2019

National Tuberculosis Management Guidelines

Government of Nepal
Ministry of Health and Population
Department of Health Services
National Tuberculosis Centre
Thimi, Bhaktapur

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FOREWORD

Tuberculosis remains a public health problem in Nepal. TB is one of Nepal's top health challenges. It is estimated that 45000 new cases of active TB occur in the country annually, with nearly 6000-7000 deaths due to TB. Male are found to develop TB disease nearly twice more than female. Each day, about 123 people fall ill due to TB and 20 people die due to this preventable and curable disease in Nepal.

National TB Programme implemented the DOTS strategy since 1996 and adopted the Stop TB Strategy in 2006. With the end of Millennium Development Goal (MDG) era in 2015, NTP has now entered a new phase of END TB STRATEGY with aims to end TB epidemic in Nepal, with targets to reduce TB deaths by 95% and to cut new cases by 90% between by 2035 as compared to 2015, and to ensure that no family is burdened with catastrophic costs due to TB. This Strategy sets out directions to achieve NTP goals and targets set for the coming years in line with the Global End TB Strategy.

This new guideline describes briefly about National Tuberculosis Programme (NTP) policies and roles and responsibilities of different levels of the Government including community and TB patient, national treatment and diagnostic policies and guidelines for managing people with tuberculosis and other supporting components of the programme. This guideline must be used by the doctors, paramedics, nurses, TB experts, TB service providers and trainers as the reference for the management of TB patients. This is primarily for health staff working at the central hospitals up to the primary health care centre in the community. It can also to be used as a reference for policymakers and managers.

We would also like to take this opportunity to acknowledge the contributions by my team at NTC for their valuable efforts during the preparation of this guideline. Our special thanks go to the WHO country office Nepal particularly to the communicable disease team for the strong technical support for the development of this guideline based on the latest WHO recommendations. We would also like to acknowledge and thank the previous director at NTC Dr Bhim Singh Tinkari for his leadership and guidance in the preparation of this document. We would further like to thank all the contributing members, experts, partners and organizations who actively engaged and contributed to the development of this important guideline.

Dr. Sagar Rajbhandari
Director

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ABBREVIATIONS

AFB	Acid-Fast Bacillus
AM	Amikacin
AIDS	Acquired Immuno-Deficiency Syndrome
ART	Anti-Retroviral Therapy
BCG	Bacillus Calmette-Guerin (vaccine)
BMU	Basic Management Unit
BMI	Body Mass Index
Cat	Treatment Category
CNS	Central Nervous System
CPT	Cotrimoxazole Preventive Therapy
CSS	Community System Strengthening
CFR	Case Fatality Rate
CNR	Case Notification Rate
CM	Centimetre
CXR	Chest X-ray
CSF	Cerebrospinal Fluid
CM	Capreomycin
DC	Disease Control
DOT	Directly Observed Treatment
DOTS	Directly Observed Treatment, Short Course, (TB Strategy)
DRTB	Drug Resistant Tuberculosis
DPT	Diphtheria Preventative Therapy (DPT)
DST	Drug Susceptible Test
DRS	Drug Resistant Survey
E	Ethambutol
EQA	External Quality Assurance
Eto	Ethionamide
EPTB (EP)	Extra-pulmonary tuberculosis
EFV	Efavirenz
FDC	Fixed Dose Combination
FEFO	First expiring, first out
FoDST	Fluoroquinolone Drug Susceptible Tuberculosis
FNA	Fine Needle Aspiration
FNAB	Fine Needle Aspiration Biopsy
FNAC	Fine Needle Aspiration Cytology
GA	Gastric Aspirate
H	Isoniazid
HC	Health Centre
HEO	Health Extension Officer
HIV	Human Immunodeficiency Virus
HPF	High Power Field (i.e. 100x10 magnification)
HMIS	Health Management Information System
HSC	Health Sub-Centre
HRZE	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol

HR	Isoniazid, Rifampicin
HRZELfx	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol, Levofloxacin
H&Fq	Isoniazid, Fluoroquinolone
HCW	Health Care Worker
INH	Isoniazid
IPT	Isoniazid Preventive Therapy
IDP	Internally Displaced People
KM	Kanamycin
LPV/r	Lopinavir Ritonavir
LIP	Lymphocytic Interstitial Pneumonia
LJ	Lowenstein-Jensen
MDR	Multi-Drug Resistant
M & E	Monitoring and Evaluation
MTB	Multi Drug Resistant Tuberculosis
MTB/RIF	Multi Drug Resistant TB/Rifampicin Resistant
MAM	Moderate Acute Malnutrition
MUAC	Mid Upper Arm Circumference
mg	Milligram
NTC	National Tuberculosis Programme
NTP	National Tuberculosis Programme
NVP	Nevirapine
NRL	National Reference Laboratory
NG	Nasogastric Tube
Ofx	Ofloxacin
PMDT	Programmatic Management of Drug Resistant Tuberculosis
PICT	Provider Initiated Counselling and Testing
PTB	Pulmonary Tuberculosis
PBC TB	Pulmonary Bacteriological Confirmed Tuberculosis
PYZ	Pyrazinamide
PLHIV	People Living with HIV
PAS	Para Amino Salicylic Acid
QMRL	Quality Management in Reference Laboratory
R/RIF	Rifampicin
RR/MDR	Rifampicin Resistant/ Multi Drug Resistant
SDG	Sustainable Development Goal
SAM	Severe Acute Malnutrition
SL-LPA	Second Line- Line Probe Assay
SLD	Second Line Drug
SS-ve	Sputum Smear Negative
SS+ve	Sputum Smear Positive
SOP	Standard Operation Procedure
TB	Tuberculosis
TB/HIV	Tuberculosis/Human Immune Virus
TBM	Tuberculosis Meningitis
TWG	Technical Working Group
UVGI	Ultraviolet Germicidal Irradiation
VCT	Voluntary Counselling and Testing (for HIV/AIDS)
WHO	World Health Organization
W/A	Weight for Age
XDRTB	Extremely Drug Resistant Tuberculosis
Z	Pyrazinamide

CHAPTER 1

INTRODUCTION AND INFORMATION ON THE NATIONAL TB PROGRAM

1.1 INTRODUCTION

This guideline is to provide basic information about TB and its management to all health workers in Nepal. Early detection, appropriate diagnosis and timely treatment of TB result in good treatment outcomes. Health workers need to be equipped with the right information on the diagnosis and treatment of TB. **Poor management of TB results in death and creates drug resistant (DR) TB** which is very hard and costly to treat resulting in often poorer outcomes.

All health workers in Nepal regardless of their involvement in TB services should be aware of TB, its transmission and prevention and its diagnosis and management. Health workers managing TB patients need proper guidance in diagnosis and treatment of TB and it is for this purpose that this guideline is produced. In developing this guideline, the National TB Program takes into consideration the emerging problems of TB/HIV and DR TB as well as other revisions including Latent TB infection made to TB management by World Health Organization. This guideline is therefore, an update from the 2012 General Manual (Third Edition) and the following are the major changes to TB management for Nepal:

- Only 2 sputum samples required for initial diagnosis of TB.
- Same-day diagnosis of TB by Microscopy (2 samples same day-1 hour apart)
- Only 1 sputum sample required for follow up examination.
- Even new presumptive TB cases should have access to GeneXpert diagnosis whereever it is possible
- Treatment is not extended at the end of the intensive phase, even though the sputum follow up examination result remains positive at the end of two months, continuation phase is commenced regardless of whether the sputum is positive or not.
- Streptomycin containing Category II regimen for retreatment cases will ***No Longer*** be used in Nepal
- New definitions
    - TB suspect is changed to Presumptive TB
    - Previously treated patients' definitions have been changed and are based on the outcome of their most recent course of treatment and are independent of bacteriological confirmation or site of disease.
    - The treatment regimen for re-treatment TB cases has been removed. All previously treated TB patients will receive new treatment regimen and will be screened for drug resistant TB.
    - Recording and reporting forms have been edited to suit new definitions and change in the treatment regimen

1.2 NATIONAL TB STRATEGY ALIGNMENT TO END TB STRATEGY AND THE RESPONSIBILITIES OF TB TEAMS AT DIFFERENT LEVELS

WHO's End TB Strategy, developed within the context of the United Nations Sustainable Development Goals (SDGs), is a logical evolution, reflecting a paradigm shift from past global TB strategies. The original WHO DOTS strategy of 1994 created the basis for effective TB control activities by standardizing the requirements for addressing the epidemic. WHO's Stop TB Strategy of 2006 broadened this response by addressing the emerging challenges of HIV- associated TB and MDR-TB. It contributed to improving access to quality TB care by engaging all public and private care providers, and civil society organizations and communities, and it encouraged investment in research to develop better tools and approaches. Ending the TB epidemic is one of the SDG targets that requires the implementation of a mix of biomedical, public health and socioeconomic interventions, often extending beyond the health sector, along with major breakthroughs in research and innovation to accelerate the decline in global TB incidence rates to reach the 2030 and 2035 targets for the End TB Strategy.

The End TB Strategy encompasses a comprehensive package of interventions based on three fundamental pillars and four underlying principles (Fig. 1).

FIGURE 1. WHO's End TB Strategy: Three fundamental pillars and four underlying principles

In line with WHO recommended End TB Strategy, Nepal National TB Programme developed its five years National TB Strategy Plan for 2016 to 2021 which is intended at effectively carrying out interventions for ending TB by increasing the local ownership, support and participation in all provinces and involving all healthcare workers and the community to reduce the suffering and socioeconomic burden associated with TB. The National TB strategy 2016 to 2021 is framed to implement the well-proven and effective DOTS strategy for TB control adapting to local health systems in Nepal and will be aligned to the End-TB strategy in the delivery of TB services.

The Vision, Goal and objectives of the National Strategy Plan are as follows:

Vision

To end the TB by 2030 and make Nepal free of TB by 2050.

Nepal has set an ambitious vision of ending TB in Nepal by 2050 in accordance with the National Health Policy 2014 and under the strategic direction of the worldwide initiative to end TB –The End TB Strategy. Ending TB is defined as a decrease in incidence rate of more than 80% by 2030 and 90% by 2035 compared to 2015 baseline. It is believed that a rapid expansion of the quality TB care services leading to increased access and effective implementation of the program through responsible and integrated health system, intensified case finding and using appropriate preventive measures will help achieve the vision.

Goal

To decrease the TB Incidence Rate by 20% by 2021 as compared to 2015. It may not only be difficult but may even be impossible to measure the part of the goal. Nevertheless, the prevalence survey being undertaken in 2018/19 will provide a true picture on the burden of TB disease for the first time, which will also be used to measure the achievement of the goal.

Objective 1: To increase the TB case notification rate by strengthening the facility-based TB diagnostic services

To increase the diagnosis and treatment of TB among children from 6% to 10% by 2021, to expand the TB diagnostic services in the vulnerable population like people who have come in close contact with a case of TB, people with diabetes, HIV and increase the case notification rate among these population, for instance, to increase the diagnosis of TB in HIV positive patients to more than 1100 cases by 2021.

Objective 2: To achieve and sustain the treatment success rate of 90% for all forms of TB (except drug resistant TB) by 2021

Objective 3: To diagnose 50% of the MDR TB patients by 2018 and 100% by 2021 and to successfully treat at least 75% of those diagnosed.

Objective 4: Formal agreements will be made with different government and non-government organizations, medical colleges and private firms on the basis of result-based financing model in order to implement the program and strengthen the TB diagnosis and treatment services.

Objective 5: Community System Strengthening Program (CSS) will be gradually implemented at 60% of the local administrative units by 2018 and to 100% of the administrative units by 2021. It will help in creating a patient-friendly ambiance in the health facilities, advocacy for TB patients regarding their rights, which will, in turn, contribute to the diagnosis and management of TB cases

Objective 6: To contribute to the NTP strengthening process by human resource management, capacity building, financial management, infrastructure development and logistics management and supplies

Objective 7: To carry out the Tuberculosis Prevalence Survey and develop monitoring and supervision system

Objective 8: To formulate plans so that NTP can function even at times of crises like natural disasters.

Nepal Government recognizes the responsibility of contribution towards the global efforts of ending the TB epidemic by 2030 by increasing access and availability of quality TB services in the country supported by out reached activities. The National Strategic Plan (NSP) for Tuberculosis Prevention, Care and Control (2016-2021) incorporates the sentiments of the constitution of Nepal, the current health policies, aligns to the international strategy such as the End TB Strategy and takes into consideration the rights of the people, inclusive of vulnerable population and community affected by Tuberculosis.

The implementation of this strategy by the TB Control Programme under the federal and local context through the strengthening of the health services at all levels will increase access to affordable, patient-friendly prevention, diagnosis, treatment and care with the goal of ending the TB epidemic in the country which will, in turn, contribute towards global targets.

Quality TB services will be delivered through the existing health service delivery network consisting of hospitals, primary health care centers, outreach clinics and several microscopy centers backed by National Reference Laboratories.

The Government of Nepal has increasingly engaged in multi-sectoral innovative approaches including community engagement, use of newer diagnostics and new drugs and shorter MDR-TB regimen in responding to the TB epidemic.

To ensure full impact of these actions, Government is committed to take stewardship and engagement of the wider set of collaborators across government, partners, civil societies and community in expanding scope and reach of intervention for TB care and prevention and in perusing contextualized innovations that can dramatically change TB prevention and care in the country. Nepal has also aligned the roles and functions of various levels of health care system in the context of decentralized system for efficient delivery of TB services to its people. The functions of different levels are as below:

A1. National Level (NTP)

- Develop the National policies, strategies, standards, and guidelines on TB management. Support Provinces and sub-national levels for capacity building.
- Support planning, coordination, monitoring and evaluation of ending TB activities with concerned stakeholders and partners.
- Monitoring and supportive supervision of tuberculosis service delivery.
- Manage and advise on the procurement and distribution of TB drugs and supplies.
- Prepare standardized tools for recording and reporting, health education and training materials for TB
- Analyse all reported TB data, produce reports and feedback to lower levels
- Plan and carry out capacity enhancement activities at all levels on TB management
- Coordinate with partner agencies

- Serve as secretariat to the TB Technical working group
- Ensure and advocate for budget allocation for implementation of the program.
- Collaborate with other diseases contral programs and centers like HIV, Diabetes, and RMNCAH for organizing effective cross-referral, monitoring and coordination.

A2. TB Technical Working Group (TWG) in National Tuberculosis Programme

National Technical Working Group for Tuberculosis (TB TWG) was formed in 2013. Given the crucial need to have a coordinated mechanism for quality TB programme delivery in the country, the National Technical Working Group for Tuberculosis (TB TWG) was formally endorsed by the Honourable Secretary of the Ministry of Health and Population (MOHP) on 26 November 2018.

The terms of reference of the TWG are as follows:

- Support to establish governance arrangement and management structure for the programme through the meaningful involvement of technical experts, development partners, other stakeholders and civil societies into the process of technical advice, coordination and resource mobilization
- Provide a forum for technical discussion and advice in overall TB programme approaches including in the areas TB care and prevention, TB/HIV collaborative approaches, PPM, DRTB, CSS, etc. in line with the National TB Strategic Plan for Nepal (2016-2021)
- Promote understanding and support for the Programme targets among technical institutions, professional associations and bilateral/multilateral and other relevant agencies/partners;
- Ensure broad agreement of all relevant stakeholders and key experts regarding the structure and content of the relevant programmatic directions
- Ensure availability of key local and international technical expertise during the development of the initial request for any funding and resource mobilization for TB Programs from different donors
- Ensure stakeholder/s contributions are harmonized and are aligned with the National Strategic Plan for TB Control in Nepal 2016-2021
- Ensure quality program planning, implementation and monitoring is in line with the National Strategic Plan for Ending TB in Nepal
- To advise on operational research, implementation lessons and other research evidence from both local and international contexts and ensure that it is used to inform decision-making, revision of policies and inform programme planning and implementation where appropriate
- To provide oversight and coordination of all different funding sources for TB programme, grants and projects related to TB service delivery
- To provide high-quality technical advice and technical sign off on any proposal, operational research, pilot and other related activities for health-related to TB service delivery
- Make technical recommendations that will help to strengthen national efforts to implement policies and strategies for Ending TB, including M/XDR-TB and TB/HIV co-infection in line with the Health System Strengthening, and help to monitor progress through set targets in line with the NSP (2016-2021)
- Facilitate the governmental and non-governmental partners to share up-to-date information, to collectively trouble-shoot problem areas and to discuss possibly contentious issues
- Provide technically sound and relevant programmatic directions in a coordinated manner and to provide support to the NTC in its efforts to provide access to high-quality TB services in the country

B. Provincial Health Directorate (PHD) Office

- Align plan, policies and strategies for TB programme implementation in line with national policy and standards
- Carry out capacity enhancement activities at provincial and local levels of health care workers on TB management
- Implement, coordinate and supervise tuberculosis control activities
- Review, validate, compile and send quarterly reports on case-finding and treatment to NTP on time (end of the month following the quarter that just ended)
- Coordinate with partner agencies in the provinces
- Request, receive, distribute and manage TB drugs, diagnostics and other supplies for the diagnosis and management of TB
- Monitor and provide supportive supervision at the provincial level
- Establish provincial TB, TB /HIV and PMDT committees and coordinate implementation of their respective activities in their provinces
- Provide feedback to the health facilities on the quality of the reports
- Conduct and ensure external quality assurance (EQA) for sputum microscopy and other diagnositic services for TB diagnosis centres
- Coordinate with partners and mobilise community-based organizations to support monitoring and implementation of TB activities
- Collaborate with other disease programmes like HIV, Diabetes, and RMNCAH for organizing effective cross-referral, monitoring and coordination

C. District Level

- Coordinate with a focal point for TB at the municipalities
- Develop TB service plan at the district level
- Manage, organise and facilitate TB training to health workers
- Monitor and supervise district TB programme
- Implement TB programme following the national policies and guideline
- Manage drugs, reagents and required logistics for the programme
- Coordinate with different stakeholders at the district level
- Organise awareness and education programme to increase knowledge on TB in the community
- Ensure proper recording keeping and reporting as per NTP guidelines
- Update recording and reporting and master register on a monthly basis in HMIS-9.3
- Coordination and monitor cross-referral between other programmes like HIV, Diabetes and RMNCAH
- Establish district PMDT committee to monitor programme for drug-resistant TB

D. Local Level (Palikas)

- Support the focal point for TB at the treatment centre
- Develop TB service plan for treatment centres that are under local levels
- Manage, organise and facilitate TB training to health workers

- Organise supportive supervision at the treatment centre to enhance the performance of the programme
- Organise quarterly review of performance of treatment and diagnostic centres
- Coordinate with different stakeholders at the local level in TB service delivery
- Implement the programme following the national policies and guidelines
- Manage drugs, reagents and required logistics for the programme
- Organise awareness and education programme to increase knowledge on TB in the community
- Provide transportation and other treatment enablers where applicable

E. Health Facility and Health Worker Levels

- Diagnose and initiate TB treatment and preventive treatment where applicable ensuring quality and accurate diagnosis and right treatment
- Provide directly observed Treatment (DOT) for all TB patients through health worker-based DOT or Community-based DOT.
- Monitor TB treatment through regular follow up sputum examinations and reviews.
- Trace and retrieve lost to follow up and or patients missing treatment or poor compliant patients.
- Complete and update all recording and reporting forms including TB treatment cards and registers and submit monthly/quarterly reports on time
- Provide health education and counselling to the patients and the community.
- Supervise peripheral health staff and treatment supporters in giving DOT.
- Collaborate with the microscopy/diagnostic services, for examination of sputum or other biological specimens.
- Coordinate referral of TB patients between hospitals and peripheral centres.
- Promote and implement TB/HIV activities and referral of presumptive MDR TB
- Organise contact investigation activities in the community
- Supply and update necessary information to the treatment providers
- Manage necessary drugs, reagent and other necessary logistics for the TB programme
- Update records of patient details and report on time using appropriate forms.

F. DOT/Treatment Provider at the community level (eg. CBDOT provider)

- Provide daily DOT to a patient and maintain treatment card
- Educate patients on TB and counsel them for treatment adherence
- Recognize adverse events during treatment and refer where necessary
- Complete necessary patient documentation;
- Collaborate with local health facilities (public/private)
- Visit treatment centre twice a month to collect drugs for patients or as needed
- Support TB patients to ensure they do all necessary follow up at the Treatment centers along with regular follow up sputum (2/3, 5 and end of the treatment) by the patient and maintain their test results.
- Report patient treatment status to the Treatment centre in the given format

- Maintain the confidentiality of the patients
- Refer the presumptive TB patient for sputum test support in contact investigation where possible
- If DOT provider will be absent for providing DOT due to their personal reasons, manage alternate options.
- Refer for psychological, social and legal support and other services including substance abuse treatment; joint (integrated) support for TB patients with addictive behaviours
- Ensure completion of treatment of patients under their care

G. Patient and Community Level

- TB patients to faithfully take TB drugs under supervision and complete treatment
- Attend regular follow-ups with the health facility staff for monitoring of treatment, submit sputum on time for follow up and report side effects
- The community to supervise and support TB patients to ensure treatment completion
- Refer presumptive TB sputum samples to microscopy centres for investigation
- Directly observe all TB patients in their communities
- Mobilise patient and peer support groups, which may help also reduce stigma

CHAPTER 2

BACKGROUND ON TUBERCULOSIS BURDEN

2.1 GLOBAL TB BURDEN

TB is an old disease that was once a death sentence. Effective drug treatments first became available in the 1940s, and in combination with social and economic development they allowed countries in western Europe, North America and some other parts of the world to reduce their burden of TB disease to very low levels. For most countries, however, the "End" of TB as an epidemic and major public health problem remains an aspiration rather than a reality. The UN high-level meeting on TB on 26 September 2018, with attendance of heads of state and other eminent people, provided a platform to step up the commitments and actions needed to end the global TB epidemic, by the SDG deadline of 2030. Worldwide, TB is one of the top 10 causes of death and the leading cause of a single infectious agent (above HIV/AIDS). Millions of people continue to fall sick with TB each year. Globally, nearly 10 million population developed TB in 2017 and TB caused an estimated 1.3 million deaths (including 0.3 million among people with HIV) in the same year, making TB one of the leading cause of deaths for HIV-positive people. There were cases in all countries and age groups, but overall 90% were adults (aged ≥15 years) and 64% of them were males, 9% were people living with HIV. South East Asia Region alone holds nearly 45 % of global TB cases. Almost 10% of TB is still among the children. Because diagnosing and reporting of TB in children has always been difficult and faces lots of technical and programmatic challenges. WHO's list of 30 high TB burden countries accounted for 87% of the world's cases with India alone holding nearly 27% of cases followed by 9% of cases in China. One of key factor contributing to TB is smoking tobacco, which nearly increases the risk of TB by two and half times. More than 20% of global TB incidence may be attributable to smoking. Controlling the tobacco epidemic will help control the TB epidemic. By 2020, the TB incidence rate (new cases per 100 000 population per year) needs to be falling at 4–5% per year, and the proportion of people with TB who die from the disease (the case fatality ratio, CFR) needs to fall to <=5%. The disease burden caused by TB is falling globally but not fast enough to reach the first (2030) milestones of the End TB.

MDR-TB remains a public health crisis and a health security threat. In 2017, WHO estimates that there were 558,000 new cases with resistance to rifampicin, the most effective first-line drug of which 82% had MDR-TB. The MDR-TB burden largely falls on 3 countries India, China and the Russian Federation, which together account for nearly half of the global cases. About 8.5% of MDR-TB cases had extensively drug resistant TB (XDR-TB) in 2017. About 1.7 billion people, 23% of the world's population, are estimated to have a latent TB infection, and are thus at risk of developing active TB disease during their lifetime.

Diagnosis and successful treatment of people with TB avert millions of deaths each year (an estimated 54 million over the period 2000–2017), but there are still large and persistent gaps in detection and treatment. Globally, among 10 million estimated new cases, only 6.4 million cases were reported. Gaps between the estimated number of new cases and the number reported are due to a mixture of underreporting of detected cases and underdiagnoses which

is still a major programmatic gap of TB program. Investing in Ending TB has maximum return for every dollar invested, there is an estimated USD 43 in return. Hence, we must encourage investment in Ending TB efforts both at global, national, and local levels.

2.2 TUBERCULOSIS BURDEN IN NEPAL

Tuberculosis (TB) remains one of the major public health problems in Nepal. In 2017/18, a total of 32,474 cases of TB were notified and registered at NTP. TB case notification, as well as estimated incidence, has been stagnant for more than decades now in Nepal (CNR 152/100,000 in 2018) despite best efforts of the program is trying to find and cure more TB cases. TB cases were reported from all parts of the country, but the Flat/Terai belt reported the highest numbers of cases followed by hills and mountains. The childhood TB cases reported are nearly 5.5% of all cases which is still a huge challenge in Nepal. Among the reported cases, men are nearly 1.7 times as compared to women cases (M:F = 1.7:1). Nepal TB program is also missing out to find nearly 28% of estimated cases annually, which has played a big role in control of TB program with 20-25% among them estimated to be held and unreported by private sector.

TB-HIV co-infection rate in Nepal is 1.1% (HIV among TB) and 8.5% (TB among HIV) based on the sentinel survey, 2013 and HIV testing among TB patient are also improving (18% of 2017 to 54% 2018). Multidrug-resistant TB (MDR-TB) is another challenge for the country. The proportion of MDR-TB was 2.2% among new cases and 15.4% among retreatment cases based on DRS survey carried out in 2011/12, and another DRS survey is planned to be carried out in 2019-2020. The routine surveillance showed a much higher proportion of drug resistant pattern among second-line drugs used for the treatment of MDR patients in Nepal. Among RR-MTB/MDR TB initially diagnosed, 42.3% of MDR patients may require Pre-XDR treatment similarly 4% may require XDR treatment.

TB DOT services are provided through all Government health facilities in the communities (even up to the Heath post level, nearly 4000 in numbers) throughout the country. For the management of critical TB cases, TB hospital is being built which will be operational by recent future. Diagnostic services are provided through identified Microscopic centers (nearly 600 in numbers). Rapid DST with Xpert MTB/ Rif testing is expanding through GeneXpert centers (at-least 1 center per district by 2021). Nepal also planned at-least 1 Lab with LPA and culture services per province by 2021 which will be managed and supported through 2 National Reference Laboratories.

Despite all the challenges, Nepal sustained treatment success rates of 90% or more for DS-TB and 70% or more for DR TB cases. Significant challenges still lie in finding those missing cases and managing TB through quality and equitable services. Ongoing efforts are being made to develop comprehensive multisectoral approaches and patient-centered care and meaningful engagement of private sectors and community TB care.

CHAPTER 3

GENERAL INFORMATION ABOUT TUBERCULOSIS

3.1 WHAT IS TUBERCULOSIS AND HOW DOES IT AFFECT US?

Tuberculosis (TB) is an infectious disease caused by the bacillus Mycobacterium tuberculosis. It typically affects the lungs (pulmonary TB) but can also affect other sites (extrapulmonary TB). The disease is spread when people who are sick with pulmonary. TB expel bacteria into the air, for example by coughing. The tuberculosis bacilli enter the body through the lung and spread to other parts of the body through the blood system, the lymphatic system, or through the direct extension to other organs.

A relatively small proportion (5–10%) of the estimated 1.7 billion people infected with M. tuberculosis will develop TB disease during their lifetime. However, the probability of developing TB disease is much higher among people infected with HIV; it is also higher among people affected by risk factors such as undernutrition, diabetes, smoking and alcohol consumption. Tuberculosis is curable and preventable.

The tubercle bacilli are (are) so small it can only be seen through a microscope. The bacilli must be confirmed in the sputum or other clinical specimens for a confirmed diagnosis of TB before a patient can be commenced on treatment

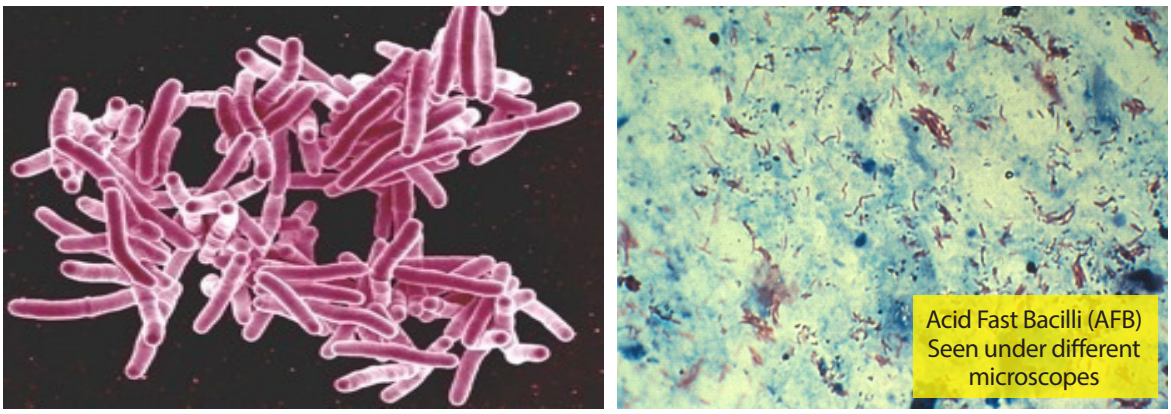


FIGURE 2. **TB bacilli are so small it can only be seen through a microscope and must be confirmed before treatment can be commenced.**

3.2 WHY SHOULD TB BE A PRIORITY IN OUR HEALTH SERVICE DELIVERY?

TB spreads easily through the air and the transmission of TB can be prevented if infectious patients are treated early and infection control measures are ensured. Health workers once informed with basic information on TB can protect themselves and other people from getting infected with TB.

3.3 HOW DOES TB SPREAD?

TB is airborne and easily spreads when an untreated individual with infectious tuberculosis expels TB bacilli into the air as droplets when he or she coughs, sings sneezes, etc. Coughing produces tiny infectious droplets (droplet nuclei). One cough can produce 3,000 droplet nuclei. Transmission generally occurs indoors; where droplet nuclei can stay in the air for a long time. Anyone who breaths in the droplets containing the TB bacilli can become infected with TB. Most infections are caused by inhalation of droplets containing TB bacilli. Not all infected people will develop TB disease. Only about 5-10% will develop TB disease, half of them shortly after an infection, half of them later in their life. A strong immune system keeps TB bacilli dormant and prevents TB bacilli from multiplying and developing TB infection into TB disease. HIV infected people are more at risk of developing TB disease once infected by M. tuberculosis.

TB spreads in the air when an infected untreated person coughs, sneezes, sings, etc and passes to others when they breathe in the TB bacteria through infected air.

FIGURE 3. **How TB spreads**

Pulmonary tuberculosis or (PTB) is the most frequent type and accounts for more than 80% of all TB. Extra-pulmonary tuberculosis (EPTB) can involve sites such as glands, bones, brain, intestine, skin, genito-urinary system or almost any other part of the body except hair, nails and teeth. People with smear-positive TB or bacteriologically confirmed pulmonary TB and who are not treated are infectious. TB bacilli can be killed by sunlight thus exposure to natural sunlight or good ventilation with effective air flow moving polluted air into the open is vital for TB prevention.

An untreated infectious patient may infect up to 10 -20 people per year. It is estimated that 2 people among the infected persons will develop TB disease and continue to infect others if left untreated. The bacteriologically confirmed pulmonary TB patients form the highest priority for the TB programme. Untreated bacteriologically confirmed patients are like an open tap. As long as they remain untreated in the community, they will continue the flow of TB transmission in the community.

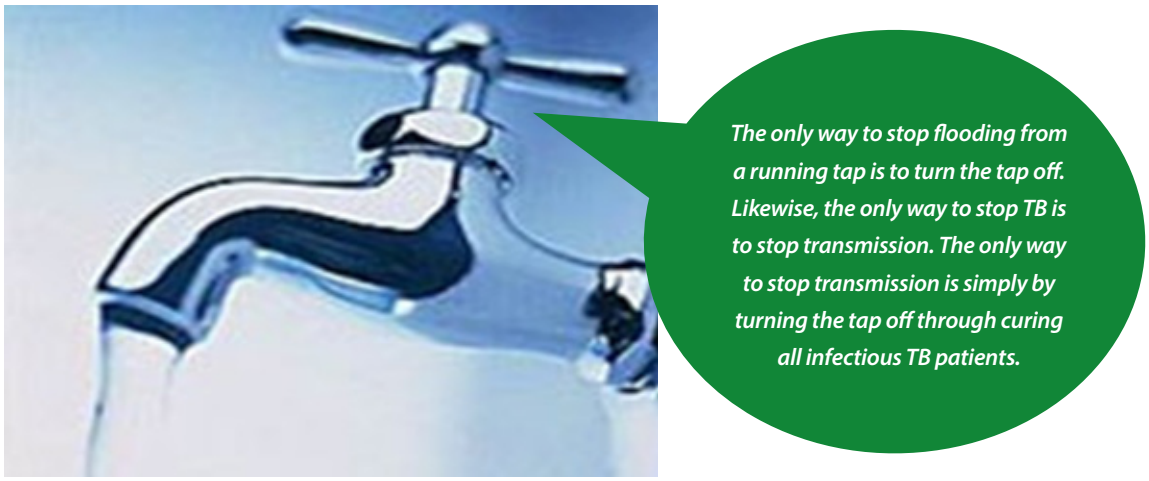


FIGURE 4. Untreated smear-positive patients are like an open tap.

All pulmonary TB patients should have sputum examined by microscopy/Xpert MTB/RIF to determine if they are infectious or not.

3.4 HOW DOES SOMEONE DEVELOP TB AND WHY IS HIV IMPORTANT IN TB?

Not everyone who is exposed to the TB bacilli will develop TB infection. And not everyone who is infected with TB bacilli will develop TB disease.

A person must come in contact with an untreated bacteriologically confirmed PTB patient or atmosphere containing lots of bacilli and breathe in droplets containing TB bacilli. When the TB bacilli enter the body, it infects the body thus, TB infection is said to occur. The body then produces antibodies against TB within 4 to 6 weeks and normally responds through a cell-mediated immune response. If the immune response is strong, it kills the bacilli, and this happens in 90% of the cases infected with the TB bacilli.

In about 5-10% of the cases the bacilli overcome the immune response. This may occur if the immune system is not strong and the body's immune response is weak and is not able to get rid of bacilli. The bacilli then multiply in the body and cause TB disease.

The weakening of the immune system is therefore, the most important trigger for TB disease. HIV, diabetes, stress, young age are some factors that result in a reduced immune response.

Patients who are infected with HIV are at greater risk of developing TB disease in their lifetimes and also have a higher risk of relapse every year. TB disease increases the progression of HIV disease and likewise HIV increases the progression of TB disease.

3.5 WHAT ARE THE COMMON SIGNS AND SYMPTOMS OF TUBERCULOSIS?

Pulmonary TB should be suspected if a patient presents with cough for more than two weeks and / or coughing of blood (hemoptysis) and sputum. A TB patient may also have low-grade fever, chest pain, and shortness of breath, weight loss, night sweats and loss of appetite.

Sputum examination should always be done for a patient who has a cough of 2 weeks or more even in the absence of any other symptoms.

Extra Pulmonary TB (EPTB) patients may have other symptoms, other than a cough. They may have pain, swelling etc of the affected organ. For example, for Gland TB: Swelling of the glands, not painful, low-grade fever, etc.

CHAPTER 4

TUBERCULOSIS CLASSIFICATION AND DEFINITIONS

4.1. TUBERCULOSIS CASE DEFINITIONS:

- A **bacteriologically confirmed TB case** is one from whom a specimen is positive by smear microscopy, culture or WHO-recommended rapid diagnostics-WRD such as Xpert MTB/RIF. All such cases should be notified, regardless of whether TB treatment has started or not.
- A **clinically diagnosed TB case** is one who does not fulfill the criteria for bacteriological confirmation but has been diagnosed with active TB by a health worker based on strong clinical evidence and has decided to give the patient a full course of TB treatment. This definition includes cases diagnosed by clinicians on the basis of X-ray abnormalities or suggestive histology and extra-pulmonary cases without bacteriological confirmation. ***Clinically diagnosed cases subsequently found to be bacteriologically confirmed (before or after starting treatment) should be reclassified as bacteriologically confirmed case.***
  - ***All patients should be confirmed bacteriologically or clinically diagnosed before commencing on TB treatment. No patient should be commenced on trial TB treatment.***
  - ***All pulmonary TB cases MUST have sputum examined for TB.***

4.2 CLASSIFICATION OF TB

TB cases whether bacteriologically confirmed or clinically diagnosed cases are classified according to:

1. **Anatomical site of disease**
2. **History of previous treatment**
3. **Drug resistance**
4. **HIV status**

4.2.1 Classification based on anatomical site of disease

Patients are classified on the anatomical site of disease into pulmonary and extra pulmonary TB.

Pulmonary tuberculosis (PTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or the tracheobronchial tree. ***Miliary TB is classified as PTB because there are lesions in the lungs.*** Tuberculous intra-thoracic lymphadenopathy (mediastinal and/or hilar) or tuberculous pleural effusion, without radiographic abnormalities in the lungs, constitutes a case of extra-pulmonary TB. A patient with **both pulmonary and extrapulmonary TB should be classified as a case of PTB.**

Extra-pulmonary tuberculosis (EPTB) is any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs, e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin, joints, bones and meninges.

4.2.2 Classification based on the history of previous TB treatment (patient registration group)

Classifications based on the history of previous TB treatment follows the updated WHO definitions and reporting framework for Tuberculosis[1]

Table 4.1: Classification of TB

TYPE OF PATIENTS	DEFINITION
1. New patients	Patients who have never been treated for TB of have taken anti-TB drugs for less than one month.
Previously treated patients: Patients who have received 1 month or more of anti-TB drugs in the past. They are further classified by the outcome of their most recent course of treatment as follows:	
2. Relapse patients	Patients who have previously been treated for TB were declared cured or treatment completed at the end of their most recent course of treatment, and are now diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by reinfection).
3. Treatment after failure patients	Are those who have previously been treated for TB and whose treatment failed at the end of their most recent course of treatment.
4. Treatment after loss to follow-up patients	Patients who have previously been treated for TB and were declared lost to follow-up at the end of their most recent course of treatment. (These were previously known as Treatment After Default patients)
5. Other previously treated patients	Patients are those who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.
6. Patients with unknown previous TB treatment history	Patients with unknown previous TB treatment history who do not fit into any other categories listed above.

*New and relapse cases of TB are *incident* TB cases.

4.2.3 Classification based on HIV status

TB patients are also classified based on their HIV status.

HIV- positive TB patient refers to any bacteriologically confirmed or clinically diagnosed case of TB who has a positive result from HIV testing conducted at the time of TB diagnosis or other documented evidence of enrolment in HIV care, such as enrolment in the pre-ART register or in the ART register once ART has been started.

HIV-negative TB patient refers to any bacteriologically confirmed or clinically diagnosed case of TB who has a negative result from HIV testing conducted at the time of TB diagnosis. Any HIV-negative TB patient, subsequently found to be HIV-positive should be reclassified accordingly

HIV status unknown TB patient refers to any bacteriologically confirmed or clinically diagnosed case of TB who has no result of HIV testing and no other documented evidence of enrolment in HIV care. If the patient's HIV status is subsequently determined, he or she should be reclassified accordingly.

1 Definitions and reporting framework for tuberculosis – 2013 revision (World Health Organization)

4.2.4 Classification based on drug resistance

Cases are classified in categories based on drug susceptibility testing (DST) of clinical isolates confirmed to be M. tuberculosis as shown in the table below:

Table 4.2: Classification based on drug resistance

TYPE OF RESISTANT	DEFINITION
Mono-resistance	Resistance to one first-line anti TB drug only
Poly-resistance	Resistance to more than one first-line anti-TB drug (other than both isoniazid and rifampicin).
Rifampicin Resistance (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 mono-resistance, multidrug resistance, poly-drug resistance or extensive drug resistance.
Isoniazid-resistant TB (Hr-TB)	Refers to mycobacterium tuberculosis strains in which resisitance to isoniazid and susceptibility to rifampicin has been confirmed in vitro.
Multi drug Resistance (MDR TB)	Resistance to at least both isoniazid and rifampicin
Extensive Drug Resistance (XDR-TB)	Resistance to any fluoroquinolone and to at least one of three second-line injectable drugs (capreomycin, kanamycin and amikacin), in addition to multidrug resistance.

CHAPTER 5

TUBERCULOSIS CASE DETECTION AND DIAGNOSIS

5.1 HOW TO DETECT TB CASES

Presumptive TB refers to a patient who presents with symptoms or signs suggestive of TB (previously known as a TB suspect). A person with cough for 2 (two) weeks or more is a presumptive TB patient and must have a sputum examination. Persons to be evaluated for TB both adults and children are the following:

- Signs and symptoms suggestive of TB:
  - Cough for 2 weeks or more
  - Coughing sputum with or without blood
  - Fever (evening rise/low grade) and night sweats
  - Loss of appetite and unintentional weight loss
- Household or other close contacts of bacteriologically confirmed pulmonary TB
- Chest X-ray suggestive of any lung field abnormality (including TB)

Routine screening of patients with illness who are at high risk for TB includes the followings.

1. HIV positive patients
2. Patients on long term steroid therapy
3. Diabetic patients
4. Cancer patients
5. Severe Acute Malnutrition (SAM)
6. Symptomatic moderate acute malnutrition (MAM)
7. Elderly

TB is common in Nepal and is widespread in every community in the country with some experiencing very high burdens. Health workers should not wait for patients to present with cough or the typical symptoms of TB to their health facilities to diagnose TB. Health workers must be proactive and take every opportunity when they see patients or clients accessing their services and ask for cough and other symptoms. TB must be diagnosed as early as possible and patients affected with TB must be treated as early as possible.

All health facilities should ask every person who comes to seek health services for whatever reason whether they have a cough, if so, for how long? Identifying presumptive and confirming TB patients early ensures early treatment limits TB transmission and ensures better survival for TB patients.

*All patients with HIV should be screened regularly (every visit) for signs and symptoms of TB (Current cough, Blood in sputum, weight loss, fever and night sweats). For children (poor weight gain, fever or current cough and contact history with a TB case)

BE AWARE!!!!

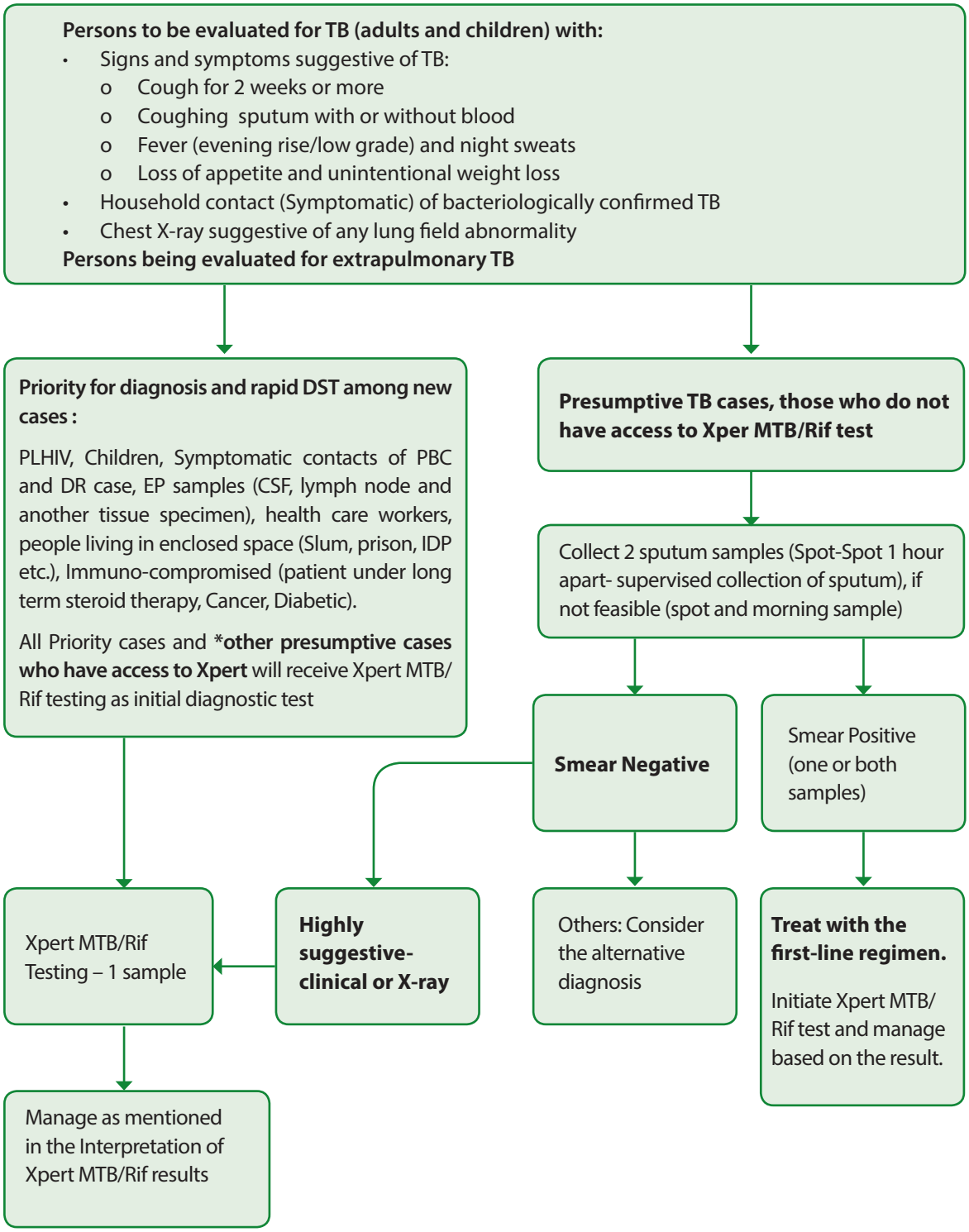
Bacteriologically confirmed patients are very INFECTIOUS and can transmit the disease to others. The longer they remain in their communities untreated, the more people they will infect with TB. Identifying presumptive TB patients and treating them early can cut down on the transmission of TB to other people including health workers.

Identifying coughing patients through triaging and segregating them to areas with open- air or better ventilation in health facilities is part of infection control for TB in health facilities and can prevent transmission of TB to health workers and other people assessing health services. All persons with cough must be advised on cough etiquette including offering them a mask if possible and attended to quickly to limit their stay in the health facilities. Coughing patients regardless of the duration of their coughs should not be allowed to remain in enclosed rooms in the health facility for a prolonged duration.

Chest X-ray may show various abnormalities, or it may occasionally be normal. Specimen from extra pulmonary sites such as CSF, Lymph node, etc, should be sent for examination including for Xpert MTB/RIF. The diagnosis of extra pulmonary TB should always be confirmed by a trained clinician or medical officer. Patients with extra-pulmonary TB should also have a sputum examination if they have a cough of any duration.

All presumptive TB patients must be registered in the presumptive TB register and must be followed up. Patients found to be bacteriologically confirmed for TB by smear or Xpert MTB/RIF or other bacteriological methods must be commenced on TB treatment right away. Patients whose sputum or other specimens confirmed on bacteriological examination and who do not turn up for treatment, results must be followed up and commenced on treatment as soon as possible.

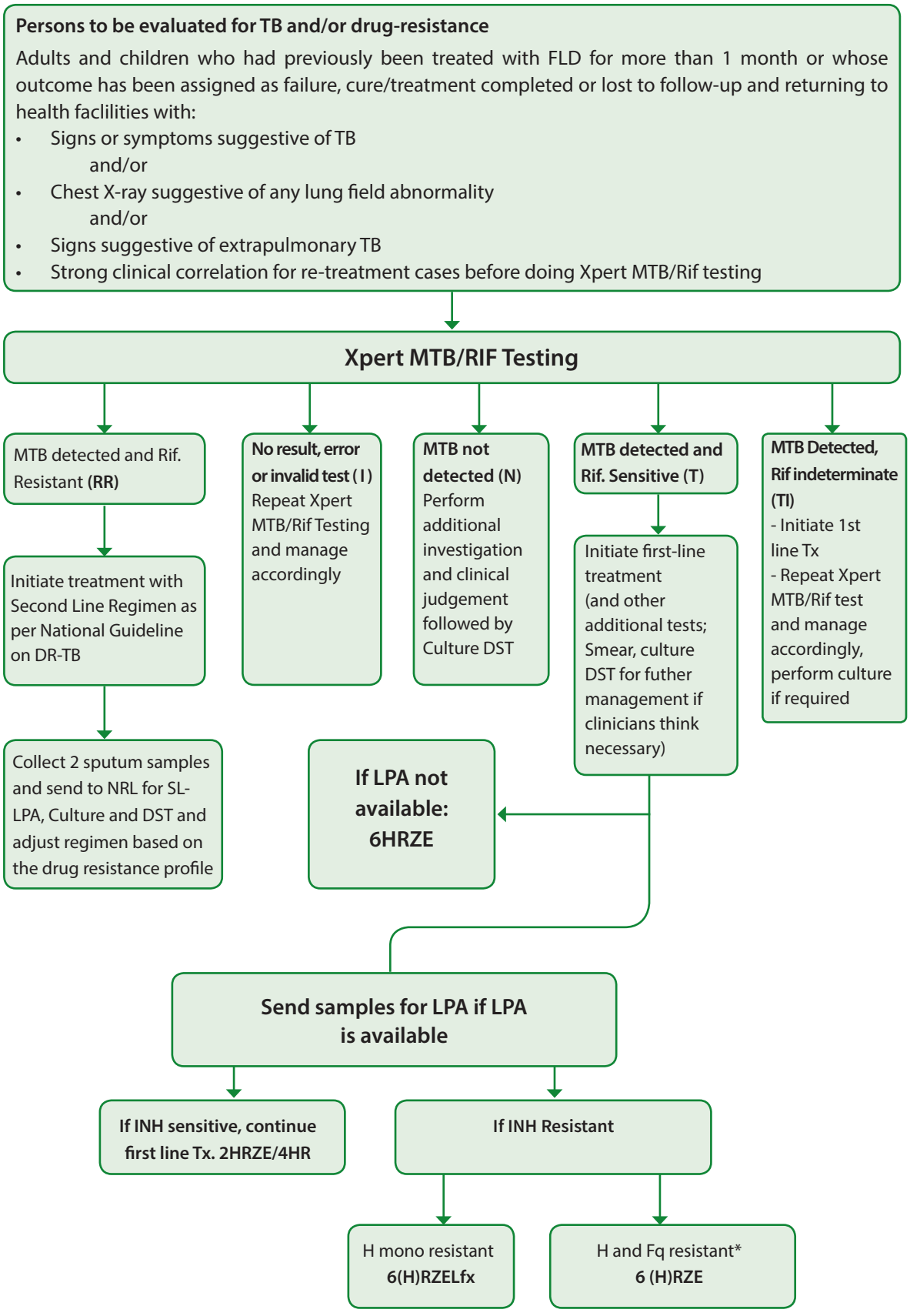
FIGURE 5.1: Diagnosis and Treatment Algorithm (New Cases)



**Wherever possible access to GeneXpert, the initial diagnostic can be GeneXpert for all presumptive cases.*

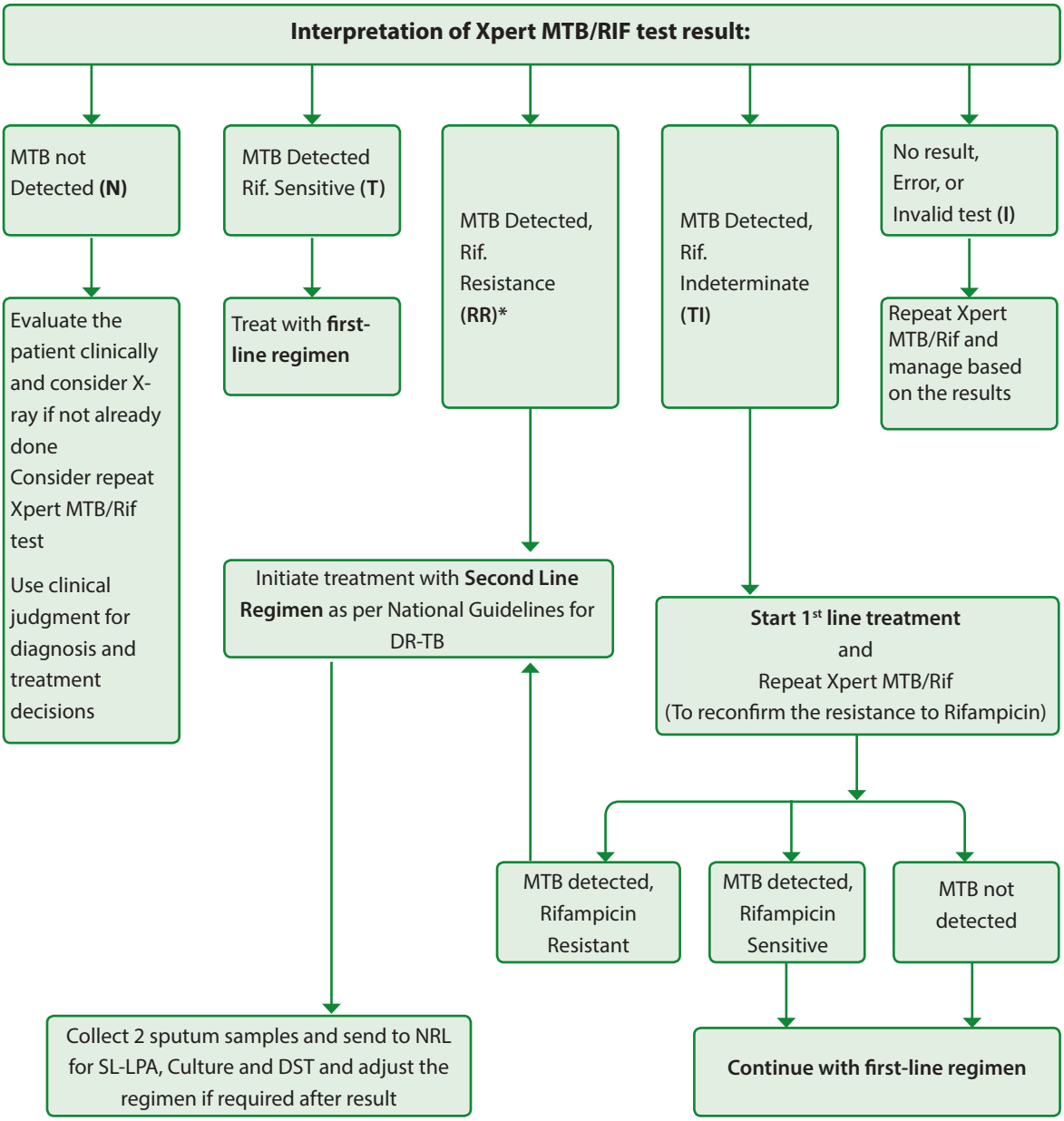
Sputum microscopy should be done for all diagnosed TB cases for monitoring purpose and where there is no access to Xpert MTB/Rif Test .

FIGURE 5.2: Diagnosis & Treatment Algorithm (Retreatment Cases)



**Depending on patients' response and laboratory evidence, clinicians at the higher-level centre can use laboratory evidence/result to inform further management where necessary.*

FIGURE 5.3: Interpretation of XpertMTB/RIF result and treatment initiation for New TB cases



* For new cases with low risk of DR-TB, the clinician can decide to repeat in case required

5.2 HOW TO DIAGNOSE EXTRA PULMONARY TB

Extra pulmonary TB is usually difficult to diagnose, and its diagnosis should be supported with investigations and bacteriological examination where possible. Positive contact history of TB is an indication for suspicion of TB when a patient presents with symptoms. Symptoms and signs of extra-pulmonary tuberculosis usually depend on the site involved. The following table shows the common signs and symptoms of EPTB.

Diagnosis of EPTB should preferably be confirmed clinically or bacteriologically if an appropriate sample is available before starting treatment. Xpert/MTB/RIF should be performed for EPTB investigation.

Common symptoms of EPTB:

1) Fever (found in up to 80% of all patients)
2) Weight loss
3) Night sweats
4) Loss of appetite

TABLE 5.1: Extra-pulmonary TB symptoms

Sites	Symptoms and signs
Pleural	1. Pleuritic chest pain 2. Shortness of breath 3. Effusions are usually unilateral
Lymphatic	1. The most common site of extra-pulmonary disease; 2. Usually presents as a painless swelling, most commonly in the neck. Any nodes can be involved; 3. Involvement of any notes 4. Adenopathy usually occurs in a single lymph node or chain.
Central Nervous System	1. Headache, altered mental status, nausea and vomiting; 2. Meningeal signs, with characteristic neck rigidity; 3. Paralysis of the oculomotor nerve, leading to strabismus and/or ptosis (drooping/floppy eyelids) and sometimes convulsions.
Bone and Joint	1) Most commonly affects the spine and the weight-bearing joints; 2) Insidious onset of joint pain and swelling; 3) Involvement of the cervical vertebrae may signal its presence by pain in the neck and shoulders. It may lead to rigidity of the neck, a cervical cold abscess behind the sterno-mastoid muscle, and more rarely neurological signs leading to progressive tetraplegia. Involvement of the dorsal vertebrae is indicated by localized back pain, deformity of the spine, and in extreme cases an angulated kyphosis (gibbus): the chief risk is spinal cord compression and paraplegia.
Genitourinary	1. Flank pain 2. Hematuria 3. Recurrent urinary tract infections 4. Pyuria
Abdominal	1. Abdominal pain and swelling 2. Abdominal tenderness 3. Ascites
Disseminated	1. Clinical signs: general deterioration, high fever and dyspnoea. 2. Other organs may be affected include: pleural effusion, digestive problems, hepatosplenomegaly and sometimes meningeal signs.

5.3 ROUTINE SCREENING FOR TB FOR HEALTH WORKERS

Routine screening for TB must be done for health workers and other workers in health facilities and institutions on an annual basis. Annual screening involves symptomatic screening followed by Chest X-Ray. Health workers found to have symptoms and signs suggestive of TB should be further investigated by sputum examination, Xpert MTB/RIF and culture whichever is appropriate. And those found to have TB should be commenced on appropriate treatment as soon as possible. Such persons should also be assigned to appropriate departments to reduce the risk of transmission to visiting patients and other health workers.

5.4 ROLE OF THE LABORATORY IN THE DIAGNOSIS OF TB

Quality of TB diagnosis is complimented/ assured by the laboratory via the various bacteriological examinations. All diagnosed TB, whether smear-negative or smear-positive must be screened at least for Rifampicin resistance by laboratory examination at the start of the treatment itself. Treatment of pulmonary bacteriologically confirmed TB is monitored by sputum microscopy (section 6).

5.5. QUALITY DIAGNOSIS OF TUBERCULOSIS

A. Role of Sputum Smear Microscopy

Diagnosis of TB rests on the identification of TB bacilli by sputum smear microscopy or by Xpert MTB/RIF. Where Xpert MTB/RIF is available, Xpert MTB/RIF can be the first-line diagnostic for TB diagnosis and where Xpert MTB/RIF is not available, direct sputum smear examination should be done for all patients with presumptive TB. Patients seen in health facilities with clinical symptoms suggestive of TB should be sputum examined for TB before commencing on TB treatment.

Two sputum samples are required for diagnosis of pulmonary TB. The first specimen can be taken on the spot and second specimen can also be taken on SPOT at least an hour apart.

In circumstances where second spot cannot be produced by the patients, next day early morning sample should be collected by the patient and bought to the health facility

Proper counselling of the patients on how to produce a good sputum sample is a MUST for better quality of sputum

All patients with any chest X-Ray abnormalities should have sputum collected and examined to confirm diagnosis of TB.

Globally, use of rapid molecular tests is increasing, and many countries are phasing out the use of smear microscopy for diagnostic purposes (although microscopy and culture remain necessary for treatment monitoring).

5.5.1 Procedure for Sputum Collection

Sputum should be collected outdoors or in a well-ventilated area. Sample ONE is collected **"ON THE SPOT"**. Give instructions on how to produce and collect sputum. Explain why the sputum is needed and show patient TB case how to cough up. Sample **TWO** is collected on the SPOT at least one hour apart or in circumstances, a second spot cannot be produced the second sample is collected by the person upon awaking the next morning and is brought to the health facility in the morning.

The patient may be asked to take warm water a few minutes before taking a sample to increase sputum production. A few deep breaths, moderate thumping of the upper back of patient or resting in supine position also may elicit a productive cough.

IEC for sputum collection

Patients should be explained properly on collection methods of sputum to get good quality sputum for diagnosis.

Remember:

- Label the containers (not the lids) before collecting the sputum samples.
- Collect sputum in a well-ventilated area, preferably outdoors, and away from other people.
- **DO NOT COLLECT SPUTUM IN THE TOILET.**
  - Quality of sputum is very important. Check whether the sample contains sufficient mucopurulent sputum, not just saliva. If not, ask the coughing person to add more.
  - After collecting the sputum, be sure that the lid is closed tightly. Wipe off the outside of the container if needed.
  - Wash your hands thoroughly with soap and water.
  - Supervise collection of the second spot sample as the first sample at least one hour apart
  - In circumstances where second spot cannot be produced, request the patient to bring the second early morning sample next day to the health facility.
  - Fill out the laboratory request form (Figure 5.2)
  - Send the samples with the request form from the health facility to the laboratory.

FIGURE 5.2: Laboratory Request Form

Government of Nepal
Health Management Information System
Laboratory Request and Reporting Form

Date……/……/…..

1. Name of Health Facility……2. Presumptive/OPD/Contact Reg No… 3.DR/ TB Reg. No……..

4. Name of Patient…….. 5. Age…… 6. Sex……..……..

7. Ethnicity …… 8. Code ……

9. Address: Province……District……M/RM…… ward…… Tole ……..

10. Name of Guardian ……11. Contact no……

12. Purpose for Examination. i- Diagnosis. ii- Follow-up (.....month) iii- RR detection:

1-LABORATORY REQUEST

Part (A)-for Detection of TB
Microscopy and Xpert/MTB RIF
(to be filled at OPD/DOTS centre)

13. History of Treatment for TB: (a) No previous Treatment (b) Previous History of Treatment
(c) Current on Treatment- (i- New ii- Retreatment iii- Others)
14. Specimen Type: i- Sputum ii- Other (specify).....
15. Test Request for: i- Microscopy ii-. Xpert MTB/RIF

Part (B)-For INH Resistance identification
For patients who meet all three below mentioned criteria;
i. Retreatment cases, ii. Rifampicin Sensitive (via Xpert MTB/RIF), iii. Smear Positive
(to be filled at OPD/DOTS centre)

16. Test Requested: i. LPA
17. Specimen Type: 1. Sputum 2. Other(specify).....
18. Details of Past TB Treatmen: i. New ii- Relapse ii- Tx After Failure iii- Tx After LTFU
iv- Others Previously Treated vi. Unknown Previous TB Treatment History
19. History of Contacts with known TB: 1. Yes 2. No
If yes, Mention DST result of: i- INH…… ii-Rif……iii- Others:……
20. Retro Status: i – Reactive ii – Non-reactive iii- Unknown

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Part (C)- **For Presumptive DR TB cases**
MTB not detected, or MTB detected with Rif Indeterminant through Xpert MTB/RIF testing
(to be filled at OPD/DOTS centre)

21. Test Requested: i. Culture/DST
22. Specimen Type: 1. Sputum 2. Others (specify).....
23. Details of Past TB Treatment: i- New ii- Relapse iii- Tx After Failure iv- Tx After LTFU
v- Others Previously Treated vi – Unknown Previous TB Treatment History
24. Retro Status: i – Reactive ii – Nonreactive iii- Unknown

Part (D) – For DR TB Baseline and follow up cases

25 i) Routine collection for 0 month: ☐ Collect 2 samples
ii) Routine collection for follow up months : …….. ☐ Collect 1 sample

26. Specimen Type: 1. Sputum 2. Others (specify).....

27. Details of Past TB Treatment: i- New ii- Relapse iii- Tx After Failure iv- Tx After LTFU
v- Others Previously Treated vi – Unknown Previous TB Treatment History

Date of Sample Collection: .....

Part (E)- For all cases Detected with TB (All Forms of TB)

28. Test Request for HIV ☐ ("✓" if HIV Test Requested)

Requested by:

Name:.....

Designation:.....

Contact Number: .....

Signature:.....

2- LABORATORY TEST RESULT

Name of Laboratory/GeneXpert Site:……..

Lab no. ... ... Result Date:……./……./…..

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1. Microscopy Test Results

Sample	Visual Appearance	Result					Examined by:	
		Neg (✓)	Positive (circle the grading)				Name NHPC No	Signature and date
A	B M S		Scanty	1+	2+	3+		
B	B M S		Scanty	1+	2+	3+		

(B) blood-stained (M) mucopurulent (S) saliva

Neg.=(0 AFB/100 OF), Scanty= (1-9 AFB /100 OF) 1+=(10−99 AFB/100 OF),2+ = (1−10 AFB/ OF), 3+=(>10 AFB/ OF),

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2. Xpert MTB/RIF test result

Mycobacterium tuberculosis:	1. Detected	2. Not detected	3. Invalid / No result / Error
Rifampicin Resistance:	1. Detected	2. Not detected	3. Indeterminate

3. HIV Test Result

a) (A1) Determine Test i - Reactive ii- Non-Reactive

b) (A2) Uni-Gold Test ii- Reactive ii- Non-Reactive

c) (A3) Stat pack Test iii- Reactive ii- Non-Reactive

Examined by: Name: .....

Designation: .....

NHPC No.....

Signature and date .....

- Sputum should be sent to the laboratory within 24-48 hrs but no later than 5 days after collection.
- Sputum samples should be stored in the refrigerator (4 – 8 degrees) if there is a delay of more than 24 hrs, till then, store in a cool dry place away from direct sunlight.
- Clinicians should fill one lab request form completely per patient and submit with the specimen for sputum microscopy, Xpert MTB/RIF, LPA or culture. It is very important that clinicians fill the form correctly and indicate by ticking the specific investigation requested.

5.6 ROLE OF XPERT MTB/RIF

For diagnosis of TB Xpert MTB/RIF is the rapid molecular test, currently recommended by WHO. It can provide results within 2 hours. Since 2013, it has also been recommended for use in children and to diagnose specific forms of extrapulmonary TB. The test has much better sensitivity than sputum smear microscopy.

Xpert MTB/RIF test can detect TB and rifampicin-resistant TB. In Nepal, Xpert MTB/RIF will be used for all presumptive TB cases for diagnosis of TB where Xpert MTB/RIF is available and where not available, only a priority group of patients will receive Xpert MTB/RIF as first-line diagnostic tool. In addition, it should also be used for Rifampicin resistance screening in all diagnosed TB cases and treatment non-responders (non-converters).

1. Selected group for diagnosis of TB by GeneXpert

Sputum or specimen from the following group of people should be sent for Xpert MTB/RIF testing for the diagnosis of TB in facilities where Xpert MTB/RIF test is not easily available on-site or accessible

1) All re-treatment cases including relapse and loss to follow up
2) Symptomatic contacts of DR-TB
3) Non-converters
4) Symptomatic contacts of PBC
5) People diagnosed with or living with HIV
6) Health Care Workers (HCW)
7) Children (age less than or equal to 14 years)
8) Patients from congregate settings (Prisons, Monasteries, Hostels, etc)
9) New patients of high-risk groups such as uncontrolled Diabetes and other immuno-compromised conditions
10) EP samples

Xpert MTB/RIF is also used in bacteriological confirmation of TB in sputum smear-negative patients with symptoms and signs suggestive of TB, or X-Ray suggestive and smear-negative cases, though a negative Xpert may not rule out TB. Other specimens such as CSF, gastric aspirates, lymph node biopsies, pus, excised solid tissues may also be examined using Xpert MTB/RIF in EP TB cases (refer EP section).

5.7 ROLE OF LINE PROBE ASSAY (LPA)

Indication

LPA is a PCR based test used for diagnosis of TB and for determining susceptibility to different anti TB drugs. First (1st) line LPA includes INH and Rifampicin susceptibilities and Second (2nd) line LPA includes Fluoroquinolones and injectable anti TB drugs (aminoglycosides and polypeptides) susceptibilities. LPA needs higher bacterial load in samples than for Xpert MTB/RIF for a positive result and hence smear-positive samples and cultures are preferred although this is not a mandatory requirement while performing second-line DST.

Patients eligible for LPA are:

- All previously treated patients presenting with TB should be tested with LPA (1st line) as per diagnostic algorithm o re-treatment cases
- All Rifampicin resistant TB cases should be tested with LPA (1st and 2nd line) and culture DST preferably at the start of treatment.
- All treatment non-responders as per the diagnostic algorithm

Specimen collection and Transportation

The quality of the result depends much on the quality of the sample especially in sputum samples. Two samples (either two spot-spot samples OR spot morning as per patient's convenience)) are collected in sterile falcon tubes after rinsing the mouth with drinking water. These samples are used for LPA and culture (no separate set of samples needed for culture). Samples are packed in standard "triple-layer" packing and should reach the lab within 24-48 hrs. Packing materials and sputum containers should be supplied to the labs which are supposed to send samples for LPA and culture. Samples may be stored in a refrigerator if delays are expected and a cold packing with gel packs is advisable in case of longer transit periods. (Annex 5)

Result interpretation

LPA results should be ready within one to two weeks. The test identifies the presence of TB bacteria in the sample and susceptibilities to 1st line drugs; Rifampicin, INH, 2nd line drugs; FQs, SLI and Ethionamide (indirectly).

A proportion of the tests may fail to give results (inconclusive results) or may give only partial results e.g. susceptibility to one drug only. In such cases the test may either need to be repeated from the same sample or after a positive culture is available after 2 – 8 weeks.

Being an open PCR method, the test is susceptible to cross-contamination which would be detected by the integrated controls. In such cases the test need to be repeated.

5.8 ROLE OF TB CULTURE AND DRUG SENSITIVITY TESTING (DST)

1. Indications for TB culture and DST:

All patients with Rifampicin resistant TB identified by Xpert MTB/RIF should have specimen sent for TB culture and DST and LPA where applicable. The specimens should be sent from the DR treatment centres/GeneXpert centres to the designated laboratories.

What DST drugs to ask for or perform:

- First-line drugs – INH (H), Rifampicin (R), Pyrazinamide (Pz), Ethambutol (E)
- Second line – Levofloxacin/Moxifloxacin (Lfx/Mfx), Linezolid (Lz), Clofazimine (Cfz), Amikacin (Am), Para Aminosalicylic Acid (PAS), Ethionamide (Eto)
- DST to new/repurposed drugs like Bedquiline, Delamanid and Linezolild will be established in the country and will be included in this list

2. Procedure for the specimen transport for TB culture

Sputum specimens for DST/culture should be collected from DR-TB treatment centres / GeneXpert centres. Sputum from patients requiring TB culture DST should reach culture labs within 24-48 hours after collection for better yield. Where possible the samples need to be kept refrigerated at 2 - 8 degree celsius prior to transporting to the designated culture labs. Sputum collection procedure and packing are the same as that for LPA.

3. Result interpretation

TB bacilli are grown on special media which can be solid (Lowenstein Jensen media - LJ) or liquid (MGIT). The liquid media takes 2 – 6 weeks while the traditional solid LJ media takes 2 - 8 weeks for a culture result. The culture basically provides the growth of bacilli which is then tested further to see how well the bacteria grow in the presence of drugs. The TB bacilli are either sensitive or resistant to the different drugs e.g. Rifampicin [R], Isoniazid [H], Ethambutol [E], Pyrazinamide [Z], Amikacin [Am], Levofloxacin (Lfx), etc. The DST testing may take 2 weeks more for MGIT and 4 – 6 weeks more for LJ.

As sputum will be always be contaminated with oral microbial flora which is fast growing compared to Mycobacteria, the culture may get contaminated by them despite decontamination. Normally it is expected to have up to 5% contaminated results among LJ culture and up to 10% contaminated results among Liquid culture (MGIT).

In the case of a contaminated result, the lab would request a repeat pair of samples.

4. Quality of Sputum

Fresher the sputum and lesser the amount of saliva the, better is the culture yield. Therefore, proper counseling during the collection of sputum, good quality sputum collection and transportation within 24-48 hours is very important.

5.9 ROLE OF X-RAY IN THE DIAGNOSIS OF TUBERCULOSIS

Pulmonary tuberculosis (PTB) should be diagnosed by sputum bacteriology examination. Pulmonary TB bacteriologically confirmed patients may have a Chest X-Ray to help in assessing the extent of lung damage in complicated cases but not for a diagnosis. Chest X-ray may also be used as a screening tools in the group considered at risk of developing TB followed by a confirmatory test for diagnosis. Chest X-Ray is required for diagnosis of TB in bacteriologically non-confirmed patients with persistent symptoms and extra-pulmonary cases such as pleural effusion. Chest X-Ray findings suggestive of PTB in patients who are bacteriologically not confirmed should always be supported by clinical findings and good judgement. Chest X-ray, clinical information and contact history are important in the diagnosis of pulmonary tuberculosis in small children and in Miliary tuberculosis which is bacteriologically not confirmed, as well as in some forms of extra-pulmonary TB.

5.10 DIAGNOSIS OF TB IN CHILDREN (SEE THE CHAPTER ON TB IN CHILDREN FOR DETAIL INFORMATION)

Bacteriological diagnosis of TB in children is difficult due to problems in obtaining and producing sputum. Whenever sputum is produced, all possible effort to collect sputum should be made

and sputum should be examined by Xpert MTB/RIF test. In children unable to produce sputum (usually < 6 years) a gastric aspirate may be performed and tested for ABF smear and Xpert MTB/RIF as outlined in annex 1a and 1b. The following steps should be used in the diagnosis of TB in children;

1. History - Symptoms, contact with TB patients/contacts.
2. Clinical examination including growth assessment.
3. Chest X-Ray
4. Bacteriological investigations including Xpert MTB/RIF test
5. Use of TB score chart.
6. HIV testing of all confirmed TB children.

Based on findings from the above steps and using the additional Childhood TB algorithm the diagnosis of TB in children is made. The TB score chart can guide clinicians to screen childhood TB. A TB score of more than 7 in the absence of any other disease indicates a likelihood of TB and possible diagnostics can be utilized for diagnosis. If child is found to be TB, then the child should be commenced on TB treatment. As the TB score chart is only a screening tool, HIV infection must be ruled out in those with TB score of more than 7 before interpreting the TB score. See TB score chart in Table 7.4a &7.4b.

5.11 SUMMARY OF TECHNICAL POINTS OF CASE-FINDING AND DIAGNOSIS

5.11.1 Practical methods-Procedures for collecting sputum for examination:

1. ***For diagnosis two (2) spot sputum specimens should be collected*** a minimum one hour apart. Only in cases, the second spot is not available, an early morning sample can be obtained.
2. Explain to patient reasons for the sputum examination. Fill sputum request form (TB02a) and label the side of the sputum cup and not the lid.
3. Collect sputum in a well-ventilated room, preferably outdoors. Collect sufficient sputum (3-5 ml) and **NOT** saliva. Avoid contamination of the cup and if contaminated discard the specimen container and collect a new specimen.
4. Close lid properly and wash your hands thoroughly.
5. Send sputum to the lab within 24 to 48 hours. Results should be ready within 24 to 72 hours and efforts should be made to communicate positive results as soon as possible.
6. Tell the patient when to come for the result. If the results are not collected, call the patients for treatment initiation at the earliest or a home visit by health worker be made.
7. Any sputum collected for more than one week before the examination is of limited value. The smear should be prepared and fixed if the sputum will not reach the laboratory with in stipulated time.

5.11.2 Procedures for collecting a gastric aspirate specimen - Annexure 1a and 1b:

1. Put on gloves and wear an N95 mask
2. Insert NG tube into stomach and aspirate 5-10 ml. 5 ml is minimum but try for 10ml
   a. If unable to get 5 ml, reposition the child, advance NG tube while aspirating
   b. If still it doesn't work add 20 ml sterile water, wait 5 min, and re-aspirate
3. Add 2 ml of sodium bicarbonate if you have it available to neutralize stomach acid
4. Send to the laboratory just as you do for sputum.

Interpretation of sputum/sample microscopy results

- Negative means no Acid-Fast Bacilli (AFB)was seen
- Scanty means between 1-9 AFBs were seen
- + means between 10-99 AFBs were seen
- ++ means between 100-999 AFBs were seen or between 1-10 AFBs seen per field
- +++ means between 1000 or more AFBs were seen or more than 10 AFB seen per field.

If one sample is positive or at least one AFB is seen in any one of the samples, the sputum/ sample is positive, and the patient has bacteriologically confirmed pulmonary TB.

Interpretation of Xpert MTB/RIF test results

T	MTB detected, rifampicin not detected
RR	MTB detected, and rifampicin resistance detected
TI	MTB detected, rifampicin resistance indeterminate (repeat test)
N	MTB not detected
I	Invalid/no result/error (repeat test)

A sputum smear-positive pulmonary TB case is diagnosed based on the presence of at least one acid-fast bacillus (AFB+) in at least one sputum sample (falls in the bacteriologically confirmed case by the new definition)

A bacteriologically confirmed PTB case is one from whom a biological specimen is positive by smear microscopy, culture or other diagnostic methods (such as Xpert MTB/RIF).

A sputum smear-negative pulmonary TB case is diagnosed when all sputum specimens are negative but radiographic abnormalities and clinical examination are consistent with active pulmonary TB and no response to broad-spectrum antibiotics plus decision is taken by a clinician. A sputum smear-negative pulmonary TB can be bacteriologically confirmed if Xpert MTB/RIF test or culture were used for diagnosis

✶ **Every presumptive PTB should have sputum smear/ Xpert MTB/RIF examination and not doing it is considered substandard care.**

5.11.3 External Quality Assurance (EQA) on Sputum Microscopy

Laboratories and microscopy centres doing sputum microscopy and or GeneXpert should participate in the National EQA program. All microscopy centres should be provided EQA by their higher-level laboratory as per the standard operating procedure and under the overall guidance of the National Reference Laboratory (NRL) and NRL in turn, should be quality assured by the Supra National Reference Laboratory (SRL).

CHAPTER 6

TREATMENT OF TUBERCULOSIS

6.1 STARTING TREATMENT

TB treatment is one of the key interventions for preventing and controlling TB. Deciding the right treatment regimen for the TB patient is important to ensure effective treatment and prevent drug resistant TB.

Treatment of tuberculosis should be started immediately after confirmation of TB diagnosis. **There is NO room for trial treatment**. TB treatment is given to cure patients, alleviate suffering, prevent death from TB and its complications, reduce the spread of TB in the community, prevent relapse and prevent development and transmission of drugs resistant TB.

For TB patients to be effectively treated, TB patients must be given the right drugs in the right combinations, appropriate dosage, administered correctly and regularly for the appropriate duration of time under observation.

The best way to ensure effective treatment for TB patients is to support medicine intake through **Directly Observed Treatment (DOT)** using fixed-dose combination (FDC) tablets. All TB treatment must be given under DOT.

6.2. TREATMENT CATEGORY FOR ALL TB PATIENTS

There is now only one category of treatment for TB patients needing first-line treatment. All TB patients whether bacteriologically confirmed or clinically diagnosed will receive **Treatment Regimen (2HRZE/4HR)**. In patients who require TB re-treatment, drug susceptibility testing should be conducted to inform the choice of treatment regimen. If susceptible to rifampicin and isoniazid, treatment regimen **(2HRZE/4HR)** should be given and if resistant, should be managed as per resistance pattern. There is no room for addition of an injectable agent for drug-sensitive mycobacterium.

***The Category II regimen should no longer be used in Nepal.**

The following table indicates the drugs and different durations of treatment.

TABLE 6.1: Categories of Treatment and their Anti-TB Drug Regimens

TYPE OF TB		INTENSIVE PHASE	CONTINUATION PHASE
New TB cases - Adult and Childhood - Bacteriological or clinically diagnosed - Pulmonary or extra-pulmonary		**2HRZE**	**4HR**
Complicated/Severe EP cases (CNS TB, TB Pericarditis, Musculoskeletal TB, Miliary TB etc.)		**2HRZE**	**7- 10 HRE ***
Retreatment cases All forms: 1st Rapid DST with Xpert MTB/RIF testing should be done to see the status of resistance to Rifampicin Followed by LPA among those having MTB+ve and Rifampicin sensitive for Isoniazid (INH) resistance status.	Xpert MTB/RIF– Rifampicin sensitive LPA – Isoniazid sensitive	**2HRZE**	**4HR**
	Xpert MTB/Rif– Rifampicin sensitive LPA – Isoniazid Resistant and FQ sensitive	**6 (H)RZE + Levofloxacin (Full Duration)**	
	Xpert MTB/Rif– Rifampicin sensitive LPA – Isoniazid Not known because of no access to LPA	**6 HRZE (Full duration)**	
	Rifampicin sensitive INH resistance and FQ resistant**	**6(H)RZE**	
DR TB	Refer to national guidlines on DR-TB management (2019)		

* For complicated EP cases, if treatment is required beyond 12 months, then refer to a higher level centre for treatment decisions

**Depending on the patients' response and laboratory evidence, clinicians at the higher-level centre can use laboratory evidence/result to inform futher management where necessary.

Please Note:

1. All TB patients whether pulmonary or EPTB, new or previously treated and regardless of (whether bacteriologically confirmed or clinically diagnosed) will receive New treatment regimen unless drug resistant. (If access to LPA)
2. The new treatment regimen consists of only 2 months of intensive phase with 4 drugs (RHZE) and 4 months continuation phase with 2 drugs (RH) only. All health workers in Nepal must strictly adhere to above the table no 6.1. In certain complicated / severe cases mentioned above and unresolved TB Lymphadenitis, the continuation phase may be extended.
3. **Category II treatment previously used for retreatment cases is no longer used and is no longer recommended.**
4. All patients who are suspected of drug resistant TB including all previously treated TB patients, contact of DR-TB patients and all patients started on 1st line treatment who do not convert their smears to negative during treatment or do not improve on new treatment regimen during any stage, in the treatment must be screened for drug resistant TB at least by Xpert MTB/RIF test.
5. All TB patients must be treated using Fixed Dose Combination (FDC) drugs and treatment must be given daily dose under direct observation.
6. All treatment must be directly supervised or observed by a treatment provider.

6.3 MONITORING TREATMENT

Sputum must be examined to monitor the progress of treatment for all pulmonary TB patients at the end of the intensive phase (2 months), at the end of 5th month and at the end of treatment (6 months). Sputum must be examined for patients who were smear-negative to start (PCD & EP cases) with at 2nd month. If EP cases develop chest symptoms, then sputum should be collected and examined. For those patients who remain sputum positive during different follow-up examinations, sputum should be collected and sent for Xpert MTB/RIF testing.

For those do not convert at 2nd month after the intensive phase and Xpert MTB/RIF results are sensitive for rifampicin, initiate continuation phase and repeat sputum examination at 3rd month.

NOTE:

**** If a patient is found to harbor a drug-resistant strain of TB at any time during therapy, treatment is declared as failed and the patient should be referred for DR-TB management.***

**** If new pulmonary TB patients treated with a regimen containing rifampicin throughout the treatment, if a positive sputum is found at the completion of the intensive phase, the extension of intensive phase is not recommended***

TABLE 6.2 : Sputum monitoring by smear microscopy in pulmonary TB patients

MONTHS OF TREATMENT					
1	2	3	4	5	6
[========	========] ❖ if sm +, obtain Xpert MTB/RIF [b] Culture/DST	[----------	----------	---------- ❖ [a] if sm +, obtain Xpert MTB/RIF[b] Culture/DST	----------] ❖ [a] if sm +, obtain Xpert MTB/RIF[b] Culture/DST

If smear-positive at month 2 and Xpert MTB/RIF sensitive, obtain sputum again at month 3. If smear-positive at month 3, obtain Xpert MTB/RIF.

1	2	3	4	5	6
[==========	==========] ❖ if sm +, obtain Xpert MTB/RIF [b] Culture/DST	[---------- ❖ if sm +, obtain Xpert MTB/RIF[b] Culture/DST	----------	---------- ❖ if sm +, obtain Xpert MTB/RIF[b] and Cultur/DST	----------] ❖ if sm +, obtain Xpert MTB/RIF[b] and Cultur/DST

Key:

[========] intensive phase of treatment (HRZE)

[----------] continuation phase (HR)

❖ Sputum smear examination

[a] omit if a patient was smear-negative at the start of treatment and at 2 months.

[b] Smear- or culture-positivity at the fifth month or later (or detection of DR-TB at any point) is defined as treatment failure and necessitates re-registration and change of treatment

6.3 TREATMENT FOR EXTRAPULMONARY TB PATIENTS

All EPTB patients will receive the same treatment as pulmonary TB patients and the total duration of treatment is 6 months **(2 months intensive, 4 months continuation phase) 2HRZE/4 HR.** For the complicated/severe forms of EPTB total 9-month treatment should be considered and can be extended for additional three months of continuation phase by treating physicians (**2 months (HRZE) intensive, 7-10 months (HRE) continuation phase, a total duration of 9-12 months)**

EPTB patients who do not improve at the end of 6 months must be investigated for drug resistant TB and should be referred to physicians or seek consultation with a higher level of health care centers (district or provincial hospitals). If lymph node TB does not improve in 2 months of intensive phase treatment then based on clinical judgement, continuation phase of 7-10 month of HRE should be initiated and should be investigated for DR-TB.

Unless drug resistant TB is suspected, adjuvant corticosteroids treatment should only be included for TB meningitis and TB pericarditis with dexamethasone or prednisolone tapered over 6-8 weeks. The drug most frequently used is prednisolone, in a dosage of 2mg/kg daily, increased up to 4 mg/kg daily in the case of the most severely ill patients for 4 weeks. The dose then should be gradually tapered (0.5mg/kg) every week over 4 weeks until finished (2 months in total duration).

Alternatively, dexamethasome for CNS disease in the dose of 0.3 - 0.4 mg/kg/day for 2-4 weeks then taper 0.1mg/kg/week until 0.1mg/kg then, 4mg/day and taper by 1mg/week: total duration of 12 weeks.

Monitoring response to Extrapulmonary treatment:

For patients with extrapulmonary TB, clinical monitoring is the usual way of assessing the response to treatment **(Standard 10 of the ISTC (1)).** As in pulmonary smear-negative disease, the weight of the patient is a useful indicator.

6.4 PATIENT REGISTRATION GROUPS

Patient registration group is based on a history of previous TB treatment. The following table lists the new patient registration groups:

TABLE 6.3: Patient Registration Groups

TYPE OF PATIENTS	DEFINITION
1. New patients	Patients who have never been treated for TB of have taken anti-TB drugs for less than one month
Previously treated patients: Patients who have received 1 month or more of anti-TB drugs in the past. They are further classified by the outcome of their most recent course of treatment as follows:	
2. Relapse patients	A patient who have previously been treated for TB, were declared cured or treatment completed at the end of their most recent course of treatment, and are now diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by reinfection).
3. Treatment after failure patients	Are those who have previously been treated for TB and whose treatment failed at the end of their most recent course of treatment.
4. Treatment after loss to follow-up patients	Patients have previously been treated for TB and were declared lost to follow-up at the end of their most recent course of treatment. (These were previously known as Treatment After Default patients)
5. Other previously treated patients	Patients those who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.
6. Patients with unknown previous TB treatment history	Patients with unknown previous TB treatment history who do not fit into any other categories listed above.

*New and relapse cases of TB are incident TB cases.

6.5 Dosage and frequency

- Treatment dosage is based on weight. Dosage is simplified for different weight groups.
- Dosage should be adjusted if the patient changes to new weight range during the course of treatment.
- 7 days is equal to 1 week and 4 weeks are counted for 1 month.
- For TB treatment 28 days equal one month.
- All intensive phase is given daily, and intensive phase is given for 2 months.
- Thus 2 months of intensive phase equals a total of 56 doses (28 days x 2 months = 56 days treatment taken).
- Intensive phase is stopped after the patient completes 56 doses. **The intensive phase must not be extended for any duration for any reason.**

- All continuation phase is daily and continuation phase is given for 4 months.
- Thus 4 months of continuation phase equals a total of 112 doses (28 days x 4 months = 112 days treatment taken).
- Continuation phase is stopped after the patient completes 112 doses. **Continuation phase must not be extended for any duration for any reason except for severe forms of EPTB as mentioned in Table 6.1.**

It is very important that all TB patients MUST RECEIVE SUPERVISED TB TREATMENT OR DOT (Directly Observed Treatment). Patients who live further away (more than 8-kilo-metres from the nearest health facility or 30 minutes by walk) or are not able to come to a health facility for daily DOT, TB medicine should be supplied for DOT by an identified DOT provider.

Good health education and information about the disease and how many tablets to take, when to take them, cough etiquette, contact investigation and counselling on treatment adherence must be provided including the importance of taking the tablets regularly and the consequences of not taking the tablets regularly/stop taking tablets should be given to each patients.

PLEASE DO NOT SIMPLY ASSUME PATIENTS KNOW HOW TO TAKE TB DRUGS AND JUST TRUST THAT THEY WILL TAKE THE TABLETS. Patients are very important people who will help stop the spread of TB when they take their treatment properly and faithfully.

When supplying treatment follow the following instructions:

1. DOT for all patients living closer to the health facility in the intensive phase
2. Supply 15 days supply to community DOT provider who lives further away and after identifyng DOT/Treatment provider for each patient as per CBDOT criteria for intensive as well as continuation phase
3. For patients who do not have a TB treatment supporter, ask them to appoint one-person neighbor or shopkeeper/pharmacist/etc. who is willing to supervise the patient while taking treatment.

6.6 COMMUNITY-BASED DIRECTLY OBSERVED TREATMENT (CBDOT)

Community-Based DOT

The community-based DOTS means any TB patients who cannot attend to the TB Treatment Centre regularly due to the different reasons and such patients will be treated in the community closed to their home by a community volunteer. Treatment supervisors from the community make sure that patients swallow the pills in front of them and maintain the patient's records as per NTP recording/reporting system.

Objectives of the CBDOT:

1. To increase Tuberculosis treatment accessibility for the patients who are unable to visit treatment center daily due to the physical, social or mental issues, geographical difficulties or other conditions
2. To increase treatment adherence, raise awareness on disease conditions in the community and decrease social stigma by involving community members

Criteria for selecting patients in CBDOT

The below are some of the reasons that patients cannot come to health facility every day; in such cases to ensure DOT, a community member (volunteer) will be selected as treatment supervisor who will be willing to provide TB medicines.

In the following conditions, patients should be treated under community-based DOTS.

- Students, job holders and daily wage workers (who are unable to visit the treatment center during the opening time)
- Physically weak or disabled TB patients.
- More than 60 years of age/senior citizens who do not want to come daily to treatment centers
- Children
- Bed ridden TB patients
- Pregnant or maternity TB patients
- Other conditions such as patients like who cannot move and travel due to the accident, etc.

Criteria to select treatment observers

Following criteria will be followed to select the treatment observers:

1. Interested to provide DOT for TB patients every day and committed to volunteerism.
2. Able to read and write (Recording, reporting and use of educational materials)
3. Staying most of the time in the community.
4. Living in an accessible area of the ward (centrally located in the ward)
5. Following people could be selected as a treatment supervisor:
    - Teachers, social worker, private drug seller, retired health care providers etc.
    - Cured TB patients
    - Trained Female Community Health Volunteers (FCHV).

Responsibility of treatment observers (Volunteer)

- Provide treatment for patients as directed by the TB treatment/DOTS clinic in-charge.
- Complete the treatment cards as per instructions and keep the treatment card safely.
- Visit the health facility every 15 days to collect the medicine if needed, any time.
- Acompany patient to the treatment center every month for review and follow-ups.
- Ensure sputum follow-up examination of patients in 2/3, 5 and end of treatment and maintain the record in the patient's card and the treatment card kept by the treatment supervisor.
- Monitor adverse events every day, ask with the patient about any problems regularly and inform the health facility when necessary.
- Monthly report to the health facility with the patient's treatment card and the patients for follow up.
- Be alert with patient's disease and maintain confidentiality.
- Counsel and refer close contacts of bacteriologically confirmed TB patients to the health facility for investigations.
- Inform in-charge of the health facility for alternate arrangements, one week before if in case he/she will be busy for that week and find an alternate supervisor for that period.

6.7. DOSAGE AND FREQUENCY OF THE DRUG REGIMEN

Blister packs are currently used for treatment of TB in Nepal. A single blister pack contains 28 tablets. The number of tablets to give to each patient is based on their weight band and the number of blister packs to be given depends on the number of tablets each patient takes, and the number of days supplied. The following table shows the recommended number of tablets to be given to TB patients in the different weight ranges and the number of blister packs needed for the full course of treatment and numbers to supply using 28-tablet blister packs.

Please refer table no 6.3a, 6.3b, 6.3c for drug dosages

TABLE 6.3a: TB treatment

Weight bands	Intensive Phase	Continuation Phase	INH Resistant (Hr-TB)	
	HRZE 75/150/400/275	HR 75/150	HRZE 75/150/400/275	Leveofloxacin (Lfx) 250mg
30-39 kg	2 Tablets	2 Tablets	2 Tablets	2 Tablets
40-54 kg	3 Tablets	3 Tablets	3 Tablets	3 Tablets
55-70 kg	4 Tablets	4 Tablets	4 Tablets	4 Tablets
>70 kg	5 Tablets	5 Tablets	5 Tablets	5 Tablets

TABLE 6.3b: Drug Dosages (Intensive phase)

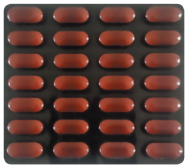
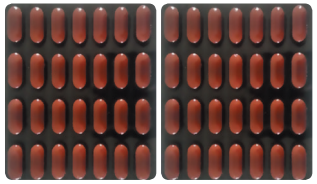
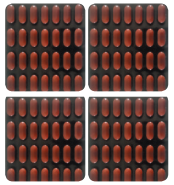
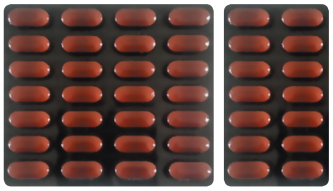
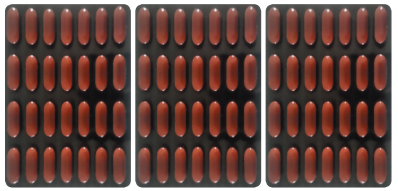
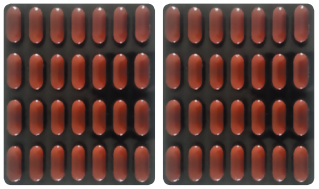
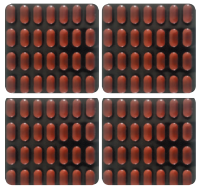
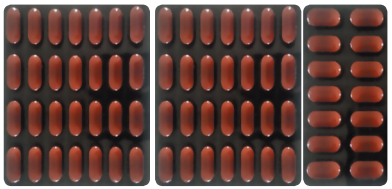
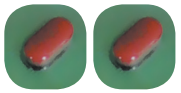
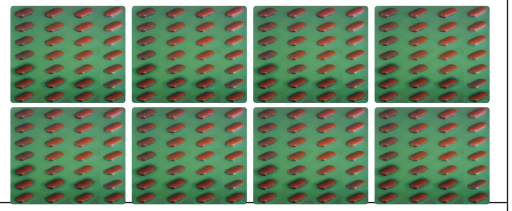
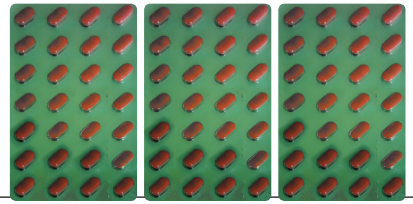
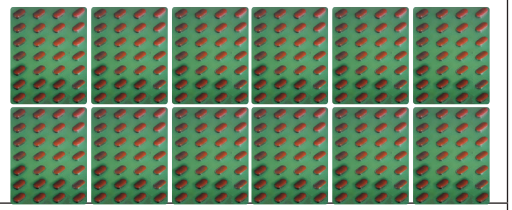
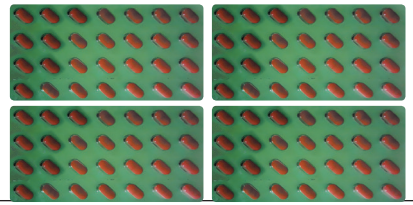
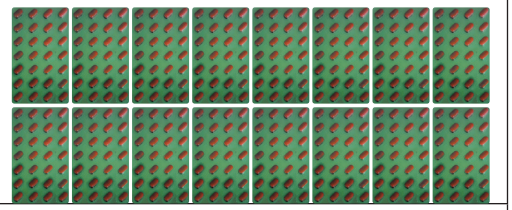
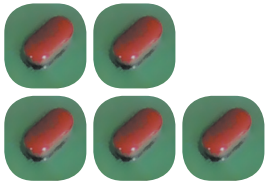
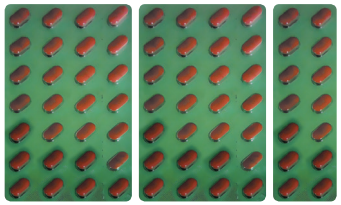
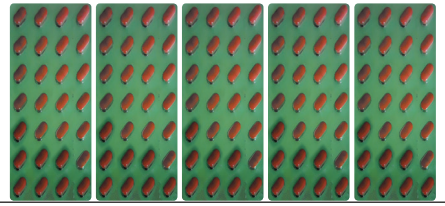
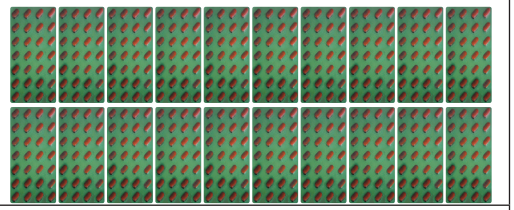
Intensive Phase: 2 months /HRZE, doses given daily, in total – 56 doses				
Weight Range	No. of tablets for the daily treatment	No. of blister packs to supply for 2 weeks treatment (For CBDOT)	Number of blister packs needed for 1-month treatment	Number of blister packs needed for full intensive phase
30-39 kg	2 tablets 	1 blister 	2 blisters 	4 blisters 
40-54 kg	3 tablets 	1 and ½ blisters 	3 blisters 	6 blisters 
55 -70 kg	4 tablets 	2 blisters 	4 blisters 	8 blisters 
Over 70 kg	5 tablets 	2 ½ blisters 	5 blisters 	10 blisters 

TABLE 6.3c: Drug Dosages (Continuation phase)

Continuation Phase: 4 months / HR, doses given daily, in total - 112 doses.				
Weight Range	No. of tablets for daily treatment	No. of blister packs to supply for 2 weeks treatment (For CBDOT)	Number of blister packs needed for 1 month treatment	Number of blister packs needed for full continuation phase
30-39 kg	2 tablets 	1 blister 	2 blisters 	8 blisters 
40-54 kg	3 tablets 	1 ½ blisters 	3 blisters 	12 blisters 
55 -70 kg	4 tablets 	2 blisters 	4 blisters 	16 blisters 
Over 70 kg	5 tablets 	2 ½ blisters 	5 blisters 	20 blisters 

- ✓ The number of blister packs to supply for 1 month is the same as the number of tablets taken daily eg. If 3 tablets daily treatment then 3 blister packs are needed for one month.
- ✓ The number of tablets per day per weight range is the same for intensive and continuation phase, eg, a patient who weighs 57kg will take 4 tablets daily in intensive phase and also 4 tablets daily the in the continuation phase.
- ✓ When patients gain weight, increase the number of tablets according to the new weight range.
- ✓ Do not decrease the number of tablets if the patient's weight decreases to a lower weight range.

TB treatment for New Cases (all forms of TB)					INH Resistant (also called HrTB)				
Patient Body Weight	Intensive Phase HRZE - 2 Months Number of tablets		Continuation Phase HR - 4 Months Number of tablets		Patient Body Weight	6HRZE Lfx HRZE Number of tablets		Lfx 250mg Number of tablets	
30 - 39 Kg	2		2		30 - 39 Kg	2		2	
40 - 54 Kg	3		3		40 - 54 Kg	3		3	
55 - 70 kg	4		4		55 - 70 kg	4		4	
> 70 kg	5		5		> 70 kg	5		5	
Note: Severe form of New TB cases (eg. Musculoskeletal TB, TB Meningitis etc) 2HRZE+7-10 HRE									
* patients <30 kg may receive the same dose as weight band of 30-39 kg (ie. 2 Tab for HRZE and HR, and 3 Tab for Lfx) if tolerated.									

6.8. SPECIAL SITUATIONS

TABLE 6.4: Recommendations for special situations when deciding TB treatment.

Special Situation	Recommended regimen
Pregnancy	A pregnant woman should be advised that successful treatment of TB with the standard regimen is important for successful outcome of pregnancy. The first line anti-TB drugs are safe for use in pregnancy.
Breast feeding	Mother should be given normal full course of TB treatment. Timely and properly applied chemotherapy is the best way to prevent transmission of tubercle bacilli to the baby. Mother and baby should stay together, and the baby should continue to breastfeed. Use mask while brestfeeding and practice other infection measures. After active TB in the baby is ruled out, the baby should be given **3 months RH preventive therapy, followed by BCG vaccination.** **Pyridoxine 10 mg daily** supplementation is recommended for all pregnant or breastfeeding women taking isoniazid (INH) throughout the TB treatment
TB/HIV	Same regimen as a non-HIV TB patient for same duration.
Oral contraceptive pills	Since rifampicin reduces the effectiveness of oral contraceptives, women should be advised to choose between one of two options for contraception. Following consultation with a clinician, the patient may use an oral contraceptive pill containing a higher dose of estrogen (50 µg); alternatively, some non-hormonal methods of contraception may be used throughout rifampicin treatment and for at least one month subsequently
Liver disorder	Patients with hepatitis virus carriage, a past history of acute hepatitis and current excessive alcohol consumption provided that there is no clinical evidence of chronic liver disease can receive usual regimen but should be closely monitored. Exception and an alternate regimen are given below
Renal failure and severe renal insufficiency	The recommended initial TB treatment regimen for patients with renal failure or severe renal insufficiency is same as normal TB treatment. Exception and an alternate regimen are given below:

6.8.1. Liver disorders

Patients with hepatitis virus carriage, a history of acute hepatitis and current excessive alcohol consumption can receive usual regimen provided that there is no clinical evidence of chronic liver disease but should be closely monitored. However, hepatotoxic reactions to anti-TB drugs may be more common among these patients and should therefore, be anticipated.

In patients with unstable or advanced liver disease, liver function tests should be done at the start of treatment, if possible. If the **serum alanine aminotransferase** level is more than **3 times the normal** before the initiation of treatment, the following regimens should be considered. Expert consultation is advisable.

The more unstable or severe liver disease is, the fewer hepatotoxic drugs should be used.

The regimen used for Liver disorders:

- Patients with hepatitis virus carriage, a history of acute hepatitis and current excessive alcohol consumption can receive **2(HRZE)/4(HR)** provided that there is no clinical evidence of chronic liver disease with close monitoring.
- Two hepatotoxic drugs (rather than the three in the standard regimen).
- 9 months of isoniazid and rifampicin, plus ethambutol- **9 (HRE)** (until or unless isoniazid susceptibility is documented).
- Expert consultation is advisable in treating patients with advanced or unstable liver disease. Clinical monitoring (and liver function tests, if possible) of all patients with pre-existing liver disease should be performed during treatment.

6.8.2 Renal failure and severe renal insufficiency

The recommended initial TB treatment regimen for patients with renal failure or severe renal insufficiency is the same normal TB treatment regimen **2(HRZE)/4(HR)**

Isoniazid and **Rifampicin** are eliminated by biliary excretion, so no change in dosing are necessary. There is significant renal excretion of **ethambutol** and **metabolites of pyrazinamide**, and doses should therefore, be adjusted.

Three times per week administration of these two drugs at the following doses is recommended: **pyrazinamide (25 mg/kg), and ethambutol (15 mg/kg)**

These are the same mg/kg doses as those listed under daily dosages in Annex 3b. While receiving Isoniazid, patients with severe renal insufficiency or failure should also be given **Pyridoxine 10 mg** daily to prevent peripheral neuropathy.

Loose drugs will be stored at the central level and procured based on the requirement for special situations only

6.9 MANAGEMENT OF DRUG INDUCED HEPATITIS

If ALT is more than three times of normal range and the patient is symptomatic or five times the normal range without symptom, please follow the following guideline:

Hold all TB drugs for 7-10 days (Wait until symptoms resolve and liver enzyme is < than 2.5 times upper limit of normal) before re-starting ATT.

Note: Patients with severe TB should be treated with Streptomycin, Ethambutol, and Levofloxacin until they are well enough to attempt re-introduction.

Most patients with ATT drug –induced hepatitis will tolerate re-introduction of all first line drugs.

Step wise Reintroduction of ATT after drug Induced hepatitis

Day	Drug and dose	Remarks
1#	Rifampicin 300 mg + Ethambutol *	
2#	Rifampicin 450 mg + Ethambutol*	If patient remains asymptomatic
3#	Rifampicin 600 mg + Ethambutol*	If patient remains asymptomatic; Check LFT
4#	Isoniazide 100 mg + Ethambutol *	If patient remains asymptomatic
5#	Isoniazide 200 mg + Ethambutol*	If patient remains asymptomatic
6#	Isoniazide 300 mg + Ethambutol	If patient remains asymptomatic: Check LFT
7#		
8#	Pyrazinamide 400 mg+ Ethambutol *	If patient remains asymptomatic
9#	Pyrazinamide 800 mg+ Ethambutol *	If patient remains asymptomatic
10#	Pyrazinamide 1200 mg+ Ethambutol *	If patient remains asymptomatic: Check LFT

* Ethambutol is not hepatotoxic so it should be started on Day 1 at full dose. Regarding the PZA, if the patient has liver disorder, do not re-introduce it.

If signs and symptoms recur at any day of re-introduction or follow up LFT shows ALT more than three times of normal range (irrespective of signs and symptoms), discontinue the responsible drug and modify the regimen and/or duration of therapy as required. This needs to be done in consultation with clinical TWG.

Drug omitted	Total duration	Intensive phase	Continuation phase
Rifampicin	18months	INH, Levofloxacin, Ethambutol, Streptomycin x 2 months*	INH, Levofloxacin, Ethambutol x 16 months
INH	12 months	Rifampicin, Levofloxacin Ethambutol Streptomycin x 2 months*	Rifampicin, Levofloxacin Ethambutol x 10 months
PZA	9 months	Rifampicin, INH, Ethambutol x 9 months	

*The above is broad guidance. The drug induced cases may be refered to higher centre or clinical committee for individualized treatment.

6.10 SUMMARY OF WHAT TO DO WHEN A PATIENT IS DIAGNOSED WITH TB.

1. Establish the diagnosis based on investigations (bacteriologically confirmed or clinically diagnosed)
2. Determine the type of disease based on site (PTB or EPTB)
3. Determine the type of patient based on the outcome of their most recent course of treatment according to the patient registration groups mentioned above.

4. Weigh the patient and based on the patient's weight determine the number of tablets of FDC tablets patient will receive for intensive phase and the continuation phase. Table 6.3b and 6.3c; indicate the number of tablets for different weight ranges for intensive and continuation phase.
5. Inform the patient about the disease and its treatment and provide good health education.
6. Fill a TB treatment card **(TB05)** for the patient correctly and accurately.
7. Register the patient in the TB Register **(TB 04)** of treatment center
8. Issue TB patient ID card
9. Ensure that all patient on TB treatment is provided under DOT

6.11 REGISTRATION

A TB treatment card **(TB 05)** is completed with information of the patient's diagnosis and treatment and updated during the treatment. It is kept at the registering centre and a copy is made available for the treatment supporter. All diagnosed TB patients are registered in the TB register **(TB 04)** and are allocated a unique TB registration number. This number is also entered on the patient treatment card.

6.12 HEALTH EDUCATION

Before starting a TB patient on TB treatment, adequate health education must be given to the patient and family. The following topics should be included:

- Information on TB disease- What is Tuberculosis, how TB spreads, how to prevent the spread of TB
- TB treatment information – TB is curable, details of treatment and its duration
- Importance of directly observed treatment and regularity of treatment
- Inform the patients about common side effects of anti-TB drugs and reassure them
- Advise patients sputum to follow up and drug collection schedules and side effects to watch for and report when necessary
- Assign if a treatment supporter is required for the patient who will not be able to visit the treatment centre regularly.

6.13 TREATMENT ADMINISTRATION AND ADHERENCE

6.13.1 Directly Observed Treatment (DOT)

All TB treatment should be given under DOT for both the intensive and continuation phases.

DOT means supporting the patient swallow the drugs under direct observation and then recording the treatment in the treatment card. It does not mean giving the patient drugs to take by him/herself in the treatment room or ward. DOT should be convenient for the patient. Patients for DOT must not wait in a queue. Health workers are the primary people responsible for ensuring effective treatment. They are directly responsible for ensuring DOT for all TB patients under their care. If health workers who are not able to directly observe their patient's treatment, they can help the patient to identify someone who can supervise the patient. Anyone can be trained and supervised by the health worker to do DOT.

The following ways of supervising treatment are considered (in order of priority):

1. The patient goes daily to the health facility and swallows the drugs in front of the health worker.
2. The patient is supervised daily by a treatment supporter trained in DOT in the community.
3. The patient is hospitalized for the intensive phase in a rare case and in case there are other co-morbidities that warrant a hospital stay.

Patients attend monthly for follow up on treatment, sputum collection at the required time and also for continuous health education. Community TB treatment supporters can also be non-health care workers who can be trained and supervised by the health facility and preferably should be selected by patients based on their convenience.

6.13.2 Ensuring continuation of treatment

Continuation of treatment is very important, even when a TB patient is referred or transferred to another facility a referral/transfer slip **(TB10)** should be filled and sent with the patient. Whether a patient is transferred or referred or travels temporarily, the patient should be supplied TB treatment for the duration of travel.

6.13.3 Management of patients who interrupted treatment

Retrieval action should be taken within 24 -48 hours if a TB patient misses a dose for more than 24 hours or a treatment supporter or self-administered patient fails to collect drugs. The treatment centre should identify early defaulters and act immediately. Priority is given to bacteriologically confirmed PTB. Treatment is continued and prolonged to make up for missed doses. It is very important to find the cause of the interruption and take appropriate action to prevent further interruptions. A patient is regarded as lost to follow up after he or she misses treatment for **more than 2 consecutive months.**

6.13.4 The following is the summary of actions to take after interruption of treatment

Interruption for less than 1 month:

Patients who interrupt treatment must be traced urgently within 24-48 hrs. to prevent the development of drug resistance.

Interruption for 1 up to 2 months:

<table>
<tr><th>FIRST</th><th colspan="2">THEN, ACT BASED ON THE RESULTS OF SPUTUM EXAMINATION</th></tr>
<tr><td rowspan="2">▪ Trace the patient
▪ Solve the cause of the interruption
▪ Collect 2 sputum samples and send for microscopy/Xpert MTB/RIF</td><td>If all smears are negative, or no RR or if the patient has extra-pulmonary TB</td><td>Continue treatment and prolong it to compensate for missed doses. Ensure that the total number of doses planned for the initial phase and continuation phase is given.</td></tr>
<tr><td>If one or more smears are positive and RR not detected

If RR detected</td><td>Restart treatment and complete full course under DOT

Refer to National Guidelines on Drug Resistant TB (2019)</td></tr>
</table>

Interruption for 2 months or more:

- Trace the patient
- Determine and address the cause of interruption

Do the following :

FIRST	THEN, ACT BASED ON THE RESULTS OF SPUTUM EXAMINATION	
▪ Trace the patient ▪ Solve the cause of the interruption, if possible	If all smears are negative, and RR not detected or if the patient has extra-pulmonary TB	Restart treatment
▪ Collect 2 sputum samples for smear microscopy and Xpert MTB/RIF	If one or more smears positive and RR not detected	Restart treatment
	If RR detected	Refer to National Guidelines on Drug Resistant TB (2019)

6.14 ADVERSE EFFECTS OF ANTI-TB DRUGS

Minor side effects can be managed at the health facilities. However, if major side effects occur treatment should be stopped, and the patient should be referred to a trained clinician or hospital.

TABLE 6.5: Common adverse effects of anti-TB drugs

SIDE EFFECTS	DRUGS RESPONSIBLE	MANAGEMENT
MINOR ADVERSE EFFECTS		
Anorexia, nausea, vomiting, Abdominal pain (and no jaundice)	Pyrazinamide, Rifampicin	Take drugs with food or juice or before sleeping and reassurance.
Joint pain	Pyrazinamide	Aspirin / Indomethacin
Burning sensation in the feet, tingling	Isoniazid	Pyridoxine 100 mg daily (when better reduce to 25 mg/day
Confusion, sleep disturbance	Isoniazid	Pyridoxine 25 mg/day
Orange/red urine	Rifampicin	Reassurance
Itching, rash without blisters	Any drug (or skin disease)	Phenergan, promethazine
MAJOR ADVERSE EFFECTS		
Deafness	Injectables	Stop Injectables
Dizziness, vertigo, nystagmus	Injectables	Stop Injectables
Jaundice (other causes excluded), hepatitis	All drugs but commonly isoniazid. Also, rifampicin and Pyrazinamide	Stop anti-TB drugs, start the same regimen after two weeks or refer.
Confusion	Most anti-TB drugs	Stop anti-TB drugs, refer
Difficulty with vision	Ethambutol	Stop ethambutol, refer
Shock, purpura, acute renal failure	Rifampicin	Stop rifampicin, refer

6.15 MONITORING TREATMENT

6.15.1 Sputum follow up

Three different follow-up sputum examinations for AFB are done during TB treatment to evaluate the progress of treatment of smear-positive PTB. **Only one sputum sample is required during each follow up.** If sputum is positive at 5 months or end of treatment the patient is declared a "failure". The following is the schedule for follow up sputum examination during the TB treatment

Note for children: If the child is able to produce sputum then send a sample. However, if the child is clinically improving and unable to produce sputum (no cough, gaining weight, etc) then you may follow the child clinically.

TABLE 6.6: All Pulmonary TB cases follow up sputum schedule

FOLLOW UP	THE MONTH OF FOLLOW UP	ACTION TO TAKE IF POSITIVE
End of intensive phase	**2**	1. Start the continuation phase. 2. Collect sputum for microscopy 3. If positive, send sputum for Xpert MTB/RIF test, **No extension of the intensive phase**
Incase smear-positive at the end of the intensive phase (2nd month) and Xpert MTB/RIF (R-sensitive)	**3**	1. Repeat sputum again at 3rd month and if positive; Collect sputum and send for Xpert MTB/RIF test 2. Treat based on Xpert results
During continuation phase	**5**	1. Repeat sputum. 2. If repeat sputum is negative and no symptoms of TB continue treatment. 3. If repeat sputum is positive declare failure and registered treatment outcome as failed. 4. Collect sputum and send for Xpert MTB/RIF test. 5. If Xpert MTB/RIF test shows rifampicin sensitive, assess DOT, restart treatment under strict DOT. Re-resigster as treatment after failure. 6. If Xpert MTB/RIF test shows Rifampicin Resistant, refer to National Guidelines on DR TB Management 2019. 7. Send sputum for culture and DST
End of treatment	**6**	1. Repeat sputum. 2. If repeat sputum is negative, determine treatment outcome as "Cure" or "Treatment Completed". 3. If sputum is not being produced and there is no other signs of clinical detrioration, the outcome is treatment completed. 4. If repeat sputum is positive declare failure and record outcome as treatment failed 5. Collect sputum and send for Xpert MTB/RIF test. 6. If Xpert MTB/RIF test shows rifampicin sensitive, assess DOT, restart treatment under strict DOT. Re-resigster as treatment after failure. If Xpert MTB/RIF test shows rifampicin-resistant, send a sample for cultures and DST and refer to National Guidelines on Drug Resistant TB 2019

When submitting sputum for follow up, consider 2 sputum sample collection for patients who are not improving and /or are likely to fail treatment or suspected of drug resistant TB. Indicate Xpert MTB/RIF test examination on one of the specimen.

Any patient in whom MDR TB is diagnosed should be started on appropriate MDR TB regimen- Refer to National Guidelines on Drug Resistant TB (2019)

6.15.2 Bacteriologically negative PTB and EPTB cases

Monitor treatment of bacteriologically not confirmed PTB and EPTB by clinical assessment, weight and eventually X-Ray. New PTB bacteriologically not confirmed cases and EPTB should have ***sputum examination at the end of the intensive phase.*** Both PTB bacteriologically not confirmed and EPTB cases sputum should be checked in case of suspicion of failure. If a bacteriologically non-confirmed PTB case becomes smear / Xpert MTB/RIF test positive at the end of the intensive phase, then the patient should be declared treatment failure and should be re-registered as a treatment after failure. The patient should be restarted on treatment under strict DOT and if RR detected refer to National Guidelines on Drug Resistant TB (2019)

6.16 RECORDING TREATMENT OUTCOMES

Every registered patient should be evaluated at the end of treatment or when closing the file for another reason. The following table shows the possible outcomes for TB patients.

TABLE 6.7: Possible Treatment Outcomes

TREATMENT OUTCOME	DEFINITION
1. Cured	A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear-negative in the last month of treatment and on at least one previous occasion.
2. Treatment Completed	A TB patient who completed treatment without evidence of failure BUT with no record to show that sputum smear results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable
3. Treatment Failed	A TB patient whose sputum smear is positive at month 5 or later during treatment. Also applies to smear-negative patient and EPTB who become smear positive at 2 months.
4. Died	A TB patient who dies for any reason before starting or during the course of treatment.
5. Lost to follow up	A TB patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more.
6. Not Evaluated	A TB patient for whom no treatment outcome is assigned. This includes cases who were “transferred out” to another treatment center as well as cases for whom the treatment outcome is unknown to the reporting unit

Treatment Success is the sum of cured and completed treatment. The treatment outcome should be recorded on the back of the TB treatment card and TB Register.

MANAGEMENT OF TB IN CHILDREN

CHAPTER 7

DIAGNOSIS AND TREATMENT OF TUBERCULOSIS IN CHILDREN

As the symptoms are subtle and mimic other common childhood illness, diagnosing childhood TB is challenging. Clinical picture and diagnostic approach are not straight forward as adult TB (see the table 7.1). A child usually gets the disease from an infectious adult hence the contact history is very important. Most of the cases in children are smear-negative and paucibacillary. Moreover, children below 6 years usually cannot expectorate sputum.

While bacteriology testing should always be attempted, the challenges with specimen collection at lower health care levels and the suboptimal accuracy of the present tools in children need to be recognized. Therefore, clinical diagnosis needs to be done based on a high index of suspicion on the basis of contact history, risk factor and symptom analysis.

TABLE 7.1: Difference between adult TB and childhood TB

CRITERIA	ADULT TB	CHILDHOOD TB
Symptoms	Suggestive	Non-specific
Physical signs	Easily elicited	Often subtle or absent
Sputum sample	Easy to obtain	Difficult to obtain
Sputum microscopy/ GeneXpert	Usually contains numerous bacilli	Often negative, sputum is paucibacillary (a negative test result does not exclude TB in children).
CXR	Easy to interpret	Difficult to interpret

7.1 RISK FACTORS FOR TB DISEASE:

Certain groups of children are at increased risk of developing TB disease as below.

Key risk factors for TB disease in children

1. Household or close contact with a bacteriologically confirmed TB (parents, siblings, close relatives, caregivers, neighbors and teachers)
2. Age <5 years: The risk of developing TB disease is highest in very young children, who are immune immature
3. Severe malnutrition or other Immunosuppressive conditions
   - Measles in the previous 3 months
   - Whooping cough
   - HIV infection
   - Being on drugs like steroids or immunosuppressive drugs
4. The time since exposure or infection: the vast majority of children who develop TB disease do so within the first year after M. tuberculosis exposure or infection

NB : Other high-risk factors are HIV/AIDS, diabetes (both type 1 and type 2 diabetes) patient, end-stage renal failure, cancer, connective tissue disease, silicosis, gastrectomy, solid organ transplantation and patients on prolonged steroid treatment.

7.2 DIAGNOSIS OF TB IN CHILDREN

Diagnosis of TB in children is not as straight-forward as in adult TB patient. It requires a careful and thorough assessment of all the data derived from a careful history, clinical examination, and relevant investigations. e.g. Mantoux test (MT), chest X-ray (CXR), Xpert MTB/RIF (a negative test result does not exclude TB in children) and other investigations. Pulmonary TB is a common form of TB in children although bacteriological confirmation through Xpert MTB/RIF sputum microscopy is not always possible for young children. In this group sputum induction and gastric aspiration have been documented to be an effective method for collection of specimen. Every attempt to collect sputum should be sought whenever possible. Sputum sample collection is strongly encouraged for the children who are able to produce a sputum sample Xpert MTB/RIF is the 1st diagnostic test for children who can produce sputum.

Also, a child with a fever of unknown origin, failure to thrive, whooping cough, severe malnutrition and/or other immunosuppressive conditions such as measles in the previous 3 months, PLHIV, AIDS or being on medication like steroids or unexplained lymphadenopathy should be evaluated for TB. Any child with pneumonia, pleural effusion, or a cavitary or mass lesion or other abnormality in the lung that does not improve with standard antibacterial therapy should also be evaluated for TB. A common differential diagnosis like asthma, bronchiectasis, lymphoma, non-tubercular mycobacterial diseases etc. should be kept in mind.

Diagnosis of TB in children is often difficult for several reasons:

- Symptoms are often non-specific particularly in young children and often mimics common childhood illness.
- Childhood TB is paucibacillary & a microbiological diagnosis is often not possible.
- It is difficult to obtain sputum or other respiratory specimens for bacteriological confirmation.
- The Mantoux Test (MT) or Tuberculin Skin Test (TST) is often negative in malnourished children. Moreover, a positive MT cannot differentiate active TB disease from infection.
- CXRs are often non-specific and prone to variable interpretation.

Recommended approach to diagnose TB in children

1. Careful history (including a history of TB contact and symptoms suggestive of TB)
2. Clinical assessment (including serial weight monitoring/growth assessment, use of TB Score chart for identifying presumptive TB in children)
3. Investigations
   - 3.1 Mantoux test
   - 3.2 Chest X-ray and other radiological evaluation
   - 3.3 Bacteriological investigations including Xpert MTB/RIF use in children
   - 3.4 Investigations relevant to suspected PTB/EPTB
   - 3.5 HIV testing

Step 1. Take a careful history of symptoms and contacts

Typical symptoms suggestive of TB

TB in children commonly presents with fever and failure to thrive. But these symptoms are non-specific. In most cases, children with symptomatic TB develop chronic unremitting symptoms (symptoms persisting for >2 weeks even after appropriate treatment). Haemoptysis or coughing up of blood (a common symptom in adults) is rare in children with TB but may occur in adolescents.

Symptom criteria for PTB

Persistent, non-remitting cough for >2 weeks not responding to conventional antibiotics (amoxicillin, co-trimoxazole or cephalosporin) and/or bronchodilators

and/or

Persistent documented fever (>38^0 C/100.40F) >2 weeks after common cases such as pneumonia, typhoid, malaria have been excluded

and/or

Documented weight loss or not gaining weight during the past 3 months (especially if not responding to de-worming together with food and/or micronutrient supplementation) OR severe malnutrition

and/or

Fatigue, reduced playfulness, decreased activity

NB: Any one of the above symptom criteria in a child (<=14 years) in close contact with a known bacteriologically confirmed TB or clinically confirmed TB should be regarded as presumptive TB case and referred to for evaluation.

Ask about symptoms that may indicate TB, as required to complete the TB score (see Table 7.4a and 7.4b). These symptoms include chronic respiratory symptoms, prolonged fevers, weight loss, fatigue, lymph node swelling, persistent back pain and chronic headache.

Ask detailed questions about respiratory symptoms. If a cough is present, has it lasted for more than two weeks, despite taking a course of appropriate antibiotics? Try to make the distinction between cough that is intermittent in a well-nourished child (likely to be due to recurrent upper respiratory tract infections) and cough that is persistent and non-remitting in a malnourished child (likely to be TB).

Ask similar detailed questions about fever. If fever is present, is it intermittent (e.g. once a week or month) or present every day? If fever is intermittent, it is more likely to be due to recurrent viral infections. If fever is present every day for more than two weeks and has not responded to antibiotics or malaria treatment, it is suggestive of TB.

History of contacts

- Take a careful family and contact history and take careful note of the following:
  - Closeness of contact
  - Sputum smear result of the index case (if known)
  - Timing of contact

- Children usually develop TB within 2 years after exposure and most (90%) within the first year
- If no source case is identified, always ask about anyone in household with cough; if so, request an assessment of that person for possible TB

Step 2. Clinical examination for presumed TB

Always interpret clinical examination findings along with the history and growth assessment, and not in isolation.

A. Growth Assessment: Think of TB if:

a. Failure to thrive (a "flat" or "falling" weight curve)
b. Weight loss
c. Eeight of age less than -2 SD (80% line_)
d. MUAC less than 12.5 cm
e. Severe malnutrition with no improvement after 4 weeks of treatment

Nutritional status of a child is determined by calculating the weight for age (W/A) and the mid-upper arm circumference (MUAC). For adolescents use the Body Mass Index (BMI, see below)

Failure to thrive or weight loss is an important feature of childhood TB. Plot out the child's weight on the growth chart in the Growth monitoring card (Bal Swastha Card) (or if there is no growth monitoring card, check the middle pages of the Standard Treatment Guidelines). Most children with TB will have a weight less than the -2 SD line of the expected value for age. A flattening or falling weight curve on the weight chart for the past three weights in the past 3 months is suggestive of chronic illness such as TB.

Measuring the mid-upper arm circumference (MUAC) is also very useful. A MUAC less than 12.5 cm in a child between 6 months and 5 years of age indicates malnutrition. A child who has severe malnutrition (severe visible wasting, bilateral oedema, very low W/A, or if the child is more than 6 months old - a MUAC of less than 12.5cm) with no improvement in nutritional status after four weeks of treatment for severe malnutrition, then the child is likely to have TB. This treatment should include broad-spectrum antibiotics for 14 days, and appropriate diet and micronutrients for a month.

A child with severe or moderate malnutrition, plus any of the suggestive clinical features listed above (under Clinical Examination), is highly likely to have TB. The TB score chart can help to assess this (see table 7.4a and 7.4b).

For children over 5 years of age and adolescents, measure body mass index, which is weight (kg) / height (m) 2. Thus, an adolescent who is 43kg and 1.56 m in height has a BMI of 43 / (1.56)2 = 43/2.4336 = 17.7. Below are BMI cut-offs for degrees of thinness:

BMI of <16 = severe thinness (severe malnutrition)
BMI 16-17 = moderate thinness (17 corresponds to -2SD)
BMI 17-18.5 = mild thinness
BMI > 18.5 normal weight
Many studies show that the lower the BMI the higher the risk of tuberculosis

B. Clinical examination

In general, TB is a slowly-developing chronic disease. But it may present acutely (eg. pneumonia, TBM) in young and HIV-infected children. Pulmonary TB in children can manifest in various ways in different age groups (table 7.2).

Infants (<1 year): primarily pneumonia-like
Children (1-9 years): usually with a chronic cough
Adolescents (10-19 years): as in adults

TABLE 7.2: Frequency of symptoms and sign of pulmonary TB stratified by child age

CLINICAL FEATURES	INFANTS (0-11 MO)	CHILDREN (1-9 YR)	ADOLESCENTS (10-19 YR)
Symptom			
Fever	Common	Uncommon	Common
Night sweats	Rare	Rare	Common
Cough	Common	Common	Common
Productive cough	Rare	Rare	Common
Haemoptysis	Never	Rare	Rare
Dyspnoea	Common	Rare	Rare
Sign			
Crepitations	Common	Uncommon	Rare
Wheezing	Common	Uncommon	Uncommon
Dullness to percussion	Rare	Rare	Uncommon
Decreased breath sounds	Common	Rare	Uncommon

Diagnosis of Extra-Pulmonary TB – Clinical Approach

Extra-pulmonary TB is common in children and presentation varies with age.

- The table below lists typical clinical features of forms of EPTB and suggested investigations for each category.
- Symptoms vary depending on site of disease and characteristically are persistent, progressive and may be associated with weight loss or poor weight gain.
- Clinical assessment in all cases should consider: History of contact, Sputum/other relevant samples for smear microscopy/Xpert MTB/RIF and HIV test

TABLE 7.3: Clinical approach to the diagnosis of EPTB

SITE OF EPTB	TYPICAL CLINICAL PRESENTATION	INVESTIGATION	COMMENT
TB adenitis	Asymmetrical, painless, non-tender lymph node enlargement for more than one month +/- discharging sinus Most commonly in the neck area	Fine needle aspiration when possible for AFB smear and if possible for culture. Xpert MTB/RIF can be done on FNA specimens	Treat for TB If axillary node enlarged on the same side as BCG, consider BCG disease
Pleural TB	Dullness on percussion and reduced breath sounds +/-chest pain	CXR Pleural tap	Treat for TB If pus in pleural tap, consider empyema
Usually young (< 5 years) with disseminated disease and severely ill			
TB meningitis	Headache, irritability/ abnormal behaviour, vomiting (without diarrhoea), lethargic/reduced level of consciousness, convulsions, neck stiffness, bulging fontanelle, cranial nerve palsies	Lumbar puncture obtain CSF CXR Xpert MTB/RIF should be done on CSF	Hospitalise for TB treatment
Miliary TB	Non-specific, lethargic, fever, wasted	CXR	Treat and refer to higher centers with Paediatricians
Usually 5 years and older			
Abdominal TB	Abdominal swelling with ascites or abdominal masses	Ascitic tap	Refer to higher centers with Paediatricians
Spinal TB	Deformity of spine (Gibbus formation) May have lower limb weakness/paralysis	X-ray spine	Refer to higher centers with Paediatricians
Pericardial TB	Cardiac failure Distant heart sounds Apex beat difficult to palpate	CXR Cardiac ultrasound Pericardial tap#	Refer to higher centers with Paediatricians
TB of bone and joint	Swelling end of long bones with limited movement Unilateral effusion usually of the knee or hip	X-ray bone/joint Joint tap	Refer to higher centers with Paediatricians

Danger signs requiring urgent hospital referral

Although TB is usually a chronic disease, there are certain danger signs that require urgent hospital referral.

Danger signs requiring urgent referral

- ✓ Severe respiratory distress (TB pneumonia with/without bacterial super infection, Pleural effusion)
- ✓ Severe wheezing not responding to bronchodilators (signs of severe airway compression)
- ✓ Headache (especially if accompanied by vomiting), irritability, drowsiness, neck stiffness and convulsions (signs of TB meningitis)
- ✓ Acutely ill with hepatosplenomegaly and ascites (signs of disseminated TB)
- ✓ Breathlessness and peripheral edema (signs of pericardial effusion)
- ✓ Acute angulation (bending) of the spine with/without paraplegia (a sign of TB spine – "gibbus")
- ✓ Other co-morbidities e.g. severe anemia, severe malnutrition

NB: Hospital referral should also be considered if there is any diagnostic uncertainty that warrants further investigations. Before referral, the patient must be stabilized with necessary treatment.

Uncommon signs indicative of recent TB infection

- ✓ Phlyctenular conjunctivitis - raised red nodule at the junction of the sclera and cornea surrounded by a red area of conjunctivitis.
- ✓ Erythema nodosum - raised, tender, purple patches on the shin.

Growth Assessment :

Documented weight loss/failure to gain weight specially after being treated in a nutritional rehabilitation programme, is a good indicator of cromic diesease in children of which TB may be the cause. SAM is recognised risk factor of progression of TB disease in children.

Step 3: Investigation

Mantoux test (MT)/ Tuberculin skin test (TST)

TST is useful to support a diagnosis of TB in children with suggestive clinical features who are sputum smear-negative or who cannot produce sputum

- A positive TST indicates an infection:
  - positive in any child if ≥ 10 mm irrespective of BCG immunization
  - also, positive if ≥ 5 mm in HIV-infected or severely malnourished child
- A positive TST is particularly useful to indicate TB infection when there is no known TB exposure on clinical assessment i.e. no positive contact history
- Caution
  - A positive TST does not distinguish between TB infection and active disease
- A negative TST does not exclude TB disease

Chest X-Ray

CXR remains an important tool for the diagnosis of PTB in children who are sputum smear-negative or who cannot produce sputum.

The following abnormalities on CXR are suggestive of TB:

- Enlarged hilar lymph nodes and opacification in the lung tissue
- Miliary mottling in lung tissue
- Cavitation (tends to occur in older children)
- Pleural or pericardial effusion – though seen on CXR – are forms of extra pulmonary TB that tend to occur in older children

The finding of marked abnormality on CXR in a child with no signs of respiratory distress (no fast breathing or chest indrawing) is supportive of TB

Step 4: Bacteriological investigations including Xpert MTB/RIF use in children

If appropriate to the clinical picture, collection of other fluid specimens for microscopy may be possible in some rural health facilities by medical officers or other trained clinicians. Appropriate specimens include two spot sputum specimens if possible, or 2 early morning gastric aspirates. Other samples include pleural fluid, ascites fluid, & cerebrospinal fluid. Some of these tests (pleural aspirate, lumbar puncture, ascites tap) must be done under strict aseptic conditions, so it is important to be done by trained health workers using proper technique.

Laboratory tests from other specimens may include:

- **Sputum:** Common way to obtain sputum sample for Xpert MTB/RIF includes expectoration, sputum induction and gastric aspirate. Gastric aspirate sample for children who cannot cough up sputum (usually < 6 or small children) take two gastric aspirate specimens in the early mornings (because the child coughs and swallows sputum overnight). These can be tested with microscopy and AFB staining. The gastric aspirate is taken using a nasogastric tube. Xpert MTB/RIF is the prefer test done on gastric aspirate, the yield is not as high as for a good sputum sample, but it can help in suspected drug-resistant cases for young children who cannot expectorate sputum. (Refer Annex 1a and 1b)
- **CSF:** Xpert MTB/RIF test, microscopy, AFB staining, protein and glucose measurement. High CSF lymphocyte count and high protein are common in TB meningitis.
- **Enlarged lymph nodes:** Fine needle aspiration cytology/biopsy (FNAC) for Xpert MTB/RIF test GeneXpert, microscopic examination, histology, and culture (if available).
- **Pleural effusion aspirate:** The macroscopic appearance of pleural fluid can help discriminate TB from bacterial pneumonia. Straw-colored or blood-tinged serous fluid suggests TB, especially if the child is not "toxic". On the other hand, purulent pleural fluid (pus), especially in an unwell "toxic" child, suggests bacterial pneumonia with empyema *(see page 88 WHO Pocketbook of Hospital Care for Children)*.
- **Ascites fluid:** Microscopy, AFB staining, protein, and glucose measurement. A high lymphocyte count and high protein are common in abdominal TB. If possible, an abdominal ultrasound is also useful in diagnosing abdominal TB: this shows ascites with strands of fibrin, enlarged mesenteric lymph nodes and sometimes thickened bowel wall and abscesses in the spleen. An abdominal ultrasound is not needed to diagnose most cases of abdominal TB, but it can help.

Limitations of diagnostics

All of the above diagnostic investigations for TB in children have recognized limitations:

TST is often unavailable in primary or secondary healthcare settings. Therefore, the above mentioned suggested diagnostic approaches have not included TST so that they can still be used when TST is unavailable. TST does not distinguish between TB infection and active disease, and a negative TST does not rule out the possibility of TB.

CXR abnormalities in children with pulmonary TB are often non-specific which means that children with other common forms of lower respiratory tract infection (or pneumonia) can have the same abnormalities, and so it cannot alone determine the correct treatment for the child. CXR is used to add further support to a clinical diagnosis of pulmonary TB when TB is suspected, and smear microscopy or Xpert MTB/RIF is negative.

The diagnostic yield of smear **AFB microscopy** from sputum obtained by any method in young children with TB is very low.

Xpert MTB/RIF is more likely to be positive than smear microscopy but will only be positive in less than one-third of children with TB. Therefore, a negative result from either test does not mean that the child does not have TB.

An advantage of Xpert MTB/RIF is that, if positive, it also provides information on whether the child might have MDR-TB or not. Therefore, it is strongly recommended to obtain suitable samples for Xpert MTB/RIF testing in children for whom MDR-TB is suspected as this will determine the choice of the appropriate treatment regimen for the child.

For children with EPTB, Xpert MTB/RIF provides a high positive yield from lymph node aspiration or cerebro-spinal fluid (CSF), but not from the pleural, pericardial or peritoneal fluid. Again Xpert MTB/RIF result does not rule out the diagnosis. Xpert MTB/RIF test can detect dead bacilli. Therefore, this test should not be used to determine treatment response

HIV Test

- All children diagnosed with TB should be offered PITC for HIV.
- Treatment for TB is the same as for HIV-uninfected children
- For children with HIV and TB, both TB treatment and ART are necessary
    - If a child with TB is newly diagnosed with HIV start ART after 2 weeks of starting TB treatment.
- Any child who is found to have HIV, but not active TB should receive Preventive Treatment

Other tests

Xpert-Ultra where available is more sensitive. A complete blood count may be indicated in seriously ill patient but is not useful in diagnosis of TB. Erythrocyte sedimentation rate (ESR) is a nonspecific test of inflammation and has no role in confirming or excluding TB in children. Baseline liver function tests are indicated if the TB is severe or there is underlying liver disease or history of intake of hepatotoxic drugs.

Newer tests like Novel T-cell or interferon-gamma release assays (IGRAs) provide essentially the same information as MT and offer little additional diagnostic benefit. This should not replace routine MT test. IGRAs should not be used for the diagnosis of TB disease.

Other specialized tests e.g. CT scan and bronchoscopy are not recommended for the routine diagnosis of TB in children. These tests can be performed in higher centers under the specialist's supervision if needed.

Establishing the diagnosis of TB in children

It can be a challenge to establish a confirmed TB diagnosis in children. However, it is not very difficult to establish an accurate presumptive diagnosis, even in the absence of sophisticated tests.

Use of TB score chart

The TB score chart is a screening tool and does not exclusively include or exclude TB in a child. It is however very helpful in the diagnosis of TB and should be interpreted with the history, examination and the results of investigations.

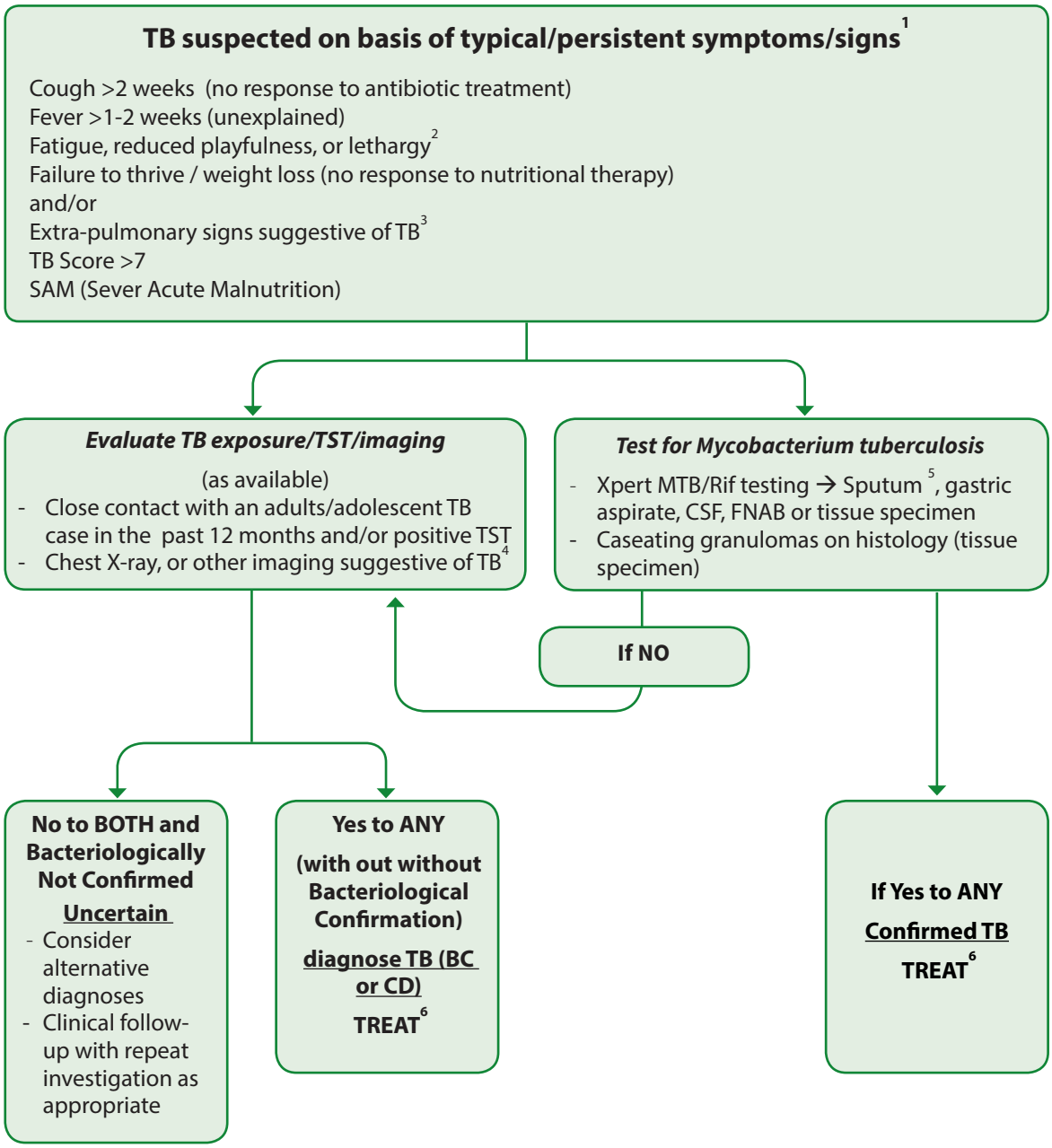
TABLE 7.4a: TB score Chart

FEATURE	0	1	2	3	4	SCORE
Length of Illness (in weeks)	< 2	2-4		> 4		
Nutritional status (weight for age)	Above the -2 SD line	Between the -2 and -3 SD line		Less than the -3 SD line		
Recent close contact with an infectious TB case (adult PTB or bacteriologically confirmed)	None	Verbal history of TB contact		Proven bacteriologically confirmed contact		
Lymph nodes: large, painless, firm, soft sinus in neck/axilla				Yes		
Night sweats, unexplained fever			Yes			
Angle deformity of the spine					Yes	
Malnutrition not improving after 4 weeks of treatment				Yes		
Joint swelling, firm, on-fluid, on-traumatic				Yes		
Unexplained abdominal mass, ascites				Yes		
Coma for more than 48 hours (with or without convulsions)				Yes		
If the child scores 7 or more and has no other disease more likely to explain the illness, confirm using other diagnostic as mentioned and then commence TB treatment based on the result and clinical judgement					**TOTAL**	

TABLE 7.4b: How to use the TB score Chart

Length of illness in weeks:	This means how long the child has been sick with the symptom e.g. cough, diarrhoea, swollen neck glands. Previous episodes should not be counted if the child recovered completely from them.
Nutritional status:	This refers to the child's position on the weight-for-age chart. For children over five years of age, use an MUAC tape to decide nutrition status: MUAC cut-offs for children **over 5 years are: >14.5 cm score = 0, 13.5-14.5cm = 1, <13.5cm= 3**
Family contact history of TB:	Ask the child's guardians about contact with TB. If they give a convincing story of a close family relative or contact that was thin and coughing up blood, then score 1. If your Health Center has written evidence of positive sputum in a close family member or contact, then score 3.
Enlarged painless rubbery neck glands:	Feel the child's neck from behind. TB glands are usually stuck together (matted); don't move easily under the skin and non-painful. If in doubt and the child is otherwise well, treat with amoxicillin or erythromycin for 10 – 14 days and check the size of the glands after 2 weeks. Other common conditions that cause swelling of the neck in children are reactive lymphadenitis from a sore throat or scalp sores, a dental abscess from a tooth infection
Night sweats or unexplained fever:	TB can cause recurrent fever, especially at night, which does not respond to antimalarial or antibiotic treatment and continues for more than two weeks.
Angle deformity of the spine	A sharp angle bend in the spine (backbone) is almost always caused by TB. Check all children for this deformity by looking and feeling the spine with your hand.
Malnutrition not improved after one-month treatment:	This refers to patients admitted to the nutrition ward. If no weight gain after 1 month or weight loss after 14 days score 3. This is after being on extra nutrition and has been treated for infections and anaemia.
Firm non-fluid non-traumatic swelling of a joint:	TB arthritis is not acutely painful. If pain is present always consider and treat for septic arthritis. Chronic arthritis of the hip joint is TB until proven otherwise. If in doubt send to the hospital.
If the child scores 7 or more and has no other disease more likely to explain the illness, confirm using other diagnostic as mentioned and then commence TB treatment based on the result and clinical judgement	

FIGURE 7.1 Diagnostic Algorithm for the Diagnosis of TB in Children



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[1] if symptoms do not meet strict criteria, arrange follow-up in 1-2 weeks to assess symptom persistence despite alternative management. There is increased diagnostic certainty if more than 1 symptom is present.

[2] lethargy or any other danger sign (as defined in IMNCI guidelines), should result in immediate referral for investigation and appropriate management

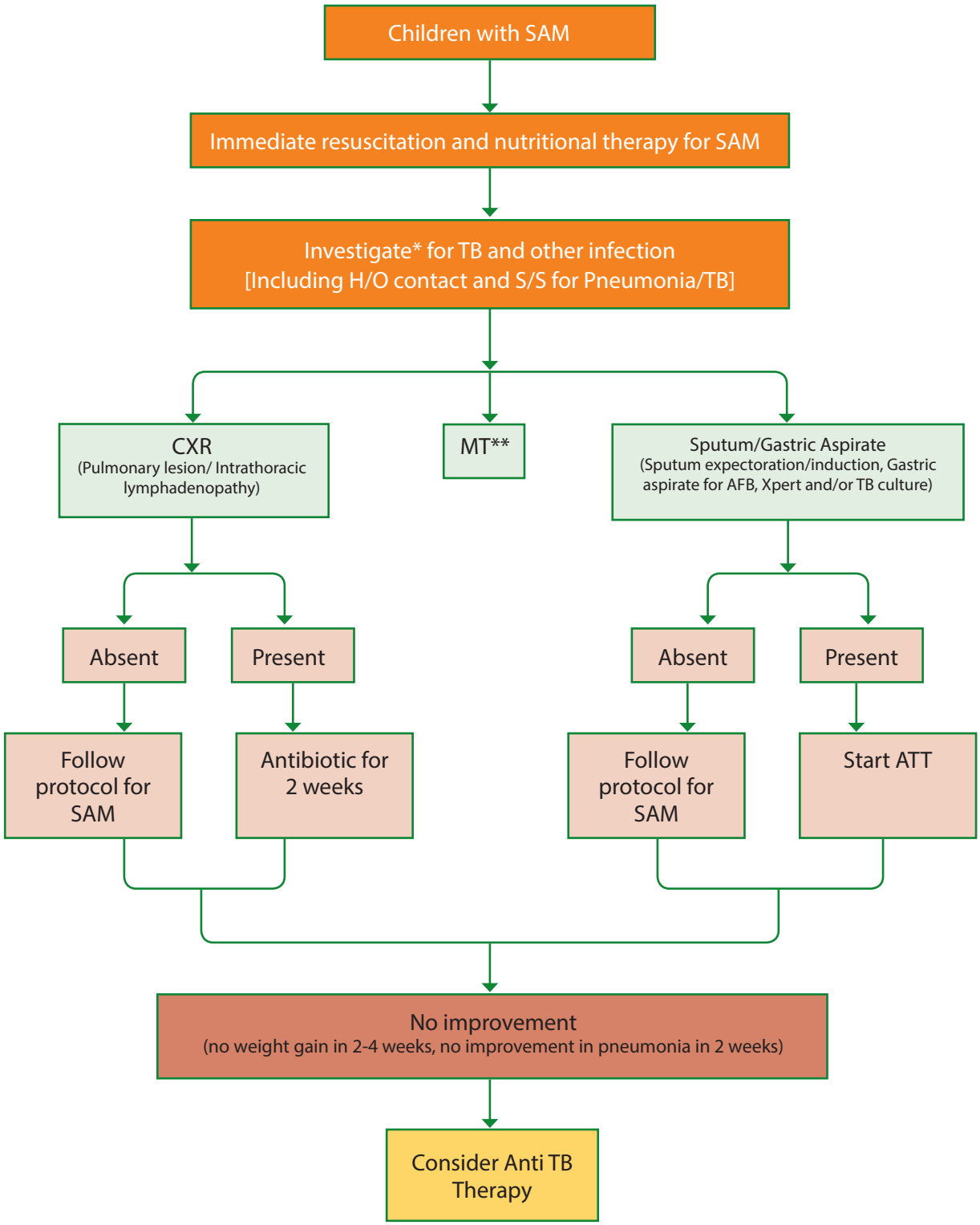
[3] Extra-pulmonary signs include a cervical mass, which can be clinically diagnosed as TB if it meets specified criteria, or convulsions/meningism, which can be clinically diagnosed as TB meningitis if cerebrospinal fluid (CSF) is suggestive

[4] If imaging results are 'uncertain' then repeat evaluation in 1-2 weeks is indicated. Only miliary TB and TB meningitis require immediate treatment initiation.

[5] Child old enough to produce a sputum specimen

[6] Child-friendly fixed dose combination tablets as per the treatment regimen in this guideline should be provided using directly observed therapy (DOT); monitor treatment response; a "trial of treatment" is not advised; if no treatment response after 1-2 months of treatment consider treatment adherence, correct diagnosis, or drug resistance. Treatment response in children with TB cervical adenitis or TB meningitis may be delayed.

FIGURE 7.2 Screening TB in SAM child



**Exposure to TB patient is known by contact with sputum positive TB patient (smear/Xpert/culture) or positive*

***Mantoux test*

Note: Gene Xpert should be prioritized first for the diagnosis of TB among presumptive TB children

7.3 TREATMENT OF TB IN CHILDREN

Some Important rules

1. **NEW FDC:** A new child-friendly TB drug is available that dissolves in water (dispersible tablet). The new fixed-dose combinations of **HRZ 50:75:150** and **HR 50:75** should be used. Further, the revised WHO recommendations for dosages in children now cut-off at 25 kg so children of **≥25 kg** can have adult's dosages and adult formulations. This medication is available country wide.
2. **Categories of treatment:** Children are **no longer** classified as Category I or Category II patients. All children will be treated with New treatment regimen 2 months intensive phase: daily rifampicin (R), isoniazid (H), pyrazinamide (Z), ethambutol (E). The continuation phase will be rifampicin (R) and isoniazid (H) for 4 months
3. **Record weight at each visit:** Children gain weight while receiving TB treatment and dosages should be adjusted. Accordingly, weight is important for monitoring of treatment response
4. **Treatment duration:** Pulmonary TB and EP TB are treated for 6 months (2 months HRZE + 4 months HR). Severe forms of TB including TB meningitis, TB osteomyelitis, miliary TB, TB pericarditis is treated for 9-12 months (2 months RHZE + 7-10 months RHE) where continuation phase can be increased by additional 3 months.
5. **Once treatment starts it must be completed;** "trial of TB treatment" should not be used as a diagnostic tool
6. **Poor adherence and defaulting:** Children who have failed to complete a full course of treatment previously (i.e. defaulted from treatment) and re-treatment cases will be treated the same way, as an adult.
7. **Children suspected of having MDR** should be evaluated by a qualified doctor and have an Xpert MTB/RIF test. Children who have MDR should be treated by a paediatrician or a healthcare worker familiar with MDR-TB and refer the National Guidelines for DR-TB Management 2019

7.3.1 Anti-Tuberculosis drug doses for children

Dosages are calculated according to body weight and not according to age. Weight is important for monitoring treatment response and should be taken initially and at every visit. TB drugs are very well tolerated in almost all children.

The risk of developing optic neuritis (eye damage) from Ethambutol in children is very small, thus four drugs are now used in all new cases of paediatric TB. It is important to be aware that eye problems are possible and to check all children for visual problems during their treatment course.

The pharmacokinetics of anti-tuberculosis drugs is such that children generally need higher doses (per kg body weight) than adults do to achieve effective serum concentration.

TABLE 7.5: Anti-TB drug dosages.

ANTI-TB DRUG	PAEDIATRIC DAILY DOSES
Rifampicin	15 mg/kg (10-20 mg/day) with a max of 600 mg per day
Isoniazid	10 mg/kg (7-15 mg/kg) with a max of 300 mg
Pyrazinamide	35 mg/kg (30-40 mg/kg)
Ethambutol	20 mg/kg (15-25 mg/kg)
Levofloxacin for H resistant cases	15-20 mg/kg

7.3.2 Treatment for childhood TB with weight bands and classifications

All children with TB will receive a new treatment regimen. There is no **Category II treatment is NO LONGER USED in NEPAL**. All seriously ill children who have been previously treated for TB such as relapse, treatment after failure, treatment after default or not improving on new treatment regimen should be investigated for drug resistant TB. Ensure strict DOT in all cases of TB in children.

Classification

The same classification of TB and type of patient applies to children.

Regimens and dosages for children

TB drugs for the treatment of TB in children come in Fixed Dose Combinations (FDC) and dosed according to standardized weight bands. Depending on their weight, children can be treated using the pediatric FDCs or the adult FDCs. Bigger children falling into higher weight ranges will receive adult FDCs.

All children must be treated using child-friendly FDC. The new fixed-dose combination of **HRZ (50/75/150) and HR (50/75).**

Ethambutol is included for the treatment of TB in children and comes as a separate tablet with the paediatric formulation.

The new FDC dosing table is as below:

TABLE 7.6: Weight band for new FDC

Weight bands	Number of Tablets		
	Intensive Phase		Continuation Phase
	HRZ 50/75/150	E 100mg	HR 50/75
4-7.9kg	1	1	1
8-11.9kg	2	2	2
12-15.9kg	3	3	3
16-24.9kg	4	4	4
25kg+	Use adult dosages and preparations		

Weight band for INH mono resistant TB (HrTB)

Weight bands	Number of Tablets		
	6(H) RZ+E		
	RHZ 75/50/150	E 100	Lfx 100
4-7.9kg	1	1	1
8-11.9kg	2	2	2
12-15.9kg	3	3	3
16-24.9kg	4	4	4
25kg+	Use adult dosages and preparations (up to 1.5g / day)		

If levofloxacin 100mg dispersible tablet is not available, the 250mg tablet can be used with 6(H) RZ+E in children aged 0-14 years, based on a slightly different weight band from the one above:

Weight bands in children	Levofloxacin 250mg
5 - 6 kg	½ tablet / day
7 - 9 kg	¾ tablet / day
10 – 15 kg	1-1.5 tablet / day
16 – 23 kg	1.5-2 tablets / day
24 – 30 kg	2-2.5 tablets / day
31 kg +	Follow adult schedule (up to 1.5g / day)

Treatment duration

Pulmonary TB and EP TB are treated for 6 months (2 months of HRZE + 4 months HR). All severe forms of EP TB are treated for 9-12 months. This includes TB meningitis, TB osteomyelitis, military TB, TB pericarditis/effusion, and other severe forms of TB (2 months HRZE+ 7-10 months HRE, a total of 9 to 12 months duration).

TABLE 7.7: TB Treatment Duration

<table>
<tr><th colspan="2">TYPE OF TB</th><th>INTENSIVE PHASE</th><th>CONTINUATION PHASE</th></tr>
<tr><td colspan="2">New TB cases
- Adult and Childhood
- Bacteriological or clinically diagnosed
- Pulmonary or extra-pulmonary</td><td>2HRZE</td><td>4HR</td></tr>
<tr><td colspan="2">Complicated/Severe EP cases (CNS TB, TB Pericarditis, Musculoskeletal TB, Miliary TB etc.)</td><td>2HRZE</td><td>7- 10 HRE *</td></tr>
<tr><td rowspan="4">Retreatment cases

All forms:

1st Rapid DST with Xpert MTB/RIF testing should be done to see the status of resistance to Rifampicin Followed by LPA among those having MTB+ve and Rifampicin sensitive for Isoniazid (INH) resistance status.</td><td>Xpert MTB/RIF– Rifampicin sensitive LPA – Isoniazid sensitive</td><td>2HRZE</td><td>4HR</td></tr>
<tr><td>Xpert MTB/Rif– Rifampicin sensitive LPA – Isoniazid Resistant and FQ sensitive</td><td colspan="2">6 (H)RZE + Levofloxacin (Full Duration)</td></tr>
<tr><td>Xpert MTB/Rif– Rifampicin sensitive LPA – Isoniazid Not known because of no access to LPA</td><td colspan="2">6 HRZE (Full duration)</td></tr>
<tr><td>Rifampicin sensitive INH resistance and FQ resistant**</td><td colspan="2">6(H)RZE</td></tr>
<tr><td>DR TB</td><td colspan="3">Refer to National Guidelines on DR-TB management guidelines (2019)</td></tr>
</table>

* For complicated EP cases, if treatment is required beyond 12 months, then refer to a higher level centre for treatment decisions

**Depending on the patients' response and laboratory evidence, clinicians at higher-level centre can use laboratory evidence/result to inform further management where necessary.

The frequency of treatment in both the intensive and continuation phase is daily using the FDC drugs

7.4 PREVENTION OF TB IN CHILDREN

WHO has adopted a global strategy framework (The End TB Strategy) to achieve its vision of a world free of tuberculosis and the end of the global TB epidemic as a post-2015 strategy with some targets. Besides other targets, WHO envisions to reduce TB incidence by 90% by 2035 as compared to 2015 baseline. To achieve this, in addition to early diagnosis and prompt treatment, preventive treatment of people at risk is important.

In Nepal all People living with HIV (PLHIV) and children under five who do not have active TB are eligible for TB preventive therapy (treatment of TB infection).

Preventive measures can be taken through:

- Rational and proper case management of adult TB cases
- Intensified Case Finding (ICF)
- Contact tracing and investigation

- Preventive measures:
  - Preventive therapy (PT) - treatment of TB infection. -(Nepal is transitioning to 3HR Regimen for preventive therapy in children under five years) except for those children living with HIV who are on Nevirapine and PI due to drug interaction with Rif. 3RH is recommended for children and adolencent not on NVP/PI based ART. 6H will still be relevant until future child-friendly 3HP comes in the market and HIV new guideline is endorsed.
- **3 months of Isoniazid and Rifampicin (3HR)**
  - BCG vaccination
- TB infection control

7.4.1 Intensified Case Finding (ICF)

Finding and treating adults with TB is an important step to prevent disease transmission to a child. But is not enough in preventing disease. All close contacts and family members including children should be screened and provided appropriate diagnosis and treatment and preventive therapy where applicable. Children are 50% less likely to develop TB when this strategy is adopted.

Contact Tracing and Investigation

This is a systematic process intended to identify previously undiagnosed cases of TB among the contacts of an index case. It consists of two components:

FIGURE 7.4 a. Identification and prioritization:

A systematic approach for identifying contacts who have or are at risk of developing TB disease.

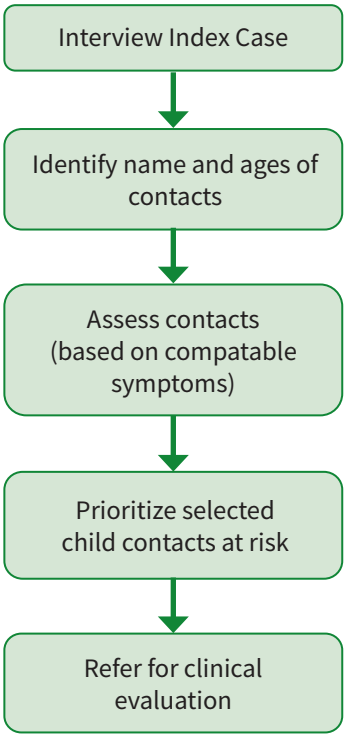
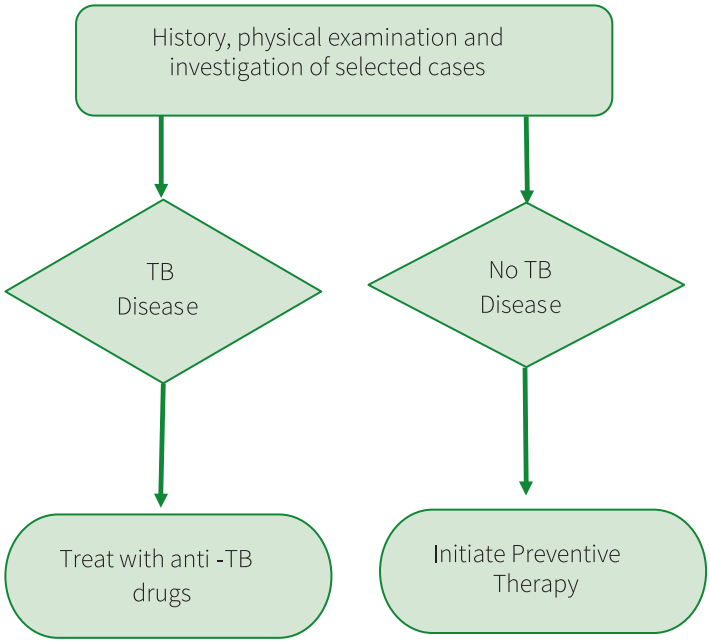


FIGURE 7.4 b: Clinical evaluation



Clinical evaluation should also be done in children or other close contacts with:

1. Symptoms suggestive of TB disease
2. Age < 5 years
3. Immunocompromised conditions (e.g. those living with HIV, on anti-cancer medication or immune suppressants)
4. The index case is considered MDR-TB or Pre-XDR-TB or XDR-TB

7.4.2 Preventive Therapy (PT)

Preventive therapy is providing Rifampicin and Isoniazid (RH) for 3 months to children less than 5 years of age, who do not have TB disease to prevent children from developing TB disease in the near future. These children are household contacts or close contacts with a TB index case, and highly likely to be infected with the Mycobacterium tuberculosis. PT should also be provided to all immunocompromised children with a history of contact, regardless of age. PT is safe and effective. For children living with HIV, 3RH is recommended for children and adolencent not on NVP/PI based ART, 6H for children on (NVP/PI) based ART until child friendly 3HP comes in the market.

Who Should Receive Preventive Therapy?

Due to limited resources, preventive therapy is only given to the most vulnerable children (those at highest risk to develop TB disease in the near future) following documented TB exposure and/or infection, after the active disease has been ruled out.

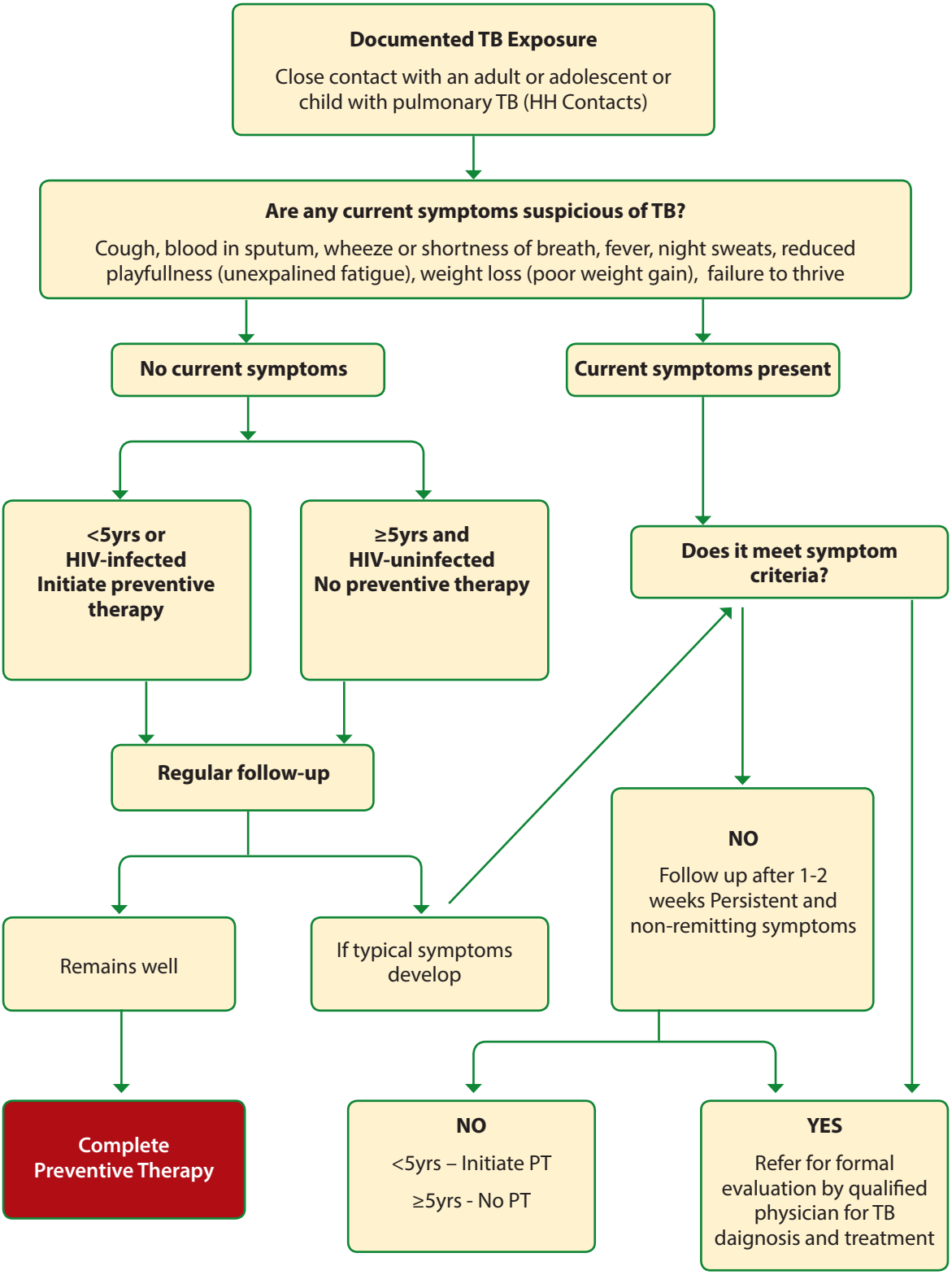
The following should receive PT:

- Young (immune immature) children (<5 years of age)
- Immunocompromised children (e.g. severely malnourished or HIV-infected, or on steroids/ immunosuppressive drugs), irrespective of their age
- Baby born to infected mother

Previous TB preventive therapy or treatment does not protect the child against subsequent TB exposure/infection. Therefore, highly vulnerable children (as defined above) should receive preventive therapy after each episode of documented TB exposure, unless the child is currently receiving TB prophylaxis or treatment. Always exclude TB disease before starting preventive therapy.

- Asymptomatic children (playful and thriving, no cough or wheeze, no fever, no unusual fatigue or lethargy, no visible neck mass or gibbus) do not require additional tests to exclude TB disease, before providing preventive therapy. Children <5 years of age or immunocompromised children of any age in close contact with an adult or adolescent with pulmonary TB, should receive a course of preventive therapy to prevent the development of TB.
- Chest radiography may be offered, and preventive treatment given to those with no abnormal radiographic findings. BUT the absence of chest radiography should not be considered barrier for initiating preventive treatment.

FIGURE 7.5: Algorithm for the Screening of Children with Close Household Contact



How is Preventive Therapy Given?

Preventive therapy comprises of either combination of rifampicin and isoniazid for 3 months. This is usually not given as DOTS, but poor adherence is a serious concern. Hence parents/ caregivers must be adequately counselled to explain why the medicine is given and encouraged good adherence. Parents/caregivers should also be counselled to recognize the symptoms of TB disease, such as a persistent non-remitting cough or fever, unusual fatigue or lethargy and/ or weight loss, which should prompt them to bring the children back to the clinic for further evaluation. Follow-up should be carried every month after initiation of PT. Cases should be recorded in the TB PT register.

TABLE 7.8: Guidance for Dosing of HR Preventive Therapy

WEIGHT BANDS	NUMBER OF TABLETS RH (75/50)*
4-7.9 kg	1
8-11.9 kg	2
12-15.9 kg	3
16-24.9 kg	4
25kg+	Use adult dosages and preparations

* 3RH can be used in children and adolescent up to 15 years with HIV not on (NVP/PI) based ART

7.4.3 BCG (Bacillus Calmette-Guerin) Vaccination

BCG is prepared from a strain of the attenuated (virulence-reduced) live bovine tuberculosis bacillus, Mycobacterium bovis, that has lost its ability to cause disease in humans. BCG is not fully protective against TB disease in children, but it provides some protection against severe forms of TB (73% in TBM and 77% in Miliary TB). Many children continue to get TB despite routine BCG vaccination and the youngest remain the most vulnerable. Nevertheless, BCG vaccination at birth or as soon as possible thereafter is recommended to avoid severe TB diseases.

How should a baby born to a mother or other close contact with TB be managed?

A baby born to a mother diagnosed with TB in the last two months of pregnancy (or who has no documented sputum smear-conversion) needs to be carefully managed.

If the baby is symptomatic (difficulty breathing, feeding problems, poor weight gain, abdominal distension, enlarged liver or spleen, or jaundice), refer to hospital for evaluation to exclude TB.

- If such child is diagnosed as TB, the baby should receive a full course of TB treatment.
- Ensure correct dosages in consultation with a pediatrician.

If the baby is asymptomatic:

- Withhold BCG at birth
- Give preventive therapy
- Give BCG after completion of preventive therapy
- Follow up for symptoms. If symptomatic, the baby needs to be referred to a higher centre for evaluation to exclude TB.

Mothers should be encouraged to breastfeed their children. Anti-TB drugs are secreted in breast milk, but the concentrations are very low and do not affect the baby. The drug levels in breast milk are too low to protect the baby and therefore the baby must receive preventive therapy as indicated.

As the TB drugs are likely to kill the live BCG vaccine, BCG should not be given at birth in patients receiving PT or TB treatment. BCG should be given after completion of PT or TB treatment.

7.7 TREATMENT OUTCOME

Treatment outcomes should be routinely recorded and reported for child TB cases. Treatment outcome categories for children are the same as that of adults. (refer to Table 6.7)

CHAPTER 8

DRUG RESISTANT /MDR TB MANAGEMENT

8.1 DEFINITIONS FOR DR-TB

Drug Resistant TB (DR TB) is TB that is resistant to TB drugs. Resistance can be developed to one or more TB drugs (1st or 2nd line drugs). MDR TB and other drug resistant TB result from poor management of susceptible TB and thus the primary way to prevent any drug resistant TB is to ensure that all TB patients with susceptible TB are diagnosed and treated properly under DOTS. Ensuring all TB patients complete TB treatment under supervision (DOT) is the most effective way to ensure TB patients are successfully treated and that drug resistant strains of TB are not created.

TYPE OF RESISTANT	DEFINITION
Mono-resistance	Resistance to one first-line anti TB drug only
Poly-resistance	Resistance to more than one first-line anti-TB drug (other than both isoniazid and rifampicin).
Rifampicin Resistance (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 mono-resistance, multidrug resistance, poly-drug resistance or extensive drug resistance.
Isoniazid-Resistance TB (Hr-TB)	Refers to mycobacterium tuberculosis strains in which resisitance to isoniazid and susceptibility to rifampicin has been confirmed in vitro.
Multi drug Resistance (MDR TB)	Resistance to at least both isoniazid and rifampicin
Extensive Drug Resistance (XDR-TB)	Resistance to any fluoroquinolone and to at least one of three second-line injectable drugs (capreomycin, kanamycin and amikacin), in addition to multidrug resistance.

8.1.1 Diagnosis of Drug Resistant TB:

Identification of presumptive DR-TB

All staff who are managing TB patients must be able to identify presumptive DR-TB. The following categories of TB patients are at risk of having DR-TB and need to be screened for drug resistance:

1. Close contact of DR-TB case
2. Previously treated patients who either:
   - failed
   - relapsed
   - returned after loss to follow-up
3. Smear positive at 2 months or subsequent follow up during first-line treatment
4. Not getting better / getting worse during the continuation phase of the first-line treatment and patients with frequent interruptions and irregular first line drugs
5. Health care workers with presumptive TB

6. PLHIV, DM and other immunocompromised on individuals
7. Belonging to vulnerable groups such as migrants and refugees

Most patients with presumptive DR-TB will be bacteriologically positive pulmonary cases, but clinically confirmed pulmonary or extrapulmonary TB cases may also present with presumptive DR-TB if they show a clinically unfavorable evolution.

8.1.2 Management of presumptive DR-TB

1. Perform an Xpert MTB/Rif test

Carry out the Xpert MTB/RIF testing for all presumptive DR TB cases as per the diagnostic algorithm. Testing can be done directly via patient going to GeneXpert centers themselves or thorough the courier to the GeneXpert sites form peripheral health facilities.

2. What to do if the Xpert MTB/Rif test shows rifampicin resistance (RR)?

If the result shows RR, the patient must be sent immediately to the nearest DR-TB Centre for registration and further appropriate management as per the treatment and diagnostic algorithm.

Attention! Patients with Low risk of DR TB: It is also possible that a person with presumptive TB, whose sputum is examined with Xpert MTB/RIF to confirm the diagnosis of TB, presents with an RR result. Since the test was done because of a presumption of TB and not because of a presumption of MDR-TB, it is necessary to repeat the test.

If the repeat Xpert MTB/RIF test also shows an RR result, the patient must be sent to the nearest DR-TB Centre without delay.

Following are the DR-TB regimens are used in Nepal as per the National Guidelines on DR-TB (2019).

3. The commonest DR/MDR-TB regimen used in Nepal are:

1. Shorter Standardized Treatment Regimen (SSTR)

The STR consists of an intensive phase of 4 months with 7 drugs, followed by a continuation phase of 5 months with 4 drugs. The intensive phase will be extended if smear conversion is not achieved within 4 months, with a maximum of 6 months.

	INTENSIVE PHASE	
	4 (+1 OR 2) MONTHS	
Amikacin		Continuation phase **5 months** (fixed)
Ethionamide		
Isoniazid high-dose		
Moxifloxacin high-dose		
Clofazimine		
Pyrazinamide		
Ethambutol		

FIXED

4-6 Am Mfx^{h} Eto H^{h} Cfz E Z / 5 Mfx^{h} Cfz E Z

2. Longer Regimen 1:

The following all oral regimen(LR1) will be initiated if non- eligible for SSTR

	RESISTANCE PATTERN AND BACKGROUND HISTORY	REGIMEN	COMMENTS
LR1	Standard **longer RR**/MDR TB Regimen for adults and children 6 yrs and above Non-eligible for STR and for those whose FQ results unknown/ awaited/sensitive	**Bdq(6), 18 Lfx,Lzd,Cfz,Z**	1. In case of toxicity or need to decrease or substitute Lzd with Cs Refer to aDSM relevant section 2. If Lzd is well- tolerated, should be continued throughout the treatment duration

3. Longer Regimen 2:

However, in patients with FQ resistance/risk of FQ resistance/XDR TB will be started on following regimen(LR2);

LR2	RR TB with a risk of FQ resistance/ FQ resistance at baseline (Pre-XDR) and XDR TB	**Bdq (12),18Lzd, Cfz, Cs,Z**	1. High dose Lfx or Mfx can be added once resistance level to FQs are known 2. In cases with intolerance/ toxicity to Lzd, stopping Lzd, replacing with Dlm may be a suitable option. If Dlm cannot be added, then Eto can be used instead 3. Close and careful monitoring with a combination of three cardiotoxic drugs (Bdq, Cfz,Dlm)

For more details refer to Nepal DR-TB Management guidelines for DR/MDR-TB management when necessary.

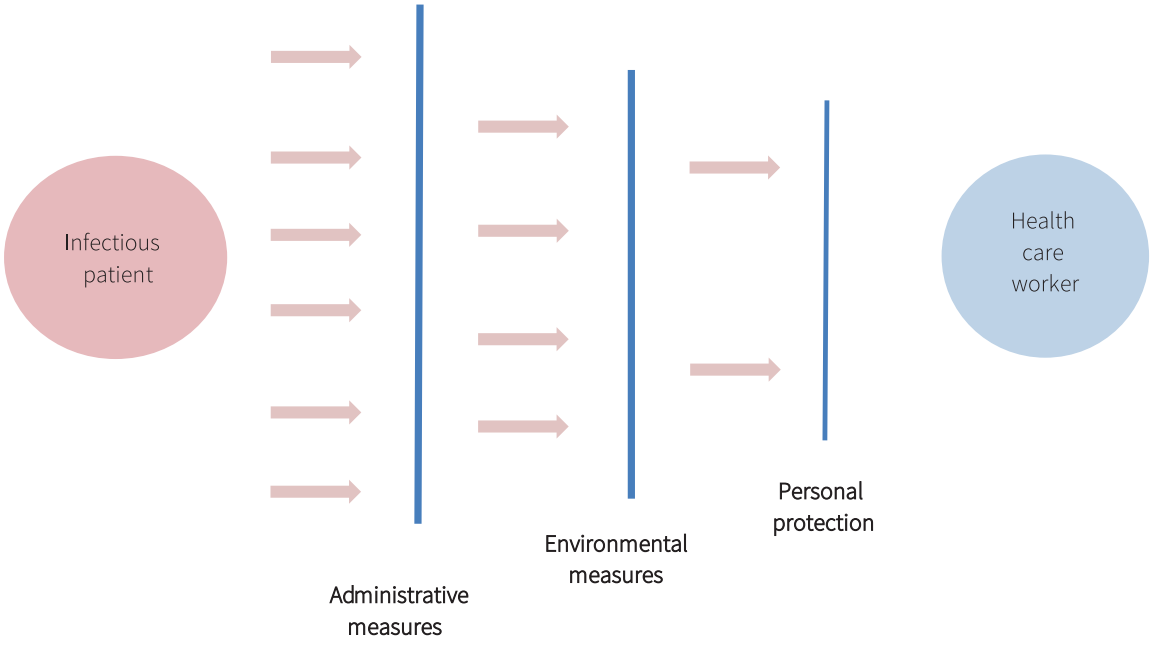
CHAPTER 9

TB INFECTION CONTROL

TB infection control is a combination of measures aimed at minimizing the risk of TB transmission within populations. The foundation of infection control in the early and rapid diagnosis, and proper treatment of TB patients.

9.1 GENERAL PRINCIPLES OF INFECTION CONTROL

There are three levels of infection control measures, operating at different points in the transmission process, and all are interdependent:



9.1.1 Administrative (managerial) controls

Administrative controls should be implemented as a first priority because they have been shown to reduce transmission of TB in health-care facilities. Such controls are a vital part of sound infection control practices, which require people with TB symptoms to be promptly identified, separated and treated.

Administrative control includes:

- Develop and implement written policies and protocols to ensure:
  - Rapid identification of TB cases (e.g. improving the turn-around time for obtaining sputum results)
  - Isolation of patients with PTB
  - Rapid diagnostic evaluation
  - Rapid initiation of treatment
- Educate, train, and counsel HCWs about TB
- To the extent possible, avoid mixing TB patients and HIV patients in the hospital or clinic setting
- **F**ind cases **A**ctively, **S**eparate Temporarily and **T**reat effectively (FAST) is intensified, refocused administrative approach to TB transmission control in healthcare facilities. Active case finding with cough screening followed by rapid molecular diagnostics, which enables prompt treatment of unsuspected drug-sensitive and drug-resistant TB, thereby decreasing TB transmission. The basic principle for FAST is as follows:
  - TB is spread in institutions predominantly by coughing patients with unsuspected TB or unsuspected drug resistance
  - Most potentially infectious patients can be identified by cough surveillance
  - Coughing TB patients most likely to be infectious can be diagnosed using rapid molecular sputum tests
  - By dramatically reducing the duration of institutional exposure through effective treatment, transmission among patients and to health care workers will be reduced proportionately

For detail please consult FAST Guideline

9.1.2 Environmental controls

Environment controls include methods to reduce the concentration of infectious respiratory aerosols (i.e. droplet nuclei) in the air, and methods to control the direction of infectious air.

Such measures include:

- Use of ventilation systems.
- Use ultraviolet germicidal irradiation (UVGI) fixtures, at least when adequate ventilation cannot be achieved

9.1.2.1 Use ventilation systems

Adequate ventilation in health-care facilities is essential for preventing transmission of airborne infections and is strongly recommended for controlling the spread of TB. The choice of ventilation system will be based on the assessment of the facility and informed by local programmatic, climatic and socioeconomic conditions. Any ventilation system must be monitored and maintained on a regular schedule.

Kind of ventilation systems:

- Natural
- Mechanical

Natural Ventilation can be created by the use of external airflows generated by natural forces such as:

- Wind
- Differences in temperature

Naturally ventilated rooms can achieve very high ventilation rates (ACH) under ideal conditions but natural ventilation is unpredictable.

Maximize Natural Ventilation

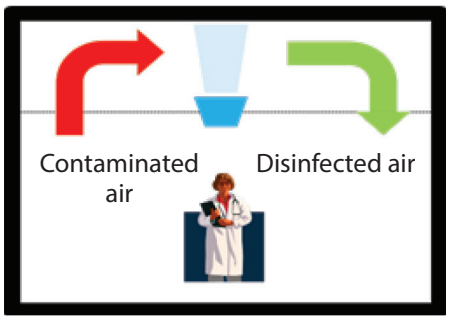
- Openings on opposite walls (cross ventilation)
- Openings are unrestricted (stay open)
- 10% of floor space should be openable- window-area on each wall
- Upper levels of the building
- Building and openings are oriented to use the prevailing wind, without obstruction by other nearby buildings

Mechanical ventilation

Well-designed, maintained and operated fans (mixed-mode ventilation) can help to obtain adequate dilution when natural ventilation alone cannot provide sufficient ventilation rates. In some settings, mechanical ventilation (with or without climate control) will be needed. This may be the case, for example, where natural or mixed-mode ventilation systems cannot be implemented effectively, or where such systems are inadequate given local conditions (e.g. building structure, climate, regulations, culture, cost and outdoor air quality).

9.1.2.2 Use of upper room or shielded ultraviolet germicidal irradiation fixtures

Priority should be given to achieving adequate ACH using ventilation systems. However, in some settings it is not possible to achieve adequate ventilation; for example, because of climatic changes (e.g. in winter or during the night) or building structure, or because transmission of TB would pose a high risk of morbidity and mortality (e.g. in MDR-TB wards). In such cases, a complementary option is to use the upper room or shielded ultraviolet germicidal irradiation (UVGI) devices. This environmental control does not provide fresh air or directional airflow.



9.1.3 Personal respiratory protection aims to protect the health workers in areas where the concentration of droplet nuclei cannot be adequately reduced by administrative and environmental controls. Health workers should use high filtration masks (N95) or "respirators" to protect them against the inhalation of airborne infectious droplets. The patients should wear a surgical mask to reduce the spread of droplets.

Respirator Vs Surgical Mask

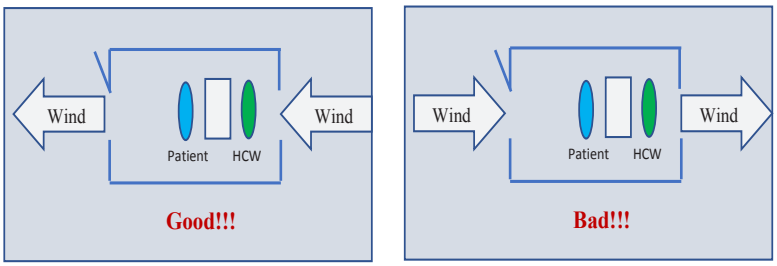
RESPIRATORS	SURGICAL MASKS
• Designed to filter out droplet nuclei from being inhaled by the health-care worker and other individuals. • Should properly fit different face sizes and features. • Should NOT be worn by the patient	• Designed to stop droplet nuclei from being spread (exhaled) by the patient. • Should NOT be worn by the health-care worker

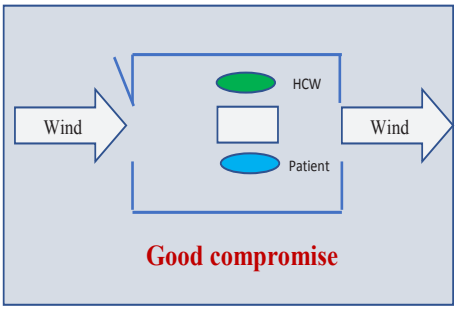
Personal respiratory protection by themselves is insufficient to prevent TB transmission. They will not be worn continuously and are likely not to be in use when unsuspected TB cases are encountered. Administrative and environmental controls are more important.

9.2 INFECTION CONTROL AT TB CONSULTATION ROOM

The rooms for TB consultation, counselling and health education should be arranged according to sound infection control principles:

- Both windows and door should be open all the time.
- Direct sunlight gets into the room easily
- A stand fan ensures an airflow direction toward the opened window
- Patient and health staff sit in front of each other across the airflow
- Exhaust fan to extract the air
- One patient at a time should be received in the room
- The patient should wear a surgical mask
- Staff and family should wear an N95 mask
- Appropriate cough hygiene must be observed by the patient





9.3 INFECTION CONTROL AT HOME

A contagious or potentially contagious patient may have to be isolated at home. The following infection control measures can be taken:

- If feasible, the patient should stay and sleep in a specific room separated from the other family members.
- If possible, the isolation room should have good ventilation with a large opened window, direct exposure to sunlight, and preferably with good air flow direction (natural or with fan).
- Other people should not enter the room unless necessary. If they do so, a patient must wear a surgical mask.
- At all stages, the patient should be encouraged to stay outside.
- The patient should eat separately, outside or in the room.
- The patient should wear a surgical mask all the time when in contact with other people.
- Strict coughing hygiene must be observed by the patient, inside as well as outside the house.
- If other people come to see the patient, they should meet outside. They need to keep a safe distance and duration of contact should be kept as short as possible.
- The patient should avoid contact with children or other high-risk groups and restrict close contacts with other people during the contagious period.

Role of TB patient in infection control:

- The patient should maintain a well-balanced diet to keep the immune system strong
- The patient should TB patient to stop smoking and minimize intake of alcohol
- The patientshould wear mask and hold a cloth or handkerchief over mouth when coughing
- The patient should not spit on the floor but in a container (preferably disposable) and dispose of properly

9.4 HEALTH WORKER AND INFECTION CONTROL

Always follow the recommended infection control procedures in your work in the health facility. Be aware of the possible signs and symptoms of TB in yourself. Ensure that annual X-Ray screening for health workers particularly, working in TB facilities is encouraged. If one or more of these develop, report promptly for assessment and care. If diagnosed with TB, start treatment promptly and adhere to treatment until it is completed.

Health workers should decrease their risk factors for TB disease to the extent possible eg. Living healthy live-styles, stress-free, stop smoking, or following treatment for diabetes, knowing their HIV status or getting retested periodically, etc. If a health worker is HIV-infected, he/she may decrease his/her risk of developing TB by taking CPT, ART and IPT as appropriate. Health workers who have positive HIV status should not work in TB facilities. Therefore, should be given alternate choices of work area by the employers.

CHAPTER 10

TUBERCULOSIS AND HIV

10.1 TUBERCULOSIS AND HIV CO-INFECTION

The human immunodeficiency virus (HIV) pandemic presents a significant challenge to global tuberculosis (TB) control. TB is a leading preventable cause of death among people living with HIV.HIV is the most potent risk factor for TB. HIV infection increases the risk of TB disease by 30-fold compared with HIV-seronegative in high HIV prevalence countries. The actual burden of HIV infection among TB cases and TB infection among HIV cases in Nepal is not known. The sentinel site survey conducted among both HIV infected and TB infected cases in Nepal in 2014, showed that among TB cases 1.1 % were HIV positive and among PLHIV 8.5 % were infected with M. Tuberculosis.

HIV infection and risk of TB

HIV increases the risk of progression of M. tuberculosis infection to TB disease. This risk increases with increasing immunosuppression. HIV increases not only the risk but also the rate of progression of recent or latent M. tuberculosis infection to disease.

Impact of HIV on TB

Direct:

- Reactivation of TB infection acquired before HIV infection (from 10% lifetime to 7-10%/year)
- Rapid progression of TB infection acquired after HIV infection

Indirect:

- Transmission to the population not infected with HIV

Impact of TB on HIV

- A high rate of primary TB and reactivation
- Increase incidence of extrapulmonary/disseminated TB
- More adverse drug reactions
- Increase incidence of MDR-TB
- High mortality rate

TB is the most common opportunistic infection among people living with HIV, including among those taking antiretroviral treatment and it is the major cause of HIV-related death. Main reasons for HIV/TB deaths are:

- HIV not diagnosed / TB not diagnosed (bi-directional screening not optimal)
- HIV diagnosed too late (HIV diagnosis with advanced disease)
- TB not appropriately treated (M/XDR-TB)
- HIV not promptly treated (ART coverage still not universal)

Whom to Investigate for HIV Infection?

All TB infected needs to be screened for HIV and all PLHIV needs to be screened for TB at each visit at the ART centers

TB/HIV Collaboration

The recommended activities for TB/HIV collaboration focuses on establishing mechanisms of collaboration between TB and HIV programs at all levels, decreasing the burden of TB in people living with HIV (PLWHIV) through **intensified case finding, Isoniazid preventive therapy & infection control (the 3 I's)** and decreasing the burden of HIV in TB patients through PITC, prevention methods, Cotrimoxazole preventive therapy (CPT), HIV treatment and care and support for TB/HIV co-infected patients. Guidelines for PITC and TB/HIV collaborative activities are now in place to guide health workers in their respective activities.

1. Intensified case finding

As TB is one of the most common OIs among the HIV-infected people, TB screening should be performed for all new HIV-infected clients on their first visit using a TB screening questionnaire, a full initial history, and physical examination and these should be continued on every visit.

2. Initiate preventive treatment

HIV positive patients who do not have active TB disease should be commenced on TB preventive treatment. PLWHIVs should be screened according to the screening algorithm and those that do not have a **current cough, night sweats, fever** and **weight loss** should be given PT. **Active TB should be excluded before TB preventive treatment.**

Preventive therapy against TB is the use of anti-TB drugs in individuals with latent Mycobacterium tuberculosis infection regardless of CD4 cell count or ART status in order to prevent the progression to active disease. HIV is the most powerful risk factor for progression from latent infection to active disease. Use of PT can reduce the number of HIV patients developing active TB.

All patients should be screened for active TB (by asking about symptoms, physical examination and sputum examination; CXR may be done routinely if available as part of screening; CXR and Xpert MTB/RIF should be done in all symptomatic patients). This should be done on every visit to the ART centre using the screening tool for TB.

PT should only be used in patients in whom active TB has been excluded, active patient follow-up is possible and high-level adherence can be attained and should be provided for six months to all clients, including children who have completed TB treatment.

Key recommendations for initiating PT:

- Those with liver-disease, active alcohol use, jaundice, habitual treatment defaulter, prior Isoniazid resistance, peripheral neuropathy, unexplained illness should be excluded.
- When PT is initiated, check the ART regimen specially Nevirapine and PI based regimens.
- Monthly supply of PT drugs should be provided.
- Providing PT to PLHIV does not increase the risk of developing resistant TB. Therefore, concerns regarding the development of TB resistance should not be a barrier to providing PT.

PT Regimen:

National HIV program is implementing TB preventive treatment. The regimen is as follows:

- For adults: 3HR daily for 3 months, Vitamin B6 25mg/day (pyridoxine) should be given together with 3HR for 3 months.
- For children and adolescent living with HIV who are unlikely to have active TB on symptom-based screening and who are not on (NVP/ PI based ART regimen) can also be given 3HR daily for 3 months with vitamin B6 (pyridoxine), for those children if on (NVP/PI based ART regimen), then 6 INH is still relevent until 3HP become available.

WHO has also recommended 3HP (Rifapentine and Isoniazid) treatment may be offered as an alternative to 3HR for both adults and children. This recommendation will be adopted by the National program once 3HP is registered and child friendly 3HP dose become available.

Follow-up visits while on TB prevetive treatment:

- A client must be seen every month for adherence check, side-effect check and medication refill.
- A client must be asked about symptoms of breakthrough TB on each visit. If any symptom occurs, evaluate for TB. Tuberculosis treatment in PLHIV is same as that of non-HIV patients

10.2 CLINICAL PICTURE

TB may present at any stage of HIV infection although the risk of developing TB increases with worsening immune status. TB may present with the classical symptoms of cough, fever, night sweats, productive cough (haemoptysis), shortness of breath, and weight loss occurring over weeks to months/poor weight gain in children. However, the clinical presentation of TB in HIV infection may be influenced by the degree of immunosuppresion (table 10.1). With normal or moderately reduced CD4 counts (>200cells/mm^3) the presentation is more typical. With increasing immunosuppresion (CD4 <200 cells/mm^3) the clinical presentation becomes less typical.

People living with HIV infection are more likely to present with extra-pulmonary TB (EPTB) or smear -negative TB than TB patients who are HIV negative. Although TB/HIV co-infection may present in other forms, the majority of cases are bacteriologically positive and therefore sputum Xpert MTB/RIF remains the first diagnostic test. No CXR pattern is typical of pulmonary TB in HIV infection.

TABLE 10.1: The presentation of pulmonary TB may differ in early and late HIV infection

Features of pulmonary TB	Stage of HIV infection	
	Early	Late
Clinical picture	Often resembles post-primary pulmonary TB	Often resembles primary pulmonary TB
Sputum smear	Often positive	May be negative
Chest X-Ray	Often cavities	Often infiltrates with no cavities (may be normal)

Figure modified from: TB/HIV: a clinical manual 2nd edition. WHO

10.3 MANAGEMENT AND PREVENTIVE THERAPY IN TB HIV COINFECTION

10.3.1. Management of TB/HIV Co-infection

- TB treatment and Cotrimoxazole preventative therapy (CPT) is commenced first.
- ART is commenced 2 to 8 weeks after commencing TB treatment depending on the progression of HIV disease.
- TB/HIV patients are treated using the same TB treatment and duration as non-HIV infection.
- Treatment should be administered under DOT at all times.

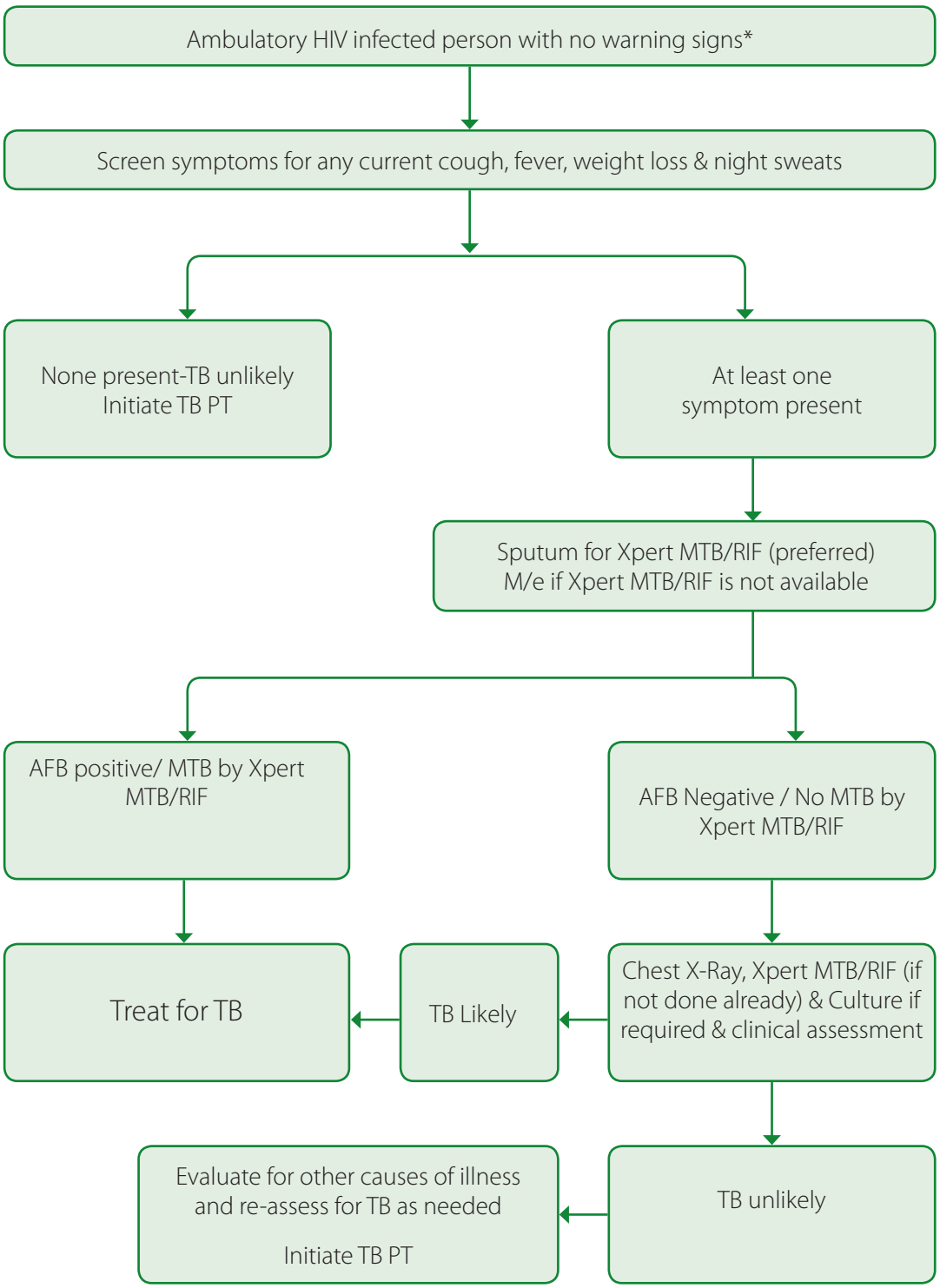
10.3.2. Cotrimoxazole Preventative Therapy

Cotrimoxazole (two single strength tablets or one double-strength tablet per day-160mg trimethoprim/800mg sulfamethoxazole) should be provided to all HIV-infected TB patients at the time of diagnosis and should be continued as per the HIV care and treatment guidelines.

10.3.3 All PLHIV with TB needs ART

- All HIV-infected patients with diagnosed active TB should be put on TB treatment immediately.
- ART should be started in all TB patients living with HIV regardless of their CD4 cell count.
- Anti-tuberculosis treatment should be initiated first, followed by ART as soon as possible within the first 8 weeks of treatment . HIV positive patients with profound immunosuppression (e.g. CD4 counts less than 50 cells/mm^3) should receive ART with in first 2 weeks of initiating TB treatment.
- In all HIV-infected pregnant women with active TB, ART should be started as early as possible, both for maternal health and for the elimination of vertical transmission of HIV.
- IRIS may occur after initiation of ART. Both ART and TB treatment should be continued while managing IRIS.
- Treatment support, which can include directly observed therapy (DOT) of TB treatment, is strongly recommended for HIV-infected patients with active TB disease.

FIGURE 10.1: Algorithm for TB screening for ambulatory people infected with HIV



*This algorithm is for patients who are not very sick. HIV infected patients who are very sick and in distress should be admitted and treated accordingly including TB treatment as needed.

10.3.4 ARV drug choice in TB coinfection

For ARV drug choice in TB-HIV co-infection, refer HIV diagnosis and treatment guideline by NCASC

10.4 PREVENTION OF HIV TRANSMISSION IN HEALTH FACILITIES

- High safety standards, sterilization and disinfection procedures must be maintained.
- One needle is used for one injection for one patient only. Dispose off used needles properly.
- HIV patients without TB should not be admitted in a TB ward.
- TB suspects and smear-positive TB patients should not be admitted in an HIV ward.
- HIV/TB co-infected patients can be admitted in a TB ward.

CHAPTER 11

TUBERCULOSIS AND TOBACCO

TB and Tobacco have strong and proven association which is well documented over the years. Smokers are almost twice as likely to be infected with TB and progress to active disease. Smoking interferes with TB at every stage of the disease. It increases the risk of latent TB infection, culture conversion, sputum smear positivity, cavitary disease, treatment delay, treatment default, poor treatment outcomes and transmission of the disease. Some of these effects are mediated by a higher bacillary load among smokers. Smokers are also twice as likely to die from TB. WHO has been guiding member states with a high prevalence of TB and tobacco to adopt integrated approach to deal with the dual epidemics. Guidance, training and advocacy materials are available for adaption and implementation at the country level.

The burden of Tobacco use in the South-East Asia Region is one of the highest among the WHO regions, and tobacco use is a growing public health problem. The prevalence across countries varies significantly. In Nepal, smoking among adult men is 10.3%. However, there is no data on TB and tobacco prevalence in Nepal.

Nepal can integrate TB and tobacco control programmes for maximum outreach through a two-pronged approach, involving health professional from TB and tobacco control areas. The strategy will help the country to achieve targets and fulfill global commitments related to TB and tobacco control.

11.1 STEPS FOR IMPLEMENTING INTEGRATED TB-TOBACCO PROGRAMME

1. Strongly enforce policy of smoke (Tobacco) free environment/health care facilities at all levels through (awareness and signage campaigns). The smoke-free policy under the tobacco control law will be used to facilitate promotion of "tobacco-free" health facilities.
2. Adopt integrated patient-centred care and prevention interventions at all DOTS centre to begin with and slowly expand to all health care centres.
3. Update available TB recording and reporting tools and formats under the TB programme including development of monitoring indicators on TB-Tobacco.
4. Screen all presumptive TB and confirmed TB patients for tobacco use and record on the TB treatment card, patient card . Use smoking cessation card for those TB patients found to be currently smoking. Update TB registers to include data regarding smoking and also regarding link to tobacco cessation program. Provide brief advise for tobacco cessation to all TB patients who use any form of tobacco – smoking or smokeless tobacco. For those who are found to be currently smoking, provide ABC (**Ask**: ask if they currently smoke, provide **Brief** Advise and provide **Cessation** support)
5. Handover advocacy material to TB patients using tobacco, informing them about the association between TB and tobacco and how their tobacco use habit can interfere with their treatment. This will include advice to quit tobacco use.

6. Develop and display IEC material on TB-tobacco in all health care facilities and implement media campaigns for the same. Promote and ensure health facilities have a 100% tobacco-free environment.
7. Train TB health workers (and DOTS providers) in delivering ABC (**Ask**: ask if they currently smoke, provide **Brief** Advise and provide **Cessation** support)
8. Encourage cross-referrals. The tobacco users who are not able to quit with "brief advice" may be referred to health facilities or cessation clinics for pharmacotherapy. Similarly, tobacco users suspected of having TB symptoms may be referred to TB diagnostic centres.

Health professionals involved in TB management and tobacco control are required to be trained to deliver **ABC** approach "Ask: ask if they currently smoke, provide **Brief** Advise and provide **Cessation** support " for tobacco cessation. This brief intervention lasts only 2-3 minutes and has been found to be very effective if delivered during the duration of treatment of tuberculosis.

11.2 BRIEF TOBACCO INTERVENTIONS

11.2.1 Purpose

The primary purpose of a brief tobacco intervention is to help the patient understand the risks of tobacco use and the benefits of quitting, and to motivate them to make a quit attempt. Brief tobacco interventions can also be used to encourage those heavy tobacco users to seek or accept a referral to more intensive treatments within their community. It is estimated that approximately 40% of tobacco users make some form of an attempt to quit in response to advice from a doctor.

11.2.2 The population impact

The success of a service or a public health programme is measured by its reach (number of people who receive the service/intervention), effectiveness (percentage of people who change their behaviour because of the service/intervention) and cost per person to deliver. Brief tobacco interventions take a few minutes – even small effect sizes – they can have significant population impact at relatively low cost if interventions are delivered routinely and widely across a health-care system.

11.2.3 Effective brief tobacco intervention models

There are several structured brief tobacco intervention models that can guide you through the right process to talk to patients about tobacco use and deliver advice. Below brief tobacco intervention models will be followed in Nepal.

ABC for TB: An approach to smoking cessation and smoke-free homes for tuberculosis patients

11.3 WHAT IS ABC FOR TB?

ABC for TB is a simple three-step method to be used each time a patient attends the tuberculosis services. It is for helping tuberculosis patients who smoke to quit smoking and for encouraging those who are exposed to smoking inside their home to make their home smokefree (have no smoking inside the home at all). It also supports patients who do not smoke to remain non-smokers and those who have smoke free homes to maintain their homes smoke free.

The three steps are:

A is for Ask At each visit, ask all patients if they currently smoke and if anyone smokes inside their home.

B is for Brief advice each visit, give all patients brief advice to quit smoking or to continue not to smoke. Advise patients to make their home smoke free. Personalise the advice by linking smoking and exposure to smoking with tuberculosis and any other associated diseases or conditions.

C is for Cessation support at each visit, provide all patients with cessation support to help them to quit smoking or to continue not to smoke. Support patients to make their home smokefree.

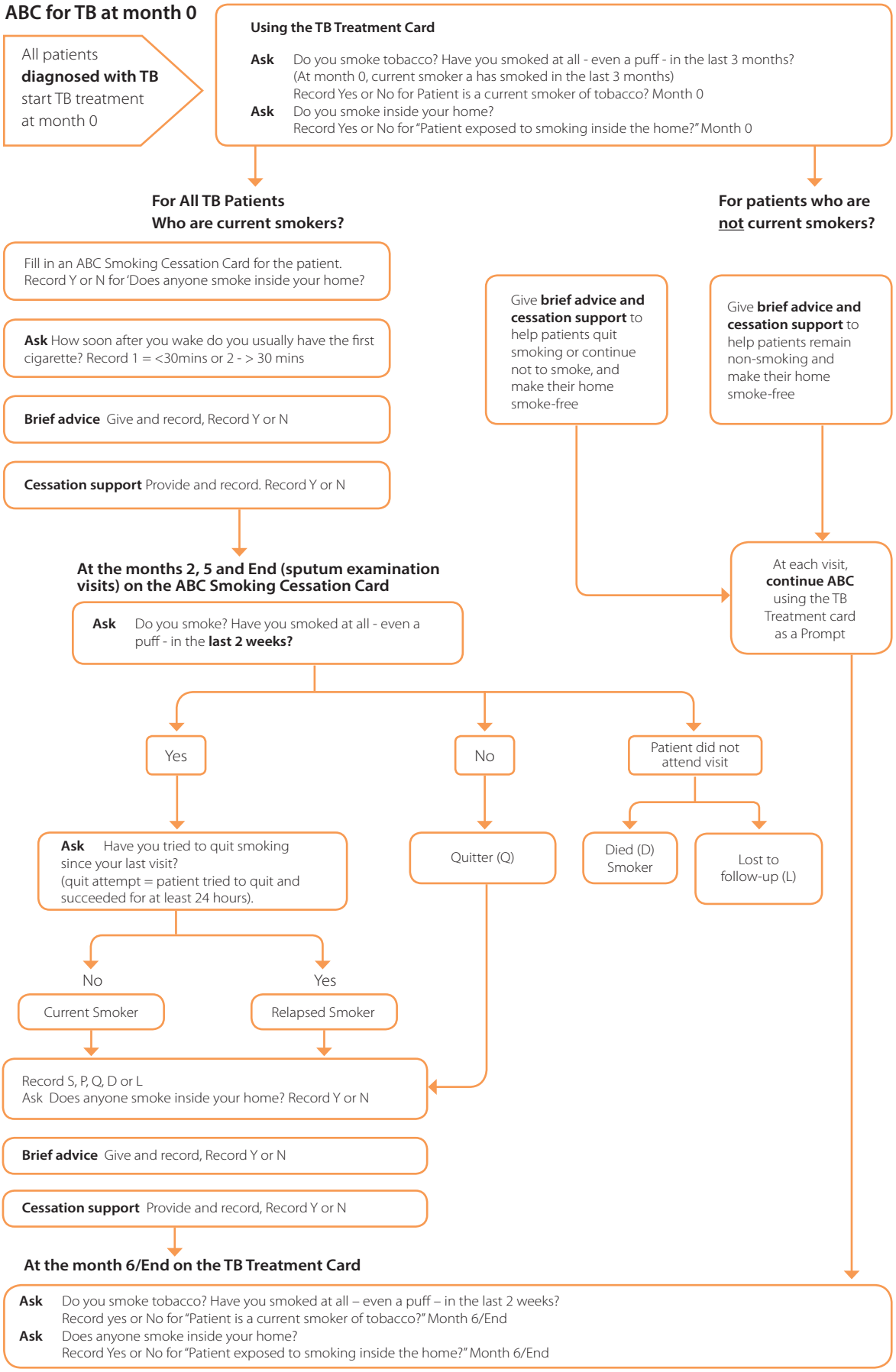
11.4 WHO RECEIVES ABC FOR TB?

All TB patients receive ABC for TB. They are all asked about smoking and exposure to smoking in the home; they are all given brief advice and they are all provided with some kind of support—e.g., to stop smoking, to remain a non-smoker, to make their home smokefree.

When patients are registered for tuberculosis treatment, ABC for TB divides them into two groups:

1. All TB patients who are current smokers – They are issued a separate Smoking Cessation Card and details of ABC for TB for them are recorded at each visit (0,2,5 and End of Treatment)
2. Patients who are not current smokers. – ABC provided but, separate Smoking Cessation Card not issued.

FIGURE 11.1: Flow chart of ABC for TB



11.5 WHO PROVIDES ABC FOR TB?

Depends upon the availability and expertise. Usually DOT provider at the DOTS facilities provides the ABC, but in higher centres, Doctors may provide A and B, whereas Cessation support may be provided by nurses or DOT focal points.

11.6 HOW IS ABC FOR TB DOCUMENTED?

Information on Tobacco use for documented in the treatment card and patient card for All TB patients. For those TB patients who are found to be currently smoking, a separate smoking cessation card is issued and details of ABC are recorded in each follow-up visit (usually 0,2, 5 and at the end of treatment). For DR TB patients, this is recorded in each month or each follow up. The details of information are then recorded in the TB register and reported in HMIS 9.3 cohort reporting forms.

11.7 HOW IS ABC FOR TB DONE?

A is for Ask

At each visit, **ask** all patients if they currently smoke and if anyone smokes inside their home.

At month 0, **ask** if they have smoked at all—even a puff—in the **last 3 months.**

At all other visits, ask if they have smoked at all—even a puff—in the **last 2 weeks.**

For all patients, record whether they are current smokers (yes or no) and whether they are exposed to smoking inside the home (yes or no) at month 0 and month 6/End on the Tuberculosis Treatment Card.

For patients with an ABC Smoking Cessation Card, record at month 0, 2, 5 and End of treatment, the status of smoking and of exposure to smoking.

B is for Brief advice

At each visit, give all patients **brief advice** to quit smoking or to continue not to smoke. Advise patients to make their home smokefree.

Personalise the advice by linking smoking and exposure to smoking with tuberculosis and any other associated diseases or conditions.

For patients with an ABC Smoking Cessation Card, record at month 0, 2, 5 and End of treatment, whether Advice was given or not (yes or no) during that visit.

C is for Cessation support

At each visit, provide all patients with **cessation support** to help them to quit smoking or to continue not to smoke. Support patients to make their home smokefree.

Provide intensive support to patients with strong nicotine dependence. Stop-smoking medications can be offered if available and affordable.

For patients with an ABC Smoking Cessation Card, record at month 0, 2, 5 and End of treatment whether support was provided or not (yes or no) during that visit. For DR TB patients, record at each follow up until the end of treatment.

The key steps are:

1. Give practical help with planning to quit smoking
2. Give advice on making a home smokefree
3. Ask about previous attempts to quit smoking
4. Emphasise the importance of complete abstinence
5. Give more information on the harm of smoking
6. Emphasise the benefits of quitting smoking
7. Advise on coping with nicotine withdrawal.
8. Advise on dealing with weight gain (Weight gain due to the stopping of nicotine)
9. Recommend stop-smoking medications (only if available and affordable)
10. Intensive cessation support (if available, then link/refer to the special programs/ center providing an intensive session of cessation support. But, maintain follow up with ABC in each visit.

CHAPTER 12

TUBERCULOSIS AND DIABETES

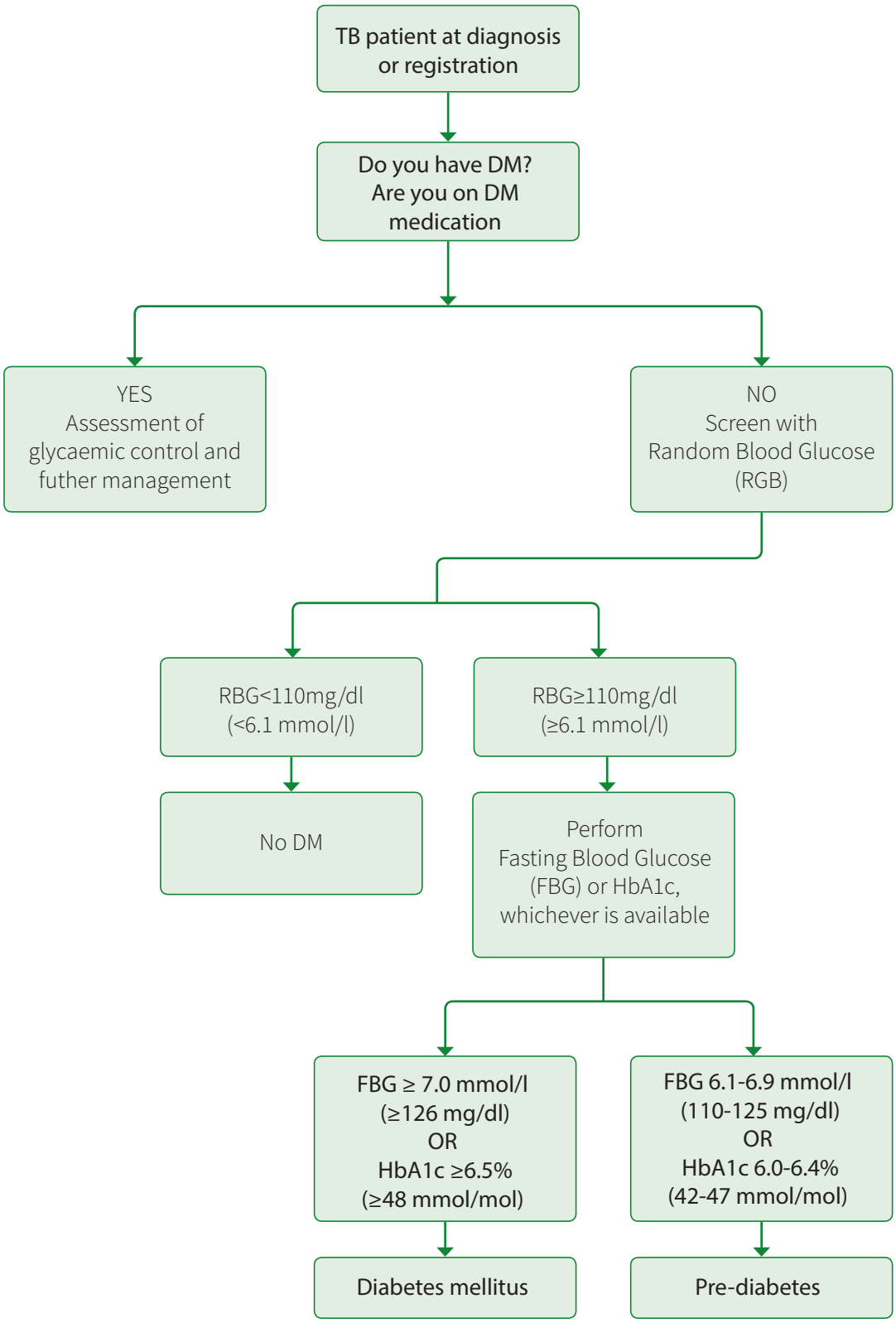
MANAGEMENT OF DIABETES MELLITUS-TUBERCULOSIS

Diabetes mellitus (DM) increases the risk of active tuberculosis (TB) disease two to three-fold and the increasing burden of DM worldwide may offset the global decrease in TB incidence. TB may present atypically with more frequent and severe symptoms and signs in those with dual disease. DM also adversely affects TB treatment outcomes by causing delays in microbiological responses and by being associated with increased rates of death, failure and relapse after completion of treatment. Long-term poor or inadequate glycaemic control appears to play a key role in the increased risk of TB and poor response to treatment. Likewise, TB may provoke hyperglycaemia and may result in overt DM in susceptible persons, which may be difficult to control in the presence of active disease.

DM screening in TB patients

- All adult TB patients should be offered screening for DM. If resources are limited, a targeted screening approach should be used (for example, screening TB patients more than 40 years of age).
- Fasting blood glucose and, HbA1c are the preferred diagnostic tests for DM in patients with TB. Although the oral glucose tolerance test is the gold standard for diagnosing DM, it is too cumbersome for routine use in busy TB clinics.

FIGURE 12.1: Algorithm for the diagnosis of DM among TB patients

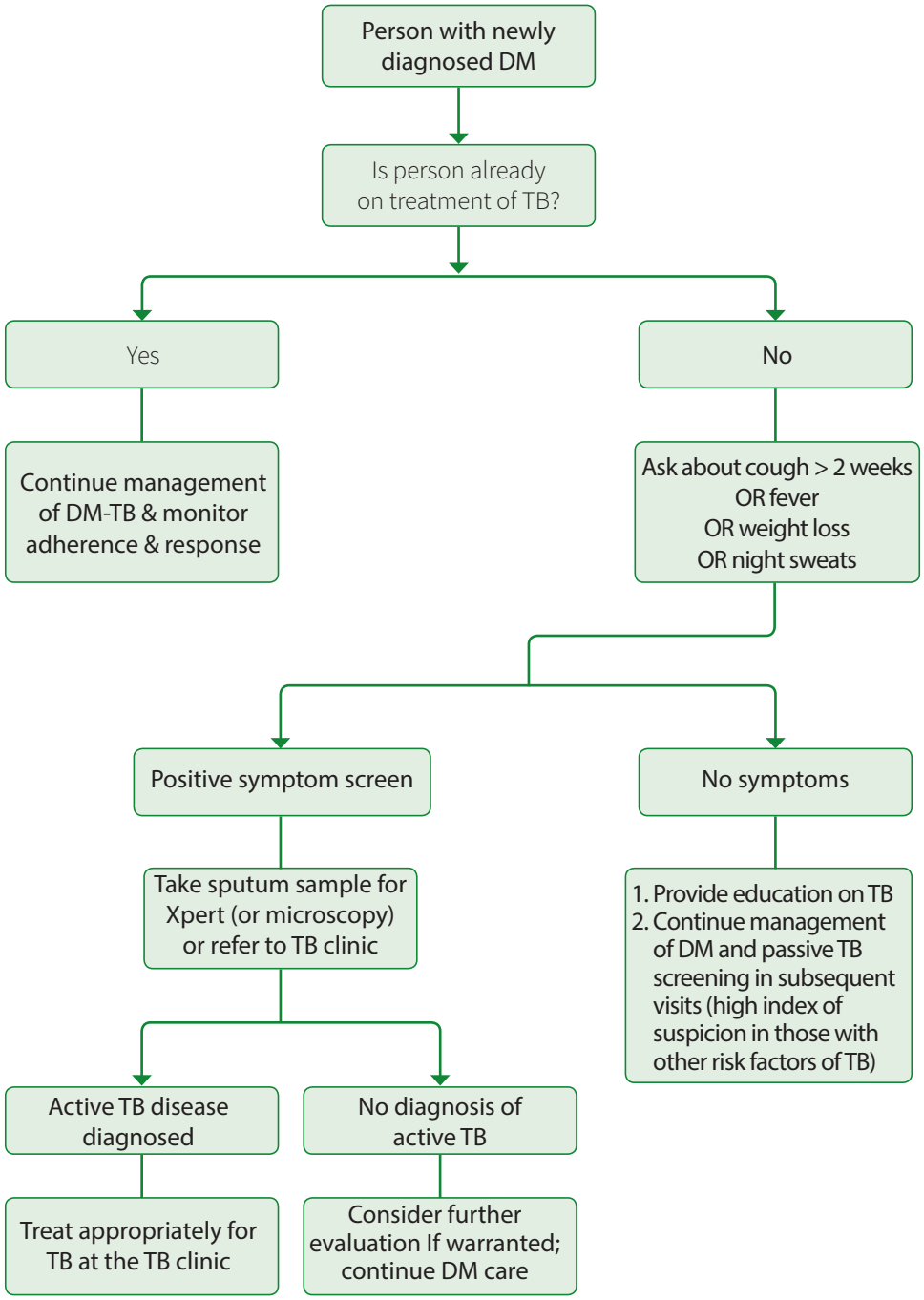


Screening people with diabetes mellitus for tuberculosis

DM patients should be offered systematic screening for TB only in high-TB burden countries where TB prevalence is greater than 100 per 100,000 people.

In persons newly diagnosed with DM, systematic TB screening should be performed actively (i.e., it should be provider-initiated) using a TB symptom screen followed by Xpert MTB/RIF if there are suggestive TB symptoms.

FIGURE 12.2: Algorithm for the screening people with DM for TB



In persons with already established DM, there should be a heightened index of suspicion of TB and health workers should have a low threshold for testing for TB if suggestive symptoms and signs are present.

Treatment for drug-susceptible and drug-resistant TB is similar in persons with and without DM. Health workers should be vigilant about monitoring treatment response as treatment failure and recurrent TB are more common in persons with DM.

Treatment of TB diabetic coinfection

Metformin is the first-line drug of choice for treating persons with DM if medication is needed to control elevated glucose levels. Insulin may have to be considered if blood glucose levels are very high or in those whose blood glucose levels are not controlled with oral hypoglycaemic drugs.

The basic essentials of these three drugs are shown in Table 12.1

TABLE 12.1: common glucose-lowering drugs used for managing DM in TB patients

CHARACTERISTIC	METFORMIN	SULPHONYLUREA DERIVATES	INSULIN
Drug of choice	First choice	Add-on Used in case there is a contraindication or intolerance to metformin	Use if targets for HbA1c or FBG cannot be reached or if there is symptomatic hyperglycemia
Risk of hypoglycemia	No	Yes	Yes
Starting dose (od = once a day; bid = twice a day)	500 mg od or bid, titrated to a maximum dose of 2000 mg daily	Gliclazide 40-80 mg OD Glibenclamide 2.5-5 mg OD Glimepiride 1-2 mg OD Glipizide 5 mg OD	10 units basal insulin per day as the starting point
Interaction with rifampicin	Not clinically relevant	Yes, 30-80% lower efficacy with rifampicin	None
Main side effects	Gastrointestinal Lactic acidosis	Hypoglycemia	Hypoglycemia
Use in reduced kidney function (GFR = glomerular filtration rate)	Dose adjustment if eGFR <45 ml/min Contraindication if eGFR <30 ml/min*	Increased risk of hypoglycemia Preference gliclazide	Can be safely used
Cardiovascular events	Recognized benefit	Neutral	Neutral

*eGFR = estimated glomerular filtration rate.

if measurement of eGFR cannot be done, metformin should not be given to patients with known chronic kidney disease without approval from their treating physician.

People with DM and a history of previous cardiovascular disease should be offered low-dose aspirin and a statin.

People with DM and TB need to be counselled about appropriate lifestyle management (smoking cessation, good diet and physical activity).

CHAPTER 13

MANAGEMENT ASPECTS OF TB CONTROL PROGRAM

13.1 HUMAN RESOURCE DEVELOPMENT

13.1.1 Health Workers

Health workers are the country's most important resources for effective TB control. All health workers should be trained in TB. Health workers who are trained or orientated in TB should be responsible for the management of TB patients in all health facilities. Treatment can be supervised by all other health workers and community volunteers.

13.1.2 Training

Training for TB is done as 3-5 days long intensive training, refresher training or on the job training. Training for TB management include training for health workers coordinators and laboratory microscopists for clinical management, other relevant modules based on the audience. All health facilities should have at least one staff trained in the management of TB. In addition, Public-Private Mix, Community System Strengthening, Laboratory Management, Infection Control and recording reporting training will also be organised as per need at various levels central, provincial and local levels.

13.1.3 Supervision

Supportive supervisory visits are carried out regularly at all levels preferably quarterly using a standard supervisory check-list. TB coordinators and technical staff from the national, provincial, district and local levels carry out supervision to the respective levels to provide technical guidance and onsite support, validate records, registers and reports, ensure and coordinate effective delivery of Ending TB activities. A supervisory checklist is used as a tool. A supervisory report should be compiled and disseminated to all responsible people at the end of every supervisory visit, every quarter.

13.2. SUPPLIES FOR TB

All TB treatment centers compile and submit quarterly reports to NTC which also include a request for drugs and supplies. All TB drugs and supplies are supplied quarterly (4 monthly) based on consumption to the provinces thus quarterly reports should be accurate and submitted on time to NTC.

Drugs and supplies for TB include:

- Drugs for TB treatment, drugs for preventive therapy
- Other supplies for treatment
- Supply for TB diagnosis such as sputum cups, laboratory reagent/kits, slides, etc.
- Forms, formats and registers for recording and reporting

13.2.1 TB Drugs (FDC)

TB drugs are now available in fixed dosed combination (FDC) formulations for both adults and children, which makes TB treatment more effective and efficient. FDC is made up of 2 to 4 drugs combined in one tablet. These come in FDC kits simplifying forecasting, ordering and distribution and completely ensuring the full course of treatment available. When ordering TB drugs, a buffer stock for four months is included in the calculation. The following formula is used when ordering drugs and supplies for TB:

Buffer for:

Treatment Centre: No buffer system existed

District: 4 Months buffer system

Provincial Medical Store: No buffer system existed

National TB Centre: Should have buffer all time as back up for all levels

A + B – C = D whereby

A = quantity used last quarter

B = A. This is for buffer stock and the number is the same as A.

C = stock left at the end of the quarter.

D= amount to order for the next quarter.

13.2.2 Storage

All TB drugs and supplies should be stored in a safe and secure room under appropriate conditions. Drugs are checked regularly for expiry dates. A stock register is maintained and updated whenever drugs and other materials are received or dispensed. A stock (bin) card should be maintained for each drug and is updated every time drugs are received or dispensed. First Expiry First Out (FEFO) should be followed at all health centres.

13.2.3 Laboratory consumables

An adequate supply of sputum containers and slides are needed for sputum microscopy. Laboratories need a good quality binocular microscope or florescence microscope, regular supply of slides and reagents. Wherever there is GeneXpert centers, the cartridges supply stock needs to be maintained.

13.4 DOCUMENTATION

Documentation is a very important part of the National TB Programme and all documents should be maintained and reported as per the National TB Control Programme guidelines. All tools and descriptions on recording and reporting for the National TB programme are mentioned in the Monitoring and evaluation section (Section 14).

CHAPTER 14

MONITORING AND EVALUATION FOR TB CONTROL PROGRAM

14.1 RECORDING AND REPORTING OF TB PROGRAMME

In Nepal, the National TB program has endorsed 13 TB Recording and Reporting tools (TB 01- TB 13) for Drug Sensitive TB.

Forms, Records and Registers

The following documents for recording and reporting are used in the Nepal Tuberculosis Control Program:

S.N	TB NUMBER	TOOLS
1	TB 01	*Presumptive TB register*
2	TB 02a	*Laboratory Request Form*
3	TB 02b	*Laboratory Report Form (LPA and Culture DST)*
4	TB 03a	*Laboratory Register (Microscopy)*
5	TB 03b	*Laboratory Register (GeneXpert)*
6	TB 03c	*Laboratory Register (Culture DST)*
7	TB 03d	*Laboratory Register (LPA)*
8	TB 03e	*Culture / DST Reporting Format*
9	TB 04	*TB Register*
10	TB 05	*TB Treatment Card*
11	TB 06	*TB Patient Identity Card*
12	TB 07	*Contact Investigation forms*
13	TB 08	*Contact and TBPT Register*
14	TB 09	*TBPT Card*
15	TB 10	*Referral / Transfer Slip*
16	TB 11	*Referral Forms (Community, Private, Contact)*
17	TB 12	*TB Drug Order Forms*
18	TB 13	*HMIS 9.3 Reporting format (for cohort TB reporting)*

The first point of contact by any patient for seeking health care is usually the OPD in health facilities. In OPD, when they present with signs and symptoms of TB, then they are registered in the Presumptive TB register. The lab where the test is done records the results in the laboratory registers different register for different tets, eg. Microscopy, GeneXpert, LPA and Culture DST registers) and provides the reports to the patients. Culture Labs additionally provide a complied culture DST information to NTP through Culture / DST Reporting Format (TB 03e).

Once the patient is back to the OPDs where they were referred from initially and based on the lab results, if a patient is diagnosed to have TB, then they are referred to DOT centers for initiation of treatment.

Once in DOT center, the details of all the other results and management of the patient are then recorded in the TB register (TB 04). A treatment card (TB 05) for each patient is maintained (which will have a component of smoking Habit and ABC details) and a patient identity card (TB 06) is also given to each patient.

DOT centers carry out contact investigation of all PBC index TB cases. Contact Investigation forms is used to screen for Presumptive TB in the community (Household contacts) and those with presumptive TB are referred to DOT center using Referral Form (Community, Private, Contact) TB 11 for further confirmation and management. Once at the DOT center, they are then registered in the Contact and TBPT register and managed accordingly. Those under TBPT management are also issued a TBPT card (TB 08).

Incase transfer out needs to be done or a patient is referred to other centers, Referral /Transfer Slip (TB 10) is filled with all the details and sent with the patient.

HMIS 9.3 form (TB 13) will be duly filled from the source documents on a monthly basis for reporting. NTP analyses all these information on 4 monthly bases and also produces a report annually.

Description of forms and registers used in the TB program.

1. **Presumptive TB register (TB 01):** Once a patient is suspected of having TB in the OPDs/ Clinics, then they are registered in the Presumptive TB Register at the OPDs by the treating physicians/health care workers. Presumptive TB Register contains sociodemographic information of TB patients, history of TB, where the patient is referred to for diagnosis, diagnosis result details, TB management suggested and details where the patient is referred for management (DOT centers). The new serial number will be assigned at the beginning of each month while using this register. The register is the same for both DS and DR TB.

2. **Laboratory Request Form (TB 02a):** These forms are filled by OPDs / clinics for diagnosis of TB and or from DOT center and for follow up purpose. There is only one Laboratory Request Form that will be used for both DS and DR TB diagnosis as well as follow up. Once the tests are done, the lab reports back the test results of Smear Microscopy and Xpert MTB/ Rif testing using the same Form. Results of LPA and Culture DST are given in separate form using Laboratory Report Form(LPA and Culture DST) (TB 02b).

   The Form is divided broadly into 2 parts.

   Part 1 is for Laboratory Test request, which has sub-sections for different requesting different types of tests (for diagnosis of TB with smear and Xpert MTB/Rif testing Part A, For LPA for HrTB diagnosis part B, for retreatment cases requiring further confirmation with culture DST part C, for DRTB baseline and followup test part D, and HIV testing part E).

   Part 2 is for reporting the results of smear and Xpert MTB/Rif testing.

3. **Laboratory Report Form(LPA and Culture DST) (TB 02b):** The results of LPA and Culture DST are reported by Lab using this form. This is also the same for DS and DR TB for initial diagnosis or follow up purpose.

4. **Laboratory Register and Formats (TB 03):** These registers are present in the Laboratories where the bacteriological test for TB are carried out. The registers are separate for different types for laboratory process even within the same Laboratory.

    a. Sputum Smear Microscopy Register (TB 03a)

    b. GeneXpert Register (TB 03b)

    c. LPA Register (TB 03c)

    d. Culture DST Register (TB 03d)

    Once the results are obtained, it is then sent back to the treatment center requesting for the tests (via patient or their accompany, courier or other means as available)

e. **Culture/DST Reporting Form (TB 03e):** There is also a separate Culture/DST Reporting Form (TB 03e), which is filled by the Culture Laboratories which contains compiled information of all Culture/DST tests performed by the respective laboratory in that given time frame. This is submitted to NTP on a monthly/quarterly basis. Compiled information of other tests; smear, GeneXpert, and LPA are captured through HMIS 9.3 reporting template, but as detail information regarding culture is required to NTP, the information is captured and reported separately using this format.

5. **TB Register (TB 04):** Once a patient is referred from OPDS/clinics to DOT center for management of TB, they are first registered in the TB register at the DOT centers. This register contains the details of patients' particulars, diagnosis details, registration category details and treatment details, sputum conversion and outcome details with other additional details on contact investigation, smoking habits. This register will be the basis for filling out the HMIS 9.3 for cohort reporting. The register is updated for each patient on month 0, 2 /3, 5 and end of treatment for DS TB.

6. **TB treatment Card (TB 05) :** Once on the TB register, a TB patient card is also issued by the DOT center which has further details of the patient with daily DOT adherence monitoring indicators in it. These are kept at the health facility level and updated every day when a patient comes for daily DOT. In the case of CBDOT, they are updated every 2 weekly when volunteers come to health facilities to collect medicine.

    The Treatment card also has a separate additional section for monitoring smoking habits (ABCs) to be updated by DOT centers during follow up(at least at 0, 2/3, 5 at end of treatment)

7. **Patient Identity Card (TB 06):** Once the treatment card is issued, the Patient's identity card is also issued to be kept by the patient, which basically has all the information from the treatment card and is updated every day.

8. **Contact Investigation forms (TB 07):** After a case is registered in the TB register, DOT centers are responsible to carry out contact investigation of close household contacts of all the PBC index cases, to assess their TB status. Volunteers are given out these Contact Investigation Forms with details of index cases, which they use while carrying out contact tracing in the community. If there are presumptive TB among contacts identified during screening, a separate Referral Form (TB 11) is filled out and issued by the volunteers and referred for further diagnosis. All the information are then recorded for all contacts screened in this form and are submitted back to the DOT centers. The same form will be used to access contacts of drug-sensitive and/or drug-resistant TB.

9. **Contact and TBPT Register (TB 08):** Once Household contacts are referred from the community, then they are then registered in the Contacts and TB Preventive Therapy (TBPT) Register at the DOT center. This register contains details of the contact, their TB status, the information regarding TBPT if provided for the children below 5 years of age and PLHIV enrolled among those contacts, etc.

10. **TBPT Card (TB 09):** Once someone is registered in TBPT, then TBPT card is provided to all these clients. The TBPT card contains the details of client's particulars, their monthly TBPT regimen intake details including weight, doses and final outcome.

11. **Referral / Transfer form (TB 10):** These forms are filled when a patient needs to be referred or transferred out from one center to the next. This contains the information of the patient's particular, diagnostic details, treatment category and regimen details along with details from where and the reason for referral/transfer out. It also has the acknowledgement slip which needs to be filled and sent back by receiving center

12. **Community Referral form (TB 11):** These forms are present in the treatment centers and are provided to the community health volunteers (esp. FCHVs). These are used while referring presumptive TB cases from the community (during contact tracing) to the health facilities for further diagnosis or can also be used for referring a TB patient if they have side effects or requiring other tests and follow up, which they identify in the community.

13. **Drug Order form (TB 12):** Drug order forms are present in the treatment centers where DOT is provided. They are filled in a regular basis and used for ordering drugs for TB program.

14. **TB Cohort reporting form (TB 13):** TB Cohort reporting forms are present at the Service delivery sites (treatment centers), where the TB register is being maintained. This form contains information on Patients' particular, Diagnosis details, treatment details, sputum conversion details, and treatment outcome details, along with some additional information on smoking habit, HIV status, contact investigation status, TBPT status, etc. TB register, Contact and TBPT registers are the main source used to fill out these reporting forms.

14.2 MONITORING OF TB CASE DETECTION AND TREATMENT ACTIVITIES

Monitoring TB control activities are important to assess progress and identify areas that need improvement. The National TB Program monitors the following indicators:

1. TB case detection indicators

A. Monitoring done at the NTP level

i. The proportion of Presumptive TB cases detected at different levels (national, provincial and local level). The monitoring is done for all forms of TB

ii. The proportion of TB cases detected (all forms) among presumptive TB cases and enrolled under treatment at different levels (national, provincial and local level). The monitoring is done for all forms of TB.

iii. The Cohort analysis (sputum conversion and treatment outcome) of the registered TB cases.

iv. The proportion of identified children screened and put on TBPT at different levels (national, provincial and local levels)

B. Monitoring done at the health facility level

i. The proportion of presumptive TB among total OPD visits.
ii. The proportion of presumptive TB tested for TB.
iii. The proportion of presumptive TB tested who are Bacteriologically confirmed and teated for TB.
iv. The proportion of children screened for TB, found negative and put on TBPT.
v. Daily adherence of patient under DOT and regular supervision of patient managed under CBDOT.
vi. Contact tracing of index TB cases and the proportion of contacts tested for TB, diagnosed with TB, treated for TB or for <5 age and PLHIV who are found negative, put on TBPT.

2. TB Treatment Outcome indicators

i. **Sputum conversion Rate:** This indicator refers to the conversion of sputum positive TB to sputum negative TB and is measured as the proportion of new sputum smear-positive cases converted to negative at the end of 2 months.

ii. **TB Treatment Outcome:** This indicator refers to treatment outcomes for new smear-positive cases, smear-positive retreatment cases and all other TB patients (cohort) registered in a particular quarter. Treatment Outcome indicators are measured as a proportion of new smear-positive cases (also other respective TB cases as well as among all TB cases) with the following treatment outcomes

1. Cured
2. Treatment Completed
3. Treatment Failed
4. Died
5. Lost to follow up
6. Not evaluated

Treatment Success Rate (proportion of cured plus completed)

The most important treatment outcome is the cure rate for bacteriologically confirmed patients. The desired cure rate for NEPAL is more than 90%.

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ANNEXURES

ANNEX 1a

Procedure for obtaining clinical samples for Bacteriological examination

This annex reviews the basic procedures for the more common methods of obtaining clinical samples from children for smear microscopy: expectoration, sputum induction and gastric aspiration.

A. Expectoration

Background

1. The sputum smear remains a valuable test to perform in any child who is able to produce a sputum specimen. Sputum should always be obtained in older children who are pulmonary TB suspects. All sputum specimens produced by children should be sent for AFB (acid-fast bacilli) test and, where available, mycobacterial culture. Children who can produce a sputum specimen may be infectious. So, as with adults, they should be asked to do this outside and not in enclosed spaces (such as toilets) unless there is a room especially equipped for this purpose. Three sputum specimens should be obtained: an on-the-spot specimen (at first evaluation), an early morning specimen and a second on the- spot specimen (at follow up visit)

Procedure

2. Give the child confidence by explaining him or her (and any family members) the reason for sputum collection.

3. Instruct the child to rinse his or her mouth with water before producing the specimen. This will help to remove food and any contaminating bacteria in the mouth.

4. Instruct the child to take two deep breaths, holding the breath for a few seconds after each inhalation and then exhaling slowly. Ask him or her to breathe in the third time and then forcefully blow the air out. Ask him or her to breathe in again and then cough. This should produce sputum from deep in the lungs. Ask the child to hold the sputum container close to the lips and to spit into it gently after a productive cough.

5. If the amount of sputum is insufficient, encourage the patient to cough again until a satisfactory specimen (2-5 ml) is obtained. Remember that many patients cannot produce sputum from deep in the respiratory tract in only a few minutes. Give the child sufficient time to produce an expectoration which he or she feels is produced by a deep cough.

6. If there is no expectoration, consider the container used and dispose of it in the appropriate manner.

B. Sputum Induction

Note that, unlike gastric aspiration, sputum induction is an aerosol-generating procedure. Wherever possible, this procedure should be performed in an isolation room that has adequate infection

control precautions (negative pressure, ultraviolet light (turned on when the room is not in use) and extractor fan).

Sputum induction is regarded as a low-risk procedure. Very few adverse events have been reported, and they include coughing spells, mild wheezing and nosebleeds. Recent studies have shown that this procedure can safely be performed even in young infants though the staff will need to have specialized training and equipment to perform this procedure.

General approach

Examine children before the procedure to ensure they are well enough to undergo the procedure. Children with the following characteristics should not undergo sputum induction.

- Inadequate fasting: if a child has been fasting for <3 hours, postpone the procedure until the appropriate time.
- Severe respiratory distress (including rapid breathing, wheezing, hypoxia).
- History of significant asthma (diagnosed and treated by a clinician)
- Reduced level of consciousness.
- Intubated.
- Bleeding: low platelet count, bleeding tendency, severe nosebleeds (symptomatic or platelet count <50,000/mm^3)

Procedure

1. Administer a bronchodilator (e.g. salbutamol) to reduce the risk of wheezing.
2. Administer nebulized hypertonic saline (3% NaCl) for 15 minutes or until 5 ml of the solution has been fully administered.
3. Give chest physiotherapy if necessary. This is useful to mobilize secretions.
4. For older children who are now able to expectorate, follow procedures as described in section A above to collect expectorated sputum.
5. For children who are unable to expectorate, do gastric aspirate/lavage.

Any equipment that is reused needs to be disinfected and sterilized before use for a subsequent patient.

C. Gastric aspiration/lavage

Background

Children with TB may swallow mucus which contains *M. tuberculosis*. Gastric aspiration is a technique used to collect gastric contents to try to confirm the diagnosis of TB by microscopy and mycobacterial culture.

Microscopy can sometimes give false-positive results (especially in HIV-infected children who are at risk of having non-tuberculous mycobacteria). Culture enables the determination of the susceptibility of the organism to anti-TB drugs.

It is most useful for young hospitalized children. The diagnostic yield (positive culture) of a set of three gastric aspirates is only about (25-30%) but the specificity is very high (90-99%) with active TB. However, a negative smear or culture never excludes TB in a child. Gastric aspirates are collected from young children suspected of having pulmonary TB. During sleep, the lung's muco-ciliary system beats mucus up into the throat. The mucus is swallowed and remains in the stomach until the stomach empties. Therefore, the highest-yield specimens are obtained from early morning sample.

Gastric aspiration on each of three consecutive mornings should be performed for each patient. This is the number that seems to maximize the yield of smear-positivity. Of note, the first gastric aspirate has the highest yield. Performing the test properly usually requires two people (one doing the test and an assistant). Children not fasting for at least 4 hours (3 hours for infants) prior to the procedure and children with a low platelet count or bleeding tendency should not undergo the procedure.

The following types of equipments are needed:

- Gloves
- Nasogastric tube (usually 10 French or larger)
- 5, 10, 20 or 30 ml syringe, with appropriate connector for the nasogastric tube
- Specimen container
- Pen (to label specimens)
- Laboratory requisition form
- Sterile water or normal saline (0.9% NaCl)
- Alcohol/chlorhexidine.

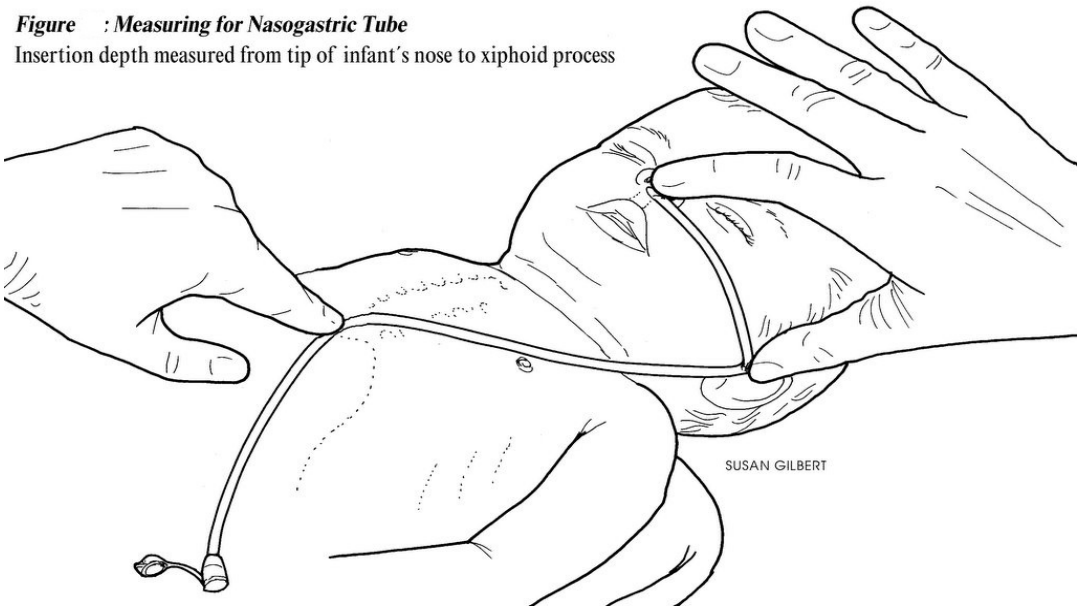
Procedure

The procedure can be carried out as an inpatient first thing in the morning when the child wakes up, at the child's bedside or in a procedure room on the ward (if one is available), or as an outpatient (provided that the facility is properly equipped). The child should have fasted for at least 4 hours (infants for 3 hours) before the procedure.

1. Find an assistant to help.
2. Prepare all equipment before starting the procedure.
3. Position the child on his or her back or side. The assistant should help to hold the child.
4. Measure the distance between the nose and stomach (from nose to tragus and to xiphoid process) to estimate the distance that will be required to insert the tube into the stomach.
5. Attach a syringe to the nasogastric tube.
6. Gently insert the nasogastric tube through the nose and advance it into the stomach.
7. To check that the position of the tube is correct, push some air (e.g. 3–5 ml) from the syringe into the stomach and listen with a stethoscope over the stomach.
8. Once the position of the tube is ensured, withdraw (aspirate) gastric contents (2–5 ml) using the syringe attached to the nasogastric tube.

9. If no fluid is aspirated, insert 5–10 ml sterile water or normal saline and attempt to aspirate again. If still unsuccessful, attempt this again (even if the nasogastric tube is in an incorrect position and water or normal saline is inserted into the airways, the risk of adverse events is still very small). Do not repeat more than three times.
10. Withdraw the gastric contents (**ideally at least 5–10 ml**)
11. Transfer gastric fluid from the syringe into a sterile container (sputum collection cup).#

Figure : Measuring for Nasogastric Tube
Insertion depth measured from tip of infant's nose to xiphoid process



An equal volume of sodium bicarbonate solution can be added to the specimen (in order to neutralize the acidic gastric contents, so as to prevent destruction the of tubercle bacilli).

After the procedure

1. Wipe the specimen container with alcohol/chlorhexidine to prevent cross-infection and label the container.
2. Fill out the laboratory requisition form.
3. Transport the specimen (in a cool box) to the laboratory for processing as soon as possible (within 4 hours).
4. If it is likely to take more than 4 hours for the specimen to be transported, place it in the refrigerator (2–8 °C) and store until transported. The specimen can be stored upto 7 days.
5. Give the child his or her usual food.

Safety

Gastric aspiration is generally not an aerosol-generating procedure. As young children are also at low risk of transmitting infection, gastric aspiration can be considered a low-risk procedure for TB transmission and can safely be performed at the child's bedside or in a routine procedure room.

ANNEX 1b

JOB AID for gastric Aspiration

How to Perform a Paediatric Gastric Aspirate

Materials

- N95 masks & gloves
- Sheet to immobilize
- 8-10 French or larger feeding tube
- Two 20mL syringes
- One 10mL syringe
- Pen/Marker
- Sterile water
- Sodium Bicarbonate (8.5%) with a needle
- Specimen containers
  - GXP (if necessary)
  - Smear (if necessary)
  - Culture
- Lab request form(s)

Note: Child should fast at least 4-6 hours prior to the procedure including no medications, water, food or breast milk.

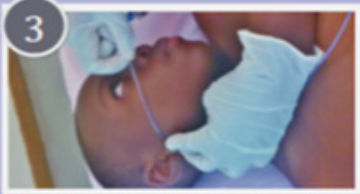
1

Gather materials needed for the procedure. Put on a N95 mask and gloves.

2

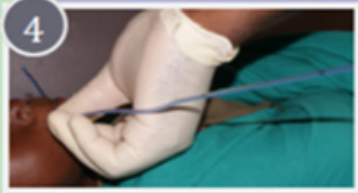
Immobilize the child with a sheet or his/her upper clothes.

3



Measure expected tube distance from tip of nose, to the tragus of the ear, then to the stomach. Mark the tube.

4



Moisten the feeding tube in the child's mouth.

5

Pass the tube through the child's nose to the stomach.

6

When tube reaches the pen mark, aspirate with a 20mL syringe to a goal volume of 5mL.

7

Slowly remove feeding tube once specimen is collected.

8

Place the specimen obtained in the appropriate specimen container(s).

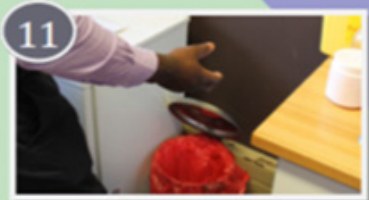
9

Neutralize aspirate with sodium bicarbonate ($NaHCO_3$) based on sample size:
- <5mL=1mL of $NaHCO_3$
- ≥5mL=2mL of $NaHCO_3$

10

Tightly secure the lid and wipe container with 70% alcohol. Label samples & complete lab request forms. Send specimens to the lab.

11



Dispose of all sharps and hazardous waste material in the appropriate containers. Clean all surfaces and wash hands.

If <5-10mL of specimen:

1) Re-position the tube and/or child and pass tube further into the stomach while continuing to aspirate.
2) If still <5-10mL of specimen, instill 20-30mL of sterile water into the tube and re-aspirate stomach contents.

To obtain the highest yield, 3 gastric aspirates should be collected when possible.

ANNEX 2

Recommended treatment regimens and dosages use of fixed dosed combined (FDC) drug

New Treatment Regimen for all TB cases (PTB & EPTB)

Regimen / Patient's Weight	INITIAL PHASE (2 MONTHS)	CONTINUATION PHASE (4 MONTHS)
	2 (HRZE)	4 (HR)
	Daily – 56 total doses	Daily – 112 total doses
	Drugs per adult FDC tablet (Isoniazid[H] 75mg + Rifampicin[R] 150mg +Pyrazinamide[Z] 400mg + Ethambutol[E] 275mg)	(Isoniazid [H] 75mg + Rifampicin [R] 150mg)
30 -39 kg	2	2
40-54kg	3	3
55-70kg	4	4
Over 70kg	5	5

Please note:

- The above dosages are constituted in such a way that the person with the average weight in each weight band receives the average drug requirement for at least Isoniazid and Rifampicin. The person in the upper limit of each weight band then receives around the minimum drug requirement for their weight therefore when any one in that weight band gains weight but remains in the same weight band no change is required in the number of tablets but if the patient gains weight and jumps their upper weight limit into the next weight band, the number of tablets should be increased and the patient should be given the same number of tablets as the next weight band.
- The maximum number of the above FDC tablets any adult should receive should be 5 only.
- Both intenseive and contiuation phase are administrated daily.
- All treatment should be given under DOT.
- When using Kits, drug boxes should be made up for both intensive and continuation phase for each individual based on their weight at the beginning of the treatment phase.
- See chapter on paediatric TB for paediatric doses.

ANNEX 3a

Guidance for Dosing of INH Preventive Therapy

DOSE RECOMMENDATIONS FOR INH PREVENTIVE THERAPY IN CHILDREN	
Body Weight (kg)	INH 100mg /tablet*
2-4.9 kg	1/2
5-9.9 kg	1
10-19.9 kg	1 1/2
20-29.9 kg	2 ½
>30 kg	3
*10 mg/kg/day, single dose	

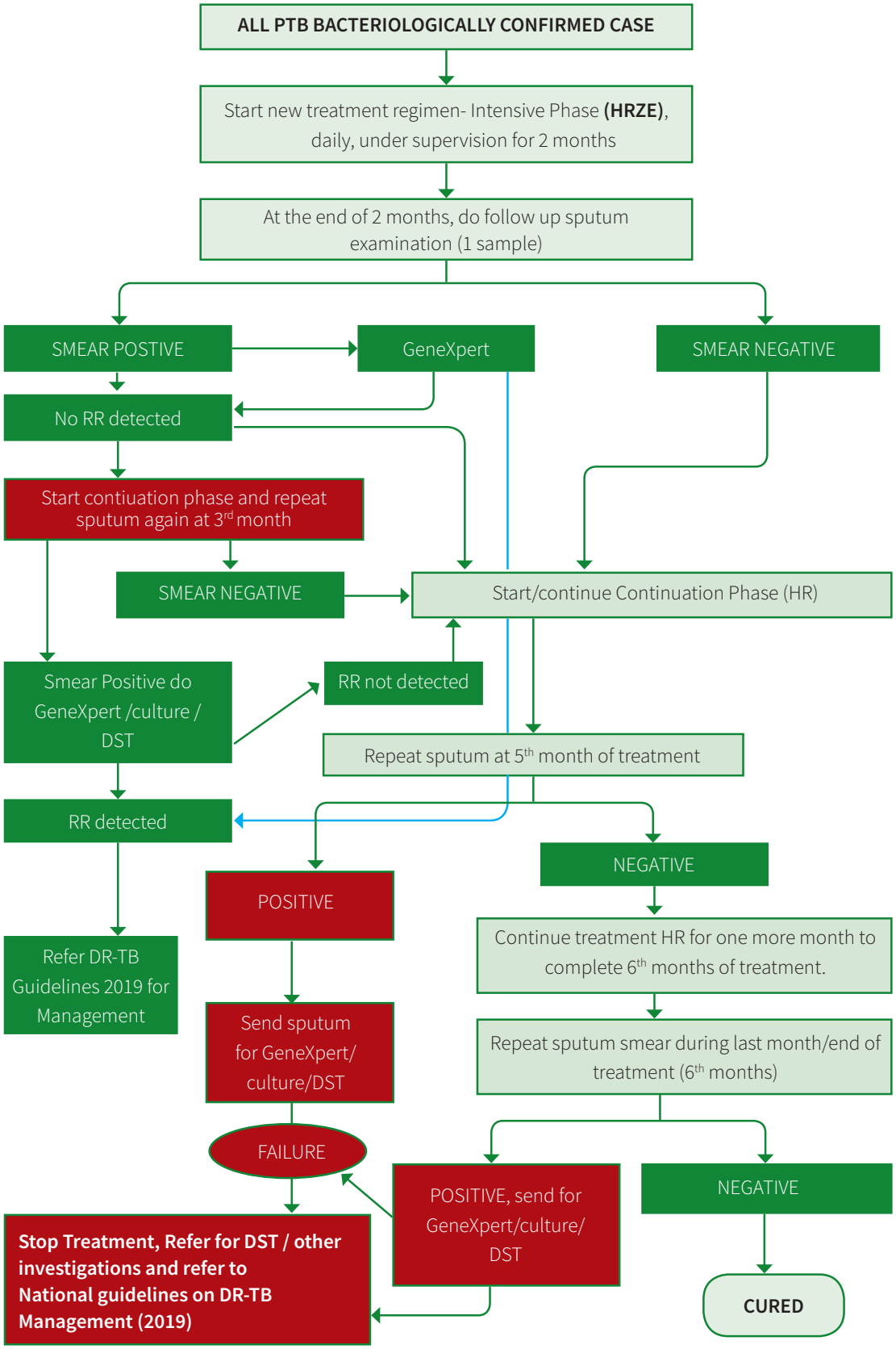
ANNEX 3b

Recommended Anti -TB drug dosages

ANTI-TB DRUGS	CHILD DAILY DOSE	ADULT DAILY DOSE
Rifampicin	15 mg/kg	10 mg/kg
Isoniazid	10 mg/kg	5 mg/kg
Pyrazinamide	35 mg/kg	25 mg/kg
Ethambutol	20 mg/kg	15 mg/kg

ANNEX 4

Flow Chart for Management of Bacteriologically Confirmed Cases



ANNEX 5

Triple Layer Packaging of Samples

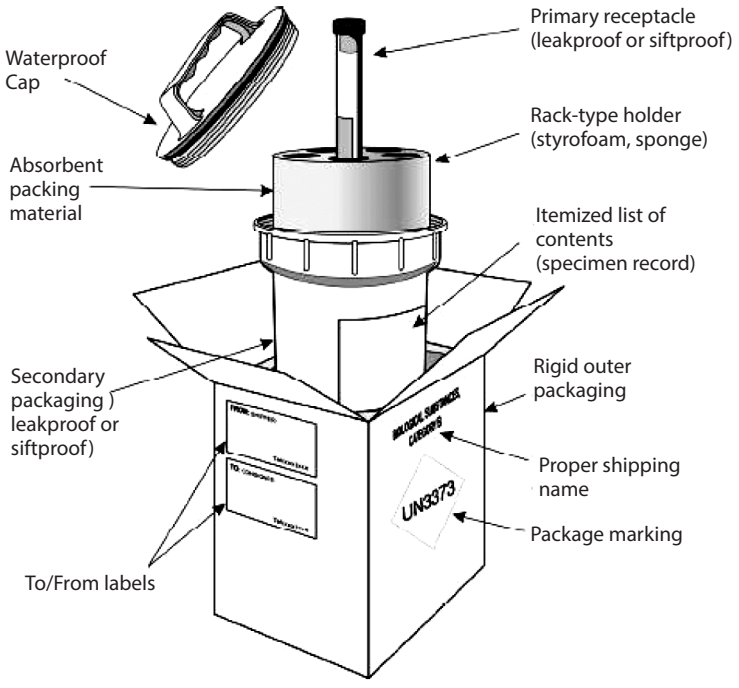
Transport conditions

- Sputa should be transported to the laboratory as soon as possible with in the 48 hours.
- Keep specimens cool (refrigerated but not frozen). Specimens should preferably be kept in a refrigerator at 4C. If none is available then cold boxes can be used with a small amount of dry ice, as long as it is ensured specimens do not freeze. Refer to below for packaging instructions.
- Up to a week in cold conditions will not significantly affect the positivity rate of smear microscopy/Xpert test; however, the additional growth of contaminants will result in an increased contamination rate on culture media after 7 days.

Transport packaging

The basic packaging system for local surface transport of all specimens consists of three layers

1) **Primary receptacle** – the specimen container – packaged with enough absorbent material to absorb all fluid in case of breakage.



2) **Secondary packaging –** a second durable, watertight, leak-proof packaging to enclose and protect the primary receptacle(s). Several cushioned primary receptacles may be placed in one secondary packaging, but sufficient additional absorbent material must be used to absorb all fluid in case of breakage. For cold transportation conditions, ice or dry ice shall be placed outside the secondary receptacle. Wet ice shall be placed in a leak-proof container;

3) **Outer packaging –** secondary packaging are placed in outer shipping packaging with suitable cushioning material. Outer packaging protects its contents from external influences, such as physical damage, during transit.

ANNEX 6

Recording and Reporting Forms

S.N	TB NUMBER	TOOLS
1	TB 01	*Presumptive TB register*
2	TB 02a	*Laboratory Request Form*
3	TB 02b	*Laboratory Report Form (LPA and Culture DST)*
4	TB 03a	*Laboratory Register (Microscopy)*
5	TB 03b	*Laboratory Register (GeneXpert)*
6	TB 03c	*Laboratory Register (Culture DST)*
7	TB 03d	*Laboratory Register (LPA)*
8	TB 03e	*Culture / DST Reporting Format*
8	TB 04	*TB Register*
9	TB 05	*TB Treatment Card*
10	TB 06	*TB Patient Identity Card*
11	TB 07	*Contact Investigation forms*
12	TB 08	*Contact and TBPT Register*
13	TB 09	*TBPT Card*
14	TB 10	*Referral / transfer Slip*
15	TB 11	*Referral form (Community, Private, Contact)*
16	TB 12	*TB Drug Order form*
17	TB 13	*HMIS 9.3 Reporting form (for cohort TB reporting)*

TB 01 - Presumptive TB Register

SN	Screened Date (DD/MM/YY)	OPD Number	Name of Patient		Age		Address	Contact No	Types of Presumptive TB	Screened By		Referred to(for Diagnosis)	Lab result received		TB Diagnosis			Referred to(For Treatment)	Status of Treatment	Remarks
			Surname	Ethnicity Code	F	M				Symptom	X-ray	Name of Lab Tests requested	Yes	No	Yes		No	Name of DOTs Center		
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
	DD /MM/ YY		Name of Patient Surname	Ethnicity Code					1. DS TB 2. DR TB	1	2	Name of Lab DD/MM/YY S / X / C / L / Other	1 DD/MM/YY	2	1 1. PBC 2. PCD 3. EP	1. DS TB 2. DR TB	2	Name of DOTs Center	1. Enrolled in TX 2. Not Enrolled in TX 3. Died	
	DD /MM/ YY		Name of Patient Surname	Ethnicity Code					1. DS TB 2. DR TB	1	2	Name of Lab DD/MM/YY S / X / C / L / Other	1 DD/MM/YY	2	1 1. PBC 2. PCD 3. EP	1. DS TB 2. DR TB	2	Name of DOTs Center	1. Enrolled in TX 2. Not Enrolled in TX 3. Died	
	DD /MM/ YY		Name of Patient Surname	Ethnicity Code					1. DS TB 2. DR TB	1	2	Name of Lab DD/MM/YY S / X / C / L / Other	1 DD/MM/YY	2	1 1. PBC 2. PCD 3. EP	1. DS TB 2. DR TB	2	Name of DOTs Center	1. Enrolled in TX 2. Not Enrolled in TX 3. Died	
	DD /MM/ YY		Name of Patient Surname	Ethnicity Code					1. DS TB 2. DR TB	1	2	Name of Lab DD/MM/YY S / X / C / L / Other	1 DD/MM/YY	2	1 1. PBC 2. PCD 3. EP	1. DS TB 2. DR TB	2	Name of DOTs Center	1. Enrolled in TX 2. Not Enrolled in TX 3. Died	
	DD /MM/ YY		Name of Patient Surname	Ethnicity Code					1. DS TB 2. DR TB	1	2	Name of Lab DD/MM/YY S / X / C / L / Other	1 DD/MM/YY	2	1 1. PBC 2. PCD 3. EP	1. DS TB 2. DR TB	2	Name of DOTs Center	1. Enrolled in TX 2. Not Enrolled in TX 3. Died	
	DD /MM/ YY		Name of Patient Surname	Ethnicity Code					1. DS TB 2. DR TB	1	2	Name of Lab DD/MM/YY S / X / C / L / Other	1 DD/MM/YY	2	1 1. PBC 2. PCD 3. EP	1. DS TB 2. DR TB	2	Name of DOTs Center	1. Enrolled in TX 2. Not Enrolled in TX 3. Died	
	DD /MM/ YY		Name of Patient Surname	Ethnicity Code					1. DS TB 2. DR TB	1	2	Name of Lab DD/MM/YY S / X / C / L / Other	1 DD/MM/YY	2	1 1. PBC 2. PCD 3. EP	1. DS TB 2. DR TB	2	Name of DOTs Center	1. Enrolled in TX 2. Not Enrolled in TX 3. Died	

TB 02a Laboratory Request and Reporting Form

HMIS 6.1

Government of Nepal
Health Management Information System
Laboratory Request and Reporting Form

Date……/……/…..

1. Name of Health Facility……2. Presumptive/OPD/Contact Reg No… 3.DR/ TB Reg. No……..…..

4. Name of Patient…….. 5. Age…… 6. Sex……..……..

7. Ethnicity …….. 8. Code ……

9. Address: Province……District…….M/RM…….. ward…… Tole ……..

10. Name of Guardian ……..11. Contact no……

12. Purpose for Examination. i- Diagnosis. ii- Follow-up (.....month) iii- RR detection:

1-LABORATORY REQUEST

Part (A)-for Detection of TB
Microscopy and Xpert/MTB RIF
(to be filled at OPD/DOTS centre)

13. History of Treatment for TB: (a) No previous Treatment (b) Previous History of Treatment
(c) Current on Treatment- (i- New ii- Retreatment iii- Others)
14. Specimen Type: i- Sputum ii- Other (specify).....
15. Test Request for: i- Microscopy ii-. Xpert MTB/RIF

Part (B)-For INH Resistance identification
For patients who meet all three below mentioned criteria;
i. Retreatment cases, ii. Rifampicin Sensitive (via Xpert MTB/RIF), iii. Smear Positive
(to be filled at OPD/DOTS centre)

16. Test Requested: i. LPA
17. Specimen Type: 1. Sputum 2. Other(specify).....
18. Details of Past TB Treatmen: i. New ii- Relapse ii- Tx After Failure iii- Tx After LTFU
iv- Others Previously Treated vi. Unknown Previous TB Treatment History
19. History of Contacts with known TB: 1. Yes 2. No
If yes, Mention DST result of: i- INH…… ii-Rif……iii- Others:……..
20. Retro Status: i – Reactive ii – Non-reactive iii- Unknown

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Part (C)- **For Presumptive DR TB cases**
MTB not detected, or MTB detected with Rif Indeterminant through Xpert MTB/RIF testing
(to be filled at OPD/DOTS centre)

21. Test Requested: i. Culture/DST
22. Specimen Type: 1. Sputum 2. Others (specify).....
23. Details of Past TB Treatment: i- New ii- Relapse iii- Tx After Failure iv- Tx After LTFU
v- Others Previously Treated vi – Unknown Previous TB Treatment History
24. Retro Status: i – Reactive ii – Nonreactive iii- Unknown

Part (D) – For DR TB Baseline and follow up cases

25 i) Routine collection for 0 month: ☐ Collect 2 samples
ii) Routine collection for follow up months : …….. ☐ Collect 1 sample

26. Specimen Type: 1. Sputum 2. Others (specify).....

27. Details of Past TB Treatment: i- New ii- Relapse iii- Tx After Failure iv- Tx After LTFU
v- Others Previously Treated vi – Unknown Previous TB Treatment History

Date of Sample Collection: ……

Part (E)- For all cases Detected with TB (All Forms of TB)

28. Test Request for HIV ☐ ("✓" if HIV Test Requested)

Requested by:

Name: .....

Designation:.....

Contact Number: .....

Signature: .....

2- LABORATORY TEST RESULT

Name of Laboratory/GeneXpert Site:……..

Lab no. ... ... Result Date:……./……./…..

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1. Microscopy Test Results

Sample	Visual Appearance	Result					Examined by:	
		Neg (✓)	Positive (circle the grading)				Name NHPC No	Signature and date
A	B M S		Scanty	1+	2+	3+		
B	B M S		Scanty	1+	2+	3+		

(B) blood-stained (M) mucopurulent (S) saliva

Neg.=(0 AFB/100 OF), Scanty= (1-9 AFB /100 OF) 1+=(10−99 AFB/100 OF),2+ = (1−10 AFB/ OF), 3+=(>10 AFB/ OF),

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2. Xpert MTB/RIF test result

Mycobacterium tuberculosis:	1. Detected	2. Not detected	3. Invalid / No result / Error
Rifampicin Resistance:	1. Detected	2. Not detected	3. Indeterminate

3. HIV Test Result

a) (A1) Determine Test i - Reactive ii- Non-Reactive

b) (A2) Uni-Gold Test ii- Reactive ii- Non-Reactive

c) (A3) Stat pack Test iii- Reactive ii- Non-Reactive

Examined by: Name: .....

Designation: .....

NHPC No.....

Signature and date .....

TB 02b Laboratory Report Form (LPA and Culure DST)

TB O2b

National Tuberculosis Programme Nepal
National Tuberculosis Centre
National T.B. Reference Laboratory
Thimi, Bhaktapur (Phone no. 01-6630706, 6630832, Ext no. 107)

LABORATORY REPORT (LPA and Culture DST)

1. Name of Health Facility…….....…… 2. Presumptive/OPD Reg No./Contact No…..
3. DR/TB Reg. No……..
4. Name of Patient…….. 5. Age. 6. Sex……
7. Address: Province…… District……..M/RM…… ward…. Tole …..
8. Specimen Type: 1. Sputum 2. Other (specify).....
11. Date of Sample Collection: …….. 12. Date of Sample Receipt: ……..
12. If for Follow up (Month): ……..

REPORTS ON CULTURE

Lab No. :

Tests	Smear Microscopy (Concentrated Sample)	Culture*
Result		

**Please see remarks below*

REPORT ON LPA

Result on LPA from: i) Direct Specimen ☐ ii) Culture ☐

Identification	**M. tuberculosis Complex**		
Drugs	**Genes**	**Mutation**	**Result/ Interpretation***
Rifampicin	**rpoB**		
Isoniazid	**KatG**		
	Inh A		
Fluoroquinolones	**gyr A**		
	gyr B		
Second Line Injectable	**rrs**		
	eis		

**Please see remarks below*

Drug Susceptibility Test (Phenotypic)

Drugs	H	Z	Lfx	Mfx 0.25 µg/ml	Mfx 1.0 µg/ml	Cfz	Lnz	Am	Bdq	Dmn	Other
Result*											
Interpretation: S: Susceptible R: Resistance C: Contaminated ND: Not Done. **Please see remarks below*											

Note: *H-Isoniazid , Z-Pyrazinamide, Eto-Ethionamide, Lfx- Levofloxacin, Mfx- Moxifloxacin, Bdq-Bedaquiline, Lnz- Linezolid, Cfz-Clofazimine, Am- Amikacin, Dmn- Delamanid*

Remarks:

Reported By: …….....…… Verified By: ….....…….. Date: .....……

TB 03a Laboratory Register (Microscopy)

HMIS 6.2

Tuberculosis Laboratory Register (Microscopy)

TB 03a

Month

Lab no	Sample collection Date			Name of Patient		Age		Address		Name of Guardian/ Family Member	Name of Health Institution requesting for test	HIV Status	Previous Treatment History					Purpose of test		Result and date		Tested by	HIV Test Result	Remarks
	DD	MM	YY	Surname	Ethnicity Code	Female	Male	District	M/RM		Presumptive/ OPD /Contact TB Registration no		No previous Treatment	Previous History of Treatment	Current on Treatment			Diagnosis	Follow up	Specimen A Result	Specimen B Result	Name post		
								ward no	Contact no						New	Retreatment	Others			Test date	Test date	Signature		
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
Lab no				Name of Patient				District	M/RM		Name of Health Institution requesting for test	1.Reactive 2.Non-Reactive 3.Unknown	1	2	3	4	5	1	..... Month	Result	Result	Name post	Reactive	
				Surname	Ethnicity code			ward no	Contact no		Presum/ OPD /TB Registration no									Test date	Test date	Signature	Non Reactive	
Lab no				Name of Patient				District	M/RM		Name of Health Institution requesting for test	1.Reactive 2.Non-Reactive 3.Unknown						1	..... Month	Result	Result	Name post	Reactive	
				Surname	Ethnicity code			ward no	Contact no		OPD दर्ता नं. अस्पताल दर्ता नं.									Test date	test date	Signature	Non Reactive	
Lab no				Name of Patient				District	M/RM		Name of Health Institution requesting for test	1.Reactive 2.Non-Reactive 3.Unknown						1	..... Month	Result	Result	Name post	Reactive	
				Surname	Ethnicity code			ward no	Contact no		Presum/ OPD /TB Registration no									Test date	Test date	Signature	Non Reactive	
Lab no				Name of Patient				District	M/RM		Name of Health Institution requesting for test	1.Reactive 2.Non-Reactive 3.Unknown						1	..... Month	Result	Result	Name post	Reactive	
				Surname	Ethnicity code			ward no	Contact no		OPD दर्ता नं. अस्पताल दर्ता नं.									Test date	test date	Signature	Non Reactive	

TB 03b Tuberculosis Laboratory Register (GeneXpert)

HMIS 6.2

TB 03b

Tuberculosis Laboratory Register (GeneXpert)

Lab no	Name of Patient		Age		Address		Name of Guardian/ Family Member	Name of Health Institution requesting for test	HIV Status	History of Treatment for TB					Purpose of test		Specimen Type	Sample received date
	Surname	Ethnicity code	Female	Male	District	M/RM				No previous Treatment	Previous History of Treatment	Current on Treatment			Diagnosis	RR Detection		
					ward no	Contact no		Presumptive/ OPD /TB Registration no				New	Retreatment	Others				
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
Lab no	Name of Patient				District	M/RM		Name of Health Institution requesting for test	1.Reactive 2.Non-reactive 3.Unknown									DD/MM/YY
	Surname	Ethnicity code			ward no	Contact no		Presum/ OPD /TB Registration no										
Lab no	Name of Patient				District	M/RM		Name of Health Institution requesting for test	1.Reactive 2.Non-reactive 3.Unknown									DD/MM/YY
	Surname	Ethnicity code			ward no	Contact no		Presum/ OPD /TB Registration no										

Test Result						Tested by	Remarks
						Name post	
MTB Not Detected	MTB + Rif sensitive	MTB+Rif resistance	MTB+Rif indeterminate	Error/Code	Test Failure (No result/Invalid)	Signature	
20	21	22	23	24	25	26	27
						Name post	
DD/MM/YY	DD/MM/YY	DD/MM/YY	DD/MM/YY	DD/MM/YY	DD/MM/YY	Signature	
						Name post	
DD/MM/YY	DD/MM/YY	DD/MM/YY	DD/MM/YY	DD/MM/YY	DD/MM/YY	Signature	

TB 03c Laboratory Register (Culture DST)

TB 03c
Month

Tuberculosis Laboratory Register (Culture)

Lab no	Sample Collection Date			Name of Patient		Age		Address		Name of Guardian/ Family Member	Name of Health Institution requesting for test	HIV Test Result	Category & month	Specimen	Visual Appearance	Dates of sample collection	Dates of Sample Receive	Refrigerated/ Non-refrigerated/ Cold chain
	DD	MM	YY	Surname	Ethnicity code	Female	Male	District	M/RM		Presum/ OPD /TB Registration no							
								Ward no	Contact no									
1	2	3	4	5	6	7	8	9		10	11	12	13	14	15	16	17	18
Lab no	DD	MM	YY	Name of Patient				District	M/RM		Name of Health Institution requesting for test	1. Reactive 2. Non Reactive 3. Unknown						
				Surname	Ethnicity code			ward no	Contact no		Presum/ OPD /TB Registration no							

Date of Processing	Smear Microscopy: Result	MGIT: Result	MGIT DST Date of Inoculation	MGIT: DST												MGIT: Date of reporting	L J: Result	L J: Date of reporting	Remarks
				R	H	Z	Am	Bdq	Cfz	Lzd	Mfx (H)	Mfx (L)	Eto	Lfx	Dlm	Others			
19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39

TB 03d Laboratory Register (LPA)

National Tuberculosis Centre
Thimi, Bhaktapur
TB 03d Laboratory Register (Line Probe Assay)

Lab no	Sample Collection Date			Name of Patient		Age		Address			HIV Test Result	Treatment Centre	Category & month	Specimen Type	Date of sample collection	Date of Sample Received
	DD	MM	YY	Surname	Ethnicity code	Female	Male	District		M/RM						
								Ward no	Contact no							
1	2	3	4	5	6	7	8	9			10	11	12	13	14	15
Lab no	DD	MM	YY	Name of Patient				District		M/RM	1. Reactive 2. Non Reactive 3. Unknown					
				Surname	Ethnicity code			ward no	Contact no							
Lab no	DD	MM	YY	Name of Patient				District		M/RM	1. Reactive 2. Non Reactive 3. Unknown					
				Surname	Ethnicity code			ward no	Contact no							

Date of Processing	Smear Microscopy Result	Specimen Type C)Culture D)Direct	Culture Result	Identification	LPA DST														Interpretation	LPA: Date of reporting	Remarks
					R		H				FLQ				AMG						
					rpob		KatG		Inh A		gyrA		gyrB		rrs		eis				
					WT	Mut	WT	Mut	WT	Mut	WT	Mut	WT	Mut	WT	Mut	WT	Mut			
16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37

TB 03e Culture/Dst Reporting Format

TB 03e Culture/Dst Reporting Format

Name of Reporting Unit: _____ **Reporting Period:**_____ **to**_____

Report Prepared by:_____ **Report Verified by**_____

Report submission date:___DD/MM/YYY_____

1 Results of first-line drug susceptibility testing in pulmonary TB patients

	Previous anti-TB treatment status						Total
	New		Previously treated [A]		Unknown treatment history [B]		
	F	M	F	M	F	M	
i) Number of pulmonary TB patients with positive identification for M. Tuberculosis complex confirmed by culture and/or line-probe assay. (Use line (vi) below for patients confirmed by Xpert MTB/RIF only)							0
(ii) Among patients reported in (i), number of patients with available DST results for isoniazid (H) and rifampicin (R)							0
(iii) Among patients reported in (ii), number of patients with resistance to H but not R							0
(iv) Among patients reported in (ii), number of patients with resistance to R but not H							0
(v) Among patients reported in (ii), number of patients with resistance to H and R (MDR-TB)							0
(vi) Number of pulmonary TB patients with positive identification for M. Tuberculosis complex confirmed by Xpert MTB/RIF alone and who are not confirmed by culture and/or line-probe assay (these cases should be additional to those reported in i)							0
(vii) Among patients reported in (vi), number of patients with resistance to R (these cases should be additional to those reported in iv and v)							0

2 Among patients with DST results in 1 line (ii): association between MDR-TB and HIV status (number of patients)

	HIV Test Result						Total
	Reactive		Non Reactive		Unknown		
	F	M	F	M	F	M	
(a) MDR-TB (resistant to both H and R)							0
(b) Not MDR-TB (drug susceptible plus any resistance that is not MDR-TB)							0
Grand Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**

3 Among patients with DST results in 1 line (ii): association between MDR-TB and age (number of patients)

	Age						Total
	0–14		≥15		Unknown		
	F	M	F	M	F	M	
(a) MDR-TB (resistant to both H and R)							0
(b) Not MDR-TB (drug susceptible plus any resistance that is not MDR-TB)							0
Grand Total	**0**	**0**	**0**	**0**	**0**	**0**	**0**

4 Results of second-line drug susceptibility testing

	F	M	Total				
(i) Total number of pulmonary MDR-TB patients with DST results for any fluoroquinolone (FQ) and any second-line injectable agent (2LI)			0				
(ii) Among MDR-TB patients reported in (i), number of patients susceptible to both FQ and 2LI			0				
(iii) Among MDR-TB patients reported in (i), number of patients with any resistance to FQ			0				
(iv) Among MDR-TB patients reported in (i), number of patients with any resistance to 2LI			0				
(v) Among MDR-TB patients reported in (i), number of patients with any resistance to both FQ and 2LI (XDR-TB)			0				

TB 04 TB Register

TB 04: Tuberculosis Register

HMIS 6.5

S.N	Registration No. / Registration Date: DD	MM	YY	Name of patient: Surname	Ethnicity Code	Age: F	Age: M	Patient's Address: Province / District / Ward No.	Patient's Address: M / RM / Contact Number	Patients Referred/ Diagnosed by: 1. Private health facilities 2. Community 3. Contact Investigation	Disease Type: PBC	PCD	EP	Treatment start date: DD	MM	YY	Registration Category: New	Previously Treated Patients: Relapse	Treatment After Failure	Treatment After Loss to Follow-up	Others Previously Treated	Unknown previous TB treatment history	Transfer In	HIV diagnosis and treatment among TB patient: HIV Test Result: Reactive	Nonreactive	Unknown	ART: Yes	ART: No	CPT: Yes	CPT: No	DST among TB patient during diagnosis/treatment: Drug Resistance: Yes	No	Un-known
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	#	26	27	#	#	#	#	32	33	34
	Registration No. / dd	mm	yyyy	Name of patient / Surname	Ethnicity Code	1	2	Province / District / Ward No.	Municipality / Contact Number		1	2	3	dd	mm	yyy	1	2	3	4	5	6	7	1	2	3	1	2	1	2	1	2	3

Sputum examination type (Microscopy/Culture/GX), result at the time of diagnosis and treatment and date: At the time of TB diagnosis: Sputum (Result / Lab No): DD	MM	YY	Xpert MTB (Result / Lab No): DD	MM	YY	LPA (Result / Lab No): DD	MM	YY	S C X	2 month Follow up (Result / Lab No): DD	MM	YY	3 month Follow-up (Result / Lab No): DD	MM	YY	S C X	5 month Follow up (Result / Lab No): DD	MM	YY	S C X	At the end of TB treatment (Result / Lab No): DD	MM	YY	Tobacco Smoking: Smoking Tobacco (Current): Yes	No	Status of Smoking (S,R,Q,) S: Current Smoker R: Relapsed Smoker Q: Quitter — F/U Months: 0	2	5	End	Status of Exposure to smoking inside the home (Y or N) — F/U Months: 0	2	5	End	Treatment Outcome: Cured	Completed	Failed	Died	Lost to Follow-up	Not Evaluated	Moved to 2nd line Treatment Register	Patient under CBDOT ?: Yes	No	Remarks
35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78
Result / DD	Lab No / MM	YY	Result / DD	Lab No / MM	YY	Result / DD	Lab No / MM	YY	S	Result / DD	Lab No / MM	YY	Result / DD	Lab No / MM	YY	S	Result / DD	Lab No / MM	YY	S	Result / DD	Lab No / MM	YY	1	2									1	2	3	4	5	6	7	yes	No	
Result / DD	Lab No / MM	YY	Result / DD	Lab No / MM	YY	Result / DD	Lab No / MM	YY	C	Result / DD	Lab No / MM	YY	Result / DD	Lab No / MM	YY	C	Result / DD	Lab No / MM	YY	C	Result / DD	Lab No / MM	YY											dd/mm/yyyy									
Result / DD	Lab No / MM	YY	Result / DD	Lab No / MM	YY	Result / DD	Lab No / MM	YY	X	Result / DD	Lab No / MM	YY	Result / DD	Lab No / MM	YY	X	Result / DD	Lab No / MM	YY	X	Result / DD	Lab No / MM	YY											dd/mm/yyyy									

TB 05 TB Treatment Card

TB-O5 HMIS 6.3

NATIONAL TUBERCULOSIS CONTROL PROGRAMME
TUBERCULOSIS TREATMENT CARD

Photo

Name of Patients							
Sex	1. Female	2. Male		Age:		Phone No:	
Address:	Province			Districts:			
M/RM:				Ward No / Tole :			
Guardian's Name							
Total no.of household member			**No. of household members screened for TB**				
Number of <5 years children in family							
Number of children under TBPT							
History of Previous treatment (if Yes, Previous TB Reg. No, Regimen and Duration of treatment):							

TB Reg. No:	**Registration Date:**	**Treatment Start Date:**
	DD/MM/YY	DD/MM/YY

Name of Health Facility:

Name of DOT Provider:		Type of DOT	
DOT Provider Phone No.		1. Health Facility	2. Community

Month	Smear Microscopy			Xpert MTB/RIF			LPA		
	Date	**Lab No.**	**Result**	**Date**	**Lab No.**	**Result**	**Date**	**Lab No.**	**Result**
Initial	DD/MM/YY			DD/MM/YY			DD/MM/YY		
2 month	DD/MM/YY			DD/MM/YY			DD/MM/YY		
3 month	DD/MM/YY			DD/MM/YY			DD/MM/YY		
5 month	DD/MM/YY								
End of Treatment	DD/MM/YY								

Classification of Disease(Please circle)	
PBC	1
PCD	2
EP	3
If EP (Site):	

Type of Patient	
1. New	4. T. After loss to F/U
2. Relapse	5. Other previously treated patient
3. T. After Failure	6. Unknown previous TB treatment history

Chest X-Ray at Start
Date: DD/MM/YY
1. Normal 2. Abnormal
3. Not Done

TB / HIV	**Date**	**Result**
Retro- Test	DD/MM/YY	
CPT Start	DD/MM/YY	
ART Start	DD/MM/YY	
Viral Load	DD/MM/YY	
ART Register No and Date	DD/MM/YY	

Treatment Type	**Adult Regimen (Please Circle)**		**Child Regimen(Please Circle)**	
New TB (all forms - Pulmonary and Extrapulmonary)	**2 HRZE+ 4 HR**	1	**2 (HRZ+ E) + 4 HR**	1
Complicated/Severe EP TB cases	**2 HRZE + 7 HRE (possibility of extension of HRE for 3 additional months)**	2	**2 (HRZ +E) + 7 (HR+E) (possibility of extension of HRE for 3 additional months)**	2
Retreatment cases (Rif Sensitive, INH Sensitive)	**2 HRZE + 4 HR**	3	**2 (HRZ+E) + 4 HR**	3
Retreatment cases (Rif Sensitive, INH Resistant and FQ Sensitive)	**6 HRZE Lfx**	4	**6 (HRZ+E) Lfx**	4
Retreatment cases (Rif Sensitive, INH Resistant and FQ Resistant)	**6 HRZE**	5	**6 (HRZ+E)**	5
Retreatment cases (Rif Sensitive, INH Not known)	**6 HRZE**	6	**6 (HRZ+E)**	6

I. INTENSIVE PHASE (Date)

	HRZE	**HRZ**	**Lfx**	**E**
Tablets				
Duration (months)				

Enter (✓) on day when medication was swallowed under direct observation, Enter (-) on day when medication not under direct observation and Enter (O) if medication was not swallowed

Month / Year	Date																													Total Dosage given		Weight (Kg)
	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	This Month	Cummulative	

II. CONTINUATION PHASE

	HR	**HRE**	**E**
Duration (Month)			
Tablets			

Enter (✓) on day when medication was swallowed under direct observation, Enter (-) on day when medication not under direct observation and Enter (O) if medication was not swallowed

Month / Year	Day																													Total Dosage given		Weight(Kg)
	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	This Month	Cummulative	

Treatment outcome (Circle O one)	1. Cured	2. Treatment Completed	3.Treatment Failure	4. Lost to Follow up	5. Died	6. Not Evaluated
Treatment outcome Date:	DD/MM/YY					

Section on ABC Smoking Cessation

At start of TB treatment then at each follow-up examination visit:		Ask				Brief advice given to patient (30 seconds-1 minute)		Cessation support provided to patient (1-3 minutes)	
Month of Treatment	Date	Do you smoke?* Yes / No			Does anyone smoke inside your home? 1 = yes 2 = no	Yes / No 1 = yes 2 = no	*Comments*	Yes / No 1 = yes 2 = no	*Comments*
	DD/MM/YY	No	Yes: Have you smoked at all—even a puff—in the last 2 weeks?(months 0, 2, 5, End)	Yes: How soon after you wake do you usually have your first cigarette? 1 = <30 min or 2 = >30 min					
0			S		1 2	1 2		1 2	
2			S , R , Q , L , D		1 2	1 2		1 2	
5			S , R , Q , L , D		1 2	1 2		1 2	
End			S , R , Q , L , D		1 2	1 2		1 2	

***Definitions for status of smoking**

For month 0, S for current smoker (has smoked in the **last 3 months)**
For months 2, 5, End, enter one of S, R, Q, D or L:
S = current smoker: has smoked in the last 2 weeks before the visit and has not made any quit attempt since the last visit (quit attempt = patient tried to quit and succeeded for at least 24 hours).
R = relapsed smoker: has smoked in the last 2 weeks before the visit but has made at least one quit attempt of at least 24 hours since the last visit.
Q = quitter: has not smoked at all in the last 2 weeks before the visit, not even a puff
D = died.
L = lost to follow-up: did not attend their appointment.
Note: If a patient is registered after month 0, draw a line through the month(s) when patient was not registered.

TB 06 TB Patient Card

General Information:
- TB is a curable disease if patient takes full course of treatment regularly.
- Treatment for TB is available in All health facilities in Nepal and is free of cost.
- Patient must follow proper cough atiquitte (cover mouth while coughing, sneezing and properly dispose the sputum) to prevent spreading of TB.

Patients' Responsibilities
You have the responsibility to:

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

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

Follow Treatment
- The responsibility to take Anti TB Drugs every day as prescribed and to conscientiously comply with the instructions given to protect the patient's health, and that of others.
- Sputum must be submitted on Month 2/3 , 5 and end of treatment.
- The responsibility to inform the health provider of any difficulties or problems with the following treatment or if any part of the treatment is not clearly understood

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

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

HMIS 6.4
TB 06

Government of Nepal
.....M/RM
.....Province

Name of Health Facility: _____
Name of DOT Provider: _____
DOT Provider Phone No. _____
Type of DOT 1. Health Facility ☐ 2. Community ☐

TB Patient Card

Name of Patient: _____
Sex: _____ Age: _____ Phone No: _____
Address: Province: _____ Districts: _____
M/RM: _____ Ward No / Tole : _____

TB Reg. No:	Registration Date:	Treatment Start Date:
	DD/MM/YY	DD/MM/YY

TB-O5

HMIS 6.3

NATIONAL TUBERCULOSIS CONTROL PROGRAMME
TUBERCULOSIS TREATMENT CARD

Photo

Guardian's Name			
Total no.of household member		**No. of household members screened for TB**	
Number of <5 years children in family			
Number of children under TBPT			
History of Previous treatment (if Yes, Previous TB Reg. No, Regimen and Duration of treatment):			

Month	Smear Microscopy			Xpert MTB/RIF			LPA		
	Date	**Lab No.**	**Result**	**Date**	**Lab No.**	**Result**	**Date**	**Lab No.**	**Result**
Initial	DD/MM/YY			DD/MM/YY			DD/MM/YY		
2 month	DD/MM/YY			DD/MM/YY			DD/MM/YY		
3 month	DD/MM/YY			DD/MM/YY			DD/MM/YY		
5 month	DD/MM/YY								
End of Treatment	DD/MM/YY								

Classification of Disease(please circle)	
1. PBC	1
2. PCD	2
3. EP	3
If EP (Site):	

Type of Patient	
1. New	4. T. After loss to F/U
2. Relapse	5. Other previously treated patient
3. T. After Failure	6. Unknown previous TB treatment history

Chest X-Ray at Start
Date: DD/MM/YY
1. Normal 2. Abnormal
3. Not Done

TB / HIV	**Date**	**Result**
Retro- Test	DD/MM/YY	
CPT Start	DD/MM/YY	
ART Start	DD/MM/YY	
Viral Load	DD/MM/YY	
ART Register No and Date	DD/MM/YY	

Treatment Type	**Adult Regimen (Please Circle)**		**Child Regimen(Please Circle)**	
New TB (all forms - Pulmonary and Extrapulmonary)	**2 HRZE+ 4 HR**	**1**	**2 (HRZ+ E) + 4 HR**	**1**
Complicated/Severe EP TB cases	**2 HRZE + 7 HRE (possibility of extension of HRE for 3 additional months)**	**2**	**2 (HRZ +E) + 7 (HR+E)(possibility of extension of HRE for 3 additional months)**	**2**
Retreatment cases (Rif Sensitive, INH Sensitive)	**2 HRZE + 4 HR**	**3**	**2 (HRZ+E) + 4 HR**	**3**
Retreatment cases (Rif Sensitive, INH Resistant and FQ Sensitive)	**6 HRZE Lfx**	**4**	**6 (HRZ+E) Lfx**	**4**
Retreatment cases (Rif Sensitive, INH Resistant and FQ Resistant)	**6 HRZE**	**5**	**6 (HRZ+E)**	**5**
Retreatment cases (Rif Sensitive, INH Not known)	**6 HRZE**	**6**	**6 (HRZ+E)**	**6**

I. INTENSIVE PHASE (Date)

	HRZE	**HRZ**	**Lfx**	**E**
Tablets				
Duration (months)				

Enter (✓) on day when medication was swallowed under direct observation, Enter (-) on day when medication not under direct observation and Enter (O) if medication was not swallowed

Month / Year	Date																													Total Dosage given		Weight (Kg)
	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	This Month	Cummulative	

II. CONTINUATION PHASE

	HR	**HRE**	**E**
Duration (Month)			
Tablets			

Enter (✓) on day when medication was swallowed under direct observation, Enter (-) on day when medication not under direct observation and Enter (O) if medication was not swallowed

Month / Year	Day																													Total Dosage given		Weight(Kg)
	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	This Month	Cummulative	

Treatment outcome (Circle O one)	1. Cured	2. Treatment Completed	3.Treatment Failure	4. Loss to Follow up	5. Died	6. Not Evaluated
Treatment outcome Date:	DD/MM/YY					

Section on ABC Smoking Cessation

At start of TB treatment then at each follow-up examination visit:		Ask				Brief advice given to patient (30 seconds-1 minute)		Cessation support provided to patient (1-3 minutes)	
Month of Treatment	Date	Do you smoke?* Yes / No			Does anyone smoke inside your home? 1 = yes 2 = no	Yes / No 1 = yes 2 = no	*Comments*	Yes / No 1 = yes 2 = no	*Comments*
	DD/MM/YY	No	Yes						
			Have you smoked at all—even a puff—in the last 2 weeks?(months 0, 2, 5, End)	How soon after you wake do you usually have your first cigarette? 1 = <30 min or 2 = >30 min					
0			S		1 2	1 2		1 2	
2			S , R , Q , L , D		1 2	1 2		1 2	
5			S , R , Q , L , D		1 2	1 2		1 2	
End			S , R , Q , L , D		1 2	1 2		1 2	

***Definitions for status of smoking**

For month 0, S for current smoker (has smoked in the **last 3 months)**
For months 2, 5, End, enter one of S, R, Q, D or L:
S = current smoker: has smoked in the last 2 weeks before the visit and has not made any quit attempt since the last visit (quit attempt = patient tried to quit and succeeded for at least 24 hours).
R = relapsed smoker: has smoked in the last 2 weeks before the visit but has made at least one quit attempt of at least 24 hours since the last visit.
Q = quitter: has not smoked at all in the last 2 weeks before the visit, not even a puff
D = died.
L = lost to follow-up: did not attend their appointment.
Note: If a patient is registered after month 0, draw a line through the month(s) when patient was not registered.

TB 07 Contact Investigation forms

National TB Program
TB 07 Contact Investigation Form

TB / DRTB Registration Number (Index case): _____ Date enrolled: __

Name (Index Case): _____ Age:_____ Sex: 1. Male 2. Female Total Number of Household Member: _____

Address: _____ Telephone Number/s: _____

TB Type: i. Drug Sensitive TB ii. Drug Resistant TB

SN	Name(s) of contacts	Age		Relationship with index case	TB Symptoms, If Yes then Mention Coode (eg. 1, 2, etc)	Referred to further diagnosis		If no symptoms of TB among children (<5 years), referred for TBPT?		Remarks
		F	M			Sputum courier	Patient Referred	Yes	No	
1					1, 2 etc	1	2	1	2	
2					1, 2 etc	1	2	1	2	
3					1, 2 etc	1	2	1	2	
4					1, 2 etc	1	2	1	2	
5					1, 2 etc	1	2	1	2	
6					1, 2 etc	1	2	1	2	
7					1, 2 etc	1	2	1	2	
8					1, 2 etc	1	2	1	2	
9					1, 2 etc	1	2	1	2	
10					1, 2 etc	1	2	1	2	

DEFINITIONS	Symptoms for Children(0-14 years old) (code)	Symptoms for Adult (15 years =>) (code)
Household contact: Someone who sleeps and eats in the same house with the Index TB case.	0 - None Persistence of: 1.Cough 2. Fever 3. Not eating well 4. Weight Loss \ Failure to thrive 5. Fatigue 6. Reduce playfulness	0. None Persistence of: 1. Cough 2. Fever (Evening Rise / Low Grade) / Night Sweats 3. Loss of Appetite 4. Weight Loss 7. Chest Pain 8. Coughing Blood/Sputum

Interviewer: Remarks: Signature:

TB 08 Contact and TBPT Register

Name of Health Facility	
Year	
Month	
Contact Tracer Name	
Contact Number	

Type of Contact Tracer (√): Health Worker ☐ FCHV ☐ Others......................................

Index TB Cases					Contacts of the IndexTB Cases											
S.N	TB Reg. No	Name of Index TB	Type of TB (DS TB, Hr TB or DR TB)	No. of Family Members	Name of Family Members	Age		Address	Contact Numbers	Guardian's Name	Type of Contact Investigation: or		Presumptive TB		If Presumptive TB (HB)	
						F	M				Health Facility Based (HFB)	Home Based (HB)	Yes	No	Contacts Directly Referred to Health facility	Sputum Transported to Health Facility
											1	2	1	2	3	4
											1	2	1	2	3	4
											1	2	1	2	3	4
											1	2	1	2	3	4
											1	2	1	2	3	4
											1	2	1	2	3	4
											1	2	1	2	3	4
											1	2	1	2	3	4
											1	2	1	2	3	4

Microscopy / GeneXpert Center for Sputum Test	Sputum Results		Lab No.	Enrolled in TB Treatment?		Child Eligible for TBPT?		Date TBPT Started	TBPT Collection Date			Date of home visit of health worker to monitor TBPT intake (D/M/Y)	Outcome	Remarks
	Microscopy 1.Neg 2.Pov	GeneXpert 1.MTB not Detected 2.MTB Rif Sensitive 3. MTB Rif Resistant		Yes	No	Yes	No		1 Month	2 Month	3 Month			
	1 / 2	1 / 2 / 3		1	2	1	2	DD/MM/YY	Wt. No. Tab	Wt. No. Tab	Wt. No. Tab	DD/MM/YY	DD/MM/YY	
	1 / 2	1 / 2 / 3		1	2	1	2	DD/MM/YY	Wt. No. Tab	Wt. No. Tab	Wt. No. Tab	DD/MM/YY	DD/MM/YY	
	1 / 2	1 / 2 / 3		1	2	1	2	DD/MM/YY	Wt. No. Tab	Wt. No. Tab	Wt. No. Tab	DD/MM/YY	DD/MM/YY	
	1 / 2	1 / 2 / 3		1	2	1	2	DD/MM/YY	Wt. No. Tab	Wt. No. Tab	Wt. No. Tab	DD/MM/YY	DD/MM/YY	
	1 / 2	1 / 2 / 3		1	2	1	2	DD/MM/YY	Wt. No. Tab	Wt. No. Tab	Wt. No. Tab	DD/MM/YY	DD/MM/YY	
	1 / 2	1 / 2 / 3		1	2	1	2	DD/MM/YY	Wt. No. Tab	Wt. No. Tab	Wt. No. Tab	DD/MM/YY	DD/MM/YY	
	1 / 2	1 / 2 / 3		1	2	1	2	DD/MM/YY	Wt. No. Tab	Wt. No. Tab	Wt. No. Tab	DD/MM/YY	DD/MM/YY	
	1 / 2	1 / 2 / 3		1	2	1	2	DD/MM/YY	Wt. No. Tab	Wt. No. Tab	Wt. No. Tab	DD/MM/YY	DD/MM/YY	
	1 / 2	1 / 2 / 3		1	2	1	2	DD/MM/YY	Wt. No. Tab	Wt. No. Tab	Wt. No. Tab	DD/MM/YY	DD/MM/YY	

TB 09 TBPT Card

TB 09 - TB Preventive Therapy (TBPT) Card

Contact / TBPT Reg. No. and Year: _____

Name: _____

Address _____

Sex (Circle) 1 F 2 M Age: _____

Name of Treatment Unit _____ Preventive Therapy Start Date _____

Eligible Group: (Cricle)
Under 5 Years 1
PLHIV 2
Others 3

Type of Examination and Result				
	Month 1	Month 2	Month 3	Remarks
Symptom screening (TB symptoms Yes or No)	1. Yes 2. No	1. Yes 2. No	1. Yes 2. No	
Weight				
No. of Tablets (HR)				

TBPT OUTCOME AND DATE (Circle) one

Outcome Date _____

1 **COMPLETED**

2 **DISCONTINUED**

3 **DIED**

4 **NOT EVALUATED**

TB 10 Referral / transfer Slip

Government of Nepal
Health Management Information System
.....District
.....Municipality/ Rural Municipality
.....Hospital/ PHC/HP/HC/CHU

Referral/Transfer slip

TB 10

Name of Client/ Patient Sex Age

Address Province District M/RM ward no

Contact no of Patient:

Drug Provided for ..... days to the patient while being transferred

Transfer/ Referral

Further examination needed ..... Reasons (Specify).....

Vital signs and other condition of Patient

BP	Pulse	Temp	Respiration	Weight (kg)	Height (cm)	MUAC (mm)	Edema on both Feet	Other
							(+ / + + / + + +)	

(For TB Patient only)

Type of TB: 1. PBC, 2. PCD , 3. EP (Site.....)

Registration Category

1. New 2. Relapse 3. T. after Failure 4. TALFU
5. Other previously Tx Pt. 6. Unknown previous TB Tx history

Treatment Regimen:.....

Examination and Result			
Test	Date	lab no / Institution	Result
Sputum			
Xpert MTB/RIF			
X-ray			
Others			

Dear sir
.....(Name of Referred Institution)
.....(Address of Referred Institution)
we are sending the above detailed client/ patient to your institution for further service. Please inform us after referred client/patient reaches your institution.

Referred by

Name Position: Signature

Contact no Date:

Government of Nepal
Health Management Information System
.....District
.....Municipality/ Rural Municipality
.....Hospital/ PHC/HP/HC/CHU

Acknowledgement slip

Date ... ... / ... ... / .....

Dear sir
.....Name of Referred institution
.....Address of institution
The client/patient referred by your institution reached this institution and we are continuing TB treatment as Transfer in case in this institution.

Name of client /patient

sex age

Address

District

Local Level ward no

Date of contact ... ... / ... ... / .....

Service provided

Name of Responder..... signature Date

Position:

Contact no

TB 11 Referral forms (Community, Private, Contact)

TB 11 - Referral Form (Community / Private / Contact)

Date: ...../...../.....

1. Name of Health facility referred to: .....

2. Name of the person referred: ..... 3. Age ..... 4. Sex : M / F

5. Address Province District M / RM Ward Tole

6. Reason for referral 1. For further diagnosis of presumptive TB 2. TB cases follow up :

3. Others including SAEs:

.....

.....

****

Referred by:

Type of Referral 1. Community 2. Private 3. Contact Investigation

Name: ..... Address: .....

Signature ..... Contact number: .....

Note: The original copy should be sent with the patient to the referred health facility and the carbon copy should be kept with the referring person

TB 12 TB Drug Order forms

TB 12_ Form No : L/FLD/006

National Tuberculosis Programme
First-Line Drugs Order Form

Fixed Dose Combination Drugs (First Line Drugs)

Report For
Fiscal Year………….Trimester:…..……… From………....To……………
Month Month

District/Treatment Unit……………………………….............................

Drug	Regimen																	
	New			Re-treatment			Complicated			H -Resistant			H -Sensitivity Unknown			TBPT (0 - 5 Years)			Total (A+B+C+D+E+F+G)= H
	Cases	Factor	Total(A)	Cases	Factor	Total (B)	Cases	Factor	Total (C)	Cases	Factor	Total (D)	Cases	Factor	Total(E)	Cases	Factor	Total (G)	
HRZE (75/150/400/275)mg	0	180	0	0	180	0	0	180	0	0	540	0	0	540	0				0
HR (75/150)mg		360	0		360				0			0			0				0
HRE (75/150/275)mg								630	0			0			0				0
Levofloxacin 250mg											720	0			0				0
HRZ Child (50/75/150)mg		180	0		180			180			540	0		540	0				0
HR Child (50/75)mg		360	0		360			630				0			0		270	0	0
Ethambutol 100mg		180	0		180			810			540	0		540	0				0
Levofloxacin 100mg (pediatric)											540	0			0				0

Drug	Current Requirement (I) (H=I)	Reserve Requirement (J) (J=H)	Total Requirement(K) (K=I+J)	Current Stock Level (L)	Expiry Date	Total Order (M) (M=K-L)
HRZE (75/150/400/275)mg	0	0	0			0
HR (75/150)mg	0	0	0			0
HRE (75/150/275)mg	0	0	0			0
HRZ Child (50/75/150)mg	0	0	0			0
HR Child (50/75)mg	0	0	0			0
Ethambutol 100mg	0	0	0			0
Levofloxacin 250 mg	0	0	0			0
Levofloxacin 100 mg	0	0	0			0

Laboratory Materials	No.of suspect examined	Factor	Total (A)	No of Follow up(B)	Current Requirement(C) (A+B=C)	Reserve Requirement (D=C)	Total Requirement(E) (E=A+D)	Current Stock Level (F)	Total Order (G) (E-F=G)
Glass Slide		2	0		0				0
Sputum Container		2	0		0				0

Prepared By (Focal person):
Signature:……………………………………………
Date: …………………………………………………
Name: …………………………………………………
Designation: …………………………………………

Verified By (Storekeeper):
Signature: ……………………………
Date: ……………………………………
Name: ……………………………………
Designation: ………………………………

TB 13 HMIS 9.3 Reporting format (for cohort TB reporting)

11. Tuberculosis Control Program (TB 13)

Block-1: Case Registration	New		Relapse		Treatment After Failure		Treatment After Loss to Follow-up		Other Previously Treated		Unknown Previous TB Treatment History		Transfer In	
	F	M	F	M	F	M	F	M	F	M	F	M	F	M
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Pulmonary (BC)														
Pulmonary (CD)														
Extra Pulmonary (BC or CD)														

Block-2: Registration (BC or CD)	0-4 Years		5-14 Years		15-24 Years		25-34 Years		35-44 Years		45-54 Years		55-64 Years		≥ 65 Years	
	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
All New																
All Relapse																

Block-3: Private Sector and Community Involvement in Referral/Diagnosis		PBC (New)		PBC (Relapse)		PBC (Exclude New & Relapse)		PCD (All)		EP (All)	
		F	M	F	M	F	M	F	M	F	M
No of TB Patients	Referred by Community										
	Referred/Diagnosed by Private HF										
	Diagnosed by Contact Investigation										

Block-4: Presumptive TB cases- Based on Presumptive TB Register

Total No. of presumptive cases	Referred for Lab diagnosis				Results of positive Lab																Linked to Treatment	
					Smear		Xpert				LPA							Culture					
											RIF	INH		FLQ		AMG						
	Smear	Xpert	LPA	Culture DST	S+	S-	MTB ND	MTB +Rif -ve "S"	MTB +Rif +ve "R"	MTB+ Rif Indeterminate "I"	rpo b	KatG	inh A	gyr A	gyr B	rrs	eis	No Growth	MTB Complex	Contamination	NTM	DS TB	DR TB
1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Female																							
Male																							

Block-12 Sputum Conversion (Bacteriologically Confirmed Cases)	No of Cases Registered		Negative		Positive		Died		Lost to Follow Up		Not Evaluated	
	F	M	F	M	F	M	F	M	F	M	F	M
1	2	3	4	5	6	7	8	9	10	11	14	15
New												
Relapse												
Treatment After Failure												
Treatment After Lost to Follow-up												
Others Previously Treated												
Unknown Previous TB Treatment History												

Block-5: Registration by Treatment Type		Adult				Child (0-14 years)			
		2HRZE+ 4HR	6HRZE	Hr TB (6HRZE+Lfx)	Complicated EP TB (2HRZE + 7-10 HRE)	2HRZE+4HR	6HRZE	Hr TB (6HRZE +Lfx)	Complicated EP TB [2(HRZ+E) + 7-10 (HR+E)]
1		2	4	5	6	7	8	9	10
Sex of Patient	Female								
	Male								

Block-6: HIV Status

At the Time of TB Diagnosis		Patients Tested for HIV	With Known HIV Status	Total HIV Positive	HIV +ve TB Patients on	
					ART	CPT
1		2	3	4	5	6
Sex of Patient	Female					
	Male					

Block-7: Contact Investigation

1	2 Female	3 Male
Total number of close contacts		
Total number contact Investigated		
Total number diagnosed with TB		
Total number linked to TB treatment and care		

Block-8: TBPT

1	2	3	4	5
Groups	Total of contacts identified	Investigated	eligible for TBPT	Put of TBPT
<5 year				
PLHIV				

Block-9: Sputum Smear Examination Result by Microscopy

Sex	Presumptive TB Case Examined (Persons)		Smear Examination				Follow - Up Case (Slides)	
			Slides A		Slides B			
	+ve	-ve	+ve	-ve	+ve	-ve	+ve	-ve
1	2	3	4	5	6	7	8	9
F								
M								

Block-10: Gene-Xpert Examination Result

Sex	MTB Detected			MTB Not Detected	Invalid /Error/No result
	RIF Sensitive	RIF Resistant	RIF Indeter-minate		
1	2	3	4	5	6
F					
M					

Block-11: LPA

Registered TB Cases	RIF	INH		FLQ		AMG	
	rpo b	KatG	inh A	gyr A	gyr B	rrs	eis
1	2	3	4	5	6	7	8
Female							
Male							

11. Tuberculosis Control Program (TB 13)

Block 13: Treatment Outcome			No of Cases Registered		Cured		Completed		Failure		Died		Lost to Follow Up		Not Evaluated*	
			F	M	F	M	F	M	F	M	F	M	F	M	F	M
1	2		3	4	5	6	7	8	9	10	11	12	13	14	15	16
PBC	New															
	Relapse															
	Treatment After Failure															
	Treatment After Loss to Follow-up															
	Others Previously Treated															
	Unknown Previous TB Treatment History															
PCD & EP	New	PCD														
		EP (BC or CD)														
	Relapse	PCD														
		EP (BC or CD)														
	Others	PCD														
		EP (BC or CD)														
HIV+ve New and Relapse																

** Due to Transfer Out & moved to second line treatment register*

Block-14: TBPT									
No of Cases Registered		Outcome							
		COMPLETED		DISCONTINUED		DIED		NOT EVALUATE	
F	M	F	M	F	M	F	M	F	M
1	2	3	4	5	6	7	8	9	10

Block-15: Status of Tobacco Smoking at End of Treatment													
No of Cases Registered		No. Patient Smoking Tobacco (Current)		No. of Patient Quitted Smoking									
				0 Months		2 Months		5 Months		End			
F	M	F	M	F	M	F	M	F	M	F	M	F	M
1	2	3	4	5	6	7	8	9	10	11	12		

TECHNICAL SUPPORT BY:

World Health Organization

Nepal