a child, as well as candidates for preventive treatment.
2. **Household contact** – a person who shared the same enclosed living space as the index person with TB.
3. **Close contact** – a person who shared an enclosed space, such as a social gathering place, workplace or facility, for extended periods during the day with the index person with TB during the three months before commencement of the current treatment episode. *In the context of this chapter, this shall refer to contacts not in the same household.*
4. **Index case (index patient) of TB** – initially identified people with TB of any age in a specific household or other comparable setting in which others may have been exposed.
5. **Source case** – a person with infectious TB (usually bacteriologically positive PTB) who transmits infection to one or more other individuals.
6. **Latent tuberculosis infection (LTBI)** – a state of persistent immune response to stimulation by MTB antigens with no evidence of clinical manifestations of active TB disease. There is no “gold standard” test for direct identification of MTB infection in humans. The vast majority of infected people have no signs or symptoms of TB but are at risk for active TB disease.
7. **TB Preventive treatment (TPT)** – treatment offered to individuals who are at risk of developing active TB disease to reduce that risk. Also referred to as LTBI treatment or preventive therapy.

POLICIES

1. TB contacts, PLHIV and TB risk groups should be evaluated for eligibility to receive TB preventive treatment.
2. Tuberculin skin test (TST) or interferon-gamma release assays (IGRA) shall not be required prior to initiation of preventive treatment in the following eligible individuals:
 - a. PLHIV;
 - b. children less than 5 years old who are household contacts of bacteriologically confirmed PTB; and
 - c. individuals aged 5 years and older who are household contacts of bacteriologically confirmed PTB and with other TB risk factors.
3. TST (or IGRA) shall be performed in other individuals prior to TB preventive treatment. Either 5-TU or 2-TU strength are regarded as similar in producing induration indicative of TB infection.
4. Active TB shall be excluded by symptom and chest X-ray screening prior to initiation of TPT.
5. Preventive treatment shall not be given to contacts of MDR-TB and RR-TB.
6. All health-care providers shall ensure completion of preventive treatment.

PROCEDURES

A. Identification of individuals eligible for TB preventive treatment

1. Identify individuals who require further evaluation to assess eligibility for TB preventive treatment:
 - a. PLHIV aged 1 year and older (regardless of history of contact);
 - b. all household contacts of bacteriologically confirmed PTB;
 - c. children less than 5 years old who are household contacts of clinically diagnosed PTB;
 - d. close contacts of bacteriologically confirmed PTB (outside the household); and
 - e. other risk groups:
 - patients receiving dialysis
 - patients preparing for an organ or hematological transplantation
 - patients initiating anti-tumor necrosis factor (TNF) treatment
 - patients with silicosis.
2. For contacts, check if the index case is MD-RTB or RR-TB. Preventive treatment should not be given to contacts of MDR-TB or RR-TB. They need to be followed up with symptom screening, chest X-ray screening or Xpert test every six months for at least two years (*page 16, Section 2.1-D. Contact Tracing*).
3. Explain the rationale for TB preventive treatment and the need for further evaluation. Evaluate the presence of other risk factors and pregnancy.
4. Exclude active TB prior to considering TPT (see next section: B. Excluding active TB). Assess presence of TB signs and symptoms and do chest X-ray. If symptoms are present

or the chest X-ray is suggestive of TB, evaluate appropriately following the procedures in Chapter 2. TB screening and diagnosis.

5. The following eligible groups do not require TST. They may be offered TPT once active TB is ruled out:
 - a. PLHIV aged 1 year or older;
 - b. children less than 5 years old who are household contacts of bacteriologically confirmed PTB; and
 - c. individuals aged 5 years and older with other TB risk factors (i.e. PLHIV, diabetes, smoking, those with immune-suppressive medical conditions, malnourished, with multiple TB cases in same household) and who are household contacts of bacteriologically confirmed PTB.

6. Perform TST in the following individuals; if TST is not available, it is not recommended to offer LTBI treatment to these individuals: (*Table 28*)
 - a. children less than 5 years old who are household contacts of clinically diagnosed PTB;
 - b. household contacts of bacteriologically confirmed PTB cases who are 5 years and older but with no other risk factors for TB;
 - c. close contacts of bacteriologically confirmed PTB; and
 - d. Other risk factors
 - patients receiving dialysis
 - patients preparing for an organ or hematological transplantation
 - patients initiating anti-TNF treatment
 - patients with silicosis.

Table 28. Checking eligibility of different risk groups for TPT using TST

	TST NOT REQUIRED (Eligible for TPT)	TST REQUIRED (Eligible only if positive)	NOT ELIGIBLE for TPT
Household contacts	< 5 years old, BCTB index	< 5 years old, CDTB index	---
	≥ 5 years old, BCTB index, with TB risk*	≥ 5 years old, BCTB index, no TB risk	≥ 5 years old, CDTB index
Close contacts	---	All ages, BCTB index	All ages, CDTB index
PLHIV	Ages ≥ 1 year old	---	Age < 1 year old (if not contact of a person with TB)
Other risk groups	---	<ul style="list-style-type: none"> • Patients receiving dialysis • Patients preparing for an organ or hematological transplantation • Patients initiating anti-TNF treatment • Patients with silicosis 	---

*TB risk – PLHIV, diabetes, smoking, those with immune-suppressive medical conditions, malnourished, with multiple people with TB in same household

7. If TST is positive or if eligible even without TST, give TB preventive treatment.

B. Excluding active TB prior to initiation of TPT

1. Ask all eligible clients for TB preventive treatment if they have TB signs and symptoms as specified in *Figs. 9–12*.
2. Those with TB signs and symptoms should be evaluated further for active tuberculosis. Refer for Xpert/SM/LAMP.
3. If no TB signs and symptoms, conduct chest x-ray, if not yet done. If there is any abnormal shadow in the lung field or other findings suggesting TB, evaluate further for active TB following procedures in diagnosis. Refer for Xpert/SM/LAMP.

Exception to chest X-ray screening prior to TPT is for children < 5 years old. Chest X-ray in this eligible group is not required prior to TB preventive treatment (*Fig. 10–11*).

For contacts > 5 years old for whom performing a chest X-ray is not feasible, physician may still decide based on clinical judgment if to give TPT but avoid rifamycin-containing regimen.

4. Once active TB is ruled out, offer TB preventive treatment based on eligibility.

Fig. 9. LTBI algorithm in adults and children with HIV ≥ 5 years old

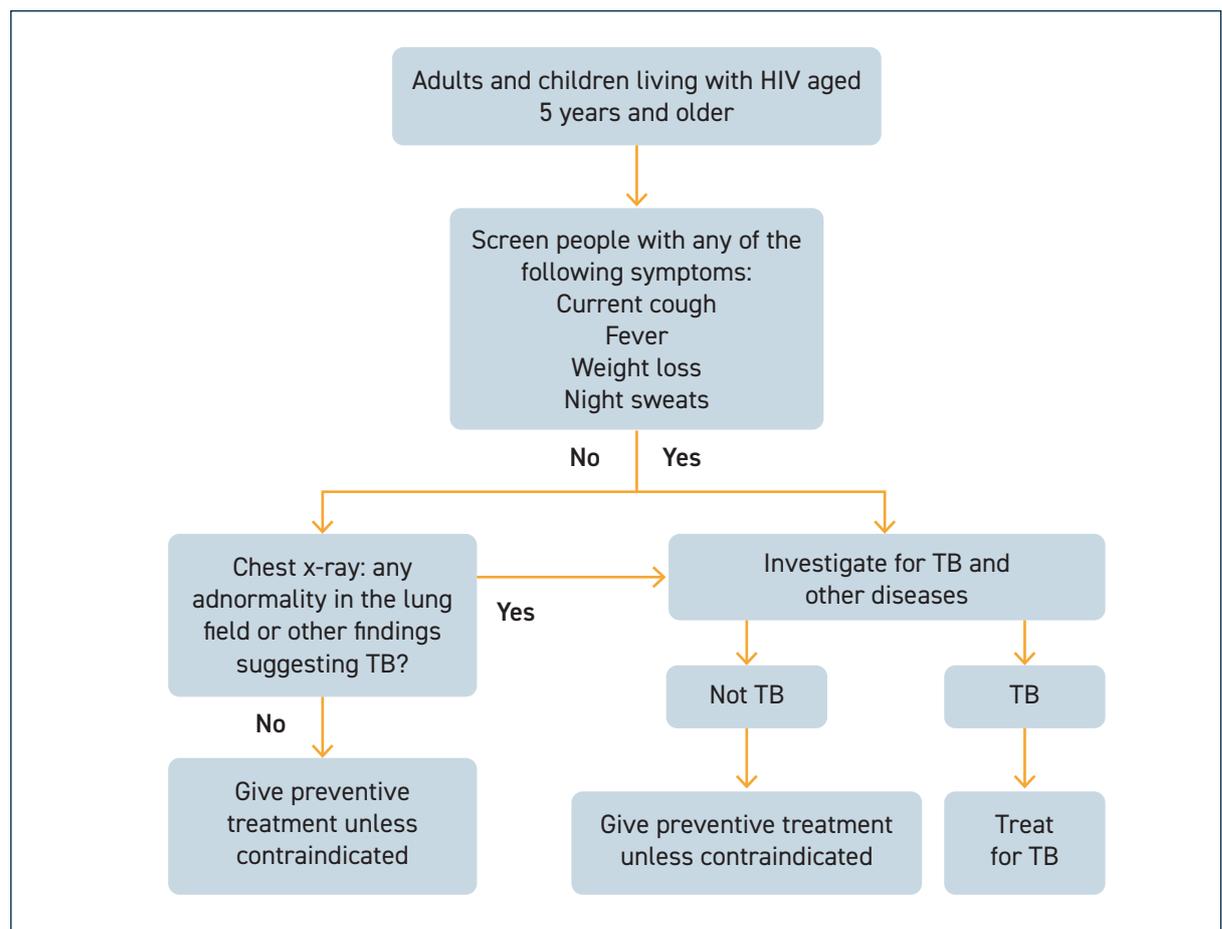


Fig. 10. LTBI algorithm in children with HIV aged 1–4 years

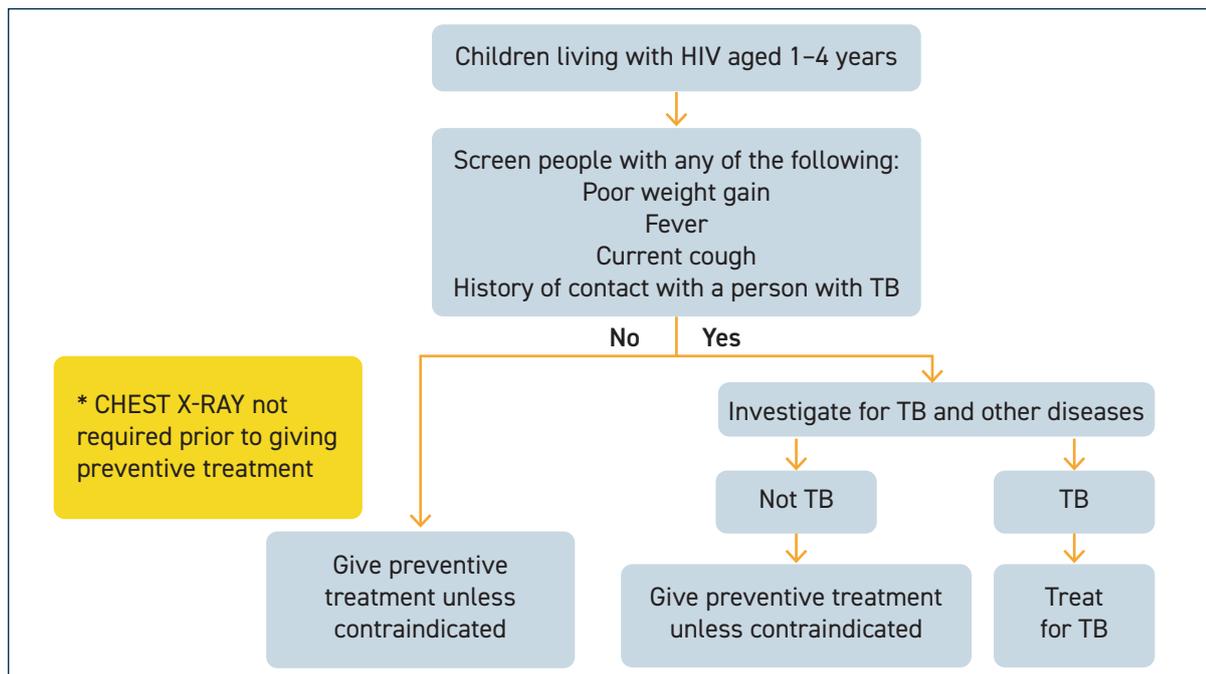


Fig. 11. LTBI algorithm in HIV-negative child contacts < 5 years old

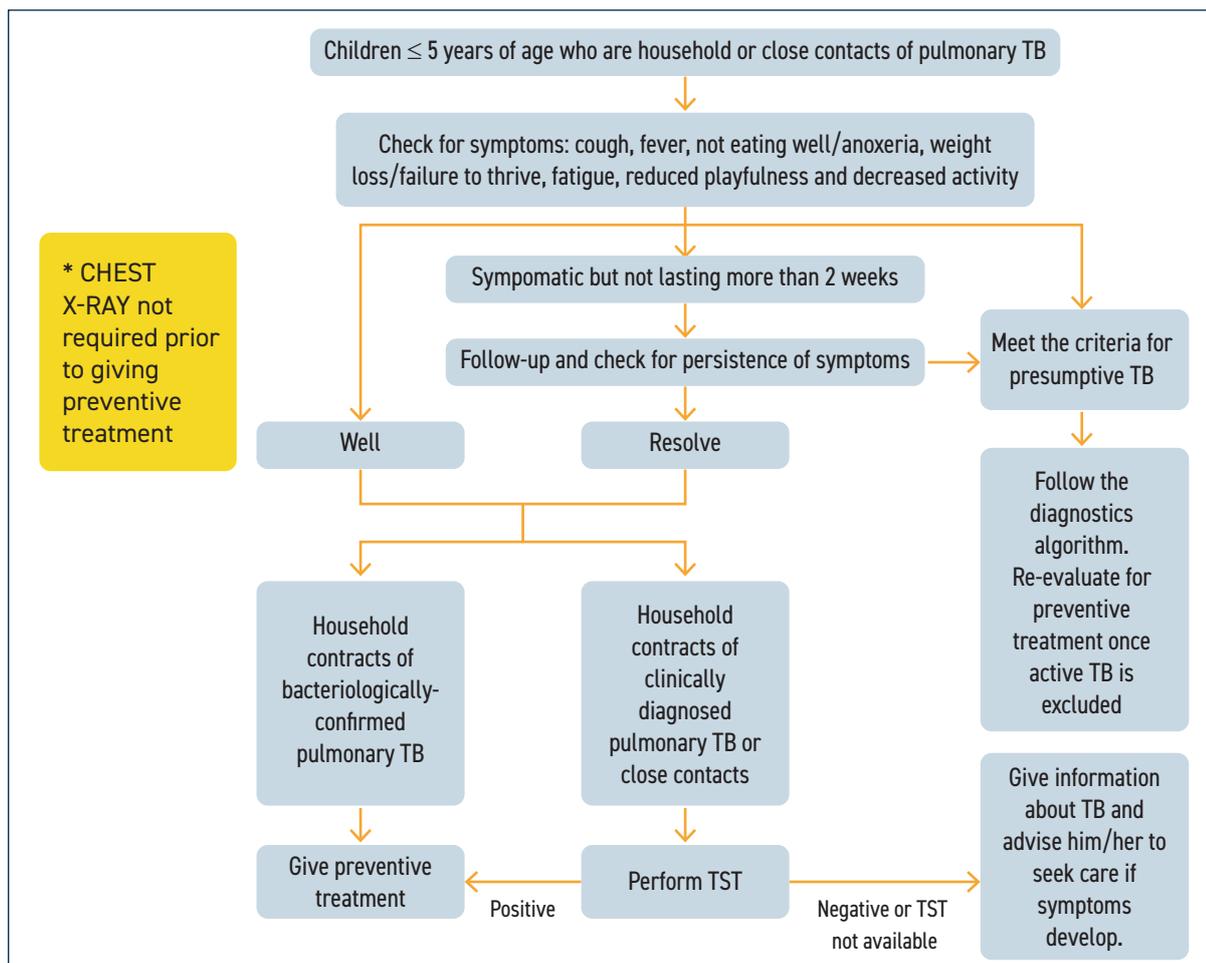
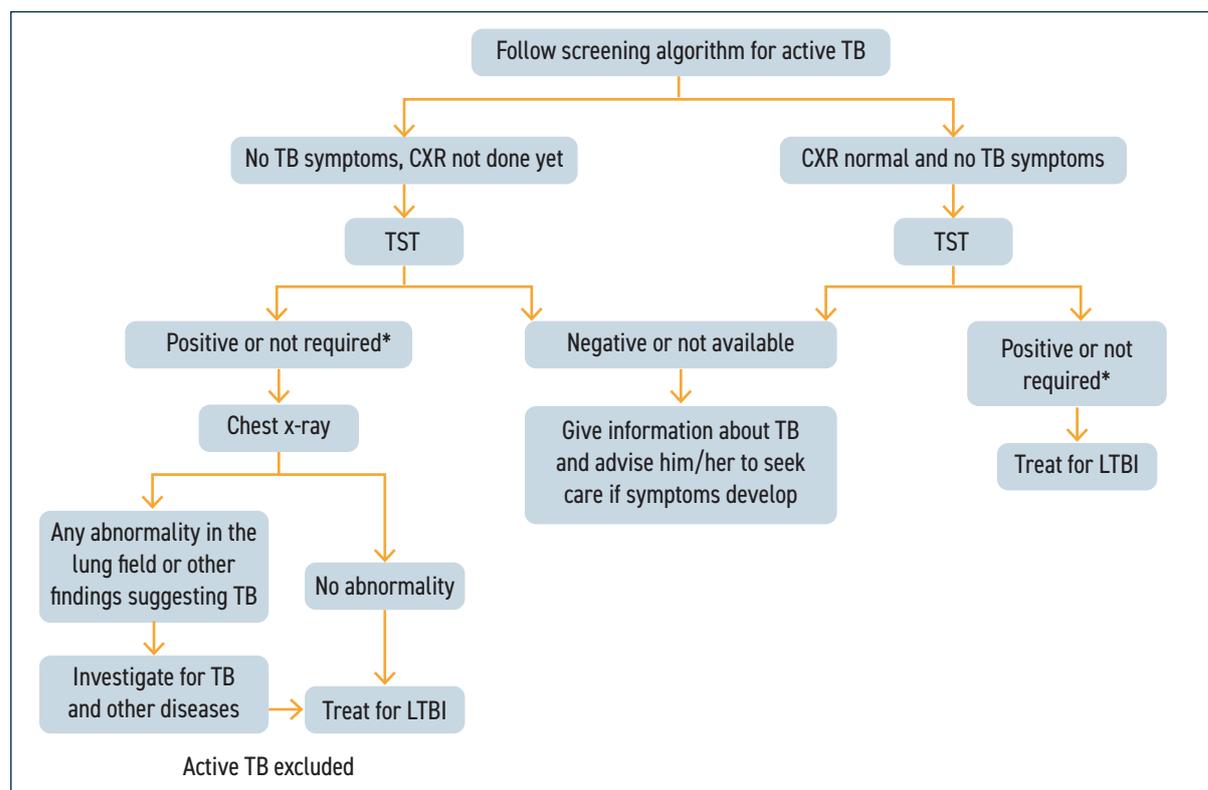


Fig. 12. LTBI algorithm in HIV-negative at-risk individuals ≥ 5 years old



*TST is not required in individuals aged 5 years and older with TB risk factors (i.e. PLHIV, diabetes, smokers, those with immune-suppressive medical conditions, malnourished, with multiple TB cases in same household) and who are household contacts of bacteriologically confirmed PTB

C. Initiation of treatment

1. Inform the patient that they are eligible for TB preventive treatment. Provide key messages for the person and their families, as necessary:
 - rationale for TB preventive treatment;
 - duration of treatment and the importance of completion;
 - the reasons and schedule of regular clinical and laboratory follow-up for treatment monitoring;
 - potential adverse events and how to address them;
 - tracing mechanism in case of treatment interruption;
 - availability of free-of-charge services for TB preventive treatment; and
 - discuss with them their social and financial needs and offer possible sources of social support to enable adherence to treatment. (e.g. DSWD, SSS, GSIS, ECC, LGUs, etc.)
2. Determine baseline weight.
3. Assign the appropriate TPT regimen (*Table 29*).
 - The currently available regimen under the program is six months of Isoniazid (6H)
 - Once available under the program, weekly dosing with isoniazid and rifapentine for three months (3HP) is the regimen of choice except for pregnant and those less than 2 years old. Alternative regimens subject to availability are isoniazid, rifampicin daily (3HR) for children and rifampicin daily (4R) for adults.

Table 29. Treatment regimens for latent tuberculosis infection (LTBI)

TB preventive treatment regimen	Indications
6H (isoniazid daily)	Currently available under the program
3HP (isoniazid, rifapentine weekly)	Weekly dosing for three months Contraindicated in pregnant and < 2 years old
3 HR (isoniazid, rifampicin daily)	Preferred for children if 3HP not available
4R (rifampicin daily)	Preferred for adults if 3HP not available

4. Instruct on proper dosage based on weight. (*Tables 30–32*).

Table 30. Dosing for 6H, 4R and 3HR in children

Body weight (Kg)	Dosage (in ml)	
	Isoniazid 200 mg/5 ml (at 10 mg/kg)	Rifampicin 200 mg/5ml (at 15 mg/kg)
2.1–3	0.75	1.0
3.1–4	1.0	1.5
4.1–5	1.25	2.0
5.1–6	1.5	2.25
6.1–7	1.75	2.5
7.1–8	2.0	3.0
8.1–9	2.25	3.5
9.1–10	2.5	3.75
10.1–11	2.75	4.0
11.1–12	3.0	4.5
12.1–13	3.25	5.0
13.1–14	3.5	5.25
14.1–15	3.75	5.5
15.1–16	4.0	6.0
16.1–17	4.25	6.5
17.1–18	4.5	6.75
18.1–19	4.75	7.0
19.1–20	5.0	7.5
20.1–21	5.25	8.0
21.1–22	5.5	8.25
22.1–23	5.75	8.5
23.1–24	6.0	9.0
24.1–25	6.25	9.5
25.1–26	6.5	9.75
26.1–27	6.75	10.0
27.1–28	7.0	10.5
28.1–29	7.25	11.0
29.1–30	7.5	11.25

Table 31. Dosing for 6H, 3RH and 4R in adults

Drug	Dosing in adults
Isoniazid (H)	5 mg/kg (range: 4–6 mg/kg) Not to exceed 300mg daily
Rifampicin (R)	10 mg/kg (range: 8–12 mg/kg) Not to exceed 600 mg daily

Table 32. Dosing for 3-month weekly rifapentine and isoniazid in adults and children

Age	≥ 2 years old	2–11 years old	≥ 12 years old
Body weight (in Kgs)	Rifapentine 150 mg/tab	Isoniazid 200 mg/5ml (at 25 mg/kg)	Isoniazid 200 mg/5ml (at 15 mg/kg)
	No. of tablets	in ml	in ml
10–12	2 tabs	7 ml	--
12.1–14	2	8.5	--
14.1–16	3	10.0	--
16.1–18	3	11.0	--
18.1–20	3	12.0	--
20.1–22	3	13.0	--
22.1–24	3	14.5	--
24.1–25	3	15.0	--
25.1–27	4	16.0	10.0 ml
27.1–30	4	18.0	11.0
30.1–32	4	19.0	12.0
32.1–35	5	21.0	13.0
35.1–37	5		14.0
37.1–40	5		15.0
40.1–42	5		16.0
42.1–45	5		17.0
45.1–50	5	22.5	18.0
50.1–55	6		20.0
55.1–58	6		21.0
≥ 58.1	6		22.5

5. Perform baseline liver function tests in the following individuals:

- Individuals with risk factors for hepatotoxicity: history of liver disease, regular use of alcohol, chronic liver disease, HIV infection, age > 60 years, pregnancy or within three months of delivery.

Do not give LTBI treatment if liver function tests (LFTs) cannot be done at baseline and monthly during treatment.

- However, for PLHIV without other risk factors for hepatotoxicity, LTBI treatment shall be given even when baseline tests cannot be done given the benefits of treatment outweighing harms.

- Adolescents and adults ≥ 15 years old regardless of hepatotoxicity risk factors when three-month daily isoniazid plus rifampicin (3HR) or six-month daily isoniazid (6H) will be used. If only these regimens are available, TPT may be still be initiated based on clinical judgment and informed decision of clients.

Other LTBI regimens (such as 3HP) can be given if LFTs cannot be done at baseline and during treatment.

For pregnant women with HIV and on ART, defer TB preventive treatment until 3 months after delivery.

6. Determine other co-morbidities such as diabetes, HIV, malnutrition and note other medications that the patient is taking. Manage or refer accordingly. Adjust the regimen if needed based on presence of any co-morbidity (*see Section D. Treatment considerations in special population*) or any possible drug-drug interaction (*Annex 3B. Drug-drug interactions of TB medications*).
7. For individuals who are given isoniazid and at risk for peripheral neuropathy (e.g. malnutrition, chronic alcohol dependence, HIV infection, renal failure or diabetes, or who are pregnant or breastfeeding), prescribe 10–25 mg/day of pyridoxine (vitamin B6). Supplemental pyridoxine of 5–10 mg/day should be given to the infant who is taking isoniazid or whose breastfeeding mother is taking isoniazid (H).
8. Discuss the appropriate treatment adherence and support mechanism with clients. Consider the most suitable location of drug intake and treatment supporter based on the client's' condition.

Options include:

- location: Home-, community- or facility-based care (option for a weekly regimen);
- treatment supporter: oriented family member/community/workplace treatment partner, health-care workers; and
- additional digital tools: video DOT/missed-call DOT, etc.

For, a weekly regimen, it is preferable that intake of each dose is checked by oriented family member, community, workplace treatment partner, or health-care workers (either in person or through a digital tool).

Dispensing of medicines should not be more than one month.

9. Accomplish **Form 4d. TPT Treatment Card** and **Form 5. TB and TPT Patient Card**. Register the patient in **Form 6c. TPT Register** (ITIS).
10. Ask if the patient requires any further social or financial support. Refer accordingly to other programs providing social protection.

D. Treatment considerations in special population

1. Pregnant women

Isoniazid and rifampicin can be used in pregnant or breastfeeding women. Rifapentine should be avoided due to lack of data on safety in pregnant or breastfeeding women.

For pregnant women with HIV who are already on ART, defer preventive treatment until three months post-partum.

2. **Breastfeeding**

Preventive treatment using isoniazid and or rifampicin can be safely given to breastfeeding women. Supplemental pyridoxine (i.e. vitamin B₆) should be given to the infant who is taking isoniazid or whose breastfeeding mother is taking isoniazid.

3. **Oral contraceptives**

Rifampicin and rifapentine interact with oral contraceptive medications with a risk of decreased protective efficacy against pregnancy. Advise a woman receiving oral contraceptives while on rifampicin or rifapentine that she has the following options: 1) take an oral contraceptive pill containing a higher dose of estrogen (50µ), following consultation with a clinician; or 2) use another form of contraception.

4. **Liver disease or history of liver disease**

Isoniazid and rifampicin/rifapentine are both associated with hepatitis. Treatment should not be initiated in individuals whose baseline liver transaminases is more than three times the upper limit of normal (ULN). Preventive treatment should not be given to individuals with end-stage liver disease.

5. **Acute hepatitis (e.g. acute viral hepatitis)**

Defer preventive treatment until the acute hepatitis has been resolved.

6. **Renal failure**

Isoniazid and rifampicin/rifapentine are eliminated by biliary excretion. These drugs, therefore, can be given in normal dosages to patients with renal failure. Patients with severe renal failure should receive isoniazid with pyridoxine to prevent peripheral neuropathy.

7. **People living with HIV**

Rifampicin and rifapentine can be co-administered with efavirenz without dose adjustment. Rifampicin or rifapentine cannot be co-administered with protease inhibitors or nevirapine.

8. **Baby born to mother with active TB disease**

- a. Assess the newborn. If the newborn is not well, refer it to a specialist/pediatrician.
- b. If the newborn is well (absence of any signs or symptoms presumptive of TB), do not give BCG first. Instead give TB preventive treatment. Give Pyridoxine at 5–10 mg/day. Preventive treatment is not necessary if the mother has received more than two months of anti-TB treatment and is not considered infectious.
- c. At the end of treatment, perform TST. If TST is negative or not available, give BCG.
- d. If the mother is taking anti-TB drugs, she can safely continue to breastfeed. Mother and baby should stay together and the baby may be breastfed while on TB preventive treatment.

E. Monitoring treatment

1. Ask patient to follow up two weeks after initiation of treatment and then at least monthly thereafter. Perform clinical assessment during follow-up visits. Get the weight on a monthly basis and adjust the dosage accordingly.

2. Check for presence of signs or symptoms of TB. If the individual is diagnosed with active TB disease after appropriate evaluation, stop TB preventive treatment and start treatment for active TB disease.
3. Check for adverse reactions. Manage any adverse drug reactions and refer if needed (see *Table 9 in Chapter 2.1 DSTB Treatment*). Follow aDSM procedures for reporting all serious adverse events and adverse events of special interests as outlined in the DR-TB chapter.
 - a. If there is a need to discontinue anti-TB drugs due to major ADRs, do not reintroduce.
 - b. In case of a flu-like syndrome due to rifapentine, consider a switch to daily rifampicin-containing regimens or, if not possible, isoniazid alone. Drugs can be started at a full dose but add one drug per day.
 - c. Advise patient to contact their health-care provider if they become aware of symptoms such as anorexia, nausea, vomiting, abdominal discomfort, persistent fatigue or weakness, dark-colored urine, pale stools or jaundice. If a health-care provider cannot be consulted at the onset of such symptoms, the patient should stop treatment immediately until they reach care.
4. Perform liver function tests (LFTs) monthly for individuals with abnormal baseline test results or adolescents and adults receiving six-month daily isoniazid (6H) or three-month daily isoniazid plus rifampicin (3HR). In addition, LFTs shall be done at any time during the treatment for individuals who have symptoms suggestive of hepatitis. Discontinue treatment if liver transaminases exceed three times the ULN associated with symptoms or if five times the ULN, regardless of symptoms.
5. Continue management of co-morbid conditions, and refer if necessary.
6. Explain the results of any baseline or follow-up tests done (e.g. LFTs).
7. Explain the importance of adherence and completion at each encounter.
 - a. Check the NTP ID card and, if with missed doses, discuss with patient and/or treatment supporter the interventions to improve treatment adherence.
 - b. Any interruptions in treatment should be discussed with the patient and treatment supporter, and interventions to address problems in adherence should be instituted.
 - c. For interruption of less than two months, continue the treatment and prolong it to compensate for missed doses. Preventive treatment should be reinitiated from the beginning if more than two months are missed.
8. Record the visit, drug intake and all findings in **Form 4d. TPT Treatment Card** .

F. Assigning treatment outcome

At the end of treatment, determine the outcome of TB preventive treatment and record in **Form 4d. TPT Treatment Card** and **Form 6c. TPT Register** (ITIS).

- a. Completed – an individual who has completed the prescribed duration of treatment and remains well or asymptomatic during the entire period.
- b. Lost to follow-up – an individual who interrupted TB preventive treatment for two consecutive months or more.
- c. Died – an individual who dies for any reason during the course of therapy.
- d. Failed – an individual who developed active TB disease anytime while on TB preventive treatment.
- e. Not evaluated – an individual who has been transferred to another health facility with proper referral slip for continuation of TB preventive treatment and whose treatment outcome is not known; include here discontinued by physician because patient cannot tolerate (e.g. severe ADR) or refused to continue.

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CHAPTER 5.

RECORDING AND REPORTING



INTRODUCTION

Recording and reporting are important in the implementation of a successful TB control program. Availability of records allows provision of appropriate and effective care for patients. Through complete and accurate recording, health workers can monitor that each presumptive TB case is examined and each TB patient is treated and cured. Records, therefore, should contain up-to-date information on patient's diagnosis, treatment, follow-up examinations, treatment outcome and post-treatment follow-up. Aside from information on the patient's care, reports also provide information on program efficiency and effectiveness, including availability of drugs and other supplies, at the health facilities.

This section discusses general guidelines on recording and reporting including utilization of the Integrated TB Information System (ITIS), procedures for records and data management, and a general description of official NTP recording forms. The detailed instructions on accomplishing the forms will be discussed during training.

OBJECTIVES

To ensure provision of appropriate and effective care for patients through standardized recording

To monitor program efficiency and effectiveness through streamlined reporting

DEFINITION OF TERMS

1. **Archiving** – the process of transferring data or records in a less frequently used storage area in order to still keep the record in case of future need.
2. **Storage** – the retention of retrievable data in a filing system or in a computer.
3. **Data privacy** – is the aspect of data management that deals with determining what data in an information system can be shared with third parties.
4. **Personal Information** – refers to any information whether recorded in a material form or not, from which the identity of an individual is apparent or can be reasonably and directly ascertained by the entity holding the information, or when put together with other information would directly and certainly identify an individual.
5. **Sensitive personal information** – refers to personal information including an individual's marital status, age, color, religious affiliations, health, education and sexual history.

POLICIES

1. Patient data shall be collected, analyzed and utilized to ensure provision of quality and adequate services.
2. NTP recording and reporting shall be implemented in all health facilities providing TB services (screening, testing, diagnosis, treatment, and/or prevention) or parts thereof, whether public or private.

3. Recording and reporting shall include all diagnosed active TB cases, as per Republic Act 10767, known popularly as the TB Law, and all treated latent TB cases shall be classified according to internationally accepted case definitions.
4. Health-care workers shall be trained in accomplishing NTP recording forms and in reporting.
5. Confidentiality of patient records shall be observed at all times to protect the privacy of the patients as per Republic Act 10173, known as the Data Privacy Act of 2012.
6. All paper-based records shall be kept for seven years before properly being discarded. Electronic records, meanwhile, shall be archived after 20 years.
7. The ITIS shall be the official electronic TB information system. It shall be the official TB Register and TPT Register to be maintained at health facilities.
8. All NTP reports shall be submitted to the DOH through ITIS following the prescribed timeline. Feedback on the submitted reports shall be provided following the prescribed flow and timeline.
9. Onsite and offsite data quality check activities shall be done regularly at all levels (facility, municipality, province/city, region, national).
10. Data collected shall allow for the calculation of the main indicators for program evaluation.
11. The NTP shall release official data annually based on the key program indicators. Performance on screening, testing and diagnosis, treatment, and TB preventive treatment will likewise be available to the public via the TB dashboard (<https://tbdashboard.doh.gov.ph>), either web-based or android software application. Request for other data shall be coursed through a formal letter to the facility, LGU, region or NTP depending on scope of request, stating the intended use of the data and means of securing them.

PROCEDURES

A. Setting-up TB recording and reporting system

1. Request inclusion of new health facilities with TB services in the TB Facilities Database of ITIS through the Regional ITIS Administrator. All registered health facilities are assigned an NTP facility code.
2. Request inclusion of new health workers in TB Care Providers Database of ITIS, through the Regional ITIS Administrator. Among those included in the database, identify who will be needing access to ITIS and request user accounts for them through the accomplishment of the Knowledge Management and Information Technology Service (KMITS) Service Request Forms (SRF). Authorized health workers include but are not limited to health facility head, nurses, designated encoders, NTP coordinators at different levels and notifying physicians. Train health workers on recording and reporting, including use of ITIS, through attendance in formal integrated training or coaching by a senior trained health staff member.
3. Obtain recording forms from the CHD through the provincial health office (PHO) or city health office (CHO).

B. Recording

1. Use appropriate ink color in accomplishing paper forms.
 - a. Use red ink for positive laboratory results (i.e. Xpert MTB/RIF, SM and TBC results), and resistance to drugs (i.e. DST results).
 - b. Use black ink for all other records not mentioned above.
2. The physician or immediate supervisor is responsible in ensuring accuracy and consistency of data recorded.
3. Ensure good recording practices. For corrections in paper records, strike through incorrect or outdated information and correct or update data. Countersign corrections with initials of health staff member and date. For correction in electronic records, the audit trail reflects corrections made.
4. Update records daily.
5. Ensure newest version of the form is used. Discard unused old paper forms as soon as new paper forms are available.
6. Do not leave any blanks. Indicate “NA” if not applicable to patient or patient is ineligible, “ND” if patient is eligible but activity was not done, “none” or “0” if nothing, and “Unk” if unknown by health staff or patient, accordingly.
7. Observe standard recording for the following fields:

Field	Standard Notation
Name	Family name first in capital letters, followed by given name and name extensions and middle name <i>e.g. DELA CRUZ, Juan Jr. Santos</i>
Sex	M or F
Contact No.	Include area code and country code if outside the country <i>e.g. 02-82309626</i>
Date	MM-DD-YYYY
Treatment monitoring	Three-letter initials – treatment observed by a treatment supporter or health worker. X – Drugs not taken/absent I – Incomplete regimen H – Drug holiday HOLD – On hold Re-challenge – Drug re-challenge Encircle date of regimen change including shift to Continuation Phase
TBC results	MTB – MTB detected 0 – MTB not detected
DST results	R – Resistant S – Susceptible

8. The ITIS serves as the official TB register and records may be encoded directly from the Treatment Card to ITIS.

C. Records and data management

1. Collection of Patient Information

- a. Upon screening and start of treatment, inform the patient that sensitive personal information will be collected from screening to treatment, even up to post-treatment follow-up, to be used only for the following purposes:
 - i. Case management – proper diagnosis, treatment, adverse event management and follow-up if lost anytime during diagnosis and treatment.
 - ii. Program management – surveillance of TB cases nationwide, management of commodities and logistic support.
 - iii. Provision of psychosocial and financial support – enablers and other assistance.

Patient should be informed and consent secured if the information will be used for other purpose not included in the above.

- b. Assure the patient that collected information will be treated with confidentiality and shared only with authorized personnel, such as but not limited to other health workers involved in the patient's TB care (e.g. medical technologists and Barangay Health Workers). Mention to the patient policies of the facility to ensure that information is secure such as, but not limited to:
 - i. records will be kept in a secure area only accessible by authorized personnel; and
 - ii. patient names in some records will be coded using TB/TPT case number to conceal identity.
- c. Inform the patient on their rights on data privacy as per Republic Act 10173 (Data Privacy Act of 2012). These rights are also listed in the health education materials.

2. Storage

- a. Store paper-based patient records in a safe, lockable place, protected from external and internal deterioration. Preferable storage is elevated or hanging cabinets with lock.
- b. Ensure proper filing of all paper forms whether chronological or alphabetical, as appropriate.
- c. Keep paper records in a secure space away from unauthorized personnel, and risk of fire or water.
- d. Avoid bringing patient records and office-issued devices with stored patient information outside the official work premises. If unavoidable, document in a logbook.
 - i. In case the records will be transferred, document in a logbook. Continuously monitor the delivery status until received by the appropriate office or person.
 - ii. When sending patient records, place it in a sealed opaque envelope.
 - iii. Transferring of patient records is discouraged outside official working hours.
- e. Copying of records in any forms, other than those mentioned in this MOP, is only allowed if approved by head of the facility or supervisor and with valid reason or purpose, e.g. back up record and decentralization.
- f. Use of personal devices in handling work health data and information is discouraged. If unavoidable, log authorized health workers that use their own device for work.

- g. In the event of lost patient record including devices storing patient information, submit an incident report to the supervisor, who in turn will elevate the incident to proper channels. Exhaust all efforts to find the missing record or device. Implement preventive and corrective measure to avoid any similar incident in the future.
 - h. ITIS serves as the backup tool for data and record recovery in case a catastrophic event such as fire, flood or other natural disasters.
 - i. Report to the facility head in writing any unlawful violation on patient's privacy within 24 hours upon discovery. Provide NTP Management Office (ntp.mne@gmail.com) a courtesy copy of this written report.
3. Archiving
- a. If storage space is available at the facility, archive all paper-based records that are dormant or inactive for five years in a separate storage space with lock. If storage space is unavailable, place the records in the municipal or city archives.
 - b. Records for archiving can also be scanned and stored electronically to save space. Make the storage device password-protected.
 - c. Archive electronic records in ITIS 20 years after the end of the most recent TB treatment episode.
4. Disposal
- a. After two years in archive, discard records.
 - b. Shredding is considered as the best method of disposing confidential documents.
 - c. When disposing patient records, document records being disposed in a logbook.

D. Use of ITIS

1. Health-care providers are trained in the utilization of ITIS through attendance in formal training or coaching by a senior trained health staff.
2. Assign at least one health staff member in the health facility as the ITIS encoder. Assign the head of the facility or the physician as ITIS validator to ensure the accuracy and consistency of records and encoded data. Delegate task of validator to another health staff member, other than the designated ITIS encoder, if head or physician is not available to be the validator.
3. Request for an ITIS user account for each ITIS user through accomplishment of the KMITS Service Request Form (download from NTP website, ntp.gov.ph) and submission to the ITIS Regional Administrator.
4. Use the KMITS Service Request Form for other user account updates such as but not limited to the following:
 - a. change of ITIS version (online to/from offline)
 - b. change of access level (facility, province/city, region, national)
 - c. update of assignment (facility/area/station) or contact information
 - d. account deactivation in the event of resignation, reassignment or retirement.
5. Accomplish paper forms, as necessary, and encode directly key information in ITIS. Key information includes those required to be reported.

- a. Use the ITIS to identify history and prior care of the patient and for real-time automated attendance checking during treatment.
 - b. For health facilities implementing the ITIS Laboratory Module, encode Laboratory Request Forms prior to sending of specimen to the laboratory.
 - c. Encode screening information, treatment cards, laboratory results and patient updates at least once a week and encode daily treatment and laboratory requests real time.
6. Validate cases and laboratory results in order to be counted in official reports. Validator must be different from the encoder. Unvalidated cases and laboratory results are not counted in the report.
 - a. Designated ITIS case validator must validate the encoded data.
 - b. Designated ITIS laboratory validator must validate the laboratory results to be automatically sent to the requesting facility.
 7. Utilize ITIS and maximize its features. Use ITIS for patient referrals, reporting adverse events, transmittal of laboratory results, updating of health staff and facility contact information, updating of stock inventory and creation of graphical representations of accomplishments.
 8. Ensure ITIS security is maintained.
 - a. System automatically logs out once idle for 20 minutes. Reload the browser or relaunch the ITIS site to login again.
 - b. Dormant account is automatically inactivated after six months of no login. Send a request to KMITS using the SRF if the health staff opts to reactivate the account.
 - c. Each ITIS user is responsible to keep the account's authentication details private. Hence, sharing of account is not allowed.
 9. ITIS e
 10. manual (found on the upper right side of ITIS page) is available for further details. Coordinate with KMITS if any problem occurs.

E. Reporting

1. The physician or immediate supervisor is responsible in ensuring accuracy and consistency of report submitted.
2. Generate monthly/quarterly reports to monitor progress of implementation.
 - a. Reports from case-based data may be generated from the ITIS on a monthly, quarterly or annual basis.
 - b. For other reports, encode the aggregate reports into ITIS at the end of each quarter.
3. In the first week of the month following the month or quarter being reported, validate the completeness, accuracy and consistency of ITIS reports.
 - a. Completeness – ensure that all required fields are encoded and updated in ITIS.
 - b. Accuracy – ensure that patients are classified according to prescribed definitions (i.e. registration group, DR-TB bacteriologic status, treatment outcome).
 - c. Consistency between TB Treatment Card and ITIS data – ensure that source documents are consistent with encoded data in ITIS.

- d. Consistency between paper records and ITIS reports – ensure that counts from source documents are consistent with aggregate reports encoded into ITIS.
4. If with corrections, update ITIS data until a correct report is generated. Once validated, click “submit” button in ITIS.
5. Await feedback from PHO/CHO and Regional Office when they check completeness, accuracy and consistency as well. If with corrections, feedback is to be given through proper channels. Once validated, PHO/CHO and Regional Office clicks “reviewed” button in ITIS.
6. Other data quality activities are conducted through the following:
 - a. Onsite activities: Monitoring and Supervisory Visits, Routine Data Quality Assessment
 - b. Offsite activities: Centralized Data Quality Check Workshop, Data Cleaning by KMITS
7. If report is already overdue, send a letter to the PHO/CHO requesting reopening of the submission of report, indicating the reason for delayed submission.

F. Data sharing

1. Observe confidentiality of records at all times to protect the privacy of the patients. Unauthorized processing of sensitive personal information such as patient records will be penalized as stipulated in Republic Act 10173 (Data Privacy Act of 2012).
2. Avoid unauthorized posting of personal data of patients, including pictures, in the facility or social media as well as uploading in websites, cloud storage and instant messaging platforms.
3. Sharing of flash drives, external hard drives and other storage devices that contain soft copies of patient records is discouraged.
4. The patient should have access to their records through the assistance of an authorized health-care worker. The patient may be provided a copy of their records upon request through issuance of a medical certificate/abstract or a duplicate of laboratory/diagnostic examination. Original copy of the NTP forms, except for the patient booklet, is owned by the health facility.
5. Course all requests for data and data access through a formal letter to the facility, municipality, city, province, region or NTP depending on scope of request, stating the intended use of the data. This includes researches and new technologies accessing patient data such as but not limited to digital adherence tools, laboratory connectivity and dashboards.
6. Use extra precaution when sharing patient data through Internet. Keep the file password-protected and send only to correct and authorized recipient. The use of confidentiality disclaimer is also recommended.

G. NTP Forms

Below is the list of NTP recording forms that will be maintained and NTP reporting forms that will be submitted quarterly (*see Annex 5. NTP Recording and Reporting Forms*). Detailed instructions are in a separate document and will be discussed during training.

Table 33. NTP Recording and Reporting Forms

Type of facility	Records	Reports
Health facility with TB Services Notifying public and private providers	Form 1. Presumptive TB Master List ^P	Report 3. Quarterly Report on TB and TB Prevention Notification and Treatment ^e
	Form 2a. Laboratory Request and Result Form ^{e or P}	Report 4a. Monthly Report on FLD, Smear Microscopy, and Xpert Inventory and Requirement ^e
	Form 2b. HIV Result Form	Report 4b. Monthly Report on SLD Inventory and Requirement ^e
	Form 4a. TB Notification	Report 5. Quarterly Report on TB and TB Preventive Treatment Outcomes ^e
	Form 4b. DSTB Treatment Card ^P	
	Form 4c. DRTB Treatment Card ^P	
	Forms 4d. TPT Card ^P	
	Form 5. TB and TPT Patient Card ^P	
	Form 6a. DSTB Register ^{e, P optional}	
	Form 6b. DRTB Register ^{e, P optional}	
	Form 6c. TPT Register ^{e, P optional}	
	Form 7. NTP Referral Form ^{e or P}	
Laboratory: Microscopy Laboratory Xpert Site Culture Center DST Center Quality Assurance Center	Form 2c. Line Probe Assay Result Form ^{P and e}	Report 1a. Quarterly Report on Xpert, Smear Microscopy, and TB LAMP ^e
	Form 2d. TB Culture Result Form ^{P and e}	Report 1b. Quarterly Report on Line Probe Assay ^e
	Form 2e. DST Result Form ^{P and e}	Report 1c. Quarterly Report on TB Culture ^e
	Form 3a. Laboratory Register for Xpert ^P	Report 1d. Quarterly Report on Drug Susceptibility Test ^e
	Form 3b. Laboratory Register for Smear Microscopy, and TB LAMP ^P	Report 2. External Quality Assessment for Smear Microscopy ^e
	Form 3c. Laboratory Register for Line Probe Assay ^P	
	Form 3d. Laboratory Register for TB Culture, and DST ^P (note: Form 2a also used by Laboratories but originates from Health Facility)	

^e signifies that this form is maintained electronically

^P means forms are maintained in paper (may be optional)

Below is the list of other supporting forms that will be used by health facilities with TB services. Templates are in the annex but detailed instructions are in a separate document.

- | | |
|---|---|
| 1. TB Laboratory Specimen Receiving Form – for laboratories and PMDT facilities | 9. EQA Form 5: Annual Smear Preparation Quality Check – for TMLs |
| 2. TB Laboratory Result Releasing Form – for laboratories and PMDT facilities | 10. Stock Card – for treatment facilities, laboratories, NTP offices, and warehouses |
| 3. TB LAMP Workbook – for TB LAMP laboratories | 11. Temperature and Humidity Monitoring Log – for treatment facilities, laboratories, NTP offices, and warehouses |
| 4. Solid TB Culture Workbook – for TB Culture laboratories | 12. TB-MAC Presentation Form |
| 5. Solid TB DST Workbook – for DST laboratories | 13. TB MAC Master List – for PMDT facilities |
| 6. Liquid TB Culture and DST Workbook – for TB Culture and DST laboratories | 14. TB Service Provider Registration Form – for NTP coordinators |
| 7. Laboratory Performance Indicator Worksheet - for TB Culture and DST laboratories | 15. KMITS Service Request Form – for NTP coordinators |
| 8. EQA Form 4: Annual Slide Reading Quality Check - for TMLs | 16. Privacy Logbook – for treatment facilities, laboratories, and NTP offices |

References

- R.A. 10767 TB Law
- R.A. 9470 National Archives of the Philippines Act of 2007
- R.A. 10173 Data Privacy Act of 2012
- DOH-DOST-PHIC-DICT Joint Administrative Order 2016-0002 Privacy Guidelines for the Implementation of the Philippine Health Information Exchange
- 2018 Privacy Impact Assessment Report



ANNEXES

ANNEX 1A. CAGE questionnaire for assessing alcohol use

1. Have you ever felt you should **cut** down on your drinking?
2. Have people **annoyed** you by criticizing your drinking?
3. Have you ever felt bad or **guilty** about your drinking?
4. Have you ever had a drink first thing in the morning to steady your nerves or to get rid of a hangover (**eye-opener**)?

Scoring: Item responses on the CAGE are scored 0 or 1, with a higher score an indication of alcohol problems. A total score of 2 or greater is considered clinically significant.

ANNEX 1B. Palliative care for TB patients

(SOURCE: DOH. 2017. PMDT Implementing Guidelines)

INTRODUCTION

The World Health Organization defines palliative care as “an approach that improves the quality of life for patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual”.²² Tuberculosis (TB) and drug-resistant tuberculosis (DR-TB) is a chronic disease that poses varied challenges to patients. These challenges can be social stigma, physical symptoms brought about by the disease and medications, and feelings of worthlessness and loss of hope.

On November 19, 2010, a declaration on Palliative Care and multidrug-resistant tuberculosis (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB) was adopted in Geneva. It was emphasized that: (1) access to palliative care for individuals with MDR-TB and XDR-TB is a human right and promotes dignity; and (2) palliative care in the context of MDR-TB and XDR-TB should be integrated into the management of MDR-TB and XDR-TB from the time of diagnosis until patient reaches cure or the end of life. Palliative care should start as soon as the patients present for care and should emphasize maintaining quality of life at any age and stage of illness. Care for patients with TB and DR-TB requires a spectrum of care delivery ranging from primary care to specialized team that will focus on addressing symptoms, treating the disease and alleviating symptoms at the end of life.

Palliative care focuses on empowering patients in their preferred type of care. It also focuses on encouraging patients to express their perception and feelings on the disease process so that the palliative care team will be able to address possible misperceptions and fears. By doing this, we will be promoting adherence to treatment, thereby increasing treatment success. For those who are no longer qualified for active treatment and those who are not candidate for being cured, they must be permitted to live out their life with minimal suffering and loss of dignity. The palliative care approach is an essential part of patient-centered care approach in DR-TB management.

OBJECTIVES

To ensure the quality of life of patients with DR-TB by:

- a. ensuring that patients and their families are given holistic management during DR-TB treatment to attain treatment completion;
- b. empowering patients to participate in the management of TB and DR-TB; and
- c. ensuring that patients and their families will not be abandoned even if cure is no longer possible

A. Providing care for relief of symptoms

All patients diagnosed to have DR-TB must be provided care to alleviate symptoms. The health-care provider shall:

1. counsel and educate patient and family about TB disease and enjoin the patient to participate in the management of their disease (e.g. decision on where to seek treatment, decision to faithfully adhere to treatment, etc.);
2. monitor adverse events, counsel and give ancillary drugs to control adverse events; and
3. instruct patient and his/her family members to implement infection control in the household and community.

B. Managing patients who refused and are not responding to available DR-TB treatment

1. Plan on how to approach the patient, their family and significant others in disclosing the plan to suspend anti-TB treatment and other options if treatment will not be initiated.
2. Discuss with the patient and family the management plan to alleviate symptoms of TB and to ensure that respiratory infection control is in place.
3. Offer options to control patient’s symptoms to maintain quality of life and dignity when giving anti-TB treatment is not an option. The following are the end-of-life support measures:

End-of-life management support measures

End-of-life support	Management
Relief of dyspnea	<ul style="list-style-type: none"> • Give oxygen support • Give morphine according to established clinical protocols in literature
Relief from pain and other symptoms	<ul style="list-style-type: none"> • Give paracetamol, or codeine with paracetamol, for relief from moderate pain. If possible, stronger analgesics, including morphine, should be used when appropriate to keep the patient adequately comfortable • Refer to WHO-developed analgesic guides, pain scales and a three-step “ladder” for pain relief for further guidance.
Infection control measures	<ul style="list-style-type: none"> • Continue infection control practice with reinforcement on environmental and personal measures including the use of N-95 mask for caregivers.
Nutritional support	<ul style="list-style-type: none"> • At the end of life, give small and frequent feeding. It is expected that intake will reduce as the patient deteriorates. • Treat nausea and vomiting that interferes with nutritional support.
Regular medical visits	<ul style="list-style-type: none"> • Visit patient to address medical needs and to ensure that infection control is being followed.

End-of-life support	Management
Continuation of ancillary medicines	<ul style="list-style-type: none"> • Give butamirate citrate, morphine, codeine to control cough. • Give metered dose inhalers to control bronchospasm • Manage anxiety and depression
Provision of psychological support	<ul style="list-style-type: none"> • Provide counseling to patient and family to assist in planning for decisions related with end of life and provide emotional support especially in which strong stigma is attached to the disease
Other supportive care	<ul style="list-style-type: none"> • Give oral care • Prevent bedsores among bed-borne patients • Advise use of egg crate mattress • Change position of patient regularly • Keep the bed dry and clean

C. Implementing palliative care

1. Organize a team to provide palliative care.
2. Train staff to promptly identify and address adverse events due to first- and second-line anti-TB drugs and due to complications of advanced TB disease and other co-morbidities.
3. Train staff in counseling to address the psycho-emotional and spiritual needs of the patients and their families.
4. Provide free ancillary drugs and other regulated drugs such as opioids (e.g. morphine), benzodiazepines, antipsychotic (e.g. haloperidol) drugs.
5. Secure an S2 license to have access to regulated drugs.

ANNEX 2A. Sample screening form

RHU/HC: _____

Date: _____

Name of Patient: _____ Age/Sex: _____

SCREENING FORM

1. Do you experience any of the following?

- Cough of 2 weeks duration
- Unexplained fever of 2 weeks duration
- Night sweats of 2 weeks duration
- Unintentional and unexplained weight loss

If YES to at least 1, identify as presumptive TB. Request for bacteriologic test.
If NO to all, proceed to question #2.

2. Have you had a chest X-ray done in the past year?

- YES
- NO

If YES, inquire about the result and determine if bacteriologic testing needed.
If NO, offer Chest X-ray screening.

If resources are limited, you have the option to prioritize those with TB risk factors as primary clients for chest X-ray screening.

Risk factors¹⁻⁸ include:

- a. contacts of TB patients
- b. those ever treated for TB (i.e. with history of previous TB treatment)
- c. people living with HIV (PLHIV)
- d. elderly (> 60 years old)
- e. diabetics
- f. smokers
- g. health-care workers
- h. urban and rural poor (indigents)
- i. those with other immune-suppressive medical conditions (silicosis, solid organ transplant, connective tissue or autoimmune disorder, end-stage renal disease, on long corticosteroid course, alcoholics or substance abuse, receipt of chemotherapy or other forms of medical treatment for cancer)

ANNEX 2B. Planning logistics and estimate of presumptive TB yield

In planning ACF screening activities, ensure sufficient supply of laboratory commodities, mainly for Xpert MTB/RIF and direct sputum smear microscopy (DSSM) tests, by estimating the number of presumptive TB cases to be identified.

Below is an illustration using the estimated yield rate of presumptive TB from different screening tools for 1,000 people. Sputum submission rate may be adjusted based on local experience and targets.

Estimation of presumptive TB yield rate by symptom-based screening and chest X-ray screening

Type of Screening Tools	Presumptive TB yield rate	No of presumptive TB cases	Sputum sample submission rate	No of Required Xpert/DSSM tests
Cough for ≥ 2 weeks at health facilities	6%	60	85%	51
Cough of any duration and other TB signs/symptoms at health facilities	12%	120	50%	60
Chest X-ray in risk groups in health facilities	25%	250	50%	125
Chest X-ray in congregate and community/workplace settings	20%	200	50%	100

* the following are estimated yield rate of presumptive TB from different screening tools for 1,000 people. To adjust to your setting, multiply the estimated number with (Population/1,000).

Another tool that can be used to estimate required logistics for active case finding activities is the calculator in the **TB dashboard** (<https://tbdashboard.doh.gov.ph/#!/pages/calculator.html>)

ANNEX 2C. Different TB diagnostic tools

Primary diagnostic tools

- Rapid molecular diagnostic tests endorsed by the WHO will be utilized by the NTP. Currently, WHO-endorsed available diagnostic tests in the country are Xpert MTB/RIF, line probe assay (LPA) and TB LAMP. Xpert MTB/RIF is an automated molecular assay and is a rapid test that detects *Mycobacterium tuberculosis* (MTB) and rifampicin resistance. Xpert Ultra is a newer generation of Xpert MTB/RIF assay. Due to its higher sensitivity than that of Xpert MTB/RIF, specificity is slightly lower.
- TB-LAMP is a manual molecular assay that can be read with the naked eye under ultraviolet light to detect MTB and can replace smear microscopy, especially in remote areas. But it cannot detect rifampicin resistance and there is limited evidence of performance in comparison to Xpert MTB/RIF in children and PLHIV who have more smear negative pulmonary TB.
- Smear microscopy (SM) is a conventional test that serve as a basis for the diagnosis of TB cases. This is also used: a) to monitor progress of patients with TB while they are on anti-TB treatment; and, b) confirm cure at the end of treatment in drug-sensitive TB cases.
- TB culture and the drug susceptibility test (DST) using solid (Ogawa or Lowenstein Jensen) or liquid media (MGIT) is used in diagnosis and monitoring of the treatment response for DR-TB under the NTP. It is also used for TB prevalence surveys, drug resistance surveillance, research and other special cases.

Adjuvant diagnostic tools

- Chest X-rays are useful tools to aid diagnosis of TB when the TB disease cannot be confirmed with bacteriological diagnostic tools. However, it has low specificity and does not differentiate DS-TB from DR-TB.
- Tuberculin skin test (TST) is a basic screening tool for TB infection among children using purified protein derivative (PPD) tuberculin solution to trigger a delayed hypersensitivity reaction among those previously infected. It is also known as the PPD test or Mantoux test. TST may be used as an adjuvant tool when a physician has doubts in making a clinical diagnosis of TB in children. However, TST can be false-positive (e.g. among recently BCG-vaccinated) or false-negative (e.g. in immunocompromised children; children with HIV/AIDS, severe malnutrition). But it is not a mandatory tool and the absence of TST test should not be a deterrent in making a diagnosis of TB or in starting TB preventive treatment. WHO-recommended TST tests are either five tuberculin units (TU) of tuberculin-purified protein derivative (PPD-S) or 2 TU of tuberculin PPD RT23, which give similar reactions in children infected with MTB. An induration of > 5 mm in children with immunosuppressed conditions, such as HIV or severe malnutrition, or >10 mm in other children regardless of BCG vaccination status is defined as TST positive.

ANNEX 3A. Management of DS-TB in special situations

1. Pregnancy

Ascertain whether or not a woman is pregnant before she starts TB treatment. Most anti-TB drugs are safe for pregnant women, **except streptomycin**, which is ototoxic to the fetus. Advise a pregnant woman that successful treatment of TB with the recommended standardized treatment regimen (i.e. 2HRZE/4HR) is important for a successful outcome of pregnancy. Pregnant women taking isoniazid should be given pyridoxine (vitamin B₆) at 25 mg/day.

2. Breastfeeding

A breastfeeding woman afflicted with TB should receive a full course of TB treatment. Timely and properly applied chemotherapy is the best way to prevent transmission of tubercle bacilli to the baby. In lactating mothers on treatment, most anti-TB drugs will be found in the breast milk in concentrations equal to only a small fraction of the therapeutic dose used in infants. However, effects of such exposure on infants have not been established. It is recommended that lactating mothers feed their infants before taking medications.

Supplemental pyridoxine (i.e. vitamin B₆) should be given to the infant who is taking INH or whose breastfeeding mother is taking INH.

3. Oral contraceptives

Rifampicin interacts with oral contraceptive medications with a risk of decreased protective efficacy against pregnancy. Advise a woman receiving oral contraceptives while on rifampicin treatment that she has the following options: 1) take an oral contraceptive pill containing a higher dose of estrogen (50µ), following consultation with a clinician; or 2) use another form of contraception.

4. Liver disease or history of liver disease

Isoniazid, rifampicin and pyrazinamide are all associated with hepatitis. Of the three drugs, rifampicin is least likely to cause hepatocellular damage, although it is associated with cholestatic jaundice. Of the three agents, pyrazinamide is the most hepatotoxic.

Treatment should be interrupted and, generally, a modified or alternative regimen used for those with ALT elevation more than three times the upper limit of normal (ULN) in the presence of hepatitis symptoms and/or jaundice. If ALT is elevated five times the ULN, treatment should likewise be interrupted even in the absence of symptoms. Refer to appropriate specialist if needed.

It is necessary to wait for the liver function test (LFT) to revert to normal and clinical symptoms (e.g. nausea, abdominal pain) to resolve before reintroducing the anti-TB drugs. If it is not possible to perform an LFT, it is advisable to wait an extra two weeks after resolution of jaundice and upper abdominal tenderness before restarting TB treatment. Once drug-induced hepatitis has resolved, the drugs are reintroduced one at a time, beginning with rifampicin. After three to seven days, isoniazid may be reintroduced. In patients who have experienced jaundice but tolerate the reintroduction of rifampicin and isoniazid, it is advisable to avoid pyrazinamide. If symptoms recur or LFTs become abnormal as the drugs are reintroduced, the last drug added should be stopped.

Patients with the following conditions can receive the usual short-course chemotherapy regimens provided there is no clinical evidence of chronic liver disease: hepatitis virus carriage; a past history of acute hepatitis; and excessive alcohol consumption. However, hepatotoxic reactions to anti-TB drugs may be more common among these patients and should therefore be anticipated.

5. Established chronic liver disease

Patients with chronic liver disease should not receive pyrazinamide. Alternative regimens are 2SHRE/6HR, 9RE or 2SHE/10HE.

6. Acute hepatitis (e.g. acute viral hepatitis)

It is not common for a patient to have TB concurrently with acute hepatitis unrelated to TB or TB treatment. Clinical judgment is necessary. In some cases, it is possible to defer TB treatment until the acute hepatitis has been resolved. When it is necessary to treat TB during acute hepatitis, the safest option is the combination of Streptomycin and Ethambutol (SE) for three months and, once the hepatitis has resolved, a continuation phase of six months isoniazid and rifampicin (i.e. 3SE/6HR). If the hepatitis has not been resolved, SE should be continued for a total of 12 months (i.e. 12SE).

7. Renal failure

Isoniazid and rifampicin are eliminated by biliary excretion. These drugs, therefore, can be given in normal dosages to patients with renal failure. Patients with severe renal failure should receive isoniazid with pyridoxine to prevent peripheral neuropathy.

Streptomycin, ethambutol and metabolites of pyrazinamide are excreted by the kidney, and doses should be adjusted (see Table 12 of the Manual of Procedures). If possible, streptomycin should be avoided in patients with renal failure.

Dosing recommendations for patients with reduced renal function or receiving hemodialysis

Drug	Change in frequency?	Recommended dose and frequency for patients with creatinine clearance <3 0mL/min or for patients receiving hemodialysis
Isoniazid	No change	300 mg once daily; or 900 mg three times per week
Rifampicin	No change	600 mg once daily; or 600mg three times per week
Pyrazinamide	Yes	25– 35mg/kg per dose three times per week (not daily)
Ethambutol	Yes	15–25 mg/kg per dose three times per week (not daily)
Streptomycin	Yes	12–15 mg/kg per dose two or three times per week

Noting the above recommendations, it would therefore be possible to give a four-drug FDC (HRZE) three times per week and then give a two-drug FDC (HR) for the rest of the week during the intensive phase. Continuation phase may proceed with 4HR. Otherwise, another safe option is 2HRZ/4HR. It is recommended that anti-TB medications be taken after hemodialysis.

ANNEX 3B. Drug-drug interactions of TB medications

Drug interactions can occur during TB treatment and potentially change the pharmacologic effects of another drug that is given concomitantly. Clinically significant drug interactions are seen mostly with rifampicin (R), isoniazid (H), and fluoroquinolones (FQ). Elderly individuals with significant co-morbidities, as well as the immune-compromised patients (e.g. HIV/AIDS patients) are at higher risk of developing drug interactions during TB treatment.

Important drug-drug interactions of rifampicin, isoniazid and other TB drugs are shown in Tables 13–15 of the Manual of Procedures. To minimize drug interactions, it is advisable that drugs be administered 12 hours apart.

Rifampicin interactions with various drug categories

Drug category	Rifampicin interaction
Anti-hypertensive medications	Markedly reduces levels of calcium channel blockers (nifedipine, amlodipine, verapamil) Reduces levels of B-blockers (propranolol, carvedilol) Isolated reports of interaction with ACE inhibitors (captopril, enalapril, lisinopril) but minor clinical significance No interactions found with diuretics (thiazides, spironolactone, furosemide)
Analgesics	Increases clearance of paracetamol (but clinical importance not yet established) Decreases levels of diclofenac no interaction with aspirin and ibuprofen; reduces opioid levels (morphine, codeine)
Antifungals	Markedly reduces serum concentration of antifungals (ketoconazole, itraconazole) Serum rifampicin levels can also be reduced with concurrent use of ketoconazole.
Anti-retroviral agents (ARV)	Reduces levels of Efavirenz (EFV), ritonavir and nevirapine Increases clearance of Zidovudine No interactions found with Didanosine, Lamivudine
Anti-epileptics	One report of increased level and toxicity of carbamazepine when H and R is given together Reduces levels of phenytoin and valproic acid

Isoniazid drug interactions

Drug category/drugs	Isoniazid interaction
Antacids	INH absorption is reduced with concurrent use of the antacid aluminium hydroxide (give INH at least one hour before the antacid)
Carbamazepine	Increases levels of carbamazepine markedly and rapidly
Oral contraceptives	Few cases of failures reported; risk of contraceptive failure is low with concurrent use of INH
Paracetamol	Potential toxicity of paracetamol even at normal dose when used with INH; more studies are needed
Phenytoin	Increased levels of phenytoin with concurrent use of INH
Theophylline	Plasma level of theophylline may be increased

Interactions of other anti-TB drugs

Drugs	Drug Interaction
Ethambutol and pyrazinamide	May interact with thiazide diuretics to cause elevated serum uric acid levels
Pyrazinamide	May interact with allopurinol and probenecid and cause elevated uric acid levels
Streptomycin	<p>Increased risk of ototoxicity or nephrotoxicity when used with ototoxic or nephrotoxic drugs</p> <p>Exercise caution when used with anesthetics and neuromuscular blocking agents as streptomycin can prolong the neuromuscular blockade and potentially lead to respiratory depression</p>
Fluoroquinolones (second-line treatment)	<p>Increases serum theophylline level</p> <p>Increased anticoagulant effect of Warfarin</p> <p>Concurrent use with sucralfate and antacids containing aluminum, calcium, or magnesium may reduce absorption of quinolones Serum level of ciprofloxacin is reduced with concurrent use of didanosine.</p>

ANNEX 3C. Other modes of treatment supervision

Source: Adherence Support Coalition to End TB (ASCENT) Project

The following are examples of other modes of treatment supervision using Digital Adherence Technologies (DAT):

1. 99 DOTS

A DAT that pairs customized medication packaging with basic phone call/SMS technology to provide accurate, real-time data on patient treatment adherence. In this approach, existing fixed-dose combination (FDC) antibiotic medication blister packs are repackaged in a custom cardstock sleeve with a series of unpredictable hidden toll-free phone numbers or SMS codes that are revealed each time a patient removes their pills for the day. Patient sends an SMS of the code which registers as drug intake for the day.

2. Smart pillboxes

This is a digital medication monitor that combines the functionality of a low-cost medication box with a small-scale, battery-powered sensor and mobile data connection. Patients store and organize their TB medications in the box, and when they open the box for daily medication intake, the sensor is activated and sends dosing-event information in real-time to the adherence platform using the mobile data connection.

3. Video-supported treatment (VOT)

An Android application (app) that utilizes video recording and mobile communication to remotely monitor and support TB medication intake. Using an asynchronous video approach (in contrast to synchronous “live” video) patients are guided to record videos of themselves ingesting their daily medication. These videos are automatically synced via secure mobile connection with the adherence platform, where they are then reviewed by the patient’s health-care provider and marked as complete.

ANNEX 3D. Special situations in DR-TB treatment

Pregnancy and lactation

- Educate and counsel female patients at reproductive age that pregnancy should be avoided during MDR-TB treatment.
- Offer an effective and appropriate method of contraception (depot medroxyprogesterone acetate-Depo Provera, intra-uterine device, implants, etc.).
- Determine initiation of treatment and management of pregnant patients with MDR-TB according to the severity of the TB disease. Pregnancy can accelerate the course of MDR-TB.
 - If clinically stable with minimal radiological disease, treatment may be deferred until the second trimester with close clinical follow-up.
 - If clinically unstable, MDR-TB treatment that is effective and safe for the mother and baby should be initiated immediately.
 - Drugs with potential teratogenic effects (e.g. injectables and prothionamide) should be avoided.
 - Delamanid, in animal studies, has been shown to be potentially teratogenic and should be avoided until more data is available.
 - Bedaquiline has been demonstrated to be safe in animal reproduction studies, and may be considered for individual women after weighing risks and benefits.
 - Mothers who are breastfeeding, but with sputum-positive MDR-TB should discontinue breastfeeding if possible. Both bedaquiline and delamanid are excreted in breast milk in animal studies and, therefore, the decision to discontinue the drug or nursing, as an alternative, should consider the benefits and risks with clinical consideration.
- If an MDR-TB patient becomes pregnant during the treatment course, follow up the newborn for 12 months to check for congenital anomalies.

Safety of MDR-TB drugs by US-FDA classification

Class A: Human studies demonstrate no risk	----
Class B: Animal studies demonstrate no risk, no human studies	Bedaquiline Meropenem Amoxicillin/clavulanate
Class C: Animal studies demonstrate risk, no human studies	Levofloxacin/moxifloxacin Linezolid Clofazimine Cycloserine/terizidone Pyrazinamide Ethionamide/prothionamide Para-aminosalicylic acid Imipenem/cilastatin
Class D: Human studies demonstrate risk	Amikacin Streptomycin
Class X: Contraindicated in pregnancy	---

Note: Delamanid – No class assigned by FDA yet

Renal Disease

Renal failure may be due to a concomitant medical problem or may be a result of previous treatment for DR-TB with an aminoglycoside or of TB itself in the case of disseminated TB with kidney involvement. There is no contraindication to Bdq and DIm for mild to moderate renal insufficiency. In severe renal insufficiency, these drugs may be used with caution. Dosing of drugs should be adjusted per patient's creatinine clearance (an estimate of the glomerular filtration rate).

Calculation of **Creatinine Clearance** (Estimated Glomerular Filtration Rate)

$$\text{weight (kg)} \times (140 - \text{age}) \times \frac{\text{Constant}}{\text{Serum Creatinine (umol/L)}}$$

Constant: for Male = 1.23; for Female = 1.04

If Serum Creatinine value is given in mg/dl, it can be converted to umol/l by multiplying by 88.4.

With the availability of newer drugs such as bedaquiline and delamanid, the use of twice- or thrice-weekly dosing of aminoglycosides because of the lack of alternative options should be discontinued.

Dose adjustment of anti-TB drugs in renal insufficiency

	Recommended dose and frequency for patients who have creatinine clearance < 30 ml/min and those having renal dialysis (unless otherwise indicated dose after dialysis)
Isoniazid	No adjustment necessary
Rifampicin	No adjustment necessary
Ethambutol	15–25 mg/kg per dose 3 times per week (not daily dose)
Pyrazinamide	25–35 mg/kg per dose 3 times per week (not daily dose)
Rifabutin	Normal dose can be used, if possible monitor drug concentration level to avoid toxicity
Rifapentine	No adjustment necessary
Levofloxacin	750–1000 mg per day three times per week (not daily)
Moxifloxacin	No adjustment necessary
Etionamide/prothionamide	No adjustment necessary
Cycloserine	250 mg once daily or (500 mg per day 3 time per week – not daily)
PAS	4 G/dose, twice daily maximum dose
Bedaquiline	No adjustment necessary in mild to moderate renal impairment, no established dosage in severe renal impairment, use with caution
Delamanid	No adjustment necessary in mild to moderate renal impairment, no established dosage in severe renal impairment, use with caution
Clofazimine	No adjustment necessary
Linezolid	No adjustment necessary
Amox/Clv	Creatine Clearance 10–30 ml/min, 1000 mg twice daily for amoxicillin component Creatinine clearance < 10 ml/min, 1000 mg once daily for amoxicillin component
High-dose isoniazid	Recommended dosage not available
Streptomycin	12–15 mg/kg per dose two-three times per week (not daily)
Amikacin	12–15 mg/kg per dose two-three times per week (not daily)
Imipenem/cilastatin	Creatine clearance < 20–40 ml/min: 500 mg every eight hours daily Creatine clearance < 20 ml/min: 500 mg every 12 hours daily
Meropenem	Creatine clearance < 20–40 ml/min: 750 mg every 12 hours daily Creatine clearance < 20 ml/min: 500 mg every 12 hours daily

Liver disease

Mild elevation of liver enzymes at the baseline may be due to disseminated TB itself in liver. There is no contraindication to bedaquiline and delamanid in case of mild and moderate hepatitis. In severe hepatitis, Bdq and Dlm may be used with caution.

Diabetes mellitus

The pharmacological management DR-TB is the same for both diabetic and non-diabetic patients. Use modern insulin or insulin analogues especially in the early phase of TB to achieve optimal blood glucose control with strict glycaemic control.

The following cautions should be taken into consideration when managing patients with diabetes:

- use of nephrotoxic agents such as aminoglycosides;
- use of neurotoxic agents such as linezolid, in patients with established diabetes;
- co-administration of Bdq and hypoglycaemic agents such as sulphonylureas and glinides since these agents function by inhibiting ATP-dependent potassium channels thus delaying repolarization which leads to prolongation of QTc; and
- co-administration of Bdq and potentially hepatotoxic hypoglycaemic agents such as thiazolidinediones.

Role of surgery in MDR-TB and RR-TB treatment

In patients with MDR-TB or RR-TB, elective partial lung resection (lobectomy or wedge resection) may be used alongside a recommended MDR-TB regimen, but in consideration only under conditions with good surgical facilities and trained and experienced surgeons, with careful selection of candidates and ability to provide proper-post operative care.

ANNEX 3E. Patient Health Questionnaire (PHQ9) for Depression

Over the last 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several Days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3

Total Score: 1–4 Minimal depression; 5–9 Mild depression; 10–14 Moderate depression; 15–19 Moderately severe depression; 20–27 Severe depression

A systematic review and meta-analysis show that depression, anxiety and psychosis were the most common mental health disorders reported among MDR-TB patients (<https://www.ncbi.nlm.nih.gov/pubmed/30036607>)

Depression

A person is considered clinically depressed if they have suffered at least one of the following for the past two weeks:

- depressed mood most of the day (self-reported or observed by others); and
- markedly diminished interest or pleasure in all or almost all activities during the day and if they have exhibited at least four of the following symptoms over the past two weeks:
 - significant weight loss (this must be compared to others in the same situation);
 - insomnia or hypersomnia;
 - psychomotor agitation or retardation observable by others (not only a subjective feeling of restlessness or slow down);
 - fatigue or loss of energy nearly every day;
 - feelings of worthlessness or excessive or inappropriate guilt nearly every day;
 - diminished ability to think or concentrate, or indecisiveness; and
 - recurrent thoughts of death, recurrent suicidal ideas without a specific plan or suicide attempts.

ANNEX 3F. Guide in designing and individualized treatment regimens for DR-TB

Main aim: To design a treatment regimen containing four likely effective drugs (more than four may be needed if there is doubt in the effectiveness of any of the first five drugs)

Drug Group	Drugs
<p>Group A: Include all three medicine (unless they cannot be used)</p>	<p>Levofloxacin (Lfx) or moxifloxacin (Mfx) Bedaquiline (Bdq) Linezolid(Lzd)</p>
<p>Group B: Add one or both medicines (unless cannot be used)</p>	<p>Clofazimine (Cfz) Cycloserine (Cs)</p>
<p>Group C: Add to complete the regimen when medicines from Groups A and B cannot be used</p>	<p>Ethambutol (E) Delamanid (Dlm) Pyrazinamide (Z) Imipenem-cilastatin (Imp/Cln) or meropenem (Mpm) Amikacin (Am)/or streptomycin (S) Prothionamide/ethionamide (Pto/Eto) P-aminosalicylic acid (PAS)</p>

ANNEX 3G. Informed consent form for off-label use of bedaquiline and delamanid

(For use of more than 24 weeks, combined use of Bdq and Dlm, Use in Pregnancy and Children < 6 years old for Bdq and < 3 years old for Dlm, Use in extrapulmonary TB)

What is the most important information I should know about bedaquiline and delamanid?

- Bedaquiline and delamanid are drugs used to treat multidrug-resistant tuberculosis (MDR-TB) in the lungs in people with limited treatment options. MDR-TB is a serious disease that can result in death, and for which there are few treatment choices.
- It is important to complete the full course of treatment of bedaquiline or delamanid and your other TB medicines and not skip doses. Skipping doses may decrease the effectiveness of the treatment and increase the likelihood that your TB disease will not be treated.

It is not known if bedaquiline or delamanid is safe in:

- Children < 6 years for Bdq and for < 3 years for Dlm
- In pregnancy
- In forms of TB that is not drug -resistant or not in the lungs.
- In patients with heart, kidney, liver or other health problems
- If use is more than 24 weeks
- If both are used together.

However, there are publications on individual case reports or for small number of patients on the efficacy and safety of prolonged use of Bdq more than 24 weeks and combined used of Bdq and Dlm, although large study reports are not yet available.

Before you take bedaquiline or delamanid, tell your health-care provider if:

- You have had an abnormal heart rhythm or other heart problems.
- Anyone in your family has or has had a heart problem called congenital long QT syndrome.
- You have liver or kidney problems or any other medical conditions, including HIV infection.
- You are pregnant or plan to become pregnant. It is not known if bedaquiline/delamanid will harm your unborn baby.
- You are breastfeeding or plan to breastfeed. It is not known if bedaquiline/delamanid passes into breast milk. You and your health-care provider should decide if you will take bedaquiline or delamanid while breastfeeding.
- You are taking any prescription and nonprescription medicines, vitamins and herbal supplements.

How should I take bedaquiline/delamanid?

-
- Bedaquiline/delamanid must always be taken with other medicines to treat TB. Your health-care provider will decide which other medicines you should take with bedaquiline or delamanid.
 - Always take bedaquiline with a light meal (not heavy in fat).
 - Swallow the tablets whole with water.

Take bedaquiline

Week 1 and Week 2: Take 400 mg (4 tablets) once a day, 7 days a week.

Week 3 to Week 24: Take 200 mg (2 tablets) thrice a week. For example, you may take bedaquiline on Monday, Wednesday and Friday of every week.

Take delamanid

100 mg (2 tablets) early in the morning and again 100 mg (2 tablets) in the evening, every day of the week.

- You will need to take bedaquiline/delamanid with your other TB medicines.
- **Treatment will be administered through a patient-centered approach.**
- Do not skip bedaquiline or delamanid doses. If you skip doses, or do not complete the total course of medicines, your treatment may not work as well and your TB may be harder to treat.
- If for some reason you miss a dose, inform the person responsible for your treatment right away, they will tell you what to do.

What should I avoid while taking bedaquiline/delamanid?

- You should not drink alcohol while taking bedaquiline.

What are the possible side effects of bedaquiline/delamanid?

- Serious heart rhythm changes. Tell your health-care provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you faint. Your heart will be monitored periodically with a machine that checks that the heart rhythm is normal.
- Liver problems (hepatotoxicity). Liver toxicity can present in many ways. Tell your doctor of symptoms such as nausea or vomiting, stomach pain, fever, weakness, itching, unusual tiredness, loss of appetite, light colored bowels, dark colored urine, yellowing of your skin or yellowing of the white of your eyes.
- Other side effects of bedaquiline include nausea, joint pain, headache, an abnormal laboratory test associated with damage to the pancreas, coughing up blood, chest pain, loss of appetite and/or rash.
- Other side effects of delamanid include nausea, vomiting and dizziness. Other important adverse drug reactions are anxiety, burning or prickling sensation and tremor. Tell your doctor of symptoms such as nausea or vomiting, dizziness, anxiety, itching or tremor.

It is possible that it may also cause some problems that we are not aware of. However, you will be followed closely for any unwanted effect or any problem. Other medicines to decrease the symptoms of the side effects or reactions may also be given.

Always tell your health-care provider of any side effect or problem you are having.

Sometimes because of side effects, bedaquiline or other drugs may need to be stopped.

What monitoring tests do I need while on bedaquiline/delamanid?

You will undergo the same monitoring tests for all MDR-TB patients on treatment. However, you will need more frequent heart monitoring and blood test for the liver.

Talk to your health-care provider on the schedule of all your monitoring tests and regular doctor visits.

General information about the risks versus the benefits of taking bedaquiline/delamanid

- *RISK:* It is possible that you will be at greater risk than you would otherwise be of certain side effects due to the drug. It is possible that a side effect could be serious and even result in death.
- *BENEFIT:* There is a greater chance that you will be cured of tuberculosis than if you did not take the medicine. You will possibly also become better very much sooner than if you only took the standard medicines for treatment of resistant TB. Also, it is less likely that the drugs you are taking will develop resistance if you are taking bedaquiline.

Confidentiality and sharing information

- Because bedaquiline and delamanid are new drugs for which we have limited experience, we are collecting information on patients taking them.
- The information that we collect from you will be kept confidential and no one but the clinical staff will be able to see your medical information.
- Any information collected to help us better use the drug in patients will be unlinked to your name (made anonymous) before we share or analyze it.

Right to refuse or withdraw

- You do not have to agree to take bedaquiline/delamanid if you do not wish to do so, and refusing to accept the drug as part of your treatment schedule will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic.
- If you agree to take bedaquiline/delamanid, you may also at any point after you start wish to stop without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.

Contact person

If you have any questions, you may contact any of the following persons:

Name _____	Title _____	Phone _____
Name _____	Title _____	Phone _____
Name _____	Title _____	Phone _____

Name of responsible physician: _____

Name of clinic/hospital/institution: _____

TREATMENT CONSENT FORM

Statement from the patient:

I have read the provided information sheet, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked been answered to my satisfaction. I consent to receive bedaquiline and/or delamanid to treat the drug-resistant tuberculosis disease that I am suffering from.

Print Name of Patient: _____

Signature of Patient: _____

Date: _____ (Day/month/year)

If illiterate, a literate witness must sign. (If possible, this person should be selected by the participant and should have no connection to the care providers). Patients who are illiterate should include their thumbprint.

Statement from the Witness:

I have witnessed the accurate reading of the consent form to the potential recipient of bedaquiline and/or delamanid, and the individual has had the opportunity to ask questions.

I confirm that the individual has given consent freely.

Print name of witness: _____ AND Thumbprint of patient

Signature of witness: _____

Date: _____ (Day/month/year)

Statement from the Person Taking Consent:

I confirm that the participant was given an opportunity to ask questions about the treatment, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this informed consent form has been provided to the participant.

Print name of person taking the consent: _____

Signature of person taking the consent: _____

Date: _____ (Day/month/year)

ANNEX 3H. Clinical management of some adverse events

(Refer to a comprehensive PMDT guide for management of all other adverse events)

A. Peripheral neuropathy

Possible anti-TB drug causes: Lzd, Cs, H, Am, S, FQ, Pto/Eto, E.

- Peripheral neuropathy is a common side effect of MDR-TB treatment caused by drug toxicity to the nerves of the peripheral nervous system.
- Signs and symptoms of peripheral neuropathy are: numbness, tingling, burning, pain in the feet or hands.
- If a patient complains of the above signs and symptoms, grading by using Brief Peripheral Neuropathy Screen (BPNS) system should be done.

Step 1. Grade subjective symptoms

Ask the subject to rate the severity of each symptom on a scale from 01 (mild) to 10 (most severe) for right and left feet and legs. Enter the score for each symptom in the columns marked R (right lower limb) and L (left lower limb).

Normal Mild -----Severe
 00 01 02 03 04 05 06 07 08 09 10

Symptoms	Right	Left
a. Pain, aching, or burning in feet, legs		
b. "Pins and needles" in feet, legs		
c. Numbness (lack of feeling) in feet, legs		
Total Score		

Use the single highest severity score above to obtain a total subjective sensory neuropathy score for severity grading.

Severity Grading of Total Score:

Grade 0 = 00

Grade 1 = 01-03

Grade 2 = 04-06

Grade 3 = 07-10

Clinical management of peripheral neuropathy according to severity grading

Severity Grade	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	Grade 4 Life-threatening
Paresthesia	Mild discomfort; no treatment required	Moderate discomfort; non-narcotic analgesia required	Severe discomfort; or narcotic analgesia required with symptomatic improvement	Incapacitating; or not responsive to narcotic analgesia

Severity Grade	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	Grade 4 Life-threatening
Action	Stop Cs and Lzd. If symptoms improve, consider restarting these drugs, and restarting Lzd at a lower dose.	Stop Cs and Lzd. If symptoms improve, consider restarting Cs. Do not reintroduce Lzd. Provide symptomatic relief as described below.	Same as Grade 2.	Same as Grade 2.

Suggested management strategy:

- Many patients experience improvement when the offending drugs are suspended, especially if the symptoms are mild.
- If linezolid should be immediately stopped and not reintroduced when symptomatic neuropathy develops (grade 2 or above), **consider additional anti-TB drugs to reinforce the regimen.**
- In HIV coinfecting patients, avoid use of d4T or ddI in combination with cycloserine or linezolid because of an increased risk of peripheral neuropathy.
- All patients taking linezolid should receive at least 50 mg of pyridoxine daily. This is largely to prevent myelosuppression, but may also prevent peripheral neuropathy.
- Symptomatic relief:
 - Non-steroidal anti-inflammatory drugs or acetaminophen may help alleviate symptoms.
 - Tricyclic antidepressants have also been used successfully. Start amitriptyline 25 mg at bedtime. The dose may be increased to a maximum of 150 mg daily for refractory symptoms.
 - Carbamazepine may also be effective in relieving pain and other symptoms of peripheral neuropathy. Carbamazepine is a strong inducer of CYP3A4 and should not be used with bedaquiline or delamanid.

B. Myelosuppression (anemia, thrombocytopenia, or neutropenia) ^{15,25}

Possible anti-TB drug causes: Lzd. Other drug: AZT

- Exclude other cause of anemia (e.g. TB itself, iron deficiency, occult blood loss, etc.). AZT induced anemia is more likely to be macrocytic anemia which can be determined by mean corpuscular volume (MCV).
- If the patient has thrombocytopenia or neutropenia, this is more likely to be due to linezolid.
- All patients taking linezolid should also be receiving at least 50 mg of pyridoxine daily. This is largely to prevent myelosuppression, but may also prevent peripheral neuropathy.
- Acute blood loss (e.g. occult GI bleeding from a peptic ulcer) can cause anemia.
- Other causes of anemia (TB, iron-deficiency, etc.) are possible, but less likely to occur in the middle of treatment, especially if the patient is clinically improving.

Clinical management of myelosuppression according to severity grading

Severity Grade	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	Grade 4 Life-threatening
Anemia	10.5–9.5 g/dL	9.4–8.0 g/dL	7.9–6.5 g/dL	< 6.5 g/dL
Platelets decreased	75,000–99,999 /mm ³	50,000–74,999 /mm ³	20,000–49,999 /mm ³	< 20,000 /mm ³
Absolute neutrophil count low	1500–1000/mm ³	999–750/mm ³	749– 500/mm ³	< 500/mm ³
Action	Monitor carefully, and consider reduction of dose of Lzd.	Monitor carefully, and consider reduction of dose of Lzd to 300 mg daily; in case of Grade 2 neutropenia, stop Lzd immediately. Restart at reduced dose once toxicity has decreased to Grade 1.	Stop Lzd immediately. Restart at reduced dose once toxicity has decreased to Grade 1.	Stop Lzd immediately. Consider hemotransfusion or erythropoietin. Restart at reduced dose once toxicity has decreased to Grade 1.

Suggested management strategy:

- Stop the causative drug immediately.
- Monitor full blood counts regularly.
- Hospitalize the patient and consider transfusion or erythropoietin if the myelosuppression is severe.

Use of erythropoietin (EPO)

Treatment with erythropoietin is not intended for patients who require immediate correction of anemia (Grade 4). In this case, blood transfusions should be considered. Whole blood count should be repeated weekly to assess the response to treatment. Blood pressure should be adequately controlled before initiation and monitored during therapy. Erythropoietin treatment should in any case be discontinued at Hemoglobin levels over 12 g/dL.

Contraindications: Erythropoietin treatment should be administered with caution in the presence of:

- Untreated, inadequately treated or poorly controlled hypertension
- Epilepsy
- Thrombocytosis
- Chronic liver failure
- Hyperkalemia

Preparation and administration:

Epoetin alfa prefilled syringes of 10,000 UI or 40,000 IU/ml to be stored in cold chain (2°– 8° C).

Dosing Epoetin alfa: 150 IU/Kg three times a week or 450 IU/Kg once a week subcutaneously or intravenously.

4. Consider additional anti-TB drugs to reinforce the regimen

C. Prolonged QT interval

Possible anti-TB drug causes: Cfz, Bdq, Mfx, Dlm, and Lfx (a mild QT prolonging drug)

Possible other causes: Many other drugs can cause QT prolongation (e.g. erythromycin, clarithromycin, quinidine, ketoconazole, fluconazole, antipsychotics (all have some risk including haloperidol, chlorpromazine and risperidone), many anti-nausea drugs (ondansetron/granisetrone, domperidone), methadone, and some antiretrovirals); genetic causes such as long QT syndrome; hypothyroidism.

Check an ECG if the patient has clinical symptoms (tachycardia, syncope, palpitations, or weakness or dizziness) of cardiotoxicity. Check the QT interval and rule out an arrhythmia.

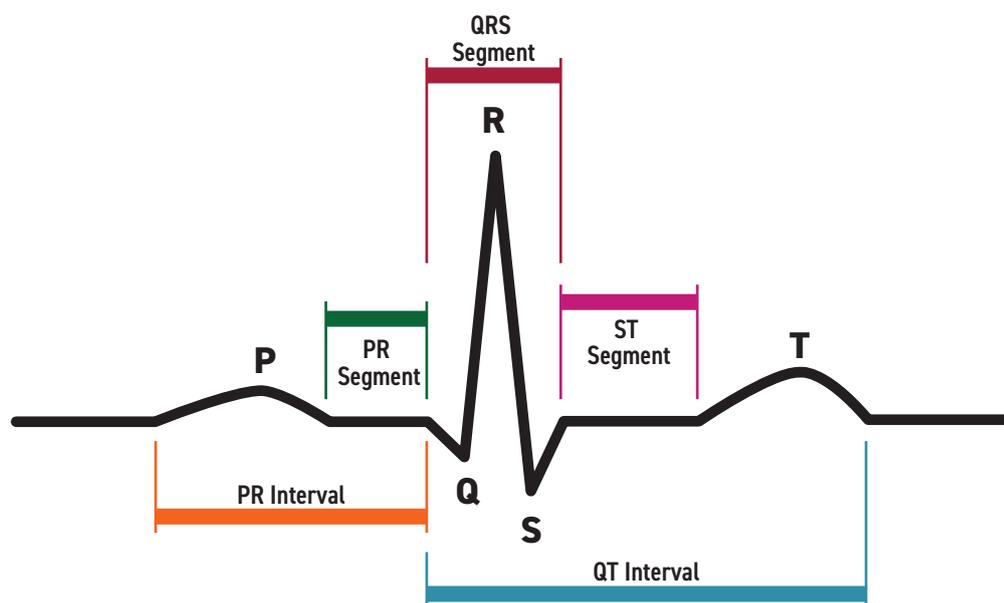
- The QTc will be calculated using the Fridericia's formula which corrects for the heart rate and has been shown to be more accurate at slower or faster heart rates than other correction formulae:

$$QTcF = \frac{QT}{\sqrt[3]{RR}}$$

QTcF = the corrected QT interval

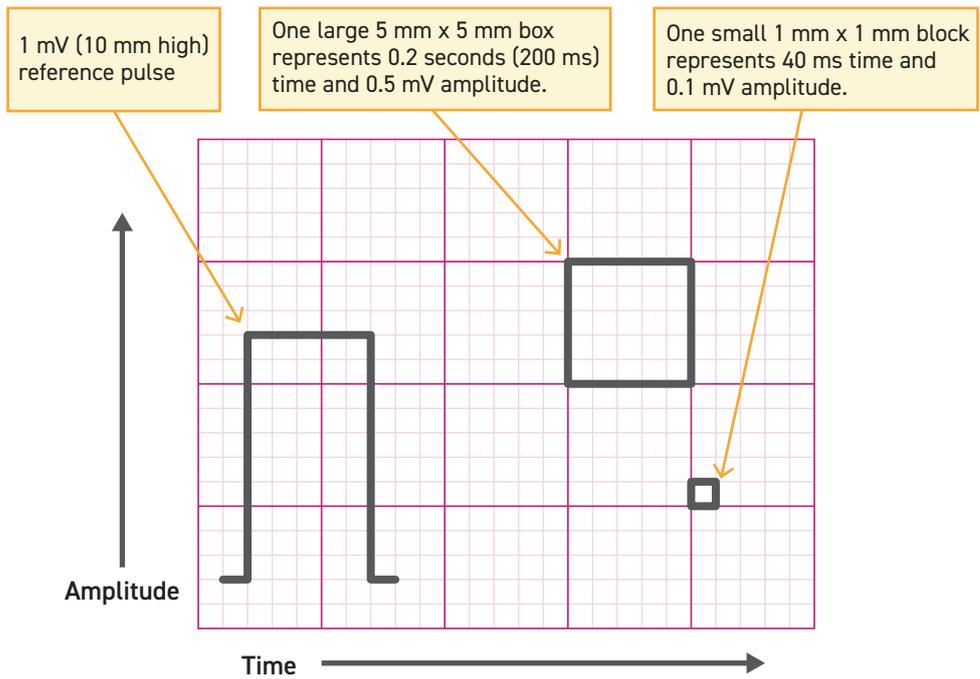
QT = the time between the start of the QRS complex and the end of the T wave

RR = the time between the start of one QRS complex and the start of the next QRS complex



- Detailed procedures on how to measure the RR and QT intervals, and how to correct the QT interval for heart rate are included in job-aid.

The ECG machine should be calibrated to ensure that the following voltage and speeds apply:



Clinical management of prolonged QT interval according to severity grading

Severity Grade	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	Grade 4 Life-threatening
Prolongation of QTcF	450–480	481–500 ms	≥ 501 ms on at least two separate ECGs.	QTcF ≥ 501 or >60 ms change from baseline and Torsade de pointes or polymorphic ventricular tachycardia or signs/symptoms of serious arrhythmia
Action	Monitor more closely; at least weekly ECG until QTcF has returned to grade 1 or less.	Monitor more closely; at least weekly ECG until QTcF has returned to grade 1 or less.	Stop the suspected causative drug(s). Hospitalize and replete electrolytes as necessary.	Stop the suspected causative drug(s). Hospitalize and replete electrolytes as necessary.

Checking and replacing serum electrolytes

- Serum potassium (K^+), ionized calcium (ionized Ca^{++}), and magnesium (Mg^{++}) should be obtained in the event a prolonged QT interval is detected.
- Abnormal electrolytes are most commonly due to the injectable and should be corrected.
- Whenever a low potassium is detected it should trigger urgent management with replacement and frequent repeat potassium testing (often daily or multiple times a day) to document the potassium is moving in the correct direction.
- If potassium is found low, always check magnesium and ionized calcium and compensate as needed. (If unable to check, consider oral empiric replacement doses of magnesium and calcium).

Suggested management strategy

- Stop all QT prolonging drugs immediately.
- Hospitalize and consider continuous electrocardiac monitoring for Grade 3. Hospitalization should occur in a facility capable in the management of Torsades de Pointes arrhythmia.
- Check electrolytes and manage as described above.
- Check a TSH and treat if any hypothyroidism found.
- Once stable (QT_CF interval below 450 or baseline value and normal electrolytes), critical QT prolonging anti-TB drugs can be added back:
 - If the patient was on moxifloxacin consider using levofloxacin instead.
 - If the patient was on clofazimine consider suspending it permanently if not critical to the regimen.
 - If the patient is on bedaquiline and it is considered critical to the regimen, consider adding the drug back to the patient's regimen while suspending all other QT prolonging drugs (with the exception of stopping ART, which should not normally be suspended in the management of QT prolongation).
 - If the patient is on delamanid and it is considered critical to the regimen, consider adding the drug back to the patient's regimen while suspending all other QT prolonging drugs (with the exception of stopping ART, which should not normally be suspended in the management of QT prolongation).

D. Optic nerve disorder (optic neuritis)

Possible anti-TB drug causes: Lzd, E, Eto/Pto, Cfz, rifabutin, H, S. Other drug: ddl

- Optic neuritis is inflammation of the optic nerve eventually resulting in permanent vision loss. The first sign of optic neuritis is usually the loss of red-green color distinction. This is best tested using the Ishihara test. Other symptoms include central scotomas.
- Linezolid is by far the most common cause of optic neuritis among all of the TB drugs. Mostly after four months of treatment.
- Patients with diabetes are at increased risk for optic neuritis. They should be managed with tight glucose control as a means of prevention. Patients with advanced kidney disease are also at increased risk for optic neuritis.

Clinical management of optic nerve disorder according to severity grading

Severity Grade	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	Grade 4 Life-threatening
Optic nerve disorder	Asymptomatic; clinical or diagnostic observations only	Limiting vision of the affected eye (20/40 or better)	Limiting vision in the affected eye (worse than 20/40 but better than 20/200)	Blindness (20/200 or worse) in the affected eye
Action	For any grade, stop Lzd immediately if there are any suspicions of optic neuritis. Do not restart it. If any doubt, refer to ophthalmologist.			

Suggested management strategy:

- Do not restart the suspected causative drug (linezolid or ethambutol).
- Refer patient to an ophthalmologist for immediate evaluation and management.
- Optic neuritis generally improves following cessation of offending drug, if it can be stopped early enough.

Consider additional anti-TB drugs to reinforce the regimen.

E. Hepatitis

Possible anti-TB drug causes: Z, Lzd, Cfz, Bdq.

- Hepatitis is characterized by nausea, vomiting, jaundice, scleral icterus, tea-colored urine, pale stool and diminished appetite in the setting of elevated liver function tests.
- Mild elevation of liver enzymes, especially at baseline, may be related to TB rather than an adverse effect of treatment.
- Generally, hepatitis due to medications resolves upon discontinuation of suspected drug.
- In HIV co-infection, nevirapine and cotrimoxazole can be a cause of hepatotoxicity.

Clinical management of hepatitis according to severity grading

Severity Grade	Grade 1 Mild	Grade 2 Moderate	Grade 3 Severe	Grade 4 Life-threatening
ALT (SGPT)	1.1 – < 2.0 x ULN	2.0 – < 3.0 x ULN	3.0 – 8.0 x ULN	> 8 x ULN
AST (SGOT)	1.1 – < 2.0 x ULN 2.0 – < 3.0 x ULN 3.0 – 8.0 x ULN > 8 x ULN			
Action	Continue treatment regimen. Patients should be followed until resolution (return to baseline) or stabilization of AST/ALT elevation.	Continue treatment regimen. Patients should be followed until resolution (return to baseline) or stabilization of AST/ALT elevation.	Stop all drugs, including anti-TB drugs; measure LFTs weekly. Treatment may be reintroduced after toxicity is resolved.	Stop all drugs, including anti-TB drugs; measure LFTs weekly. Treatment may be reintroduced after toxicity is resolved.

Reintroduction of anti-TB drugs

- Reintroduce anti-TB drugs once liver enzymes return to baseline. Anti-TB drugs should be reintroduced in serial fashion by adding a new medicine every three to four days. The least hepatotoxic drugs should be added first, while monitoring liver function tests after each new exposure.
- Consider suspending the most likely offending drug permanently if it is not essential to the regimen. This is often the case for pyrazinamide if it is less likely to be effective by clinical history. Consider additional anti-TB drugs to reinforce the regimen.

F. Hearing impairment

Possible anti-TB drug causes: Am, S

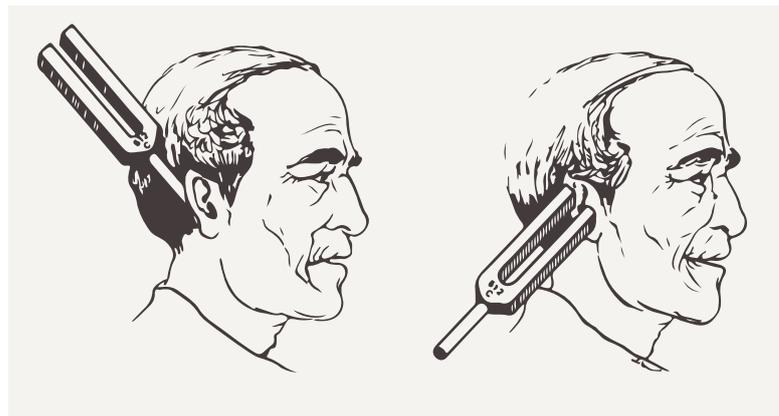
Possible other causes: none.

- Hearing impairment is a disorder characterized by partial or complete loss of the ability to detect or understand sounds resulting from damage to ear structures.
- The injectables can cause damage of the hearing apparatus of the inner ear, including the cochlea, vestibule, semicircular canals and cranial nerve VIII. Symptoms include hearing loss and tinnitus, as well as vestibular symptoms such as disequilibrium and vision problems.
- Hearing loss is commonly observed in patients receiving large cumulative doses of injectables.
- Hearing loss and vestibular dysfunction are generally not reversible upon discontinuation of therapy. Therefore, it is recommended that the use of aminoglycoside injectable should be avoided in patients who already have hearing loss at baseline due to any reason (e.g. previous treatment with streptomycin) or stop the injectable use at an early stage in case a patient experiences hearing or vestibular side effects.
- Concomitant use of furosemide, particularly in the setting of renal insufficiency, may exacerbate ototoxic effects of the injectables.

Procedures to detect hearing loss

1. Audiometry
2. Rinne's or Weber's test (used when audiometry is not readily available)

Rinne Test: This is used to evaluate the loss of hearing in one ear. It differentiates sounds transmitted by air conduction from those transmitted through the mastoid by bone conduction. The test quick screens for the conductive hearing loss and must be done with a Weber test to detect a sensorineural hearing loss.



How to perform Rinne's test:

- Use a 512 Hz tuning fork. Please avoid use 128 Hz or 256 Hz tuning fork, as these are used to assess vibration sensation in neurological examinations.
- The room should be reasonably quiet.
- Technique:
 - Place the vibrating tuning fork on the mastoid process.
 - The patient should be asked to cover the opposite ear with their hand.

- The patient should report when the sound can no longer be heard.
- Then move the vibrating tuning fork over the ear canal to the ear without touching it.
- The patient should indicate when air conduction of the sound can no longer be heard.
- Interpretation
 - **Normal finding:** Air conduction should be better than bone conduction, and air conduction should persist twice as long as bone, this is a “positive test.”
 - **Abnormal:** Bone conduction is better than air conduction, this suggests conductive hearing loss and is referred to as “negative test.”

How to perform Weber’s test

- Use a 512 Hz tuning fork. Please avoid use 128 Hz or 256 Hz tuning fork, as these are used to assess vibration sensation in neurological examinations.
- Technique:
 - Strike a tuning fork and place in on the middle of the head
 - Note were the sound is best heard – left ear, right ear or both equally.
- Interpretation
 - Normal hearing will produce equal sound in both ears.
 - Conductive loss will cause the sound to be heard best in the abnormal ear.
 - Sensorineural loss will cause the sound to be heard best in the normal ear.

ANNEX 4. Forms

Date of Consult <small>MM/DD/YYYY</small> (1)	Patient's Full Name <small>SURNAME, Given Names Name Extension and Middle Name</small> (2)	Age <small>M/ F</small> (3)	Sex <small>M/ F</small> (4)	Complete Address and Contact Number (5)	Name of Referring Facility/ Unit/ Physician/ Health worker (6)	Mode of Screening <small>P/A/V/E</small> (7)	PRESUMPTIVE TB?	
							Presumptive DS-TB <small>CHECK</small> <input type="checkbox"/>	Presumptive DR-TB <small>ONE</small> <input type="checkbox"/>
1							<input type="checkbox"/>	<input type="checkbox"/>
2							<input type="checkbox"/>	<input type="checkbox"/>
3							<input type="checkbox"/>	<input type="checkbox"/>
4							<input type="checkbox"/>	<input type="checkbox"/>
5							<input type="checkbox"/>	<input type="checkbox"/>
6							<input type="checkbox"/>	<input type="checkbox"/>
7							<input type="checkbox"/>	<input type="checkbox"/>
8							<input type="checkbox"/>	<input type="checkbox"/>
9							<input type="checkbox"/>	<input type="checkbox"/>
10							<input type="checkbox"/>	<input type="checkbox"/>
11							<input type="checkbox"/>	<input type="checkbox"/>
12							<input type="checkbox"/>	<input type="checkbox"/>
13							<input type="checkbox"/>	<input type="checkbox"/>
14							<input type="checkbox"/>	<input type="checkbox"/>
15							<input type="checkbox"/>	<input type="checkbox"/>

v.050120

Form 1. Presumptive TB Masterlist

Xpert MTB/RIF	Sputum Examination		Chest X-ray	Tuberculin Skin Test	Diagnosis			Action Taken/ Referred To and Status	Remarks
	Smear Microscopy or TB LAMP	Result (See Legend) and Date of Collection (MM/DD/YYYY)			Active TB	TB Infection	Not TB		
		Result/Impression and Date of Examination (MM/DD/YYYY)	Result and Date of Examination (MM/DD/YYYY)	Date Notified (MM/DD/YYYY) and Case Number					
(9)	(9)	(10)	(11)	(12a)	(12b)	(12c)	(13)	(14)	
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									

v. 05/01/20

Form 1.1, Presumptive TB Masterlist

Date/s	Mode of Screening A/I	Number Screened by CXR	Number of Presumptive TB Identified	Remarks TARGET RISK GROUPS, TARGET AREA, ORGANIZER
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				
32				
33				
34				
35				
36				
37				
38				
39				
40				

Date/s	Mode of Screening A/I	Number Screened by CXR	Number of Presumptive TB Identified	Remarks TARGET RISK GROUPS, TARGET AREA, ORGANIZER
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				

v. 050120

Form 1. Presumptive TB Masterlist

FORM 2A. LABORATORY REQUEST AND RESULT FORM

To be filled out by Health Worker

Name of Requesting Facility/Unit: _____	Date of Request: _____
Facility Contact Information: _____	Requesting Physician: _____
Patient's Full Name: _____	Age: _____ Sex: <input type="checkbox"/> M <input type="checkbox"/> F
Province/City: _____	Patient's Contact No.: _____

Reason for Examination: Diagnosis Baseline Follow-up TB Case No.: _____

History of Treatment: New Retreatment Month of treatment: _____

Test Requested:

<input type="checkbox"/> Xpert MTB/RIF	<input type="checkbox"/> Smear Microscopy ^a	<input type="checkbox"/> TB LAMP	<input type="checkbox"/> LPA	<input type="checkbox"/> 1st Line	<input type="checkbox"/> Culture	<input type="checkbox"/> DST
				<input type="checkbox"/> 2nd Line		

^a Is *Paragonimiasis* considered? Yes No

Type of Specimen: Sputum **Repeat Collection?** No

Other, Specify: _____ Yes, Reason: _____

Date:

Specimen	Date Collected	Date Dispatched to Laboratory
1		
2		

Remarks: _____
(i.e. pre-collection details; existing medical conditions, medications taken prior to screening, and/or known risk factors)

Prepared by: _____ Designation: _____
Signature over Printed Name

To be filled-out by Medical Technologist/Microscopist/Xpert Technician

Name of Laboratory: _____

Specimen Received by: _____ Date and Time Specimen Received: _____

Specimen Volume and Quality: _____ Accepted Rejected, reason: _____

Laboratory Serial Number: _____ Date Specimen Examined: _____

DIAGNOSTIC TESTS		RESULTS	
<input type="checkbox"/> Xpert MTB/RIF <input type="checkbox"/> Xpert MTB/RIF Ultra			
Smear Microscopy	Paragonimiasis*	1	2
	TB	Reading	1
	Laboratory Diagnosis		2**
TB LAMP			

* Results for Paragonimiasis: P – if Paragonimus ova only are seen, T – If AFB only are seen, Co-I – if BOTH ova and bacilli are seen, Neg – No ova and No bacilli are seen

** Specimen 2 is not applicable for follow-up

Performed by: _____ Verified by: _____ Noted by: _____

Signature over Printed Name *Signature over Printed Name* *Signature over Printed Name*

Date and Time Released: _____ *A separate result form for LPA, Culture, and DST will be issued.*

FORM 2B. NTP LABORATORY RESULT FORM FOR HIV SCREENING OF TB PATIENTS

Name of Requesting Facility:		Date Requested (MM/DD/YYYY):	
_____		_____	
Patient's Name (SURNAME, Given Names Name Extension and Middle Name):		Age:	Sex:
_____		_____	[] M [] F

HIV Screening Result

Lab Serial No.:	Method:	Kit/ Reagent:	Lot No.:	Result:

Medical Technologist (SIGNATURE OVER PRINTED NAME):	Date Performed (MM/DD/YYYY):	Date Released (MM/DD/YYYY):
_____	_____	_____

FORM 2C. LINE PROBE ASSAY RESULT FORM

TB Case Number: _____	Date of Request: _____
Name of Requesting Facility/Unit: _____	Requesting Physician: _____
Patient' Full Name: _____	Name of Laboratory: _____
Age: _____ Sex: [] M [] F	

Reason for Examination: [] Baseline [] Follow-up; month: _____

Type of Specimen: [] Sputum [] Isolate [] Others (specify): _____

LPA Test Requested: [] 1st Line LPA [] 2nd Line LPA [] Others (specify): _____

Date Specimen Collected: _____ Date and Time Specimen Received: _____

Laboratory Serial Number: _____ Specimen Volume and Quality: _____

<i>M. tuberculosis</i> Complex Result:			
First Line LPA		Second Line LPA	
Name of Drugs	Result	Class of Drugs	Result
Rifampicin (Rif)		Fluoroquinolones (FQ)	
Isoniazid (H)			
Ethionamide (Eto) / Prothionamide (Pto)		Second Line Injectable (SLI)	

Remarks: _____ Date and Time Released: _____

Performed by: _____ <i>Signature over Printed Name</i>	Verified by: _____ <i>Signature over Printed Name</i>	Noted by: _____ <i>Signature over Printed Name</i>
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FORM 2D. TB CULTURE RESULT FORM

TB Case Number: _____	Date of Request: _____
Name of Requesting Facility/Unit: _____	Requesting Physician: _____
Patient' Full Name: _____	Name of Laboratory: _____
Age: _____ Sex: <input type="checkbox"/> M <input type="checkbox"/> F	

Reason for Examination: Baseline Follow-up; month: _____ Diagnosis

Type of Specimen: Sputum Others (specify): _____

Method: Solid Culture Liquid Culture: MGIT

	TB Culture Laboratory Number	Date Specimen Collected	Date and Time Specimen Received	TB Culture Result
1				
2				

Remarks: _____ Date and Time Released: _____

Performed by: _____

Verified by: _____

Noted by: _____

Signature over Printed Name

Signature over Printed Name

Signature over Printed Name

FORM 2E. DRUG SUSCEPTIBILITY TESTING RESULT FORM

TB Case Number: _____	Date of Request: _____
Name of Requesting Facility/Unit: _____	Requesting Physician: _____
Patient's Full Name: _____	Name of Culture Laboratory: _____
Age: _____ Sex: <input type="checkbox"/> M <input type="checkbox"/> F	Name of DST Laboratory: _____

Reason for Examination: Baseline Follow-up; month: _____ Diagnosis

Type of Specimen: Sputum Isolate Others (specify): _____

Method: Solid Culture LI PROPORTION Liquid MGIT 960 Others (specify): _____

TB Culture Lab Number: _____ Date and Time Specimen Received: _____

First Line Drugs				Second Line Drugs			
Name of Drugs	Concentrations mg/L		Result	Name of Drugs	Concentrations mg/L		Result
	Solid	Liquid			Solid	Liquid	
Isoniazid (H)	0.2	0.10		Levofloxacin (Lfx)	2.0	1.0	
Rifampicin (R)	40	1.0		Moxifloxacin (Mfx)	1.0	0.25	
Ethambutol (E)	2.0	5.0		Amikacin (Amk)	30	1.0	
Pyrazinamide (Z)		100		Streptomycin (S)	4.0	1.0	

Remarks: _____ Date and Time Released: _____

Performed by: _____

Verified by: _____

Noted by: _____

Signature over Printed Name

Signature over Printed Name

Signature over Printed Name

Laboratory Serial Number (1)	Date Specimen Collected (2)	Date and Time Specimen Received (3)	Name of Requesting Facility/Unit (4)	Patient's Full Name (SURNAME, Given Names, Name Extension, Middle Name) (5)	Age (6)	Sex (M/F) (7)	History of Treatment (N/R) (8)	Cartridges Used (9)				Xpert MTB/RIF Result (10)	Signature of Laboratory Staff (11)		Remarks (12)
								XPERT MTB/ RIF	XPERT MTB/ RIF ULTRA	Date Specimen Examined	Date and Time Released				
1															
2															
3															
4															
5															
6															
7															
8															
9															
10															

Form 3a. Laboratory Register for Xpert MTB/RIF v.030420

Laboratory Serial Number (1)	Date Specimen Collected (2)	Date and Time Specimen Received (3)	Name of Requesting Facility/Unit (4)	Patient's Full Name <small>(SURNAME, Given Names, Name Extension, Middle Name)</small> (5)	Age (6)	Sex <small>(M/F)</small> (7)	History of Treatment <small>(N/R)</small> (8)	Reason for Examination (9)		Smear Microscopy Result (10)				TB LAMP Result (11)	Signature of Laboratory Staff (12)	Remarks (13)
								Diagnosis <small>(TB CASE NO.)</small>	Follow-up	For Acid-Fast Bacilli 1st 2nd Date Specimen Examined	For Paragonimiasis 1st 2nd NaOH Date Specimen Examined	Date Specimen Examined	Date and Time Released			
1																
2																
3																
4																
5																
6																
7																
8																
9																
10																

v.03/04/20

Form 3b. Laboratory Register for Smear Microscopy and TB LAMP

Laboratory Serial Number	Date Specimen Collected	Date and Time Specimen Received	Collection Unit Code	Patient's Full Name <small>(SURNAME, Given Names, Name Extension, Middle Name)</small>	Age	Sex <small>(M/F)</small>	History of Treatment <small>(N/R)</small>	Reason for Examination		Type of Specimen	LPA Result					Signature of Laboratory Staff Date and Time Released	Remarks		
								Baseline	Follow-up		MTB	RIF	H	Eto/Pro	FQ			SLI	
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)		(10)	(11)					(12)	(13)		
1																			
2																			
3																			
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7																			
8																			
9																			
10																			

Form 3c. Laboratory Register for Line Probe Assay V.03/04/20

FORM 4A. TB NOTIFICATION FORM

Privacy Notice: It has been explained to me that all information collected in this form shall only be used for the purposes of clinical management, program management, and/or provision of psychosocial and financial support. If I have any query on or wish to revoke this authorization, I shall notify the facility head or contact ntp.helpdesk@doh.gov.ph or (02) 8230-9626. All information collected shall remain secured and confidential and only authorized personnel shall have access to them.

Reason of Notification: New/ Diagnosis Update/Start of Treatment *Please put an * or highlight on fields updated.* Final Outcome

Patient's Signature over Printed Full Name _____

Name of Facility:	Region:
NTP Facility Code:	Province/ HUC:

A. Patient Demographic

Patient's Full Name (SURNAME, Given Names, Name Extension, Middle Name):		Age:	Sex (M/F):	Civil Status:
		YEARS MONTHS		
Permanent Address (House No., Street, Barangay, City/ Municipality, Province, Region & Zip Code):		Nationality:		
		PhilHealth No.:		

B. Laboratory Tests

Name of Test:	Xpert MTB/RIF <input type="checkbox"/> ULTRA	Smear Microscopy/TB LAMP	Chest X-ray	Tuberculin Skin Test	Other:
Date (MM/DD/YYYY):	Collection	Collection	Examination	Reading	
Result:					

C. Diagnosis

Diagnosis:	Date of Diagnosis (MM/DD/YYYY):	Date of Notification (MM/DD/YYYY):	Referred To (Name, Address, Facility Code, Province/HUC, Region):
<input type="checkbox"/> TB Disease <input type="checkbox"/> TB Infection			
TB/ TPT Case Number:	Attending Physician:		

D. TB Disease Classification

Bacteriological Status:	Drug Resistance Bacteriological Status:	Registration Group:
<input type="checkbox"/> Bacteriologically-confirmed TB <input type="checkbox"/> Clinically-diagnosed TB	<input type="checkbox"/> Drug-susceptible <input type="checkbox"/> Bacteriologically-confirmed RR-TB <input type="checkbox"/> Bacteriologically-confirmed MDR-TB	<input type="checkbox"/> New <input type="checkbox"/> TAF <input type="checkbox"/> Relapse <input type="checkbox"/> PTOU <input type="checkbox"/> TALF <input type="checkbox"/> Unknown History
Anatomical Site:	Other Drug-resistant TB _____	
<input type="checkbox"/> Pulmonary <input type="checkbox"/> Extra-pulmonary SITE: _____		

F. Treatment Outcome

Regimen Type at Start of Treatment:	Regimen Type at End of Treatment:
<input type="checkbox"/> Regimen 1 <input type="checkbox"/> Regimen 2 <input type="checkbox"/> Regimen 3 <input type="checkbox"/> Regimen 4 <input type="checkbox"/> Regimen 5 <input type="checkbox"/> Regimen 6 <input type="checkbox"/> Regimen 7 <small>2HRZE/4HR 4LX8Bq(6)CPZtotZHH/SLX0ZXE 4LX8Bq(6)CPZtotZHH/SLX0ZXE 4LX8Bq(6)CPZtotZHH/SLX0ZXE 4LX8Bq(6)CPZtotZHH/SLX0ZXE 4LX8Bq(6)CPZtotZHH/SLX0ZXE 4LX8Bq(6)CPZtotZHH/SLX0ZXE 4LX8Bq(6)CPZtotZHH/SLX0ZXE</small>	<input type="checkbox"/> Cured <input type="checkbox"/> Failed <input type="checkbox"/> Died <input type="checkbox"/> Treatment Completed <input type="checkbox"/> Lost to Follow-up Date of Outcome (MM/DD/YYYY): Reason (if Failed, LTFU, or Died):

FORM 4B. DS-TB TREATMENT CARD

Privacy Notice: It has been explained to me that all information collected in this form shall only be used for the purposes of clinical management, program management, and/or provision of psychosocial and financial support. If I have any query on or wish to revoke this authorization, I shall notify the facility head or contact ntp.helpdesk@doh.gov.ph or (02) 8230-9426. All information collected shall remain secured and confidential and only authorized personnel shall have access to them.

Patient's Signature over Printed Full Name

I. Case Finding/ Notification			
Name of Diagnosing Facility:	NTP Facility Code:	Province/ HUC:	Region:
A. Patient Demographic			
Patient's Full Name (SURNAME, Given Names, Name Extension, Middle Name):	Date of Birth (MM/DD/YYYY):	Age: YEARS MONTHS	Sex (M/F):
Permanent Address (House No., Street, Barangay, City/ Municipality, Province, Region & Zip Code):	Current Address (House No., Street, Barangay, City/ Municipality, Province, Region & Zip Code):		
Contact Number (include area code):	PhilHealth No.:		
B. Screening Information			
Referred by (Name & Location): <input type="checkbox"/> public <input type="checkbox"/> other public <input type="checkbox"/> private <input type="checkbox"/> community		Mode of Screening: <input type="checkbox"/> PCF <input type="checkbox"/> ACF <input type="checkbox"/> ICF <input type="checkbox"/> ECF	
C. Laboratory Tests			
Name of Test:	Xpert MTB/RIF <input type="checkbox"/> ULTRA	Smear Microscopy/TB LAMP	Chest X-ray
Date (MM/DD/YYYY):	Collection	Collection	Reading
Result:			Other: _____
D. Diagnosis			
Diagnosis: <input checked="" type="checkbox"/> TB Disease <input type="checkbox"/> TB Infection		Date of Diagnosis (MM/DD/YYYY):	Date of Notification (MM/DD/YYYY):
TB Case Number:		Attending Physician:	
E. TB Disease Classification			
Bacteriological Status: <input type="checkbox"/> Bacteriologically-confirmed TB <input type="checkbox"/> Clinically-diagnosed TB		Drug Resistance Bacteriological Status: <input type="checkbox"/> Drug-susceptible <input type="checkbox"/> Bacteriologically-confirmed RR-TB <input type="checkbox"/> Bacteriologically-confirmed MDR-TB	
Anatomical Site: <input type="checkbox"/> Pulmonary <input type="checkbox"/> Extra-pulmonary SITE: _____		Registration Group: <input type="checkbox"/> New <input type="checkbox"/> TAF <input type="checkbox"/> Relapse <input type="checkbox"/> PTOU <input type="checkbox"/> TALF <input type="checkbox"/> Unknown History	

National TB Control Program

TB Case No. _____

II. Treatment

Name of Treatment Facility:	NTP Facility Code:	Province/ HUC:	Region:
------------------------------------	---------------------------	-----------------------	----------------

A. Baseline Information

History of TB Treatment (most recent on top): <input type="checkbox"/> None <input type="checkbox"/> No Known			
Date Tx Started	Name of Treatment Unit	Treatment Regimen <small>(Drugs & Duration)</small>	Outcome
HIV Information:			
<input type="checkbox"/> Known PLHIV Prior to Start of Tx <input type="checkbox"/> Not Eligible for Testing			
HIV Test Date (MM/DD/YYYY):			
Confirmatory Test Date (MM/DD/YYYY):			
Result:		4Ps Beneficiary?	
<input type="checkbox"/> P <input type="checkbox"/> N <input type="checkbox"/> N <input type="checkbox"/> undetermined		<input type="checkbox"/> Yes <input type="checkbox"/> No	
<input type="checkbox"/> Started on ART? <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No	
<input type="checkbox"/> Started on CPT? <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No	
B. Treatment Regimen			
Regimen Type at Start of Treatment:			
<input type="checkbox"/> Regimen 1 <small>2HRZE/4HR</small>			
<input type="checkbox"/> Regimen 2 <small>2HRZE/15HR</small>			
Treatment Start Date (MM/DD/YYYY):			
Regimen Type at End of Treatment:			

C. Treatment Outcome

Outcome:	
<input type="checkbox"/> Cured	<input type="checkbox"/> Failed
<input type="checkbox"/> Treatment Completed	<input type="checkbox"/> Lost to Follow-up
Date of Outcome (MM/DD/YYYY):	
Reason (if Failed, LTFU, or Died):	

FORM 4C. DR-TB TREATMENT CARD

Privacy Notice: It has been explained to me that all information collected in this form shall only be used for the purposes of clinical management, program management, and/or provision of psychosocial and financial support. If I have any query on or wish to revoke this authorization, I shall notify the facility head or contact ntp.helpdesk@doh.gov.ph or (02) 8230-9626. All information collected shall remain secured and confidential and only authorized personnel shall have access to them.

Patient's Signature over Printed Full Name

I. Case Finding/ Notification			
Name of Diagnosing Facility:	NTP Facility Code:	Province/ HUC:	Region:
A. Patient Demographic			
Patient's Full Name (SURNAME, Given Names, Name Extension, Middle Name):	Date of Birth (MM/DD/YYYY):	Age: YEARS MONTHS	Sex (M/F): Civil Status:
Permanent Address (House No., Street, Barangay, City/ Municipality, Province, Region & Zip Code):			
Contact Number (include area code):	Other Contact Information:		
PhilHealth No.:			
B. Screening Information			
Referred by (Name & Location): <input type="checkbox"/> public <input type="checkbox"/> other public <input type="checkbox"/> private <input type="checkbox"/> community			
Mode of Screening: <input type="checkbox"/> PCF <input type="checkbox"/> ACF <input type="checkbox"/> ICF <input type="checkbox"/> ECF		Date of Screening (MM/DD/YYYY):	
C. Laboratory Tests			
Name of Test:	Xpert MTB/RIF <input type="checkbox"/> ULTRA	Smear Microscopy/TB LAMP	Chest X-ray
Date (MM/DD/YYYY):	Collection	Collection	Reading
Result:			Other: _____
D. Diagnosis			
Diagnosis: <input checked="" type="checkbox"/> TB Disease <input type="checkbox"/> TB Infection		Date of Diagnosis (MM/DD/YYYY):	Date of Notification (MM/DD/YYYY):
TB Case Number:		Attending Physician:	
Referred To (Name, Address, Facility Code, Province/HUC, Region):			
E. TB Disease Classification			
Bacteriological Status: <input type="checkbox"/> Bacteriologically-confirmed TB <input type="checkbox"/> Clinically-diagnosed TB		Drug Resistance Bacteriological Status: <input type="checkbox"/> Drug-susceptible <input type="checkbox"/> Bacteriologically-confirmed XDR-TB <input type="checkbox"/> Bacteriologically-confirmed RR-TB <input type="checkbox"/> Clinically-diagnosed MDR-TB <input type="checkbox"/> Bacteriologically-confirmed MDR-TB <input type="checkbox"/> Other Drug-resistant TB _____	
Anatomical Site: <input type="checkbox"/> Pulmonary <input type="checkbox"/> Extra-pulmonary SITE: _____		Registration Group: <input type="checkbox"/> New <input type="checkbox"/> TAF <input type="checkbox"/> Relapse <input type="checkbox"/> PTOU <input type="checkbox"/> TALF <input type="checkbox"/> Unknown History	

National TB Control Program

TB Case No. _____

II. Treatment

Name of Treatment Facility:	NTP Facility Code:	Province/ HUC:	Region:
------------------------------------	---------------------------	-----------------------	----------------

A. Baseline Information

History of TB Treatment (most recent on top): <input type="checkbox"/> None <input type="checkbox"/> No Known		Height:	Weight:	Co-morbidities:	Type	Treatment
Date Tx Started	Name of Treatment Unit	CM	KG	Date Diagnosed		
	Treatment Regimen (Drugs & Duration)	Other Vital Signs or Treatment Considerations:			<input type="checkbox"/> Diabetes Mellitus	
					<input type="checkbox"/> Mental Illness	
					<input type="checkbox"/> Substance Abuse	
				Person to Notify in case of Emergency:	<input type="checkbox"/> Liver Disease	
				Relationship:	<input type="checkbox"/> Renal Disease	
				Contact Information:	<input type="checkbox"/> Other: _____	
HIV Information:						
<input type="checkbox"/> Known PLHIV Prior to Start of Tx <input type="checkbox"/> Not Eligible for Testing						
HIV Test Date (MM/DD/YYYY):		Risk Factor/s for DR-TB:				
		<input type="checkbox"/> Retreatment				
Confirmatory Test Date (MM/DD/YYYY):		<input type="checkbox"/> Close Contact of a Confirmed DR-TB				
		<input type="checkbox"/> Non-converter of a DS-TB Regimen				
Result:		Occupation:				
<input type="checkbox"/> P <input type="checkbox"/> N <input type="checkbox"/> undetermined	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No	<input type="checkbox"/> HCW				
<input type="checkbox"/> Started on ART?	<input type="checkbox"/> Yes <input type="checkbox"/> No					
<input type="checkbox"/> Started on CPT?	<input type="checkbox"/> Yes <input type="checkbox"/> No					

C. Diagnosis

Regimen Type at Start of Treatment:		Regimen Type at End of Treatment:	
<input type="checkbox"/> Regimen 3 ^{SSOR} 4Lx Bdq(6)CfPzEZHhH/5Lx CfrZE	<input type="checkbox"/> Regimen 6 ^{PEDIA MDR FQ-S} a LxLzdCfzCs(Pas/Eto) b LxLzdCfzCs(Dim/PAS) c BdqLxLzdCfz (Cs/Dim)	<input type="checkbox"/> Regimen 7 ^{PEDIA MDR FQ-R} a LzdCfzCsPAS (Eto/Dim) b LzdCfzCsDim (PAS/Eto) c BdqLzdCfzCs (Dim/PAS)	<input type="checkbox"/> ITR (SPECIFY) <input type="checkbox"/> BPaL
<input type="checkbox"/> Regimen 4 ^{S LOR FQ-S} 6Lx BdqLzdCfz/12LxLzdCfz	<input type="checkbox"/> Regimen 5 ^{S LOR FQ-R} 6LzdBdqDlmCfzCs		
Treatment Start Date (MM/DD/YYYY):		Regimen Type at End of Treatment:	

D. Treatment Outcome

Outcome	Date of Outcome (MM/DD/YYYY):
<input type="checkbox"/> Cured	
<input type="checkbox"/> Treatment Completed	
<input type="checkbox"/> Failed	
<input type="checkbox"/> Died	
<input type="checkbox"/> Lost to Follow-up	
Reason (if Failed, LTFU, or Died):	

National TB Control Program

TB Case No. _____

I. Sputum Monitoring

	Date Collected (MM/DD/YYYY)	Smear Microscopy/ TB LAMP	TBC
S1			
S2		GX:	
B		GX:	/
1		/	
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			

J. Drug-Susceptibility Testing

Date Collected (MM/DD/YYYY)	Date Released (MM/DD/YYYY)	Method	H	R	E	Z	Lfx	Mfx	Pto/ Eto	Am	S

K. Chest X-ray

Mo.	Date Examined (MM/DD/YYYY)	CXR Findings	Remarks
B		<input type="checkbox"/> Normal <input type="checkbox"/> Abnormal suggestive of TB <input type="checkbox"/> Abnormal not suggestive of TB	
		<input type="checkbox"/> Improved <input type="checkbox"/> Stable/Unchanged <input type="checkbox"/> Worsened	
		<input type="checkbox"/> Improved <input type="checkbox"/> Stable/Unchanged <input type="checkbox"/> Worsened	
		<input type="checkbox"/> Improved <input type="checkbox"/> Stable/Unchanged <input type="checkbox"/> Worsened	
		<input type="checkbox"/> Improved <input type="checkbox"/> Stable/Unchanged <input type="checkbox"/> Worsened	

L. Close Contacts

Name	Age	Sex (M/F)	Relationship	Initial Screening (MM/DD/YYYY)	Ff-up (MM/DD/YYYY)	Remarks (TB/TPT Case Number)

M. Post Treatment Follow-up

Mo. After Tx	Date (MM/DD/YYYY)	CXR Findings	DSSM	LPA	TBC & DST	Remarks
PT 6						
PT 12						
PT						
PT						
Post-Treatment Outcome:		Date of Post-Tx Outcome (MM/DD/YYYY):		Reason (IF LT/FLU, OR DIED):		
<input type="checkbox"/> Non-relapsing Cure <input type="checkbox"/> Lost to Follow-up						
<input type="checkbox"/> Relapse <input type="checkbox"/> Died						

FORM 4D. TB PREVENTIVE TREATMENT CARD

Privacy Notice: It has been explained to me that all information collected in this form shall only be used for the purposes of clinical management, program management, and/or provision of psychosocial and financial support. If I have any query on or wish to revoke this authorization, I shall notify the facility head or contact ntp.helpdesk@doh.gov.ph or (02) 8230-9626. All information collected shall remain secured and confidential and only authorized personnel shall have access to them.

Patient's Signature over Printed Full Name _____			
Name of Diagnosing Facility:	NTP Facility Code:	Province/ HUC:	Region:
A. Patient Demographic			
Patient's Full Name (SURNAME, Given Names, Name Extension, Middle Name):		Date of Birth (MM/DD/YYYY):	Age: YEARS MONTHS
Sex (M/F):		Civil Status:	
Permanent Address (House No., Street, Barangay, City/ Municipality, Province, Region & Zip Code):			
Contact Number (include area code):		PhilHealth No.:	
Other Contact Information:		Nationality:	
B. Screening Information			
Referred by (Name & Location):		Mode of Screening:	
[] public [] other public [] private [] community		[] PCF [] ACF [] ICF [] ECF	
C. Laboratory Tests			
Name of Test:	Xpert MTB/RIF [] Ultra	Smear Microscopy/TB LAMP	Chest X-ray
Date (MM/DD/YYYY):	Collection	Collection	Examination
Result:			Reading
			Other: _____
D. Diagnosis			
Diagnosis:		Date of Diagnosis (MM/DD/YYYY):	Date of Notification (MM/DD/YYYY):
[] TB Disease		Referred To (Name, Address, Facility Code, Province/HUC, Region):	
[x] TB Infection		Attending Physician:	
TPT Case Number:			
E. Baseline Information			
Height:	CM	Weight:	KG
Other Vital Signs or Treatment Considerations:			
Indication for TPT:		[] Household Contact	
		[] Close Contact	
		[] PLHIV	
		[] Clinical Risk Group _____	
Occupation:		4Ps Beneficiary? [] Yes [] No	

National TB Control Program

TB Case No. _____

F. Treatment Regimen

Treatment Start Date (MM/DD/YYYY):	Regimen Type: [] 6H [] 3HR [] 3HP [] 4R	Date Start (MM/DD/YYYY):	Drug:	H	R	P
			Strength:			
			Unit:			

G. Treatment Outcome

Outcome:
 Cured Failed Died
 Treatment Completed Lost to Follow-up

Date of Outcome (MM/DD/YYYY): _____

Reason (if Failed, ITFU, or Died): _____

H. Administration of Drugs

Location of Treatment: [] Facility-based [] Community-based [] Home-based	Name, Designation, and Type of Tx Supporter: [] Facility HCW [] Community HCW [] Family [] Lay Volunteer [] Others	Tx Supporter Contact Information: <input type="checkbox"/> DAT-supported	Name of DAT/s Used:	Height (cm) for Children																																			
#	Month (MMM-YY)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	Monthly Doses Taken	Cum. Doses Taken	Monthly Missed Doses	% Adher:	Weight (kg)		
0																																							
1																																							
2																																							
3																																							
4																																							
5																																							
6																																							

Legend: Tx Supporter: 3-letter initials: Supervised
 I: Incomplete Regimen
 HOLD: On hold

STC/ TS/ CB/ HB: Satellite Treatment Center/ Treatment Site/ Community-Based/ Home-based DOT
 X: Drugs not taken/ Absent
 Re-challenge: Drug re-challenge

Encircle date of regimen change
 [brackets] - drugs dispensed to patient or treatment supporter

I. Patient Progress

Month	Date	Problem (Adverse Event, Reason of Absence)	Action Taken	Plan	Health Staff Signature

J. Serious Adverse Events and AEs of Special Interest

Date of AE (MM/DD/YYYY)	Specific AE	Date Reported to FDA (MM/DD/YYYY)

Certification of Treatment Completion

This is to certify that Mr./Ms. _____, bearer of this NTP Patient Booklet, has complied with the required treatment for

- DS-TB Treatment
- DR-TB Treatment
- TB Preventive Treatment

at _____ DOTS Facility.
S/he is no longer infectious.

Issued this ____ th day of _____, 20 ____.

Physician
(Signature over Printed Name)

	Schedule of Follow-up	Remarks	GX/ TBC
PT 6			
PT 12			
PT ____			
PT ____			

FORM 5. TB AND TPT PATIENT BOOKLET

TB/ TPT Case No.:
Treatment Facility:
Facility Address:
Facility Contact No.:

Patient Name:	
PhilHealth No.:	
Diagnosis:	<input type="checkbox"/> TB Disease <input type="checkbox"/> TB Infection
Date of Diagnosis:	
TB Disease Classification:	<input type="checkbox"/> Pulmonary <input type="checkbox"/> Extra-pulmonary: <input type="checkbox"/> Bacteriologically-confirmed <input type="checkbox"/> Clinically-diagnosed <input type="checkbox"/> New <input type="checkbox"/> Retreatment <input type="checkbox"/> Drug-susceptible <input type="checkbox"/> Drug-resistant
Location of Treatment:	<input type="checkbox"/> Facility-based <input type="checkbox"/> Community-based <input type="checkbox"/> Home-based
Name of Treatment Supporter:	
Contact Information of Treatment Supporter:	
Schedule of Treatment:	
DAT-Support:	

I understand and agree to the following:

1. I shall answer honestly all questions given to me by the health worker and I shall provide data and records relevant to the queries. I understand that collection of my information is necessary and important for my diagnosis, treatment, and care and that I can exercise my rights regarding data collected from me.
2. I shall adhere and complete the prescribed number months of treatment (from 4 to 24 months, depending on the laboratory results and physician assessment) with anti-TB medicines under direct supervision. Treatment interruption will lead to worsening of my condition and development of (further) drug-resistance, making my disease more difficult to treat.
3. To monitor my treatment progress,
 - a. A doctor shall conduct monthly medical check-up;
 - b. For DS- and DR-TB, my sputum shall be examined on a prescribed schedule;
 - c. For DR-TB, additional blood and laboratory tests such as but not limited to ECG, hearing test, and eye test shall be done as well to monitor effect of drugs to my body.
4. To ensure successful treatment, I shall:
 - a. Take the medications daily, at the right time, with the right dose under the supervision of a treatment partner;
 - b. Not stop taking the drugs unless there is an advice from the TB physician;
 - c. Stop or avoid smoking, drinking alcohol, and use of prohibited drugs while on treatment.
5. Possible side effects of anti-TB drugs have been explained to me and I shall follow advise by health worker on how these can be managed when experienced.
6. To prevent the spread of my disease, I shall:
 - a. Cover my mouth and nose with handkerchief while coughing and sneezing;
 - b. Dispose my sputum properly based on the instruction provided by the health care provider (e.g., spitting on a tissue paper and disposing it to a trash bin disinfected with Sodium hypochlorite, e.g. Chlorox, or spitting directly to the toilet bowl);
 - c. Keep my room well-ventilated by opening windows and letting the sunrays in.
7. All the tests for diagnosis and medications for the whole duration of treatment of TB patients shall be provided by the National TB Control Program free of charge.

(1) TB Case Number	(2) Date of Screening (MM/DD/YYYY)	(3) Date of Notification (MM/DD/YYYY)	(4) Date Start of Treatment (MM/DD/YYYY)	(5) Patient's Full Name (SURNAME, Given Names Name Extension and Middle Name)	(6) Date of Birth (MM/DD/YYYY)	(7) Age	(8) Sex (M/F)	(9) Permanent Address & Contact Number (House No., Street, Barangay, City/Municipality, Province, Region & include Area Code for telephone no.)	(10) Source of Patient (see legend)		(11) Mode of Screening (P/A/I/E)	(12) Anatomical Site (P/EP & specify)	(13) Registration Group (see legend)	(14) Bacteriological Status (BC/CD)	(15) Treatment Regimen at Start (1/2)
									(10) Source of Patient (see legend)	(11) Mode of Screening (P/A/I/E)					
1															
2															
3															
4															
5															
6															
7															
8															
9															
10															

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Form 6A. DS-TB Register

	(16) Number of Contacts <small>(Adults on top and Children 0-14 on bottom)</small>			(17) HIV Status <small>(see legend) & Test Date (MM/DD/YYYY)</small>	(18) DM Status <small>(see legend) & Screening Date (MM/DD/YYYY)</small>	(19) Location of Tx <small>(FB/CB/HB & DAT-specify)</small>	(20) Type of Tx Supporter <small>(HCW/ F/ V/O)</small>	(21) Xpert MTB/RIF (X) and TB Smear Microscopy (S) <small>(Results/ Date collected MM/DD)</small>					(22) Treatment Outcome <small>(Outcome, Date MM/DD/YYYY & Reason)</small>	(23) Remarks <small>(PhilHealth Number, study participated, notes, etc.)</small>		
	Identified	Tested	Diagnosed					Started on Tx	X	S	2	5			6	>7
1																
2																
3																
4																
5																
6																
7																
8																
9																
10																

TPT Case Number	Date of Screening (MM/DD/YYYY)	Date of Notification (MM/DD/YYYY)	Date Start of Treatment (MM/DD/YYYY)	Patient's Full Name (SURNAME, Given Names, Name Extensions and Middle Name)	Date of Birth (MM/DD/YYYY)	Age		Permanent Address & Contact Number (House No., Street, Barangay, City/Municipality, Province, Region & include Area Code for telephone no.)	Indication for TPT (HC/CC/H/CRG)	Regimen (6H/ 3H/ 3HR/ 4R)	Location of Tx (FB/CB/HB & DAT-specify)		Treatment Outcome (Outcome, Date MM/DD/YYYY & Reason)	Remarks (PHI/Health Number, study participated, notes, etc.)
						Type of Tx	Supporter (HCW/ F/ V/ O)							
1														
2														
3														
4														
5														
6														
7														
8														
9														
10														

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Form 6C: TB Preventive Treatment Register

ANNEX 5. Reports

REPORT 1A. QUARTERLY REPORT ON XPERT MTB/RIF, SMEAR MICROSCOPY, AND TB LAMP

(Source of Data - Form 3a. Laboratory Register for Xpert MTB/RIF and Form 3b. Laboratory Register for Smear Microscopy and TB LAMP)

Laboratory Name:			Quarter/Year:	
Region:			Date Submitted:	
Prepared by:	Name:	Signature:	Designation:	
Approved by:	Name:	Signature:	Designation:	

A. Case Finding for Tuberculosis:

Cases Examined	New		Retreatment		Total	Smear Microscopy	TB LAMP
	Xpert MTB/RIF	Xpert MTB/RIF Ultra	Xpert MTB/RIF	Xpert MTB/RIF Ultra			
1. No. of patients examined.							
2. No. of cases with positive examination results. Positivity Rate (%)							
2.1 No. of cases with Rifampicin resistance detected (RR).							
2.2 No. of cases with Rifampicin resistance not detected (T).							
2.3 No. of cases with FINAL Rifampicin resistance indeterminate (TI).							
2.4 No. of cases with MTB detected (trace), Rifampicin resistance indeterminate (TT).							
3. No. of cases with MTB not detected (N).							
4. No. of test with error/ invalid /no results (I). For TB LAMP, no. of test with indeterminate results.							
5. No. of test with INITIAL results (e.g. initial TI or initial RR, or initial TT for Xpert MTB/RIF Ultra).							
6. Total cartridges used.							

B. Case Finding for Paragonimiasis:

Cases Examined	Ziehl-Neelsen		Sodium Hydroxide (NaOH)		Total
7. No. of cases examined by method.					
7.1 No. of cases with positive results.					
	P	T	Co-I	Neg	Total
8. No. of cases examined by type of Laboratory Diagnosis.					

C. Treatment Follow-up (for Smear Microscopy only):

9. No. of cases examined by method.	For AFB	For Paragonimus Ova

Remarks: _____

REPORT 1B. QUARTERLY REPORT ON LINE PROBE ASSAY

(Source of Data – Form 3a. Laboratory Register for Xpert MTB/RIF and Form 3b. Laboratory Register for Smear Microscopy and TB LAMP)

Laboratory Name:		Quarter/Year:	
Region:		Date Submitted:	
Prepared by:	Name: _____ Signature: _____	Designation: _____	
Approved by:	Name: _____ Signature: _____	Designation: _____	

Case Finding:

Cases Examined for First Line LPA	History of Treatment		TOTAL	
	New	Retreatment	No.	%
1. Total number of cases examined for First Line LPA .				
1.1 Total number of M. tuberculosis cases examined.				
1.1.1 Total number of TB cases with resistance to Rifampicin (R) only. (RS AND RI)				
1.1.2 Total number of TB cases with high-level resistance to Isoniazid (H) only. (SR HIGH AND IR HIGH)				
1.1.3 Total number of TB cases with low-level resistance to H only and high and low resistance to Ethionamide/Prothionamide . (SR LOW, IR LOW, SR, AND IR)				
1.1.4 Total number of TB cases with resistance detected to both R and H . (RR HIGH, RR LOW, AND RR)				
1.1.5 Total number of TB cases susceptible to both R and H . (SS)				
1.1.6 Total number of TB cases with resistance indeterminate to both R and H, R indeterminate but susceptible to H, and R susceptible but indeterminate to H . (II, IS, AND SI)				
1.2 Total number of cases with negative result for <i>M. tuberculosis</i>				
1.3 Total number of TB cases with Invalid result .				

Cases Examined for Second Line LPA	History of Treatment		TOTAL	
	New	Retreatment	No.	%
1. Total number of cases examined for Second Line LPA .				
1.1 Total number of M. tuberculosis cases examined.				
1.1.1 Total number of TB cases with resistance detected to Fluoroquinolones (FLQ) only. (RS AND RI)				
1.1.2 Total number of TB cases with resistance detected to Second Line Injectable (SLI) only. (SR, IR)				
1.1.3 Total number of TB cases with resistance detected to both FLQ and SLI . (RR)				
1.1.4 Total number of TB cases susceptible to both FLQ and SLI . (SS)				
1.1.5 Total number of TB cases with resistance indeterminate to both FLQ and SLI, FLQ indeterminate but susceptible to SLI, FLQ susceptible but indeterminate to SLI . (II, IS, SI)				
1.2 Total number of cases with negative result for <i>M. tuberculosis</i>				
1.3 Total number of TB cases with Invalid result .				

No. of specimens with resistance indeterminate to specific drugs	First Line LPA			Second Line LPA		
	R (IR, IRHIGH, IRLOW, IS)	H (SI, RI)	R&H (II)	FLQ (IS, IR)	SLI (SI, RI)	FQ & SLI (II)
1. New						
2. Retreatment						
Total						

REPORT 1C. QUARTERLY REPORT ON TB CULTURE

(Source of Data - Form 3d. Laboratory Register for TB Culture and DST and TB Culture Workbooks)

Laboratory Name:		Quarter/Year:	
Region:		Date Submitted:	
Prepared by:	Name:	Signature:	Designation:
Approved by:	Name:	Signature:	Designation:

A. Case Finding:

Cases Examined	History of Treatment		TOTAL	
	New	Retreatment	No.	%
1. Total number of Baseline Cases examined in TB Culture.				
1.1 Total number of Baseline Cases with Positive result for <i>M. tuberculosis</i> .				
1.2 Total number of Baseline Cases with Non-tuberculous Mycobacteria (NTM) results.				
1.3 Total number of Baseline Cases with Negative result for <i>M. tuberculosis</i> .				
2. Total number of Baseline Cases with contaminated results.				
3. Total number of Baseline Cases sent out to another Culture Laboratory for Culture, Sub-Culture and/ or Identification testing.				
	MTB (+)	NTM	TOTAL	
4. Total number of Post Treatment Test.				

Remarks: _____

B. Recovery Rate and Culture Positivity Rate for Baseline Specimens:

Results	MTB (+)	NTM	MTB (-)	Contaminated	TOTAL
1. Total number of AFB Positive (+)	<i>(a)</i>				<i>(b)</i>
2. Total number of AFB Negative (-)					
Total	<i>(c)</i>				<i>(d)</i>
	No.				%
Recovery Rate ^(a/b)					
Culture Positivity Rate ^(c/d)					

Remarks: _____

C. Workload and Contamination Rate:

Total Number of Tests Done	Workload			Contamination <small>Bacterial/Fungal + Dissolved</small>		
	No. of Specimens	Smear Only	Smear and Culture	No. of Tubes	Total no. of Contaminated Tubes	%
1. Total Baseline Tests						
2. Total Follow-up Tests						
3. Total Post-treatment Tests						
Total						

Remarks: _____

C. Workload and Contamination Rate:

Smear Microscopy			TB Culture		
No. of Cases	No. of results released within TAT		No. of Cases	No. of results released within TAT	
	No.	%		No.	%

Number of Cases: Sum of all Baseline, Follow-up, & Post Treatment

REPORT 1D. QUARTERLY REPORT ON DRUG SUSCEPTIBILITY TEST

(Source of Data - Form 3d. Laboratory Register for TB Culture and DST and TB Solid and Liquid DST Workbooks)

Laboratory Name:		Quarter/Year:	
Region:		Date Submitted:	
Prepared by:	Name:	Signature:	Designation:
Approved by:	Name:	Signature:	Designation:

A. Case Finding:

1st Line TB DRUG SUSCEPTIBILITY TEST				
Cases Examined	History of Treatment		TOTAL	
	New	Retreatment	No.	%
1. Total number of MTB positive cases examined for 1st line DST.				
1.1 Total number of MTB positive cases resistant to Rifampicin but not to Isoniazid.				
1.2 Total number of MTB positive cases resistant to Isoniazid but not to Rifampicin.				
1.3 Total number of MTB positive cases resistant to both Isoniazid and Rifampicin.				
1.4 Total number of MTB positive cases susceptible to all first line drugs.				
1.5 Total number of MTB positive cases with other drug resistance.				
1.6 Total number of cases with non-viable results.				
1.7 Total number of cases with contaminated results.				

2nd Line TB DRUG SUSCEPTIBILITY TEST				
Cases Examined	History of Treatment		TOTAL	
	New	Retreatment	No.	%
1. Total number of MTB positive cases examined for 2nd line DST.				
1.1 Total number of MTB positive cases resistant to Fluoroquinolones only.				
1.2 Total number of MTB positive cases resistant to 2nd Line Injectable only.				
1.3 Total number of MTB positive cases resistant to both Fluoroquinolones and 2nd Line Injectable.				
1.4 Total number of MTB positive cases susceptible to all 2nd line drugs.				
1.5 Total number of cases with non-viable results.				
1.6 Total number of cases with contaminated results.				

B. Turn-Around-Time:

Number of Cases	No. of results released within TAT	
	No.	%

Number of Cases: Sum of all Baseline, Follow-up, & Post Treatment

REPORT 2. QUARTERLY REPORT ON EXTERNAL QUALITY ASSESSMENT FOR SMEAR MICROSCOPY

(Source of Data - Quality Assurance Center Records)

Region: _____ Report for _____ Quarter of _____

Province/City: _____ Date reported: _____

Quality Assurance Center: _____ Prepared by: _____

Total population of catchment area: _____ Designation: _____

TB Microscopy Laboratory	Public	Private	TOTAL
No. of TB microscopy laboratories (TML) (A)			
TML participating in EQA (B)			
$(B/A) \times 100$	%	%	%
TML with <5% major errors (C)			
$(C/A) \times 100$	%	%	%

EQA: On-site Evaluation	Number
TMLs with major error/s	(D)
Feedback done by the QAC Team to discuss corrective actions	(E)
Percentage % (E/D)	

Noted by:

NTP Medical/Nurse Coordinator
(Signature above printed name)

Note:

This form shall be submitted to the RO NTP Coordinators, together with the copy of EQA Form 3 (if On-site visit was done) and Forms 4 and 5.

REPORT 3. QUARTERLY REPORT ON TB AND TB PREVENTION NOTIFICATION AND TREATMENT

(Source of Data - Form 1. Presumptive TB Masterlist, Form 4. Notification and Treatment Cards)

Name of CHD: _____ Report for _____ Quarter of _____
 Name of Province/ HUC: _____ Date Reported: _____
 Municipality: _____ Prepared by: _____
 Name of Health Facility: _____ Designation: _____
 Population of Catchment Area: _____ Services: [] DS [] DR [] MN [] deduplication done

For Diagnosing Facilities

A. Presumptive TB Source: Presumptive TB Masterlist

	Active Case Finding	Intensified Case Finding	Enhanced Case Finding
(1) Number Screened by CXR -			
(2) Among (1), Number of Presumptive TB Identified			
	Presumptive DS-TB	Presumptive DR-TB	Total
(3) Number of Presumptive TB Identified			
(4) Among (3), Number of Presumptive Tested			
(5) Among (3), Number of Diagnosed TB Cases			

B. Diagnosed TB Cases Source: Notification Forms, DS-TB Treatment Cards, and DR-TB Treatment Cards

Classification		New		Relapse		Previously Treated (except Relapse)		Subtotal		Total
		BC	CD	BC	CD	BC	CD	BC	CD	
Pulmonary	DS									Pulmonary
	DR									
	MN									
Extra-pulmonary	DS									Extra-pulmonary
	DR									
	MN									
Unknown	MN									Unk
Subtotal	DS									DS
	DR									DR
	MN									MN
Total		<i>New</i>		<i>Relapse</i>		<i>Previously Treated</i>		<i>BC</i>	<i>CD</i>	

C. Diagnosed DR-TB Cases Source: DR-TB Treatment Cards

Classification of DR-TB Case	New	Relapse	Previously Treated (except Relapse)	Total
All Bacteriologically-confirmed RR-/ MDR-TB				
All Bacteriologically-confirmed XDR-TB				
All Clinically-diagnosed MDR-TB				
Other Drug-resistant TB cases				
Total				

D. Enrolment Status of Diagnosed Cases One Quarter Ago (COHORT: Q___Y___)

Source: Notification Forms, DS-TB Treatment Cards, and DR-TB Treatment Cards

Classification	New		Relapse		Previously Treated (except Relapse)		Total
	BC	CD	BC	CD	BC	CD	
Number Diagnosed							
Number Started on Treatment							
Number Died before Start of Treatment							
Number Refused Treatment, Lost before Start of Treatment or Unknown Status							

E. Diagnosed TB in Children

Source: Notification Forms, DS-TB Treatment Cards, and DR-TB Treatment Cards

Total TB cases less than 15 years old		Number
Pulmonary	DS-TB	
	DR-TB	
	MN	
Extra-pulmonary	DS-TB	
	DR-TB	
	MN	
Unk	MN	
Total		

F. Diagnosed All New and Relapse TB Cases (All Forms) by Age and Sex

Source: Notification Forms, DS-TB Treatment Cards, and DR-TB Treatment Cards

	0-4		5-14		15-24		25-34		35-44		45-54		55-64		>=65		Unk		Total	
	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
New																				
Relapse																				
Unk																				
Subtotal																				
Total																				

G. Source of All Diagnosed New and Relapse TB Cases (All Forms)

Source: Notification Forms, DS-TB Treatment Cards, and DR-TB Treatment Cards

Number of All New and Relapse TB Cases (All Forms)	Source of Patient																			
	Public Health Center			Other Public Facilities			Private Referral		Private Notification		Community									
Sub-types																				
Total																				

H. Xpert Testing of All Diagnosed TB Cases

Source: Notification Forms, DS-TB Treatment Cards, and DR-TB Treatment Cards

Number of All Cases		Xpert MTB/RIF Result					Total
		RR	T	TI	N	Not Done	
New	DS						
	DR						
	MN						
Relapse	DS						
	DR						
	MN						
Other Retreatment	DS						
	DR						
	MN						
Total							

For Treating Facilities

I. TB Cases Started on Treatment *Source: Notification Forms, DS-TB Treatment Cards, and DR-TB Treatment Cards*

Classification		New		Relapse		Previously Treated (except Relapse)		Subtotal		Total
		BC	CD	BC	CD	BC	CD	BC	CD	
Pulmonary	DS									Pulmonary
	DR									
	MN									
Extra-pulmonary	DS									Extra-pulmonary
	DR									
	MN									
Subtotal	DS									DS
	DR									DR
	MN									MN
Total		<i>New</i>		<i>Relapse</i>		<i>Previously Treated</i>		<i>BC</i>		

J. DR-TB Cases Started on Treatment *Source: DR-TB Treatment Cards*

Classification and Regimen of DR-TB Case		New	Relapse	Previously Treated (except Relapse)	Total
All Bacteriologically-confirmed RR-/ MDR-TB	SSOR				
	SSTR				
	SLOR FQ-S				
	SLOR FQ-R				
	BPaL				
	Individualized Regimen				
	With BDQ				
With Dlm					
With BDQ and DLM					
All Bacteriologically-confirmed XDR-TB					
All Clinically-diagnosed MDR-TB					
Other Drug-resistant TB cases					
Total					

K. LPA Testing of Drug-resistant TB Cases (Cohort: Q___ Y___) *Source: DR-TB Treatment Cards*

Classification and Regimen of DR-TB Case		Tested		Not Tested (Invalid, Not Done)	H ^a -res	Pto-res	FQ-res
		MTB Detected	MTB Not Detected				
All Bacteriologically-confirmed RR-/ MDR-TB	SSOR						
	SSTR						
	SLOR FQ-S						
	SLOR FQ-R						
	BPaL						
	Individualized Regimen						
	With BDQ						
With Dlm							
With BDQ and DLM							
All Bacteriologically-confirmed XDR-TB							
All Clinically-diagnosed MDR-TB							
Other Drug-resistant TB cases							
Total							

L. HIV Status of TB Cases Started on Treatment Among 15 Years Old and Above (Cohort: Q___ Y___)

Source: DS-TB Treatment Cards, and DR-TB Treatment Cards

	Number of TB Cases registered for the quarter (15 years old and above)	No. of cases tested or with known HIV status during the quarter	No. of TB cases confirmed positive for HIV (new & previously known)	Among HIV positive, number given	
				ART	CPT
DS-TB					
DR-TB					
Total					

M. DM Status of TB Cases Started on Treatment Among 25 Years Old and Above (Cohort: Q___ Y___)

Source: DS-TB Treatment Cards, and DR-TB Treatment Cards

	Number of TB Cases registered for the quarter (25 years old and above)	No. of cases risk assessed/ screened for DM during the quarter	No. of TB cases diagnosed with DM (new & previously known)	Among TB-DM patients, no. with DM managed	
DS-TB					
DR-TB					
Total					

N. Treatment Supporter of TB Cases Started on Treatment (Cohort: Q___ Y___)

Source: DS-TB Treatment Cards, and DR-TB Treatment Cards

	DS-TB	DR-TB	Total
Facility-based			
Community-based			
Self-administered			
DAT-based			
Total			

O. Clinical Research Participation

Title of Research	Number of TB Cases Registered during the Quarter

P. Contact Tracing of Cases Started on Treatment (Cohort: Q___ Y___)

Source: DS-TB Treatment Cards, and DR-TB Treatment Cards

	Children		Adult		Total
(1) Number of Contacts Identified					
(2) Among (1), Number of Contacts Tested					
(3) Among (2), Number of Contacts Diagnosed with TB	DR:	DR:	DR:	DR:	
(4) Among (3), Number of Contacts Started on TB Treatment*					

*includes patients referred and treated in other facilities

Q. Individuals Given TPT

Source: TPT Card

		6H	3HP	3HR	4R	TOTAL
Contact (without HIV)	Children age 0-4					
	Children age 5-14					
	Adult					
PLHIV						
Clinical Risk Groups						
Total						

REPORT 4A. MONTHLY REPORT ON FLD, SMEAR MICROSCOPY, AND XPERT INVENTORY AND REQUIREMENT

(Source of Data – Stock Cards and Delivery Receipts)

Name of CHD: _____ Report for _____ Month of _____
 Name of Province/ HUC: _____ Date Reported: _____
 Municipality: _____ Prepared by: _____
 Name of Health Facility: _____ Designation: _____

A. First Line Anti-TB Drugs

Item	Starting Balance	Delivery from			Transfer-in Items	Transfer-out Items	Damaged/Expired	Consumption	Stock-on-Hand	Stock Required
		Donation	LGU	DOH						
(a)	(+b)	(+c)	(+d)	(+e)	(+f)	(-g)	(-h)	(-i)	(+j)	(=k)
4FDC (Rifampicin + Isoniazid + Pyrazinamide + Ethambutol)										
2FDC (Rifampicin + Isoniazid)										
Isoniazid 300mg Tablets – For IPT										
Isoniazid 200mg/5mL Syrup – For IPT										
Rifampicin 200mg/5mL suspension (Anti-TB Drugs for Children)										
Isoniazid 200 mg/5mL syrup (Anti-TB Drugs for Children)										
Pyrazinamide 250mg/5mL suspension (Anti-TB Drugs for Children)										
Ethambutol 400mg tablet (Anti-TB Drugs for Children)										
Purified Protein Derivatives										
4FDC (Rifampicin + Isoniazid + Pyrazinamide + Ethambutol)										
2FDC (Rifampicin + Isoniazid)										

B. Laboratory Supplies

Item	Starting Balance	Delivery from			Transfer-in Items	Transfer-out Items	Damaged/Expired	Consumption	Stock-on-Hand	Stock Required
		Donation	LGU	DOH						
(a)	(+b)	(+c)	(+d)	(+e)	(+f)	(-g)	(-h)	(-i)	(+j)	(=k)
Xpert Cartridges										
Sputum Cups										

REPORT 4B. MONTHLY REPORT ON SLD INVENTORY AND REQUIREMENT

(Source of Data – Stock Cards and Delivery Receipts)

Name of CHD: _____ **Report for** _____ **Month of** _____
Name of Province/ HUC: _____ **Date Reported:** _____
Municipality: _____ **Prepared by:** _____
Name of DOTS Facility: _____ **Designation:** _____

A. Second Line Anti-TB Drugs

Item	Starting Balance	Delivery from			Transfer-in Items	Transfer-out Items	Damaged/Expired	Consumption	Stock-on-Hand	(1 quarter) Buffer	Stock Required
		Donation	LGU	DOH							
(a)	(+b)	(+c)	(+d)	(+e)	(+f)	(-g)	(-h)	(-i)	(+j)	(+k)	(=l)
Isoniazid 300mg											
Rifampicin 300mg											
Pyrazinamide 500mg											
Ethambutol 400mg											
Kanamycin 1g											
Capreomycin 1g											
Levofloxacin 250mg											
Levofloxacin 500mg											
Moxifloxacin 400mg											
Prothionamide 250mg											
Cycloserine 250mg											
PASER 4g											
PAS Na											
Clofazimine 50mg											
Clofazimine 100mg											
CoAmoxiclav 1g											
Clarithromycin 500mg											
Linezolid 600mg											
Bedaquiline 100mg											
Imipenem+Cilastatin 500mg											
Pyridoxine 50mg											
Delamanid 50mg											
Amikacin 500mg											

B. Ancillary Drugs

Item	Starting Balance	Delivery from			Transfer-in Items	Transfer-out Items	Damaged/Expired	Consumption	Stock-on-Hand	(1 quarter) Buffer	Stock Required
		Donation	LGU	DOH							
(a)	(+b)	(+c)	(+d)	(+e)	(+f)	(-g)	(-h)	(-i)	(+j)	(+k)	(=l)

REPORT 5. QUARTERLY REPORT ON TB AND TB PREVENTIVE TREATMENT OUTCOMES

(Data Source: Form 4. TB Notification and Treatment Cards)

Name of CHD: _____ Cohort for cases registered in _____ Quarter of _____
 Name of Province/ City: _____ Date Reported: _____
 Municipality: _____ Prepared by: _____
 Name of DOTS Facility: _____ Designation: _____
 Population of Catchment Area: _____ Services: [] DS [] DR [] MN

A. Final Outcome of New and Relapse non-RRTB Diagnosed One Year Ago

Total Number of Diagnosed TB Cases	TB Classification		Cured	Completed	Died		Failed	Lost to Ff-up		Not Evaluated	Sub-Total	Total
					Prior Tx	During Tx		Prior Tx	During Tx			
New	DOTS	BC										
		CD										
	MN	BC										
		CD										
	Other DR	BC										
		CD										
Relapse	DOTS	BC										
		CD										
	MN	BC										
		CD										
	Other DR	BC										
		CD										
Sub-Total	BC											
	CD											
Total												

Number of DR-TB cases not included in Table A = _____

Number of cases excluded from the cohort = _____

B. Final Outcome of Previously Treated non-RRTB Diagnosed One Year Ago

Total Number of Diagnosed TB Cases	TB Classification	Cured	Completed	Died		Failed	Lost to Ff-up		Not Evaluated	Total
				Prior Tx	During Tx		Prior Tx	During Tx		
	DS	BC								
		CD								
	MN	BC								
		CD								
	Other DR	BC								
		CD								
	Sub-total	BC								
		CD								
	Total									

Number of DR-TB cases not included in Table B = _____

Number of cases excluded from the cohort = _____

C. Final Outcome of Other Cohorts Diagnosed One Year Ago

Total Number of Diagnosed TB Cases		Cured	Completed	Died		Failed	Lost to Ff-up	Not Evaluated*	Total
				Prior Tx	During Tx				
	PLHIV cases (ALL REGISTRATION GROUPS)								

* Includes patients that are still on treatment at the time of this reporting.

D. Final Outcome of TB Preventive Treatment Cohort Started on Treatment One Year Ago

Total Number of TPT Cases Started on Treatment		Completed	Died	Failed	Lost to Ff-up	Not Evaluated	Total
	Contacts	0-4 y/o					
		5-14 y/o					
		Adult					
	PLHIV						
	Clinical Risk Groups						
	Total						

Number of cases excluded from the cohort = _____

E. Final Outcome of DS-TB Cases Based on Treatment Location Started on Treatment One Year Ago

Total Number of DS-TB Cases Started on Treatment	Treatment Supporter	Cured	Completed	Died	Failed	Lost to Ff-up	Not Evaluated	Total
	Facility-based							
	Community-based							
	Home-based							
	DAT-Based							
	Total							

Number of cases excluded from the cohort = _____

F. Final Outcome of TPT Cases Based on Treatment Location Started on Treatment One Year Ago

Total Number of TPT Cases Started on Treatment	Treatment Supporter	Completed	Died	Failed	Lost to Ff-up	Not Evaluated	Total
	Facility-based						
	Community-based						
	Home-based						
	DAT-Based						
	Total						

Number of cases excluded from the cohort = _____

G. Interim Outcome of All DR-TB Cases Diagnosed One Year Ago

Total Number of Diagnosed DR-TB Cases	Classification of DR-TB		Still on Treatment: Bacteriological result at 6th month			No Longer on Treatment			Sub-total	Not Started on Treatment		Total
			Negative	Positive	Not Evaluated	Failed	Died	LTFU		Died	LTFU	
	All Bacteriologically-confirmed RR-/MDR-TB	SSOR										
		SSTR										
		SLOR FQ-S										
		SLOR FQ-R										
		BPaL										
		ITR										
		With BDQ										
		With Dlm										
		With BDQ and DLM										
	All Bacteriologically-confirmed XDR-TB											
	All Clinically-diagnosed MDR-TB											
	Other Drug-resistant TB cases											
	Total											

Number of cases excluded from the cohort = _____

H. Interim Outcome Based on Treatment Supporter of All DR-TB Cases Started on Treatment One Year Ago

Total Number of TB Cases Started on Treatment	Treatment Supporter	Still on Treatment: Bacteriological result at 6th month			No Longer on Treatment			Total
		Negative	Positive	Not Evaluated	Failed	Died	LTFU	
	Facility-based							
	Community-based							
	Home-based							
	DAT-based							
	Total							

Number of cases excluded from the cohort = _____

I. Patients on Novel Drugs Started on Treatment One Year Ago

Drug	No. of Patient on Drug for More than 6 Months
Bdq	
Dlm	

J. Final Outcome of All DR-TB Cases Diagnosed Two Years Ago

Total Number of Diagnosed DR-TB Cases	Classification of DR-TB	Cured	Completed	Died			Lost to Ff-up		Not Evaluated	Still Ongoing*	Total
				Prior Tx	During Tx	Failed	Prior Tx	During Tx			
	All Bacteriologically-confirmed RR-/MDR-TB	SSOR									
		SSTR									
		SLOR FQ-S									
		SLOR FQ-R									
		BPaL									
		ITR									
		With BDQ									
		With Dlm									
		With BDQ and DLM									
	All Bacteriologically-confirmed XDR-TB										
	All Clinically-diagnosed MDR-TB										
	Other Drug-resistant TB cases										
	Total										

* Patients that are still on treatment at the time of this reporting.

Number of cases excluded from the cohort = _____

K. Final Outcome Based on Treatment Supporter of All DR-TB Cases Started on Treatment Two Years Ago

Total Number of TB Cases Started on Treatment	Treatment Supporter	Cured	Completed	Died	Failed	Lost to Ff-up	Not Evaluated	Still Ongoing*	Total
	Facility-based								
	Community-based								
	Home-based								
	DAT-based								
	Total								

* Patients that are still on treatment at the time of this reporting.

Number of cases excluded from the cohort = _____

L. Post Treatment Ff-up of:

	DR-TB Cases Given Short Regimen Two Years Ago	DR-TB Cases Given Long Regimen Three Years Ago
(1) Number of Cases Successfully Treated		
(2) Among (1), Number of Cases that had Post Treatment At Least Once in the Current Year		
(3) Among (2), Number of Relapse Cases		

M. Post Treatment Outcome of All DR-TB Cases Started on Treatment Three Years Ago

Total Number of Diagnosed DR-TB Cases	Classification of DR-TB	Non-relapsing Cure	Relapse	Died	Lost to Ff-up	Total
	All Bacteriologically-confirmed RR-/ MDR-TB	SSOR				
		SSTR				
		SLOR FQ-S				
		SLOR FQ-R				
		BPaL				
		ITR				
		With BDQ				
		With Dlm				
		With BDQ and DLM				
		All Bacteriologically-confirmed XDR-TB				
	All Clinically-diagnosed MDR-TB					
	Other Drug-resistant TB cases					
	Total					



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