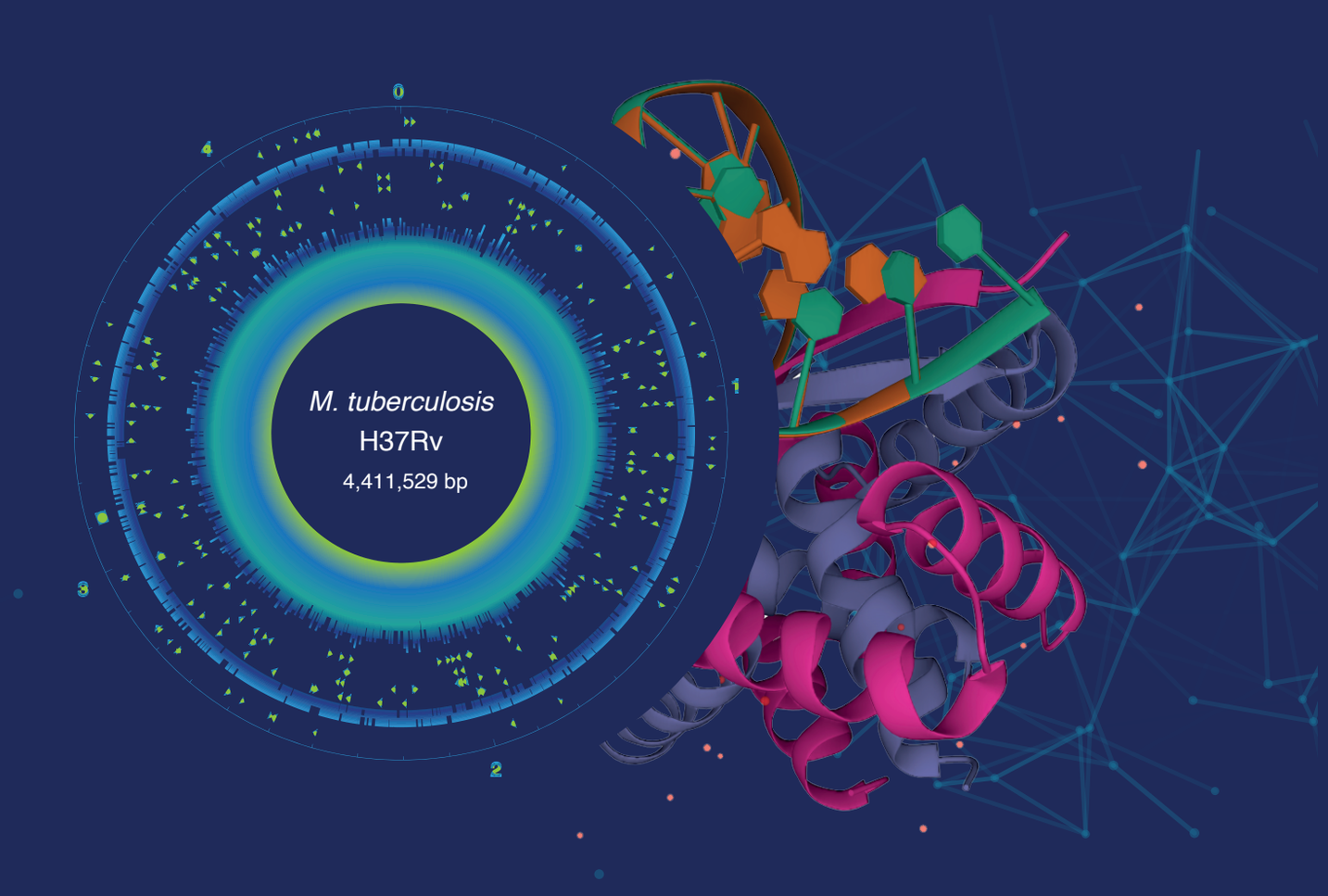
Sultanate of Oman
Ministry of Health



National Tuberculosis Manual

Fifth Edition – 2022

Directorate General for Disease Surveillance and Control

Sultanate of Oman
Ministry of Health

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Directorate General for Disease Surveillance and Control
Department of Communicable Diseases
TB and Acute Respiratory Diseases Section

H.E.Dr. Hilal Ali Hilal Al Sabti
Minister of Health

Message from H.E. the minister of Health

As we follow the status of the global TB situation, we acknowledge the burden of the TB pandemic and its huge impact on the world's population as the leading cause of deaths amongst infectious diseases, proceeded only by COVID-19 as of 2021 WHO global TB report. The impact of TB service interruption as a result of COVID-19 pandemic and its consequences on the international effort to eliminate TB is also very evident.

The Sultanate of Oman has managed to maintain a low incidence rate throughout the last decade, and has recently launched its 'End TB' strategy, with a target of reaching pre-elimination level by 2035. However, we believe that new innovations must be implemented in order for us to reach our end TB goal. We are continuously working on prevention using new technologies in diagnosing tuberculosis, introducing newer therapeutic options that can improve the compliance as well as creating a research enabling environment and promoting awareness and addressing the vulnerable groups in order to accelerate the progress towards the elimination goal.

This 5th edition of the 'National Tuberculosis Manual' will serve as a core reference and training tool for capacity building for all healthcare workers dealing with and managing TB cases; this includes private sector and non-MOH institutions covering all TB care activities. It also provides updated guidelines for prevention, diagnosis and treatment of TB patients.

My best wishes for the successful implementation of these guidelines!

Revision history

The first edition of the manual of National Tuberculosis Control Program was released in 1988. Since then the manual underwent a substantial revision several times until last (fourth edition) was released in April 2007. This fifth edition was built on the vision and mission of End TB strategy that was launched in March 2021 encountering updates in the prevention, diagnosis, treatment and activities that support meeting end TB targets.

Directorate General for Disease Surveillance and Control
PO Box 393, PC 100, Muscat, Sultanate of Oman
Phone + (968) 22357521/22357505 • Fax + (968) 22357540
omantb20@gmail.com
Website:http//www.moh.gov.om

Historical review of TB Programme in Oman

In Oman, the National TB Control Programme (NTP) was formulated in 1981 as an independent programme and implemented in phases and subsequently the NTP National Committee which was consisted of concerned stakeholders was set up in 1984. The national committee is responsible for formulating national policies and monitoring programme implementation. It recommended introducing acid-fast bacilli (AFB) culture and susceptibility testing as diagnostic tools to increase early case detection and surveillance. Over the years, several strategies used in the prevention and control of tuberculosis including the introduction of Bacille Calmette–Guérin (BCG) vaccination in 1981. In 1982, multidrug resistant TB (MDR-TB) treatment drugs introduced. The first TB manual was released in 1988 to streamline the NTP related activities.

In 1990–91, NTP became an integral component of the Department of Communicable Disease Control at the Ministry of Health (MoH) and TB reporting integrated into the National Communicable Disease Surveillance System. The committee integrated into the Communicable Disease National Committee by 2014. In 1995, TB treatment (short course chemotherapy) was available at all hospitals with appropriate laboratory capacities. The directly observed treatment, short course (DOTS) strategy recommended by World Health Organization (WHO) was implemented in Oman in 1996. Surveillance activities to monitor and assess TB drug resistance and the treatment of latent TB infection (LTBI) in high-risk groups were set up in 1998.

Monitoring, follow-up, case finding, contact tracing, screening and evaluation systems, and treatment of latent TB among household contacts have been adopted across the country over a period since 2005. Now, every governorate has a TB focal point (TBFP) to monitor the TB programme activities such as quarter audits, contact tracing, etc... .TB programme is equipped with adequate and trained human resources at all levels of care. In addition, the NTP activities have been integrated into the primary, secondary and tertiary health care services, and well-financed NTP. TB reporting made mandatory for both public and private sectors along with development of TB registry and surveillance integrated into the National Communicable Disease Surveillance System. TB cases are identified and notified at the primary health care level. Presumed TB cases are referred to the closest hospital for the confirmation of TB diagnosis and treatment.

Genotyping (spoligotyping) of TB strains with an aim to understand the pattern of transmission adopted in 2006. In 2007, the fourth edition of the TB manual launched

with the following Objectives of the TB Control Program, which is the reduction in mortality, morbidity and transmission of disease through implementation of “DOTS” and other strategies, and latent TB treatment in high-risk patients. In 2015, rapid molecular diagnostic testing (e.g. GeneXpert) was introduced initially at Central Public Health Laboratory (CPHL) with subsequent expansion of service to three governorates (North Batinah, Ad Dakhiliyah and Dhofar governorates). In order to expand, GeneXpert decentralized at the governorates level and scaled up to be the initial test for presumptive TB and digitalization of notification and follow-up in 2021. The laboratory diagnostics upgraded at CPHL to include line probe assay (LPA) for first- and second-line drugs and the introduction of molecular sequencing for drug resistant mutations using whole genome sequencing.

The WHO vision for the post-2015 global TB strategy is “a world free of TB”, also expressed as “zero deaths, disease and suffering due to the disease”. The goal is to end the global TB epidemic by reducing global TB incidence and mortality rates by 80% and 90%, respectively, in 2030 compared to 2015. A taskforce formed to assess the TB situation to reach the pre-elimination and elimination phases and prepare the End TB Strategy in Oman.

The End TB Strategy launched on 24th of March 2021 with aims of moving forward into TB’s elimination by strengthening detection using the molecular technique upon clinical suspicion of active disease, early treatment and prevention strategies using patient centred approach such as community directly observed therapy (DOT), and enhancing infection prevention and control (IPC) measures at all levels of health care. The strategy also focuses on LTBI diagnosis and treatment by expanding at-risk group to include expatriates arriving from countries with TB high incidence and health care workers, improving the cascade of care and introducing newly recommended shorter regimens. It also advocates for community awareness of all forms of the disease (active and latent) and promotes operational research that can improve the service. The notification for active TB cases and latent TB in targeted population has been upgraded to e-notification on tarassud + platform facilitating early reporting and easy follow up for patient and contact.

The current fifth edition sought to standardize all the constantly evolving approaches conceding all stockholders input for TB patients care at all levels including private institutions.

Dr. Seif Salem Al-Abri
Directorate General
Disease Surveillance and Control
Ministry o Health

Foreword

TB remains a major health problem worldwide, causing ill health for millions of people each year. TB ranks alongside HIV as a leading cause of death due to communicable diseases.

Oman is a country with a low incidence burden of TB. Nearly 400 cases of TB are detected each year. Oman has two distinct populations affected by tuberculosis; the nationals and non-nationals. The majority of the non-nationals are migrating from high TB incidence countries (> 150/100,000 population). A continuous influx and short stay of migratory workers contributes to the plateauing of TB incidence in Oman for the past 10 years in the absence of a screening programme for infection in migrants. The country adopted WHO's post-2015 "TB elimination strategy" to eliminate TB in Oman and taken initiatives to achieve its targets and objectives by 2035.

The revision of the national manual for tuberculosis management is one of the key landmarks of the TB elimination roadmap in Oman. It has been updated according to revised WHO TB classifications of 2013 and contains chapters on new diagnostic methods, standardized TBI management, as well as new monitoring and evaluation (M&E) frameworks and updated electronic surveillance information.

This manual will serve as a guide for health care professionals for patient management, care and prevention and will enable implementation of national TB policies as part of End TB Strategy.

We appreciate the efforts taken by our staff from TB and Acute Respiratory Section and our colleagues from the Directorate General for Disease Surveillance and Control, Directorates of Disease Surveillance and Control and primary health care in the governorates, infectious diseases units (paediatric and adults) in the Royal Hospital, and colleagues from the Directorate General of Private Health Establishments in participating in preparing, reviewing and updating this manual.

We are pleased to take this opportunity to congratulate all people working in the field of TB for their hard work towards eliminating TB in Oman.

Abbreviations

AIIR	Airborne respiratory isolation room
ALT	Alanine aminotransferase
AFB	Acid-fast bacilli
ART	Antiretroviral therapy
ARV	Antiretroviral
AST	Aspartate aminotransferase
ATS	American Thoracic Society
ATT	Anti-tubercular treatment
BCG	Bacille Calmette–Guérin
CBC	Complete blood count
CDC	Centers for Disease Control and Prevention
CPHL	Central Public Health Laboratory
CT	Computerized tomography
DGHS	Directorate General of Health Services
DOT	Directly observed therapy
DOTS	Directly observed treatment, short-course
DR-TB	Drug-resistant tuberculosis
DSC	Department of Disease Surveillance and Control
DST	Drug susceptibility testing
E	Ethambutol
ENT	Ear nose and throat
EPTB	Extrapulmonary tuberculosis
EFV	Efavirenz
ERS	European Respiratory Society
FDC	Fixed-dose combination
GI	Gastrointestinal
H or INH	Isoniazid
HCW	Health care workers
HEPA	High-efficiency particulate air
IDSA	Infectious Diseases Society of America
IGRA	Interferon-gamma release assays
IPC	Infection prevention and control
TPT	Tuberculosis preventive Treatment

ISTC	International Standards for TB Care
LPA	Line probe assay
LTBI	Latent tuberculosis Infection
M&E	Monitoring and evaluation
MDR-TB	Multidrug resistant tuberculosis
MoH	Ministry of Health
MRI	Magnetic resonance imaging
MTB	Mycobacterium tuberculosis
MTB/RIF	Mycobacterium tuberculosis resistance to rifampicin
NAAT	Nucleic Acid Amplification Test
NNRTI	Non-nucleoside reverse transcriptase inhibitors
NTP	National Tuberculosis Control Programme
NTM	Non-tuberculous Mycobacterial infection
PAPR	Powered air-purifying respirator
PI	Protease inhibitors
PLHIV	People living with HIV
PTB	Pulmonary tuberculosis
R or RIF	Rifampicin
RPT	Rifapentine
RR	Rifampicin-resistant
S	Streptomycin
SDG	Sustained Development Goals
SLD	Second-line (anti-TB) drugs
SOP	Standard Operating Procedure
TB	Tuberculosis
TBFP	TB focal point
TBI	Tuberculosis infection
TDF	Tenofovir disoproxil fumarate
TPT	Tuberculosis preventive treatment
TST	Tuberculin skin test
WHO	World Health Organization
XDR-TB	Extensively drug resistant tuberculosis
Xpert/MTB/RIF	Automated PCR test for the detection of MTB complex and rifampicin resistance
Z	Pyrazinamide

Acknowledgements

We thank all the health care workers in every institution in government, non-governmental institution including private sectors for their tremendous contribution in the field of tuberculosis. Without their effort Oman won't be able to reach this far in sustaining the reduction of TB incidence throughout the past years.

However, with the impact of COVID-19 pandemic in the last 2 years on TB which resulted in a sharp drop in TB notification in several high TB burden countries in 2020 according to latest WHO global TB report which necessitates much more effort globally and locally in order to reach the end TB targets. This effort is expected from all health care providers at all levels, community leaders and individuals along with sustained support from higher authorities and commitment.

The work compiled in this document is the result of the commitment of the team members who has dedicated their time to update the previous manual and cover all aspects of TB management.

Therefore We would like to express our sincere thanks and gratitude to all colleagues from governorates at all levels, DGDSC, tertiary hospital such Royal hospital, primary care directorate and colleagues from directorate from pharmacovigilance for their participation in writing up or reviewing some chapters in the document.

We are also grateful for the team who reviewed the final draft for their comments and suggestions according to their area of specialty and Miss Lesly for the English editing and formatting.

Contributors

Executive editors	Place of work	Role
Dr Seif Al Abri Mr Bader Al Rawahi	Directorate General of Disease Surveillance and Control	Reviewed content, provided general guidance and approved compliance with MoH policies
Chief editor		
Dr Fatma Al Yaquobi	TB and Acute Respiratory Diseases Section DGDSC	Overall contribution to all chapters, supervising the manual preparation, revision, final compilation and approval of the content
SSN Khalsa Al-Thuhli	TB and Acute Respiratory Diseases Section DGDSC	Overall contribution to the manual, supervising the manual preparation, tables and graphs revision.
Contributors Public health and surveillance		
Dr Sulein Alkhalili	Directorate General of Disease Surveillance and Control	
Dr Amina Al Jardani	Directorate of Disease Surveillance and Control- CPHL	
Dr Amal Al Maani	Directorate General of Disease Surveillance and Control-IPC	
Dr Adil Al Wahaibi	Directorate General of Disease Surveillance and Control Surveillance	
Dr Bader AL Abri	Directorate General of Disease Surveillance and Control Surveillance	
Dr Parag Shah	Directorate of Disease Surveillance and Control-North Sharqiyah	
Dr Muhammad Muqeet Ullah	Directorate of Disease Surveillance and Control- Al Buraimi Governorate	
SSN Khawla Al Rahbi	Directorate of Disease Surveillance and Control-Muscat Governorate	
SSN Aseela Al Jabri	Directorate of Disease Surveillance and Control- North Batinah Governorate	
Ms Ruqaiya Al Shehi	Directorate General of Disease Surveillance and Control	
Dr Ali Al Maqbali	Directorate General of Health afairs-South Batina Gevernorate	

Dr Zaid Al Mayahi	Directorate of Disease Surveillance and Control-South Batina Gevernorate
Dr Padmamohan J. Kurup	Directorate General of Disease Surveillance and Control
Samiya Mohammed Alzidjali	Directorate General of Disease Surveillance and Control-CPHL
Chamila Priyangani Adikaram	Directorate General of Disease Surveillance and Control-CPHL
Dr Saleh Al Azri	Directorate General of Disease Surveillance and Control-CPHL
Contributors clinical aspect	
Dr Feryal Al Lawati	Adult Infectious Diseases-Royal Hospital
Dr Zakaria Al Baloshi	Adult Infectious Diseases-Royal Hospital
Dr Nenad Pandak	Adult Infectious Diseases -Royal hospital
Dr Nawal Al Maskari	Paediatric -Infectious Diseases -Royal Hospital
Dr Badria Al Waili	Paediatric Infectious Diseases -Royal Hospital
Dr Hilal AL Hashami	Paediatric Infectious Diseases -Royal Hospital
Reviewers	
Dr Mohammed Al Tobi	Directorate of Disease Surveillance and Control-Dhaklia governorate
Dr Sultan Al Busaidi	Directorate of Disease Surveillance and Control-North Sharqiyah Governorate
Dr Lamia Al Balushi	Directorate of Disease Surveillance and Control-Muscat Governorate
Shabana Mohammed Al Balushi	Directorate of Pharmacovigilance
Dr Idris Al Juma	Primary Health Care

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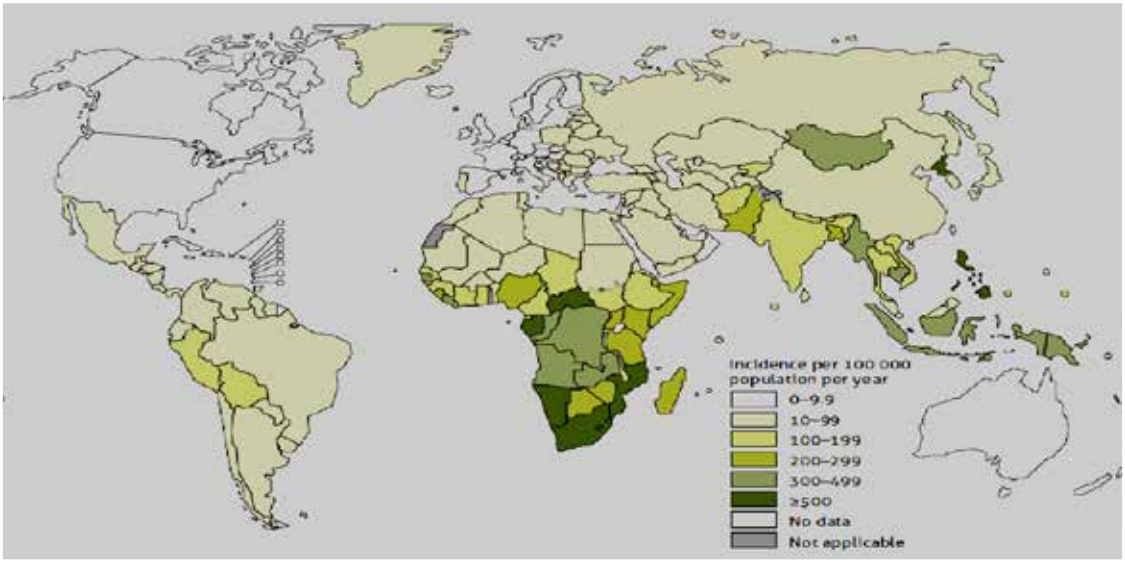
Chapter 1

TB burden: globally and Oman

1.1 Global TB burden

- Globally, several countries have adopted TB elimination as their national goal, and many were able to achieve good progress in the past decades.
- 'The End TB Strategy' was launched with the vision of 'A world free of tuberculosis – zero deaths, disease and suffering due to tuberculosis'.
- Nearly 54 million lives have been saved and there was 33% drop in deaths due to TB between 2000 and 2017 globally.
- TB However remains to be a major public health problem around the world especially in the Asian and African subcontinent.

Figure 1. Global TB burden



The four principals of global strategy:

- Government stewardship and accountability, with M&E.
- Strong coalition with civil society organizations and communities
- Protection and promotion of human rights, ethics and equity.
- Adaptation of the strategy and targets at country level, with global collaboration.

Pillars and components of global strategy:

- Integrated, patient-centred care and prevention.
- Bold policies and supportive systems.
- Intensified research and innovation.

1.1.1 High burden countries

Countries with the most cases of TB in the world with an incident rate of > 100 TB cases (all forms) per million population per year.

1.1.2 Low incidence countries

- Countries defined as those with a TB incidence rate of < 100 TB cases (all forms) per million population per year.
- Out of the nearly 31 low incidence countries, with the exception of a few very small countries, none is approaching TB elimination, while a few are getting close to pre-elimination burden, recent trends show only four would reach pre-elimination.
- "Pre-elimination" = < 10 notified TB cases/million population/year.
- "Elimination of TB as a public health problem" = < 1 notified TB case (all forms)/ million population/year.

1.1.3 WHO End TB strategy for global TB control

Globally in 2014, TB became the world's leading infectious disease killer with > 10 million people infections and 1.5 million deaths. Thus, the WHO approved the End TB Strategy, a 20-year strategy to End TB global epidemic, with the vision of a world with "zero deaths, disease and suffering due to TB".

Table 1. WHO End TB strategy for global TB control

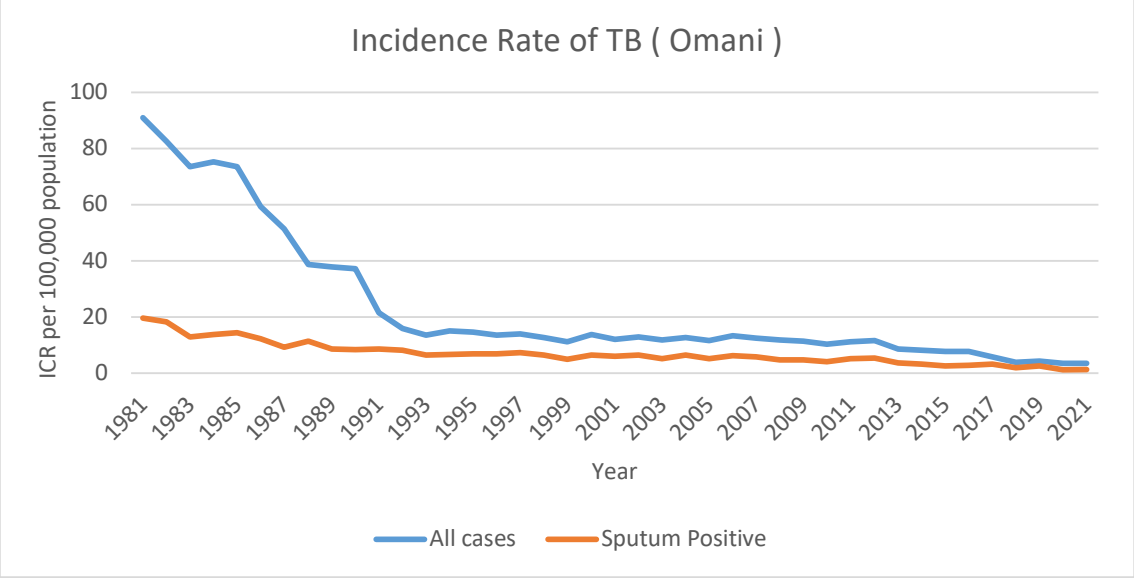
VISION	A world free of TB – zero deaths, disease and suffering due to TB			
GOAL	End the global TB epidemic			
INDICATORS	MILESTONES		TARGETS	
	2020	2025	SDG 2030	END TB 2035
Reduction in number of TB deaths compared with 2015 (%)	35%	75%	90%	95%
Reduction in TB incidence rate compared with 2015 (%)	20% (<85/100 000)	50% (<55/100 000)	80% (<20/100 000)	90% (<10/100 000)
TB-affected families facing catastrophic costs due to TB (%)	Zero	Zero	Zero	Zero

1.2 Situation in Oman

The epidemiology of TB in Oman more or less follows that of low incidence countries which are characterized by a low rate of transmission in the general population, occasional outbreak and that the majority of TB cases generated from progression of latent TB rather than recent transmission with significant contribution of TB rates from cross-border migration and changes in age distribution towards the highest number of cases among the elderly in the nationals. Transmission among family members still occurs due low rates of LTBI treatment acceptance.

Incidence rates have dramatically reduced in the last 30 years from 90.98 per 100 000 population in 1981 to 3.2 in 2021 (all forms) and 19.61 to 1.9 per 100 000 (for sputum positive pulmonary TB) in nationals.

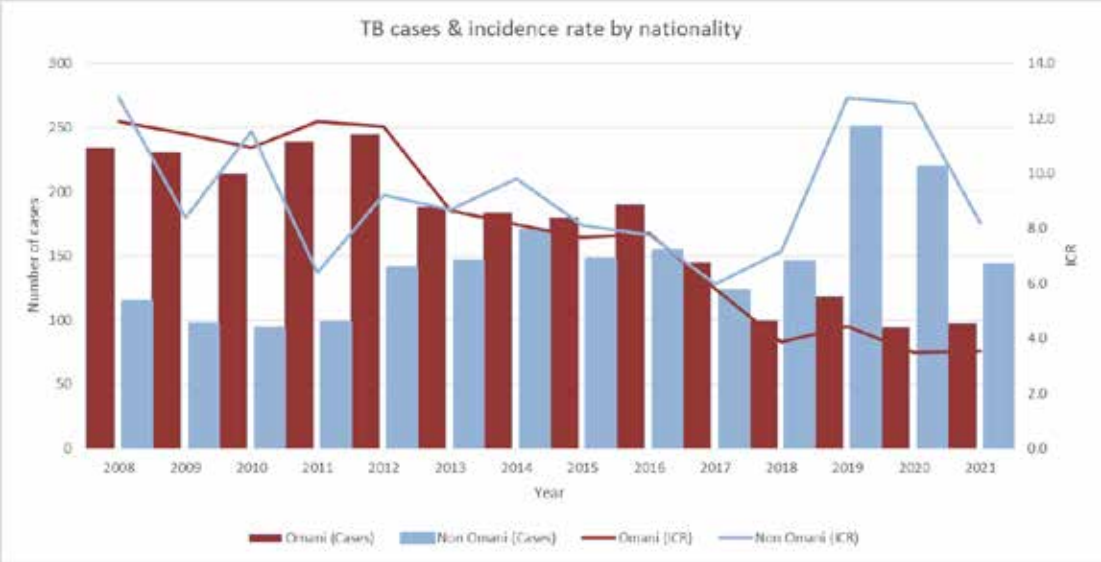
Figure 2. TB incidence rates per 100 000 population in Oman: 1981–2021



1.2.1 Notification rate

There is an overall down trend of total notified TB cases particularly in nationals over the last 10 years as shown in this figure. For non-nationals, the number is fluctuating with trending up in the last year as a results of changing screening policy of migrants where chest X-ray (CXR) for all has been implemented.

Figure 3. TB case notifications and rate (nationals versus non-nationals 2008–2021)



1.2.2 Objective of national strategic plan of TB control programme

The objective of the national strategic plan based on four pillars: Detect, Treat, Prevent and Promote.

PILLAR 1 – Detect

Aim: early identification of presumptive TB cases at first point of care in public and private sectors using rapid molecular testing that allow accurate detection of TB disease and drug resistance to ensure prompt initiation of appropriate treatment. Emphasis also on timely notification using e-notification and standardize engagement of the private sector with programmatic approach.

Activities:

- Engage public-private mix action plan to improve detection among migrants at private institutions.
- Improve case finding in at risk group mainly migrants, contacts and people living with HIV (PLHIV) using sensitive and specific test that identifies patients who can progress to active disease.
- Establish the facility for Whole Genome Sequencing in CPHL to track transmission in the community with future plan for routine use.
- Upgrade the surveillance to electronic version involving private and non-MoH institutions as web base notification.
- Support high-quality network of laboratory services, validated through proficiency testing and other quality control mechanisms for public and private laboratories and strategic plane to decentralize and upgrades the governorate laboratories.

PILLAR 2 – Treat

Aim: sustain free high-quality TB treatment (all forms), care and support services to nationals and non-nationals of all ages through patient-centred approach through community DOT while ensuring implementation of IPC at all levels of care. It is also to strengthen treatment, improve compliance and support the introduction of newly recommended shorter regimen for LTBI.

Activities:

- Update the national TB policy referral system and update TB manual.
- Ensure sustained supply of quality-controlled drugs.
- Introduction of pharmaco-vigilance approach in monitoring side-effect as per the national pharmaco-vigilance policy.
- Ensure reporting using VigiFlow system by health care professionals.
- Introduce patient-centred approach care into the management of TB through community DOT at national level.
- Update programmatic M&E system to ensure monitoring of TB program at district, governorate and central level by updating the M&E framework.
- Introduction of shorter regimen policy for LTBI treatment.
- Expand alliance with HIV program by integrating some of TB/HIV services (co-management of TB comorbidities).

PILLAR 3 – Prevent

Aim: Scale up latent TB screening and preventive therapy to meet the goals of TB elimination by including additional at risk group including HCWs, have a well-established cascade of care that can retain patients and improve the compliance that result in reduction of incidence rate and scale up IPC measures that control transmission within health care facilities, e.g., training HCWs and increase airborne respiratory isolation room (AIIR).

Activities:

- Implement updated guideline for LTBI management.
- Expand screening and preventive treatment for people with a high risk of TB such as HCWs and migrants.
- Strengthen implementation of LTBI screening and treatment in PLHIV.
- Update IPC section in the national TB manual.

- Approve and implementation of national policy for screening and prevention of infectious diseases in health care workers.
- Introduce and regular training for HCWs on prevention of TB transmission within Health care facilities.

PILLAR 4 – Promote

Aim: health promotion is a powerful tool to advocate End TB goals. The strategy is advocating for reaching the targets of elimination across all levels, political and community leaders and communication to change knowledge, attitudes, behaviours and practices among various groups of people and social mobilization to strengthen community participation for sustainability. Additionally, the strategy is promoting research that addresses additional knowledge and evidence of the effectiveness of interventions aimed at TB care and management and a more proactive approach to promoting operational research to optimize policies.

Activities

- Undertake knowledge, attitude and practice study for community and HCWs to assess the general knowledge gaps.
- Promote health and communicate risk by establishing lasting partnerships across health and social sectors.
- Scale up research to develop and rapid uptake, development, intervention, strategies and optimize implementation.
- Promote innovations by creating a research-enabling environment and enforcing the priority of tuberculosis research and priority for budget allocation and identifying resources and involving academia.
- Formulate standards and protocols and incorporation of these in the updated national legal and regulatory framework for health by updating the public health law.
- Risk communication to improve awareness, and counselling skills towards TB infection and disease.

Chapter 2

MoH policy, roles and responsibilities

2.1 General policies

- All communicable diseases are subjected to the law on control of infectious diseases (issued by the Royal Decree Number 73/92).
- TB is a notifiable disease under group A diseases and syndromes which are of high priority and should be notified and investigation initiated within 24 hours for immediate actions to control the spread of the disease as per communicable diseases policy.
- DOTS is the strategy adopted to control TB in the country since 1995. The policy has been changed from mandatory hospitalization during the intensive phase of all sputum positive patients for 2 months to early discharge of the patient and use of community DOT during both intensive and continuation phases. However, patients with complicated pulmonary TB will receive their DOT course in the hospital until their clinical condition improve.
- All primary health care institutions in MoH and private institution are responsible for early diagnosis of TB and referral for treatment.
- Any patient with persistent chest symptoms of more than 2 weeks should be investigated for pulmonary TB using Nucleic Acid Amplification Test (NAAT) (Xpert Mycobacterium TB resistance to rifampicin (MTB/RIF) assay) as initial diagnostic test** in all adults and children in addition to smear microscopy and culture. In case of uncertain diagnosis, the patient should be referred for expert opinion to regional medical/chest clinic in the governorates as soon as possible according to the referral systems.
- All presumptive pulmonary TB cases should submit sputum for bacteriologic examination with NAAT (Xpert MTB/RIF assay) sputum microscopy and culture.
- Contact tracing and follow-up is necessary for contacts of all TB patients which should be conducted in primary health care in the catchment area of the patient's residence. Other sites can be Utilised under the supervision of Department of Communicable Disease, TB and Acute Respiratory Section upon the risk assessment of situation involved eg exposure in large camps and involvement of clinics in the companies and according to the standered set. All contacts with positive Mantoux test or interferon gamma release assays (IGRA) (QuantiFERON-TB) but with no evidence of active TB disease should be treated for LTBI. For treatment options refer to guidelines for management of LTBI in children and adults.
- The treatment of TB cases is free of charge for all (nationals and non-nationals)
- Defaulters represent a potential source of infection to the community and every

effort must be made to retrieve such patients and to ensure that they continue their treatment until they are 'cured' including the use of communicable disease law. See Defaulter retrieval flow chart in annex at end of chapter.

- All TB patients should be screened for HIV infection. Similarly, all HIV cases should be screened for TB (active or latent).
- Private pharmacies are prohibited from selling anti-TB drugs including RIF to private clinics or individuals
- LTBI treatment among the contact and high-risk groups is a strategy adopted along with DOTS strategy.
- All key-staff should coordinate and cooperate so that the target for TB elimination in Oman is achieved.
- MDR-TB cases should be referred to tertiary hospital with expertise (infectious disease consultant or pulmonologist) in the management of such disease.
- At the primary health care level, the health centres should be involved in case finding, case-holding, contact tracing, treatment follow-up, ensuring regular drug supply, diagnostic materials and follow-up of the cases.
- M&E policy implementation is the responsibility of all different level of health care system (governorates and central levels)
- The transfer of the TB patient between different types and levels of health system is regulated by the referral policy.
- It is mandatory that all presumptive and confirmed TB cases of all types be reported in Tarassud through e-notification.

**** NAAT (Xpert MTB/RIF assay) have been included, as initial diagnostic tests in presumptive TB have been modified in 2018.**

2.2 Private sector

- Must adhere to the MoH policy.
- Private hospitals/clinics should not prescribe anti-tuberculous drugs.
- If a private practitioner suspects/diagnose a patient with TB, the patient should be referred to the nearest designate treatment institute. Notification should be issued as per communicable disease policy.
- Noncompliance would be subjected to the Royal Decree Number 32/2020 and to the law on the practice of Medicine and Dentistry Number 75/2019.
- Private pharmacies are banned from selling anti-tuberculous drugs including RIF to private clinics or individuals.

2.3 NTP responsibilities

- Maintaining a master register and cross-indexing received all notified of TB cases by email.
- Monitoring and supervising all Regional Institutions involved in TB control activities and providing regular feedback through monthly reports.
- Training all personnel involved in TB control activities.
- Evaluating and reporting on the progress of TB control, including treatment efficacy evaluation, i.e. cohort analysis of conversion and cure rates.
- Develop and update policies for NTP.
- Coordinate all the national surveillance activities and revise periodically.
- Ensure an appropriate M&E system at levels.
- Review the recording and reporting system including data collection, quality of data and proper data communication.
- Provide support to the intermediate level for outbreak control, case management, laboratory diagnosis, epidemiological skills, education and training activities, and logistics.
- Evaluation of reports from Governorate and prepare action plan.
- Coordinate with National and international authorities (WHO and International Health Regulation (2005)).
- Ensure active participation of all stakeholders including private, other health institutes and intersectoral coordination.
- Promote health promotion activities in sultanate of Oman.
- Provide opportunity and support for innovative research to improve the quality of services under NTP.

2.4 Governorate/sub-governorate hospitals

2.4.1 TB case finding

- All doctors are requested to suspect and detect TB cases among out-patients.
- It is the responsibilities of doctors and TBFP in institute:
  - To follow up and ensure treatment of cases until patient is cured.
  - Management and health education for the patient and the contacts.
  - Follow-up all pulmonary TB sputum AFB negative on continuation phase therapy once every 15 days for collection of drugs and ensure compliance with the medication.
  - Retrieve and report all the default cases to regional epidemiologist and the NTP.

- The TBFP should ensure that the drugs are taken under their observation on the day of collection; the remaining drugs are taken home.

- At health institution level TBFP to maintain all presumptive and confirmed cases documentation for follow-up and analysis.

2.4.2 The regional focal point epidemiologist/nurse

- Should monitor sputum examinations monthly for presumptive and confirmed patients in all health institutions.
- Ensure that contacts screening of confirmed TB cases (sputum smear positive, sputum smear-negative and extrapulmonary) is started within one week of diagnosis.
- Monitor the treatment of all cases in according to the standardized treatment schedule.
- Establish and implement national TB strategy in the governorate.
- Establish a system of M&E at the governorate in line with national M&E framework.
- Prepare quarterly and annual M&E reports on time and communicate with national level.
- Scrutinize and monitor timeliness, completeness and accuracy of notifications and other reports from health institute and provide regular feedback.
- Maintain relevant records, important circulars, registers and files.
- Conduct training and orientation programmes for the new and the staff through continuing medical education, seminars, symposia and workshops on a regular basis.
- Participate in the national continuing medical education activities and share regional data.
- Follow-up and coordination with other governmental organization to bring back the defaulters and patients who refuse admissions and treatment.
- Study and analyses of the TB cases and put up activities that assist high achievement in TB programme in the region.
- Ensure the quality, timeliness and completeness of reporting case and monthly report by the health care provider in the region.
- Ensure admission and start treatment of TB patients at the regional hospital level.

2.4.3 Health centre responsibilities

- Health centres are responsible for appropriately investigating and diagnosing a patient with symptoms suggestive of TB and notifying through Tarassud.
- Health centres lacking the diagnostic facilities (e.g. sputum microscopy, CXR) may refer the patient to a health centre with the above facilities.
- Contact tracing, screening and health education: Locate the TB contacts to educate them about TB and the importance of early diagnosis. Also ensure that these contacts attend the health centre for screening for two years (every six months). Contact addresses and names should be maintained in the health centre where the follow-up is done. Data of contacts should be updated monthly.
- Defaulter retrieval and health education: the health centre should locate, treat and ensure that the defaulter re-attend to the health centre to collect and consume their medications under supervision in a health institution or at home. Such patients may need to be admitted by the support of law in case of noncompliance (through public prosecution) if it is necessary. see annex
- Coordination between TBFP and public health supervisor for patient contact tracing and defaulters tracking.

2.5 Reporting responsibilities

2.5.1 Reporting at health institution level

- Defaulters and TB contacts identified during investigation and follow-up in the primary health care must be reported to the Directorate of Disease Surveillance and Control at the governorate level for follow-up and action.

2.5.2 Reporting at governorate level

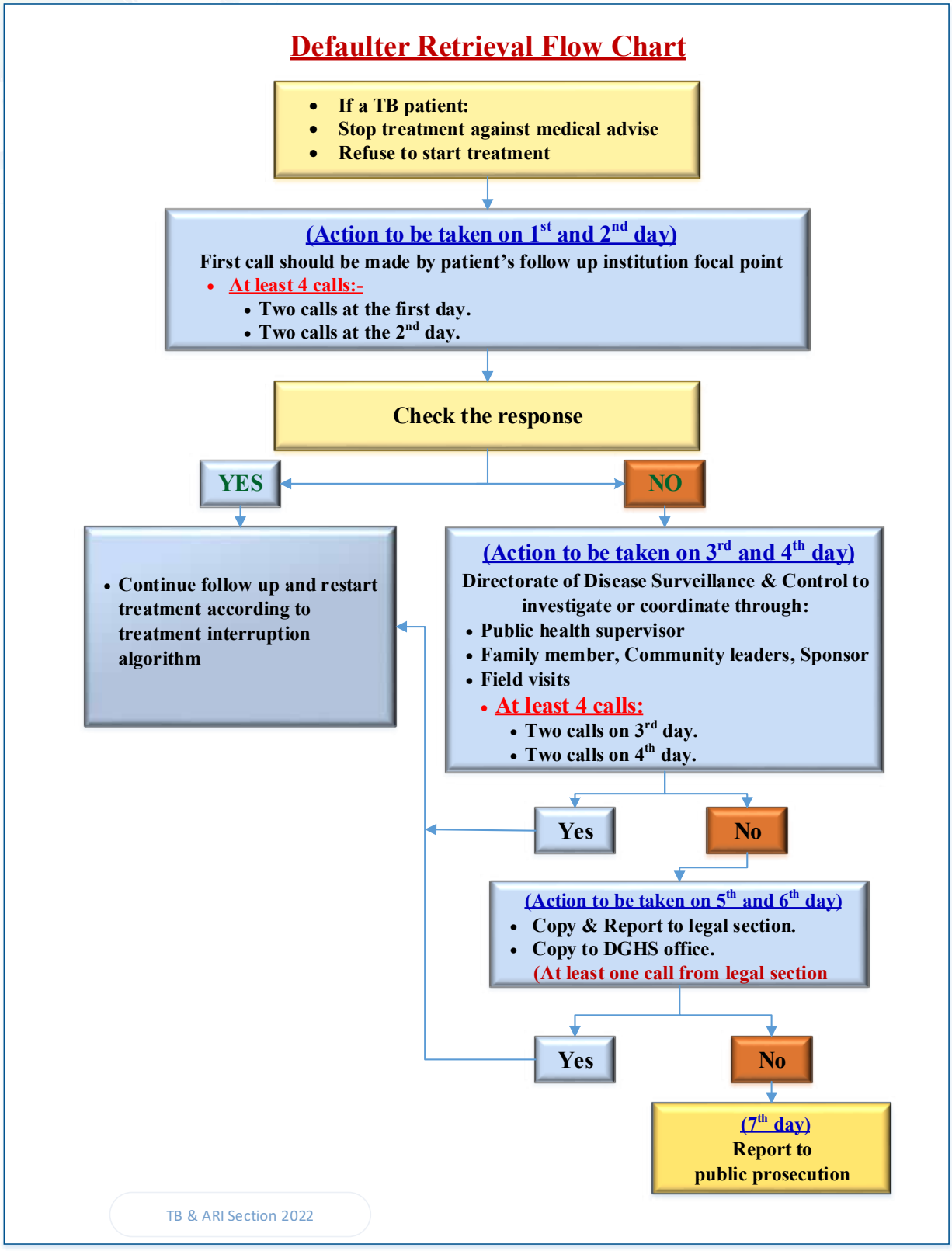
Patients with signs, symptoms, radiological evidence suggestive of TB disease or laboratory evidence of infection are considered as presumptive TB case are required to be reported within 24 hours to the National TB Control Programme as per public health law. Highly suspected pulmonary TB cases should be notified as presumptive TB without waiting for laboratory confirmation by TB e-notification form.

2.5.3 Reporting at national level

Reporting forms:

- e-notification reporting system for presumptive and confirmed TB cases.
- e-notification for contact screening.
- Quarterly report.
- Annual report.
- e-notification TB patient follow-up.

Annex: Defaulter Retrievel Flow Chart



Chapter 3

Case definition and classification definitions

3.1 Definitions

3.1.1 Active TB and LTBI

- Active TB refers to disease that occurs in someone infected with Mycobacterium tuberculosis (MTB). Active TB whether pulmonary or extrapulmonary is characterized by signs or symptoms of active disease.
- LTBI refers to a person infected with MTB without signs or symptoms of active disease.

3.1.2 Presumptive TB

Presumptive TB refers to a patient who presents with symptoms or signs suggestive of TB (previously known as a TB suspect).

3.1.3 Case definition – bacteriologically confirmed TB

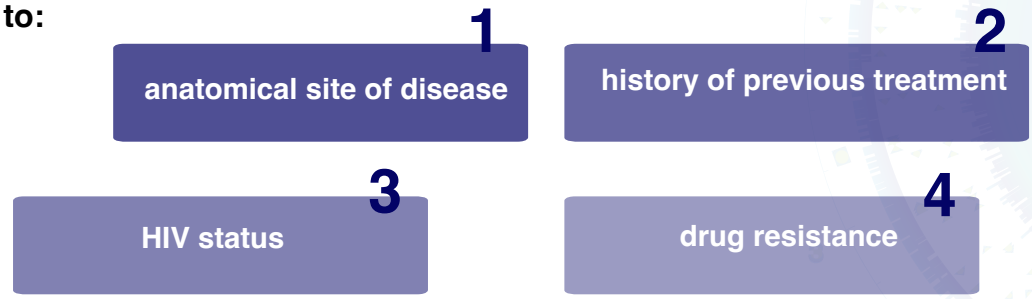
A bacteriologically confirmed TB case is one from whom a biological specimen is positive by smear microscopy, culture or molecular test (such as Xpert MTB/RIF). All such cases should be notified, regardless of whether TB treatment has started.

3.1.4 Case definition – clinically diagnosed TB

A clinically diagnosed TB case is one who does not fulfil the criteria for bacteriological confirmation but has been diagnosed with active TB by a clinician or other medical practitioner who has decided to give the patient a full course of TB treatment. This definition includes cases diagnosed on the basis of X-ray abnormalities or suggestive histology and extrapulmonary cases without laboratory confirmation.

Clinically diagnosed cases subsequently found to be bacteriologically positive (before or after starting treatment) should be reclassified as bacteriologically confirmed.

Bacteriologically confirmed or clinically diagnosed cases of TB are also classified according to:



3.2 Classifications

3.2.1 Based on anatomical site of disease

Pulmonary TB (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 extrapulmonary TB (EPTB). A patient with both pulmonary and EPTB should be classified as a case of PTB.

EPTB refers to 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 and bones, meninges.

3.2.2 Based on history of previous TB treatment (patient registration group)

- Classifications based only on history of previous TB treatment and are independent of bacteriological confirmation or site of disease.
  - New patients have never been treated for TB or have taken anti-TB drugs for less than one month.
  - Previously treated patients have received one 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:
- Relapse patients have previously been treated for TB, were declared cured or treatment completed at the end of their most recent course of treatment, and are now diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by reinfection).
- 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.
- Treatment after loss to follow-up 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.)
- Other previously treated patients are those who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.
- Patients with unknown previous TB treatment history do not fit into any of the categories listed above.
- Please note, new and relapse cases of TB are incident TB cases.

The registration groups for DR-TB are slightly different and are described in the companion handbook to the WHO guidelines for the programmatic management of drug resistant.

3.2.3 Based on 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 antiretroviral therapy (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.

3.2.4 Based on drug resistance

Cases are classified in categories based on drug susceptibility testing (DST) of clinical isolates confirmed to be MTB:

- Monoresistance: resistance to one first-line anti-TB drug only.
- Polydrug resistance: resistance to more than one first-line anti-TB drug (other than both isoniazid (INH) and RIF).
- Multidrug resistance: resistance to at least both INH and RIF.
- Pre-extensively drug resistant tuberculosis (XDR-TB): TB caused by MTB strains that fulfil the definition of MDR/RIF resistant (RR)-TB and that are also resistant to any fluoroquinolone[a/4]

XDR-TB: TB caused by MTB strains that fulfil the definition of MDR/RR-TB and that are also resistant to any fluoroquinolone and at least one additional Group A drug[b]

[a]The fluoroquinolones include levofloxacin and moxifloxacin, because these are the fluoroquinolones currently recommended by WHO for inclusion in shorter and longer regimens.

[b]The Group A drugs are currently levofloxacin or moxifloxacin, bedaquiline and linezolid; therefore, XDR-TB is MDR/RR-TB that is resistant to a fluoroquinolone and either bedaquiline or linezolid (or both). The Group A drugs may change in the future; therefore, the terminology "Group A" is appropriate here and will apply to any Group A drugs in the future.

• RIF resistance: resistance to RIF detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs. It includes any resistance to RIF, whether mono resistance, multidrug resistance, polydrug resistance or extensive drug resistance. These categories are not all mutually exclusive. When enumerating RR-TB, for instance, MDR-TB and XDR-TB are also included. While it has been the practice until now to limit the definitions of monoresistance and polydrug resistance to first-line drugs only, future drug regimens may make it important to classify patients by their strain resistance patterns to fluoroquinolones, second-line injectable agents and any other anti-TB drug for which reliable DST becomes available.

3.3 Treatment outcomes

3.3.1 Treatment outcome definitions

The new treatment outcome definitions make a clear distinction between two types of patients:

- Patients treated for drug-susceptible TB.
- Patients treated for drug resistant TB using second-line treatment (defined as combination chemotherapy for drug resistant TB which includes drugs other than those in Group 1).

The two groups are mutually exclusive. Any patient found to have drug resistant TB and placed on second-line treatment is removed from the drug-susceptible TB outcome cohort. This means that management of the standard TB register and of the second-line TB treatment register needs to be coordinated to ensure proper accounting of the outcomes of treatment.

3.3.2 Treatment outcomes for TB patients (excluding patients treated for RR-TB or MDR-TB)

All bacteriologically confirmed and clinically diagnosed TB cases should be assigned an outcome from this list except those with RR-TB or MDR-TB, who are placed on a second-line drug regimen .

Table 2. Definitions of treatment outcomes for TB without drug resistance

Treatment outcome	Definition
Cured	A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear- or culture-negative in the last month of treatment and on at least one previous occasion.
Treatment completed	A TB patient who completed treatment without evidence of failure but with no record to show that sputum smear or culture 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.
Treatment failure	A TB patient whose sputum smear or culture is positive at the end of fifth month or later during treatment.
Died	A TB patient who dies for any reason before starting or during the course of treatment.
Lost to follow-up	A TB patient who did not start treatment or whose treatment was interrupted for two consecutive months or more.
Not evaluated	A TB patient for whom no treatment outcome is assigned. This includes cases "transferred out" to another treatment unit as well as cases for whom the treatment outcome is unknown to the reporting unit.
Treatment success	The sum of cured and treatment completed.

Patients found to have an RR-TB or MDR-TB TB strain at any point in time should be started on an adequate second-line drug regimen. These cases are excluded from the main TB cohort when calculating treatment outcomes[1] and included only in the second-line TB treatment cohort analysis.

[1]This is a change from previous practice; such case used to be classified as Treatment failed

3.3.3 Outcomes for RR-TB/MDR-TB/XDR-TB patients treated using second-line treatment

Table 3. Definitions of treatment outcomes for drug resistant TB

Treatment outcome	Definition
Cured	Treatment completed as recommended by the national policy without evidence of failure AND three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase[a].
Treatment completed	Treatment completed as recommended by the national policy without evidence of failure but no record that three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase [a].
Treatment failure	• **Treatment terminated or need for permanent regimen change of at least two anti-TB drugs because of:** • lack of conversion by the end of the intensive phase, or • bacteriological reversion in the continuation phase after conversion to negative, or • evidence of additional acquired resistance to fluoroquinolones or second-line injectable drugs, or • adverse drug reactions.
Died	A patient who dies for any reason during the course of treatment.
Lost to follow-up	A patient whose treatment was interrupted for two consecutive months or more.
Not evaluated	A patient for whom no treatment outcome is assigned. (This includes cases “transferred out” to another treatment unit and whose treatment outcome is unknown).
Treatment success	The sum of cured and treatment completed.

[a]For treatment failed, lack of conversion by the end of the intensive phase implies that the patient does not convert within the maximum duration of intensive phase applied by the programme. If no maximum duration is defined, an eight-month cut off is proposed. For regimens without a clear distinction between intensive and continuation phases, a cut off eight months after the start of treatment is suggested to determine when the criteria for cured, treatment completed and treatment failed start to apply.

[b]The terms "conversion" and "reversion" of culture as used here are defined as follows:

- **Conversion (to negative):** culture is considered to have converted to negative when two consecutive cultures, taken at least 30 days apart, are found to be negative. In such a case, the specimen collection date of the first negative culture is used as the date of conversion.
- **Reversion (to positive):** culture is considered to have reverted to positive when, after an initial conversion, two consecutive cultures, taken at least 30 days apart, are found to be positive. For the purpose of defining treatment failed, reversion is considered only when it occurs in the continuation phase.

The revised definitions should be applied by the NTP at a set changeover date (e.g. 1 January): all cases on treatment on that date will be assigned outcomes according to the revised definitions. This means that patients started on treatment in the previous year may be assigned outcomes according to two different definitions of cured or treatment failed, depending on whether they completed treatment before or after the changeover date. This may be the most practical option for the transition period, given that retrospective reassignment of outcomes is not always feasible.

Patients placed on second-line anti-TB medications usually belong to one of the following groups:

- Confirmed RR-TB or MDR-TB.
- Presumptive RR-TB or MDR-TB. Patients may be registered and started on second-line anti-TB treatment on the basis of significant risk for drug resistance and before laboratory confirmation of resistance, or on the basis of a rapid molecular result.
- Poly-/mono-resistant TB without RIF resistance. Some of these cases may have second-line anti-TB drugs added to their treatment.
- XDR-TB (confirmed or presumptive). Patients may be started on XDR-TB treatment on the basis of a laboratory diagnosis or, in its absence, because of significant risk.

3.4 References

1. Guidelines for treatment of tuberculosis, fourth ed. Geneva: World Health Organization; 2009 (WHO/HTM/TB/2009.420; http://whqlibdoc.who.int/publications/2010/9789241547833_eng.pdf, accessed 24 February 2022).
2. Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis. Geneva: World Health Organization; 2014. (WHO/HTM/TB/2014.11; http://apps.who.int/iris/bitstream/10665/130918/1/9789241548809_eng.pdf, accessed 24 February 2022).
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4. Meeting report of the WHO expert consultation on the definition of extensively drug-resistant tuberculosis, 27–29 October 2020. Geneva: World Health Organization; 2020. ISBN 978–92–4-001866–2 (electronic version) ISBN 978–92–4-001867–9 (print version).

Chapter 4

Basic information about TB

4.1 What is TB?

TB is an infectious disease usually caused by a bacterium called MTB. The bacteria usually attack the lungs, but TB bacteria can attack any part of the body such as the kidney, spine and brain. Not everyone infected with TB bacteria becomes sick. As a result, two TB-related conditions exist: LTBI and TB disease. If not treated properly, TB disease can be fatal.

4.2 How does TB spread?

TB is an airborne infection. When a patient with infectious pulmonary TB coughs, sneezes, sings or laughs, bacilli are expelled into the air in the form of tiny droplets. These droplets dry up rapidly to form droplet nuclei and may remain suspended in the air for several hours. When a healthy person inhales these droplet nuclei containing the tubercle bacilli, he/she may become infected. Adequate ventilation removes and dilutes these droplet nuclei, but they can survive in the dark ill-ventilated spaces for several days.

4.3 Risk of infection

An individual's risk of infection depends on the extent of exposure to an infectious source and susceptibility of the individual to infection. The risk of infection is therefore high in a person who has close, prolonged exposure to droplets from a person with untreated pulmonary TB. An untreated sputum positive patient has the potential to infect 10–15 persons per year. The risk of transmission of infection from EPTB is lower

4.4 TB infection and disease

TB develops in two stages. The first stage occurs when the tubercle bacilli enter the body of an individual but remain dormant without causing disease. This is called tuberculous infection. The second stage is TB or tuberculous disease where the infected individual actually develops the disease. Approximately 10% of people infected with bacillus but not suffering from any other concomitant immunosuppressive condition will develop the active disease during their lifetime. This incidence increases to 10% every year in patients with HIV infection.

4.5 Pathogenesis

The infection occurs when a person inhales droplets containing tubercle bacilli that reach the alveoli in the lungs. These tubercle bacilli are engulfed by alveolar macrophages. The majority of these bacilli are destroyed or inhibited. A small number may proliferate inside cells and are released when macrophages die. If these bacilli are alive, they may spread through the lymph channels or through the bloodstream to distant tissues and organs (including the areas of the body where TB is most likely to develop: regional lymph nodes, lung apex, kidneys, brain and bones). This diffusion process prepares the immune system for a systemic response.

4.5.1 Primary infection

The primary infection occurs when a person is first exposed to tubercle bacilli. Once the tubercle bacilli enter the respiratory system by inhalation, the organisms reach the alveoli in the lungs where they are engulfed by macrophages and presented to lymphocytes. This induces an immune reaction against MTB resulting in a sub-pleural Ghon focus with enlarged, bleeding lymph nodes four to six weeks after the initial infection. Ghon focus and the enlarged draining nodes comprise primary complex. In most cases, the immune response is sufficient to stop the multiplication of bacilli and prevent disease progression. The primary lesion may heal with fibrosis or calcification. A positive tuberculin skin test (TST) may be the only evidence of infection.

In a few cases primary infection progresses and leads to complications of primary infection. Complications of primary infection can manifest as early complications such as pleural effusion, miliary TB, meningitis or late complications such as bone TB, renal TB, etc.

4.5.2 Post primary TB

Post primary TB occurs after a latent period of months or years after the primary infection. It may occur either by endogenous reactivation of the latent primary infection or by exogenous reinfection with TB bacilli. Site of post primary TB is usually the lungs and results in lung cavitation, fibrosis and patchy consolidation. These patients are the one who may become sputum positive and therefore to spread of the disease.

4.6 Common symptoms of pulmonary TB

4.6.1 Respiratory symptoms:

- Cough – usually two weeks or more. However, in immunosuppressed and in the presence of any other risk factor, cough of any duration should lead to screening for TB
- Shortness of breath
- Chest pain
- Haemoptysis (blood stained sputum)

4.6.2 Constitutional symptoms:

- Fever and night sweats
- Loss of appetite
- Loss of weight or failure to gain weight in case of children
- Tiredness (fatigue)

4.6.3 Symptoms of EPTB

EPTB symptoms usually depend on the organ involved. Patients may present with constitutional features of the disease such as, fever, night sweats, loss of weight and loss of appetite or symptoms related to the affected system (e.g. neurological symptoms when nervous system is affected) or local symptoms like swelling (most commonly due to lymph nodes enlargement) related to the site of the disease.

Chapter 5

TB diagnostic modalities

5.1 Screening and diagnosis

Early identification and cure of all TB cases is the highest priority for TB control. Therefore, any person with symptoms suggestive of TB, particularly cough for two weeks and close contacts of known TB cases should be investigated. Screening is also sometimes carried out in individuals with risk factors such as HIV infection, in prisons, for immigration purposes based on country specific requirements, priority groups as determined by local epidemiology as well as certain pockets of unreached populations.

In 2018 the Directorate General for Disease Surveillance and Control has modified the diagnostic algorithm for TB to include a molecular test (Xpert MTB/RIF assay) as an initial diagnosis test in all adults and children with signs and symptoms of pulmonary TB in addition to smear microscopy and culture. See Figure 4.

Laboratories should report initial positive smears, positive MTB cultures, and positive GeneXpert MTB/RIF results within 24 hours by telephone or fax to the health institution.

Patients with signs, symptoms, radiological evidence suggestive of TB disease or laboratory evidence of infection are considered as presumptive TB cases are required to be reported within 24 hours to the National TB Control Program as per public health law. Highly suspected pulmonary TB cases should be notified as presumptive TB without waiting for laboratory confirmation by TB e-notification form using the Tarassud platform.

Patients with confirmed laboratory tests; smear microscopy or PCR at primary health care should be transferred to nearest health institute for starting TB treatment promptly as per communicable disease low of mandatory reporting of notifiable diseases. IPC measures should be observed during transfer. More details will be found in the referral system guideline.

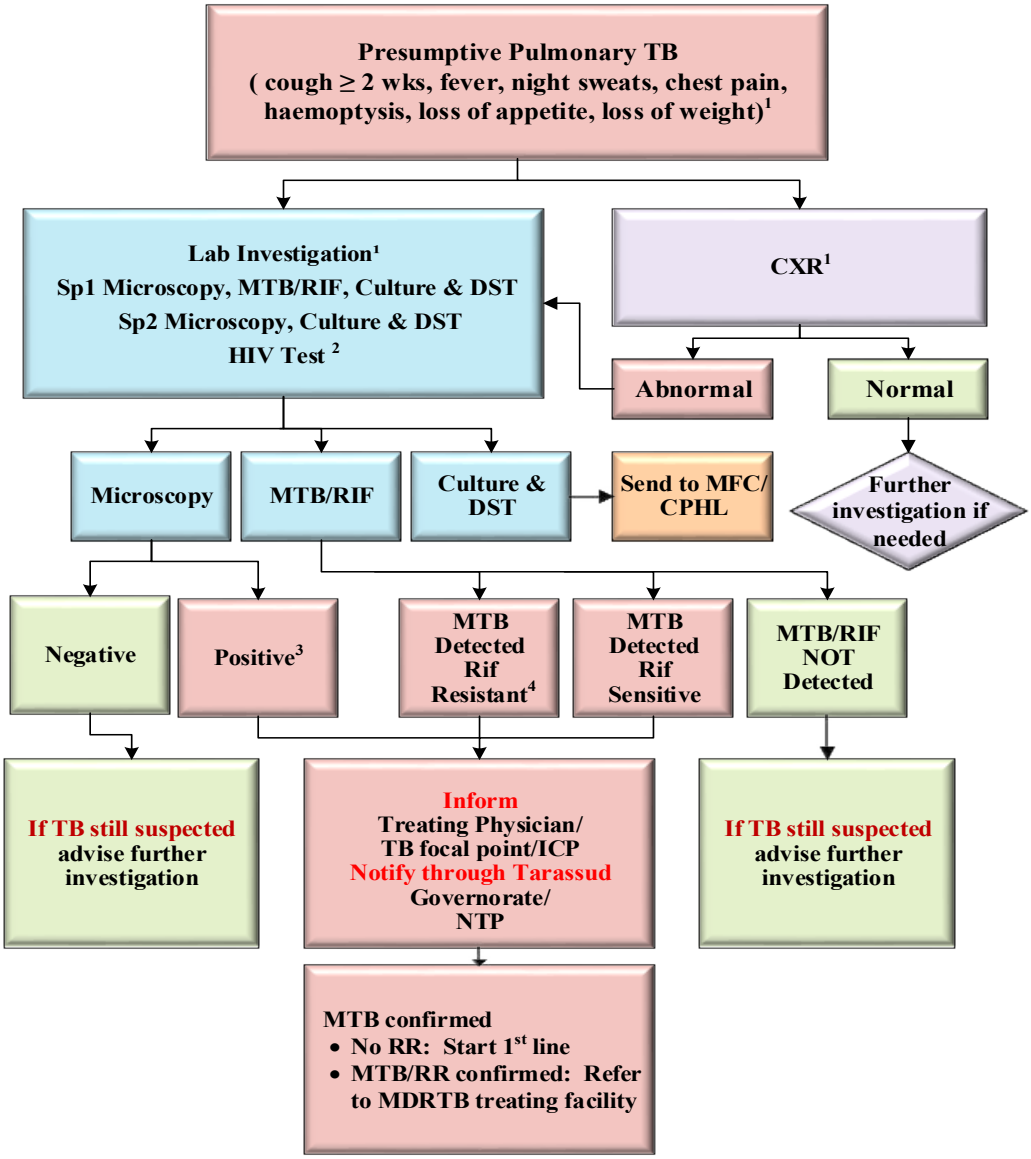
Figure 4. TB diagnostic algorithm

Sultanate of Oman

Ministry of Health

Directorate General for Disease Surveillance & Control

Diagnostic Algorithm For Presumptive TB Patient



Sp1: Specimen 1, **Sp2:** Specimen 2, **DST:** Drug Susceptibility Testing, **MTB/RIF:** Mycobacterium TB complex/Rifampicin Resistant detection Test is an automated polymerase chain reaction (PCR) currently done by (GeneXpert), **MFC:** Medical Fitness Centre, **CPHL**: Central Public Health Laboratory, **MDRTB**: Multi-Drug Resistant Tuberculosis, **RR**: Rifampicin Resistant, **ICP**: Infection Control Practitioner, **NTP**: National TB Program.

[1] For a presumptive TB based on (Symptoms/Signs/X ray/Lab) abnormalities escort immediately to designated treatment institute.

[2] HIV (Human Immuno-deficiency Virus) testing should be done for all patients with TB

[3] If microscopy positive and MTB/RIF not detected consider possibility of Mycobacteria Other Than TB (MOTT)

[4] If Rif Resistant Detected send a repeat sample to CPHL for confirmation.

5.2 Investigations for active TB

5.2.1 Radiological examinations

CXR

The diagnosis of TB cannot be established on X-ray alone. Radiological lesions may suggest but cannot confirm TB. Patients in whom CXR shows any radiological abnormality must have bacteriological and clinical examinations to rule out TB.

For EPTB (such as pleural effusions and pericardial TB) X-ray is useful for the identification of the site. It can provide additional information for the diagnosis of TB in patients with symptoms and clinical signs compatible with TB and in whom bacteriological examinations are negative (sputum smear, Xpert MTB/RIF or culture). X-ray film should be read by qualified doctors.

ULTRASOUND

The ultrasound can be used as a supplementary investigation in the diagnosis of EPTB, particularly abdominal and pericardial TB.

COMPUTERIZED TOMOGRAPHY (CT SCAN) and MAGNETIC RESONANCE IMAGING (MRI)

CT scan and MRI can provide more detailed images of body parts not easily seen on a standard X-ray. The CT scan may be of diagnostic value in

- children and immune compromised people suspected to have TB but without any positive findings;
- patients with normal or inconclusive CXR where TB diagnosis and complications are suspected;
- patients with EPTB.

5.2.2 Bacteriologic examination

Sputum smear microscopy

Sputum smear microscopy is among the least expensive methods of diagnosing infectious cases of pulmonary TB. Whenever TB is suspected in a patient who has had a cough for two weeks or more with or without any history of previous TB treatment, at least two sputum samples should be collected and subjected to microscopy (AFB), molecular testing (Xpert MTB/RIF), culture and sensitivity. further diagnostic methods such as line probe assay and DNA sequencing is done if required.

It is recommended that all patients suspected of PTB should submit at least two sputum

specimens.

Usually, a first sample is collected at the time of the consultation when the patient is identified as a suspected TB case. A second sample is collected in the early morning the day after the initial consultation (and the patient brings the sample to the health facility if it is collected at home).

'Same day' or 'spot-spot' microscopy in which two sputum specimens are collected one hour apart can be performed in order to limit the number of visits to the health facility and do not lose the patient.

In clinics or wards, sputum samples should be produced in a designated place with good ventilation and sunlight, and away from other people.

5.2.3 Specimen collection methods for pulmonary TB disease

There are four specimen collection methods for pulmonary TB disease (see Table 4):

- Spontaneous sputum sample
- Induced sputum
- Bronchoscopy
- Gastric aspiration

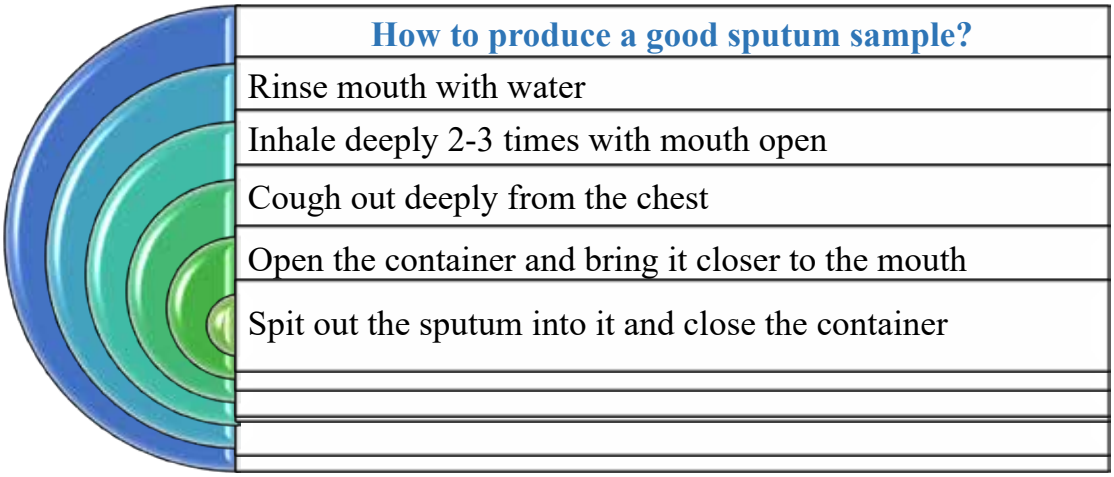
Table 4. Methods of obtaining a sputum specimen

Method	Description	Advantage	Disadvantage
Spontaneous sputum sample	**Patient coughs up sputum into a sterile container**	• **Inexpensive** • **Easy to do**	• Patient may not be able to cough up sputum without assistance or may spit up saliva instead of sputum • Health care worker has to coach and supervise the patient when collecting sputum
Sputum induction	Patient inhales a saline mist which can cause a deep cough	• Easy to do • Use to obtain sputum when coughing sputum is not productive	• Specimens may be watery and may be confused with saliva (should be labelled "induced specimen") • Requires special equipment • May cause bronchospasm
Bronchoscopy	**Bronchoscope is passed through the mouth or nose directly into the diseased portion of the lung, and sputum or lung tissue is removed**	**Use to obtain sputum when coughing or inducing sputum is not productive or other diagnoses are being considered**	• Most expensive and invasive procedure • Requires special equipment • Must be done by a specialist in a hospital or clinic • Requires anaesthesia
Gastric washing	Tube is inserted through the patient's mouth or nose and passed into the stomach to get a sample of gastric secretions that contain sputum that has been coughed into the throat and then swallowed	Use to obtain samples in children, who do not produce sputum when they cough	• Must be done as soon as patient wakes up in the morning; patient may be required to stay in hospital • Can be uncomfortable for the patient

For collection of the sputum sample the following procedure should be followed:

In order to obtain valid results and avoid getting a salivary sample from the patients, the HCW needs to instruct the patient how to collect a sputum sample correctly. Make special note that the procedure should be done in a well-ventilated space, as far away as possible from other people. Inhaling steam facilitates sputum production.

Figure 5. Correct procedure to collect a sputum sample



Collection of extrapulmonary specimen:

Patients suspected to have EPTB should have specimens obtained from the suspected site and Xpert MTB/RIF, culture and DST conducted in addition to other laboratory diagnostic procedure, e.g.

cytology other staining technique can be done. This is important for the early diagnosis of drug resistant TB particularly in high-risk groups.

5.2.4 Rapid diagnostic tests (Xpert MTB/RIF)

There are two rapid diagnostic methods available for detection of TB such as Xpert MTB/RIF, and LPA. See Figure 6.

XPERT MTB/RIF

In Oman, a molecular test (Xpert MTB/RIF assay) is an initial diagnostic test for all presumptive TB patient (PTB and EPTB) in addition to smear microscopy and culture. Xpert MTB/RIF may be conducted on gastric washings/lavages, lymph node fine needle aspirates, cerebrospinal fluid and pleural biopsies.

Xpert MTB/RIF is an automated NAAT recommended by WHO for early detection of TB and resistance to RIF which is one of the most important drugs used in the first-line regimen for treating TB. Resistance to RIF is also used as a proxy indicator of multidrug resistance MDR-TB. The test takes around two hours and requires minimal human effort to perform. Xpert MTB/RIF can detect TB bacilli at much lower concentrations as compared to smear microscopy and hence is consideredmuch more sensitive.

LPA

LPA is a molecular method for diagnosing TB and the most common genetic mutations causing resistance to RIF and INH. This technology can diagnose MDR-TB directly from smear positive sputum specimens and from culture isolates providing results in five hours. Currently this method is only available at CPHL to confirm the diagnosis of MDR-TB alongside with conventional DST.

As of now the LPA is performed on solid or liquid culture isolates and for confirmation on specimen where the Xpert MTB/RIF (GeneXpert) tests show RIF resistance.

5.2.5 Culture for AFB

Culture examination of sputum for AFB is more sensitive and specific than direct smear microscopy and is useful in detecting cases where the number of organisms is fewer than that can be detected by direct smear microscopy. It takes at least six to eight weeks to get the results by conventional methods of culture. Culture methods based on liquid media are more sensitive and can show positive results relatively early when compared with solid media.

Culture examinations should be done on all diagnostic specimens, regardless of AFB smear or NAAT (GeneXpert MTB/RIF) results.

5.2.6 DST

DST is a technique that is used to screen for susceptibility of the TB bacilli for various anti-TB drugs using either phenotypic or genotypic techniques. The initial MTB isolate should be tested for resistance to the first-line anti-TB drugs: INH, RIF, ethambutol, streptomycin and pyrazinamide.

5.2.7 Histopathology tests

Histopathological examination may be conducted on tissue specimen, but this is not considered to be bacteriological confirmation of disease. Bacteriological examination is necessary to confirm TB.

The multiplication of tubercle bacilli in any site of the body causes a specific type of inflammation, with formation of characteristic granuloma that can be found on histopathological examination. Samples that can be submitted for examination include:

- Fine needle aspiration from lymph nodes
- Tissue biopsies from serous membranes, skin, pleura, endometrium, liver, etc.,

Histopathology is helpful in setting the diagnosis of EPTB when bacteriological examinations are negative.

All diagnosed TB patients should be tested for HIV

5.2.8 Test for MTB infection

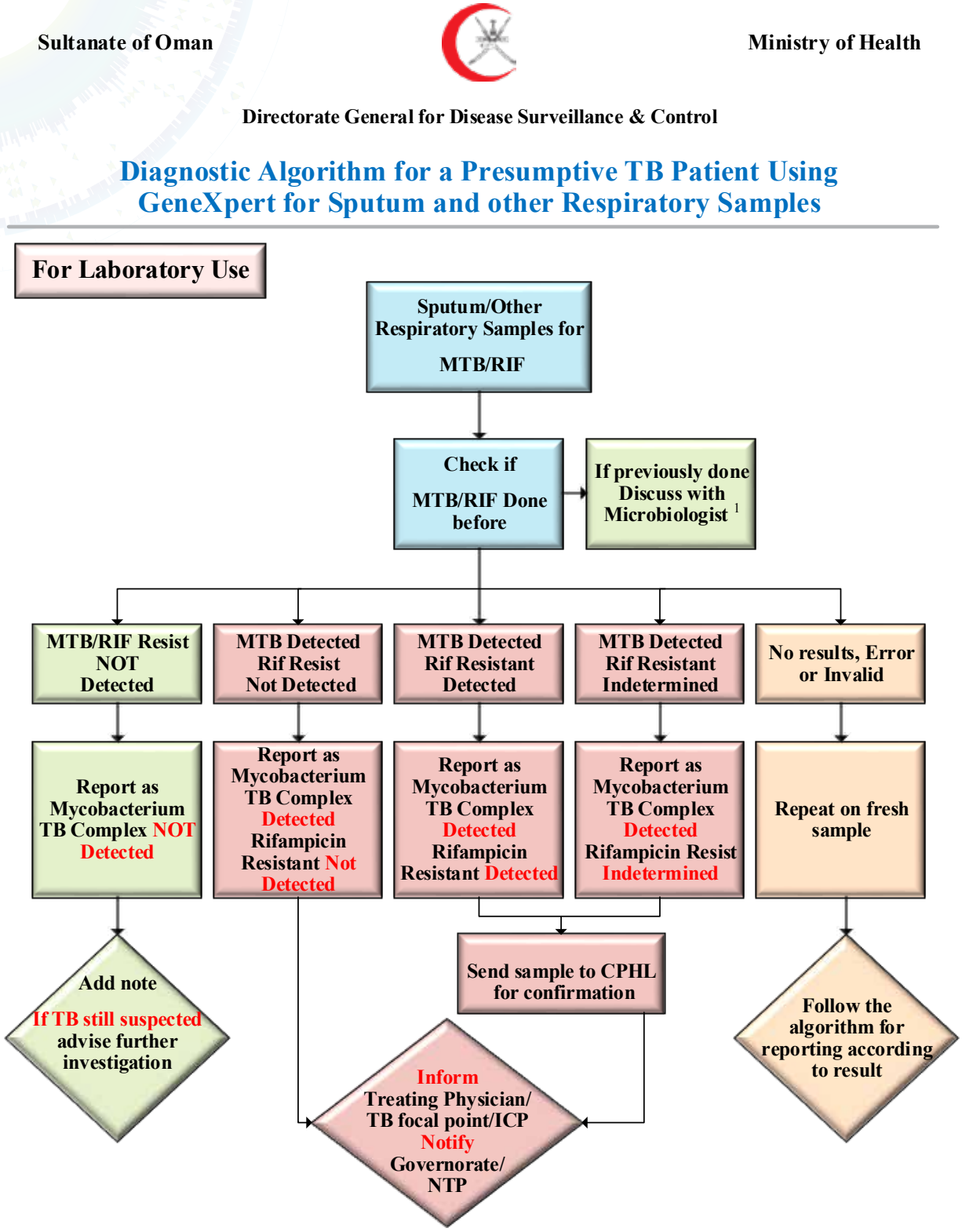
LTBI detection of MTB infection and test selection depends on several factors such as reasons and context for testing, test availability and overall cost effectiveness of testing. Currently, there are two methods available for the detection of MTB infection in Oman. The tests are:

- Mantoux TST
- IGRAs QuantiFERON®-TB Gold Plus (QFT-Plus)

These tests may help clinicians differentiate people infected with MTB from those uninfected.

However, a negative reaction to any of the tests does not exclude the diagnosis of TB disease or LTBI. For more details, see chapter 9 (TB prevention).

Figure 6. Diagnostic algorithm for a presumptive TB patient using GeneXpert for sputum and other respiratory samples



MTB/RIF: Mycobacterium TB complex/Rifampicin Resistant detection Test is an automated polymerase chain reaction (PCR) currently done by (GeneXpert), **CPHL**: Central Public Health Laboratory, **ICP**: Infection Control Practitioner, **NTP**: National TB Program.

[1] if previously done and was positive proceed for microscopy and culture, do not perform GeneXpert and if previously negative proceed to microscopy and culture and discuss indication for repeat with physician, perform GeneXpert if indicated.

Chapter 6

Treatment of drug sensitive TB disease

6.1 TB treatment in adults

Treatment of TB is the cornerstone of any NTP. The modern treatment strategy is based on standardized short course chemotherapy regimens and proper case management to ensure completion of treatment and cure.

6.1.1 Aims of treatment of TB

- To cure patients from TB,
- To prevent death from active TB or its late effects,
- To prevent relapse of TB,
- To decrease transmission of TB in the community,
- To prevent the emergence of drug resistant TB.

Short course chemotherapy is the recommended treatment for TB. When properly applied, it fulfils the above aims of anti-TB drug treatment.

6.1.2 Requirements for adequate chemotherapy

- An appropriate combination of quality assured anti-TB drugs,
- Medication prescribed in correct dosage according to the weight for the prescribed period of time taken regularly by the patient,
- Therapy must be done under DOT, which means that the patient swallows the tablets under the direct observation of a HCW or a trained person.

6.1.3 Standard codes for TB treatment regimens

There are five essential first-line anti-TB drugs namely INH, RIF, pyrazinamide, ethambutol and streptomycin. There is a standard code for TB treatment regimens and each anti-TB drug has an abbreviation.

H	Isoniazid (INH)
R	Rifampicin (RIF)
Z	Pyrazinamide
E	Ethambutol
S	Streptomycin

A TB treatment regimen consists of two phases, the intensive phase and the continuation phase.

The number before a phase is the duration of that phase in months, e.g., 4 HR means four months of INH and RIF daily.

6.2 Short course chemotherapy

Short course chemotherapy is recommended for the treatment of pulmonary TB, as well as all forms of EPTB in all new cases. The introduction of RIF and pyrazinamide has made it possible to shorten the duration of treatment regimens for a period as short as six to eight months which has contributed to the improvement of treatment adherence.

6.2.1 Basis of chemotherapy

Anti-TB drugs have the following three actions:

- Early bactericidal activity
- Sterilizing activity
- Ability to prevent emergence of drug resistance

Table 5. Qualities of TB medication

Isoniazid (H)	a potent drug exerting early bactericidal activity which prevents emergence of drug resistant mutants to any companion drug and has low rates of adverse drug reactions.
Rifampicin (R)	a potent bactericidal and sterilizing drug acting on extracellular semi-dormant bacilli which multiply intermittently and cause relapses.
Pyrazinamide (Z)	a bactericidal and sterilizing drug effective in eliminating intracellular semi-dormant bacilli multiplying slowly in an acidic environment, thus reducing the relapse rate.
Ethambutol (E)	an effective bacteriostatic drug helpful in preventing emergence of resistance to other companion drugs.
Streptomycin (S)	a bactericidal drug.

6.2.2 Recommended regimen

WHO recommends fixed-dose combination (FDC) treatment for both intensive and continuation phase. Regimens are available for adults, children, new and retreatment cases. The regimens below are based on FDC medications.

FDC Formulation		
Intensive phase	2 months	RHZE (FDC4): RIF 150 mg + INH 75 mg + pyrazinamide 400 mg + ethambutol 275 mg
Continuation phase	4 months	RH (FDC2): RIF 150 mg + INH 75 mg

6.3 TB treatment regimens

Treatment regimens consist of two phases:

6.3.1 Initial intensive phase (IP) (2 RHZE)

The objective of combining four drugs for the first two months is to achieve rapid killing of actively Multiplying bacillary population. Smear conversion at the end of two months will occur in > 90 %.

Infectious patients quickly become non-infectious (within about two weeks) and symptoms improve when given proper dosage of quality assured drugs in right combination. Patient support in taking medication using DOT is essential in the initial phase for every single dose.

6.3.2 Continuation phase (CP) (4 RH)

During continuation phase two drugs are used for four months. This will eliminate the remaining bacilli thus preventing subsequent relapses. At least once a week observation of drug intake through (DOT) is desirable.

Table 7. Number of FDC tablets used in TB treatment in adults according to body weight

Treatment regimen	No. of daily tablets/grams according to body weight (kg)* Treatment duration <35 kg	35-54 kg	>55 kg**	
Intensive phase (RHZE tablet)§	2	3	4	2 months
Continuation phase (RH tablet) ¶	2	3	4	4 months

*Change the number of tablets/grams if the weight change overtime.

** for patients over 70 kg bodyweight, additional 400 mg Pyrazinamide may be added by the clinician in the intensive phase.

§ Rifampicin 150mg + Isoniazid 75mg + Pyrazinamide 400mg + Ethambutol 275mg

¶ Rifampicin 150mg + Isoniazid 75mg

Table 8. Instructions following treatment

Special considerations		
When the patient completed the initial phase of treatment*	If sputum smear-negative at 8 weeks:	If sputum smear-positive at 8 weeks:
	Start continuation phase	Extend the intensive phase for another four weeks, then start the continuation phase regardless of sputum test results.

***In case of drug resistance a TB specialist should be consulted**

6.4 Categories and treatment regimens

The recommended treatment regimen depends on the treatment category of each patient. There are two treatment categories, new and retreatment, and two standardized treatment regimens in Oman (Table 9).

Table 9. Recommended treatment regimen based on treatment categories

Case Definition	Treatment Category	Treatment Regimen	
		Intensive Phase	Continuation Phase
New Case Pulmonary Extra-pulmonary	New	**2 HRZE**	**4 HR**
Previously treated cases **without** drug resistant (Relapse, treatment after failure, treatment after loss to follow up and other previously treated cases)	Retreatment Xpert/MTB/RIF result: MTB positive/ rifampicin resistant (RR) **NOT** detected	**2 HRZE**	**4HR (WHO recommendation 2017)**

6.4.1 Regimens for EPTB

EPTB refers to a case of TB involving organs other than the lungs, e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin, meninges, joints and bones.

All EPTB presumptive cases are to be referred to the specialty in concern for investigations (e.g. nephrology, orthopaedic, neurology, etc.). Specimen from affected site should always be sent for MTB culture. Molecular diagnostic technique should be used in consultation with the microbiologist.

Diagnosis must be based on at least one specimen with confirmed MTB by culture, histological evaluation or strong clinical evidence consistent with active EPTB, followed by a decision by a physician in consultation with an infectious disease specialist, to treat with a full course of anti-TB medications.

The continuation phase of therapy will be prolonged for TB meningitis, TB Bones and joints and spinal TB (as directed by the treating specialist). Steroids may be added as adjuvant therapy.

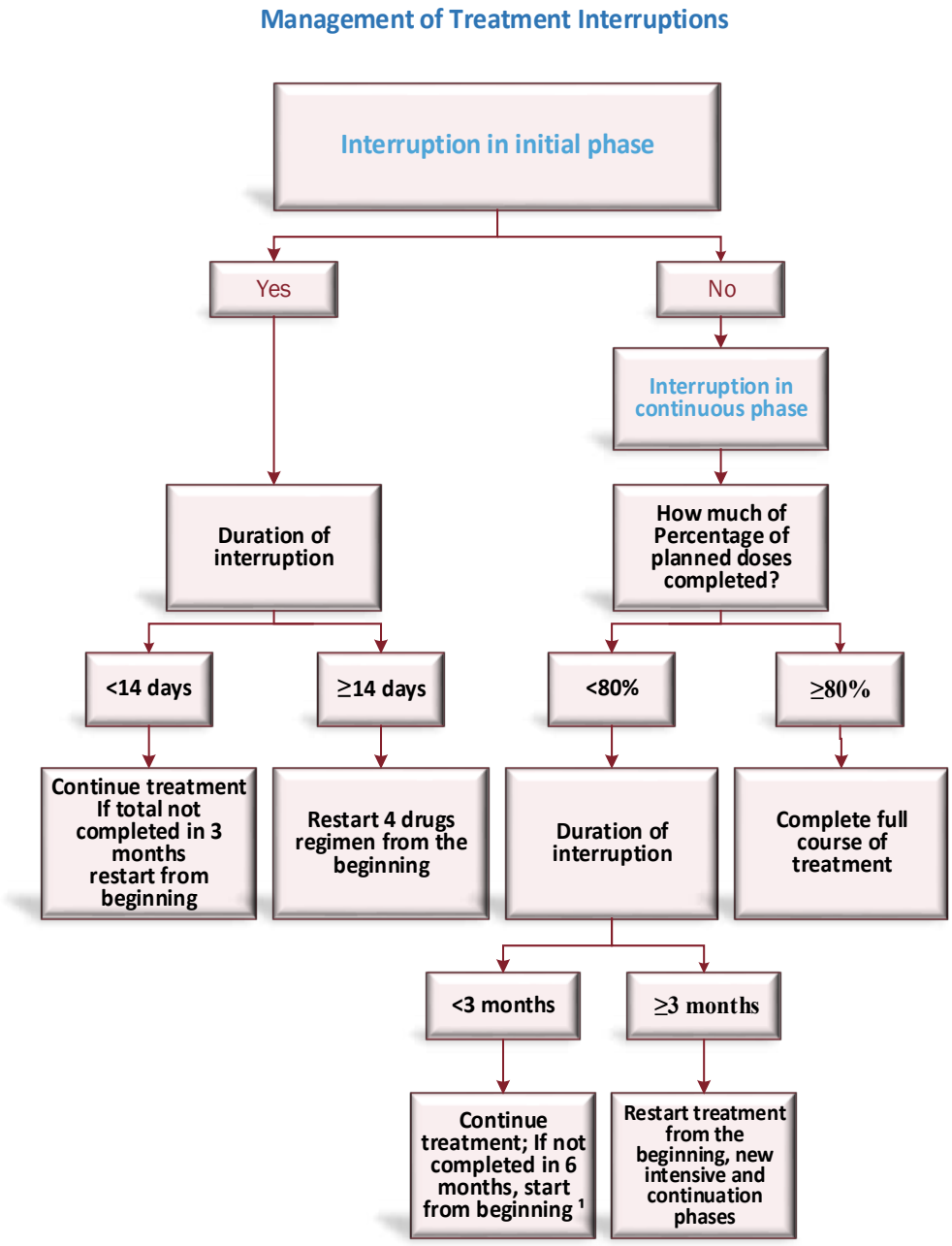
Table 10. Type of TB and associated treatment duration

Type of TB	Treatment duration
Central nervous system TB	9–12 months (2 months of intensive phase)
Osteo-articular TB	12 months (2 months of intensive phase)
Extensive pulmonary TB	Extend treatment to 12 months depending on clinical improvement (2 months of Intensive Phase)

6.4.2 Management of patients with treatment interruption

Patients who fail to follow-up as scheduled shall be immediately traced through telephone call, text message or home/workplace visit. The cause of interruption should be assessed, and the appropriate intervention is established. The patient should be brought back to therapy, sputum for AFB smear, molecular test (GeneXpert) culture, and DST should be sent immediately. All efforts should be made to convince the restart of the treatment including use of communicable disease law.

Figure 7. Management of treatment interruptions



[1] If repeat culture is positive, restart 4 drug regimen while waiting drug susceptibility results. If repeat culture is negative, continue therapy to complete regimen within 9 months of original start date.

6.5 Management of side-effects of first-line anti-TB drugs

6.5.1 Two types of side-effects for anti-TB drugs

Major side-effects cause serious health hazards where anti-TB drugs should be stopped immediately and the patient is referred to hospital for management.

Minor side-effects cause only relatively little discomfort and are often respond to symptomatic treatment. In general, a patient who develops minor side-effects should continue the anti-TB treatment.

Table 11. Symptom based management of side-effects of anti-TB drugs

Major	Stop responsible drug(s) and refer to physician urgently	
Side-effects	Drug(s) probably responsible	Management
Skin rash with or without itching	Streptomycin, INH, RIF, pyrazinamide	Stop anti-TB drugs
Deafness (no wax on otoscopy)	Streptomycin	Stop streptomycin
Dizziness (vertigo and nystagmus)	Streptomycin	Stop streptomycin
Jaundice (other causes excluded), hepatitis	INH, pyrazinamide, RIF	Stop anti-TB drugs
Confusion (suspect drug-induced acute liver failure if there is jaundice)	Most anti-TB drugs	Stop anti-TB drugs
Visual impairment (other causes excluded)	Ethambutol	Stop ethambutol
Shock, purpura, acute renal failure	RIF	Stop RIF
Nephrotoxicity, ototoxicity [1]	Streptomycin	Stop streptomycin

Minor	Continue anti-TB drugs, check drug doses	
Anorexia, nausea, abdominal pain	Pyrazinamide, RIF, INH	Give drugs with small meals or just before bedtime, and advise patient to swallow pills slowly with small sips of water. If symptoms persist or worsen, or there is protracted vomiting or any sign of bleeding, consider the side-effect to be major and refer to physician urgently. **BNF 80 - Label 8:** Pyrazinamide, RIF, INH (do not stop taking this medicine unless your doctor tells to stop). **BNF 80 - Label 22:** INH (take 30 to 60 minutes before food). **BNF 80 - Label 14:** RIF (this medicine may colour your urine). **BNF 80 - Label 23:** RIF (take this medicine when your stomach is empty. This means an hour before food or two hours after food.)2
Myalgia arthralgia Reference: (Medscape, BNF 80)	Pyrazinamide	Non-steroidal anti-inflammatory drug, or paracetamol
Burning, numbness or tingling sensation in the hands or feet	INH	Pyridoxine 50–75 mg daily
Dizziness	INH	Reassurance. Give drugs before bedtime
Orange/red urine	RIF	Reassurance.Patients should be informed when starting treatment that this may happen and is normal.

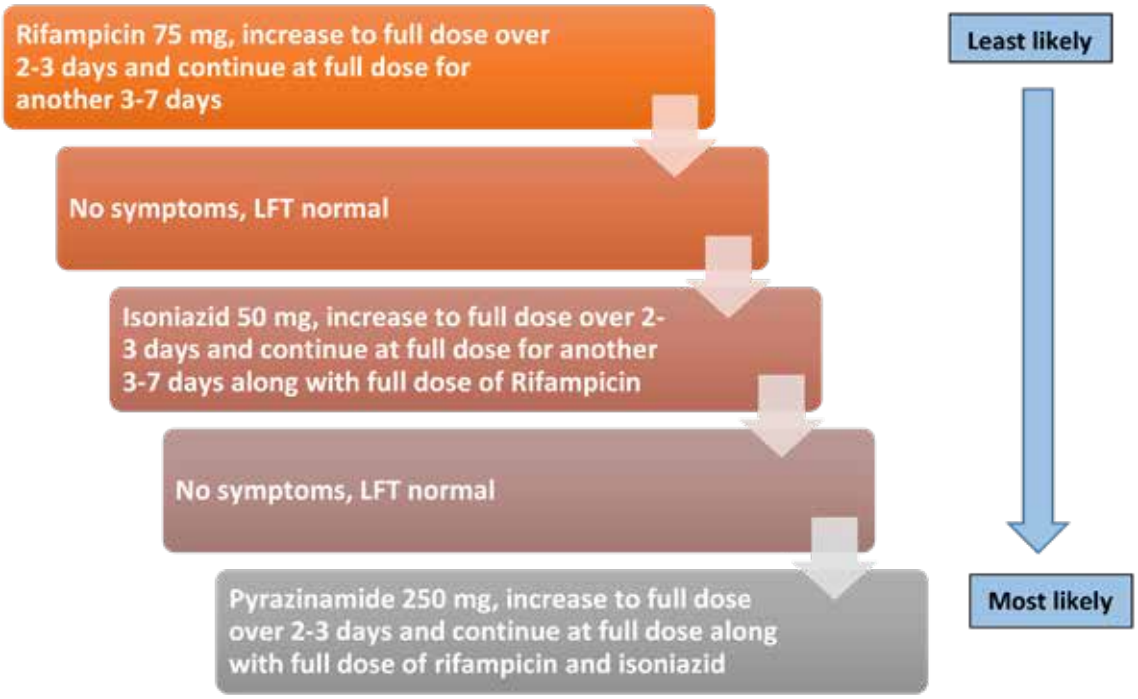
[1] Medscape

6.5.2 Monitoring requirements

RIF, pyrazinamide, ethambutol and INH

1. Renal and hepatic function should be checked before treatment.
2. Blood counts should be monitored in patients on prolonged therapy.
3. For streptomycin one hour (peak) concentration should be 15–40 mg/litre, pre-dose (trough) concentration should be less than 5mg/litre in renal impairment or in those over 50 years.
4. For reintroduction of anti-TB drugs following drug-induced hepatitis follow the guide (Figure 8) and consult specialist.

Figure 8. Method of re-introduction of anti-TB drugs following drug-induced hepatitis and after liver function tests (LFTs) return to normal



Note: Ethambutol is the least toxic
It can be added at the beginning or end of the regimen

- Definitions of hepatotoxicity: aspartate aminotransferase (AST) or alanine aminotransferase (ALT) or serum bilirubin > 3 times upper limit of normal with symptoms or > 5 times normal limit in the absence of symptoms are considered elevated. An AST or ALT or serum bilirubin under 5 times normal limit defines mild toxicity, 5 –10 times normal limit defines moderate toxicity and > 10 times normal limit defines severe toxicity.
- If the patient is severely ill with TB and it is considered unsafe to stop TB treatment, or if signs and symptoms do not resolve after stopping anti-tubercular treatment (ATT) and the liver disease is severe, a non-hepatotoxic regimen consisting of streptomycin, ethambutol and a fluoroquinolone should be started for a total of 18–24 months.
- If symptoms recur or liver function tests become abnormal as the drugs are reintroduced, the last drug added should be stopped.

6.6 Treatment of TB in special situation

6.6.1 Pregnancy

Before initiating treatment in women of childbearing age at the time of TB diagnosis, it should be determined if they are pregnant. A pregnant woman with TB must be informed that successful treatment with standard regimen is important for successful outcome of pregnancy. First-line anti-TB drugs included in standard treatment are safe in pregnancy. Streptomycin must not be given because of its ototoxicity to the foetus.
All pregnant women with TB should receive pyridoxine supplementation.

6.6.2 Breastfeeding

A breastfeeding mother with TB should receive a full course of TB treatment. This is the best way to prevent transmission of TB bacilli from mother to baby. Mother and baby should stay together and the baby should continue to be breastfed.
Additionally, breastfeeding mothers need to receive pyridoxine supplementation.

For other special situations, e.g. TB in PLHIV, those suffering from liver cirrhosis or renal failure, please discuss the management with the specialist concerned.

6.7 TB treatment in children

Active TB in children is a sentinel event that should prompt a search for the index case in thesurrounding adult population. Most cases occur in young children under five 5 years. Usually children develop TB within two years after exposure and most (90%) within the first year.TB

diagnosis in children is challenging as most cases are smear-negative pulmonary TB having paucibacillary disease. Smear positive disease usually occurs in older children. EPTB is also, common. Children with TB usually respond well with treatment and had less medication sideffect compared to adults.

6.7.1 When to suspect TB in children?

Since the clinical features of childhood TB are rather nonspecific, diagnosis is neither straightforward nor easy. Any child with any one of the following presentations should be investigated for TB:

- Persistent fever of two weeks or more with or without cough
- Persistent cough of two weeks or more with or without fever
- Loss of appetite and/or weight loss
- Haemoptysis, chest pain or shortness of breath
- A positive family history of contact with a sputum positive/contagious TB case
- Significant cervical lymph node enlargement
- Acquired deformity of the spine, especially kyphosis/gibbus
- Pain and/or swelling of joint(s), which cannot be explained clinically by any other specific disease entity
- Clinical features suspicious of tuberculous meningitis

6.7.2 Careful history includes

- History of contact with contagious pulmonary TB, sputum smear sensitivity result of index case (if known).
- Nonspecific symptoms suggestive of TB: more than two weeks of low grade fever with persistent cough unresponsive to antibiotics, loss of weight/failure to thrive (for the last three months) and lethargy. Other symptoms include haemoptysis, chest pain and shortness of breath.
- Local symptoms of affected specific site such as joint swelling, spine deformity and meningitis.

6.7.3 Examination

- General: growth assessment, fever, tachypnoea significant cervical lymphadenopathy.
- Local examination depends on the affected site:

_ Acquired deformity of the spine, especially kyphosis/gibbus.

_ Joint pain and/or swelling which cannot be explained clinically by other specific disease entity.

_ Meningeal signs.

6.7.4 Diagnostic workup

Diagnostic work-up for children is similar to adults, however additional tests such as TST or IGRA, and procedures should be considered. Gastric aspirate is used to diagnose TB for those who cannot give a sputum specimen, or in older children who have non-productive or absent cough. The best specimen for culture from children with suspected pulmonary TB is the early morning gastric aspirate obtained in the hospital by using a nasogastric. Three early morning samples for AFB smear and culture) collected through a nasogastric tube (sensitive 50 to 70%). One gastric aspirate also to be send for NAAT (GeneXpert) and culture. A negative TB culture never excludes a diagnosis of TB disease. (See Annex 6.13 at the end of this chapter: A guide to the gastric aspirate procedure). The following consideration should be taken before gastric aspirate procedure:

It has to be performed before the child see, smell or eat food.

Regarding sputum or induced sputum culture, note that sputum can be induced in children older than five years of age by administration of nebulized hypertonic saline. Collect two to three specimens on consecutive days. This technique should be done with appropriate infection control precautions. Samples should be sent for AFB smear, NAAT (GeneXpert) and TB culture as per the diagnostic algorithm in **Chapter 5**. For EPTB, the following specimen should be collected according to the affected site biopsy specimens of lymph node and other tissues. The specimen should be sent for histopathology, AFB microscopy, NAAT (GeneXpert), TB culture and bacterial cultures. Basic investigations that should be performed include complete blood count (CBC), LFT, ESR and HIV testing.

CXR findings can be non-specific in children, the following are features suggestive of childhood pulmonary TB:

- Primary pulmonary complex with a sub-pleural parenchymal focus,
- Hilar/carinal/mediastinal lymphadenopathy,
- Atelectasis,
- Focal hyperinflation,
- Non-resolving pneumonia,
- Pleural effusion,
- Miliary TB,
- Pericardial effusion that cannot be explained otherwise,
- Rarely cavitary lung lesion which are usually seen in immune compromised patients.

6.7.5 Management of the newborn of active TB disease mother

- New-born of a mother with smear positive pulmonary TB at delivery is at high risk of infection/disease.
- If a pregnant woman has been on ATT for at least four weeks before delivery and smear-negative; it is low risk that her baby will become infected.
- Always examine the placenta for evidence of tubercles as their presence may implicate vertical transmission of TB.

Table 12. Management of new-born born to mother with active TB

Maternal TB	New-born management
Mother has AFB smear positive TB disease	• Mother is treated aggressively with ATT. Can give expressed breast milk. • Isolation is recommended (smear-negative, clinical improvement and at least 2 weeks on ATT); • Examine the placenta carefully for evidence of TB, send placenta for histopathology; • Examine the baby for evidence of congenital TB (pallor, icterus, hepatosplenomegaly, feeding problems, fever, low birth weight, respiratory distress and seizure etc.); • If suspected congenital TB send for the baby: CBC, ESR, LFT and CXR, CSF (analysis, AFB smear, PCR, routine and TB culture) gastric aspirate for AFB for 3 days. • If the baby has evidence of congenital TB, start on H+R+Z+amikacin or ethambutol for 2 months the HR for 6–12 months depend on the disease; • If congenital TB is excluded start the baby on INH Continue INH for 3 months on monthly follow-up evaluation. At 3-month ages, do Mantoux test, CBC, ESR, CXR, and Mantoux test is positive, but there is no evidence of TB disease, treat as LTBI with daily INH for 6 months. If Mantoux test is negative and the mother has become AFB negative (non-contagious), INH is discontinued; • Delay BCG vaccine till 2 weeks after completion of TB prophylaxis or treatment.

Mother has AFB negative smear TB disease/ is on ATT for more than 2 weeks	• Mother: ATT to be continued; • Continue breast feeding, or give expressed breast milk; • Start the baby on INH and delay BCG vaccine till 2 weeks after completion of TB prophylaxis or treatment; • Continue INH for 3 months if congenital TB is excluded on monthly follow-up evaluation. At 3 months old, do TST (and tests for TB disease if clinically indicated). If TST test is positive, but there is no evidence of TB disease, treat as LTBI with daily INH for 6 months. If TST is negative INH is discontinued and monthly follow-up is arranged.

6.8 BCG vaccination

- BCG offers 60–80% protection against severe types of TB such as miliary TB and TB meningitis. It is contraindicated for suspected immunodeficiency conditions (congenital immunodeficiency, infant born to mother with HIV or TB infection at birth) until they are ruled out.
- BCG vaccination should then be deferred for two weeks following the neonate's complete TB prophylaxis/treatment as anti-TB medication can affect the vaccine strain.
- Adverse events related to BCG vaccination are rare. They may be local or systemic.

- Local complications include non-healing ulcer, abscess formation at the BCG site, enlargement of ipsilateral lymph nodes with or without abscess formation (BCG adenitis).

- Systemic complications, such as disseminated BCG-osis (to the lung, liver, spleen, bone or skin), usually occurring in immunocompromised patients.

6.8.1 Natural course/types of BCG adenitis

Two types of BCG adenitis are recognized in its natural course:

1- Non-suppurative (simple) BCG adenitis occurs in the beginning and generally resolves spontaneously within a few weeks to months. In some cases, it may progress to suppurative form.

2- Suppurative BCG adenitis: nodes become fluctuant with oedema and erythema of the overlying skin, followed by spontaneous discharge and sinus formation. Healing eventually takes place with closure of the sinus, but the whole process may take several months; it is unpleasant for the parents and requires meticulous wound care. The resultant scar may have aesthetic implications. The role of secondary infection by pyogenic bacteria in suppuration is not clear.

6.8.2 Diagnosis of BCG adenitis

Diagnosis of this condition is essentially clinical.

- Isolated left axillary (or supraclavicular/cervical) lymph node enlargement,
- History of BCG vaccination on same side,
- Absence of fever and other constitutional symptoms,
- CXR, Mantoux test and CBC are not helpful.

6.8.3 Treatment of suppurative BCG adenitis

- Medical: results from the controlled trials have indicated that antibiotics including ATT neither reduce the risk of suppuration nor shorten the duration of healing. Hence there is no role of medical therapy.
- Needle aspiration: although it is one of the options, we do not recommend it as a common practice because of risk of sinus formation.
- Surgical excision: indicated in cases with
- multiloculated or matted lymph nodes,
- suppurative nodes which have already drained with sinus formation.
- Surgical excision is curative but exposes the patient to the risk of general anaesthesia. There is no indication to give ATT after surgical excision.

6.8.4 Absent BCG scar

This is common. If a HCW has clearly documented on the vaccination card that the child received BCG vaccine, then there is no need for revaccination.

- For children ≤ 5 years of age brought without the BCG scar and without proper documentation of a BCG scar earlier, revaccination can be done without performing a TST.
- For children (5–10 years old), revaccination is not routinely recommended. If the TST is negative (< 10 mm) revaccination can be performed.

6.9 Treatment of TB disease

- The child has symptoms/positive gastric or sputum smear with CXR suggest of TB finding.

Table 13. Anti-tubercular drug doses in paediatric age group

Drug	Dose (mg/kg/day)	Maximum dose	Adverse reactions
Isoniazid (H)**	10 mg/kg (rang 10–15 mg/kg)	300 mg/day	Mild of AST/ALT, peripheralneuritis, hypersensitivity and concomitant use of rifampicin increases the incidence of hepatotoxicity.
Rifampicin (R)	15 mg/kg (range 10–20 mg/kg)	600 mg/day	Orange discolouration of urine, contact lenses or secretions, vomiting, hepatitis, influenza like reaction, thrombocytopenia; pruritus and oral contraceptives may be ineffective.
Pyrazinamide (Z)	35 mg/kg (range 30–40 mg/kg)	2 g	Hepatotoxicity, gastrointestinal (GI) upset, hyperuricemia, arthralgia.
Ethambutol (E)	20 mg/kg (range 15–25 mg/kg)	2.5 g	Optic neuritis (usually reversible), decreased red-green colour discrimination, GI tract disturbances, hypersensitivity.

**Pyridoxine should be given 12 hours apart from the ATT

Table 14: Recommended treatment regimens for childhood TB

TB disease category	Intensive phase	Continuation phase
All forms of TB except TB meningitis, bone and joint TB (osteoarticular TB)	2 * RHZE	4 RH
Joint TB	2 RHZE	7–12 RH
TB meningitis and bone	2 RHZE	12 RH
Drug resistant TB, TB in HIV patients or TB in immunocompromised patients, congenital TB	Refer to a paediatric infectious disease specialist	

*Numeral refers to number of months of the regimen H= isoniazid R= rifampicin Z= pyrazinamide E= ethambutol.

*In patients with cavitary lesions on initial CXR or positive sputum cultures after two months of treatment, the minimum duration of therapy should be nine months (paediatric infectious diseases consultation is indicated).

Note: Treatment is the same for HIV-infected and HIV-uninfected children

6.9.1 Steroid indication

Addition of oral steroids to ATT is recommended in:

- TB meningitis,
- Genitourinary TB with ureteric obstruction,
- Laryngeal TB with life-threatening airway obstruction (ENT (ear nose and throat) physician's opinion should also be sought),
- Spinal TB with cord compression (neuro surgeon's opinion should also be sought),
- HIV patient who has developed immune reconstitution inflammatory syndrome on anti-TB medication. Prednisolone 2 mg/kg daily (increased up to 4 mg/kg in the case of the most seriously ill children) maximum dosage of 60 mg/day) for 4 weeks. The dose should then be tapered over 2 weeks,
- RIF increases metabolism of steroids through liver enzyme induction and it can precipitate hypoadrenalism (increased metabolism of adrenocortical hormones) which necessitates addition of intravenous hydrocortisone.

6.9.2 Non-tuberculous mycobacterial infection (NTM)

NTM and AFB are widespread in the environment that exist in soil, food and water. Infections with this group of organisms are being identified with increasing frequency. Unlike MTB these organisms are rarely transmitted by human-to-human contact. They usually present as insidious. The most common site of clinically significant NTM infection in children is the superficial nodes in the head and neck. Most cases occur in children between 1 and 5 years. They usually present as insidious, painless unilateral lymphadenopathy with spontaneous sinus formation in less than 6% cases. Many of these organisms are resistant to common antibiotics and anti-tuberculous drugs. Treatment of NTM lymphadenitis by complete surgical excision has been the treatment of choice for years with a successful cure rate of over 90%. If the affected node is not amenable to surgical resection then treatment such as clarithromycin, RIF or ethambutol is recommended.

6.10 Treatment in special circumstances in children

6.10.1 TB in HIV patients:

Without preventive TB treatment, 40–50% of untreated HIV-positive infants and 15% of untreated HIV-positive older children will present with symptoms of TB disease within one or two years of becoming infected with TB. In infants, the time between TB infection and TB disease may be as little as six to eight weeks

- Treatment of TB in HIV-positive patients follows the same regimen and duration as HIV-uninfected children. It requires infectious disease expertise in the management of both HIV and TB. All children with TB/HIV should receive anti-TB, anti-retroviral medication and nutritional support as needed. ART improves outcomes for HIV-infected children treated for TB.
- All children with active TB should begin receiving ART as soon as possible, no more than 8 weeks from the start of TB treatment, regardless of their CD4 count and clinical stage (strong recommendation, low-quality evidence).
- An exception is HIV patients with TB meningitis, in whom ART should be initiated ≥ 8 weeks of anti-TB.
- Co-trimoxazole preventive therapy to all HIV-positive with TB.
- Pyridoxine supplement required.

6.10.2 Antiretroviral therapy during TB treatment

One concern is the interaction of rifampicin with certain antiretroviral (some protease inhibitors (PIs) and nonnucleoside reverse transcriptase inhibitors [NRTIs]). Rifabutin, which has fewer problematic drug interactions, may be used as an alternative to RIF for HIV-infected patients.

- Children over three years should use efavirenz (EFV), as it has less significant drug interaction with RIF and dose adjustment is not required.
- If available, rifabutin, should be used instead of RIF to reduce drug interactions.
- ART-naive children under three years of age can be started on nevirapine; maximum recommended dose (200 mg/3 mm twice daily).

6.10.3 Immune reconstitution inflammatory syndrome

Temporary clinical worsening symptoms (fever, increased size of lymph nodes and tuberculomas) and worsening of pulmonary infiltrate, signs or radiological manifestations, sometimes occurs after starting anti-TB. Treatment with steroid as mention above.

Therefore, when treating TB and giving concurrent ART, the ART regimen may require adjustment.

ART options with rifampicin are limited and are based on the various scenarios as indicated.

6.10.4 Case fatality

The case fatality of TB/HIV patients one year after starting TB treatment is about 20%. This case fatality is greater than that in HIV-negative TB patients. The excess deaths in TB/HIV patients during and after treatment are partly due to TB itself and partly due to other HIV-related problems.

6.11 Management of side-effects of first-line anti-TB drugs

6.11.1 Hepatotoxicity

- All anti-TB drugs may cause hepatotoxicity. Pyrazinamide is the most hepatotoxic and INH the second.
- All anti-TB drugs should be stopped if AST or ALT or bilirubin more than three times with symptoms or over five times in the absence of symptoms.
- Reintroduce the drugs one by one and stopping the last drug reintroduced if symptoms recur or liver tests become abnormal. Some authors recommend starting with RIF and ethambutol and reintroduce INH three to seven days later. If biochemical abnormalities have not recurred, do not introduce pyrazinamide as it is most likely the causative agent.

6.11.2 INH-associated neuropathy

If neuropathy develops, administer pyridoxine orally:

- In children less than 12 years: 20 to 40 mg/day in two divided doses
- In children over 12 years: 60 to 100 mg/day in two divided doses.

6.11.3 Recurrence of TB after completing ATT

When TB recurs after previous cure, there are two possibilities:

- Reactivation of the persister cells not killed by anti-TB drugs.
- Reinfection (due to re-exposure to another source of the infection).

6.12 References

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6.13 Annex

Paediatric TB: A guide to the gastric aspirate procedure

Introduction:

Gastric aspirate is an important tool for TB diagnosis in children as the children usually swallow sputum.

Step 1:

Explain to the caregiver that the procedure is brief, and only temporarily uncomfortable to the child, and that:

A) The patient should be restricted from eating or drinking after midnight.

B) The procedure should be performed as soon as the child awakens.

Additionally, any family members who could possibly have active TB should wear masks to prevent transmission to health care workers and other patients.)

While young children with active TB are rarely contagious, treatments that elicit cough, such as stomach aspiration, should be performed in a well-constructed facility with sufficient filtration and negative pressure. During the process, health care providers should use N-95 masks. The room should be closed for one hour, or as prescribed by your infection control provider/engineers.

Step 2:

- Measure distance the tube should be inserted into the stomach by measuring the expected distance from nose to stomach. Stretch the tube from the tip of the nose, around the ear and down to the bottom of the xiphoid process. This is the distance the tube should be inserted into the stomach.

Step 3:

- Place nasogastric tube into child's nose – stay away from the septum and aim directly perpendicular to the bed as you advance the tube.

- Look to make sure that the tube is not coiled in the mouth; at this age, children commonly vomit, so be prepared to collect any emesis.

- Once the child has swallowed the tube, quickly pass it down into the stomach. Stop when the tube's pen mark reaches the tip of the nose.

- Very rarely, the tube will pass through the airway instead of the stomach. If the child has any respiratory discomfort or a muted cry. Remove the tube as soon as possible.

- A powerful unaltered cry, gastric contents in the tube, and a forceful gurgling sound auscultated over the stomach when air is put into the tube by syringe indicate successful tube placement.

Step 4:

- Early morning when the child a wake, before he or she eats or drinks aspirate the stomach contents with the syringe.

- Place the gastric aspirates in a special bicarbonate-containing gastric aspirate tube or regular specimen cup.

- If a special bicarbonate tube or cup is not available, the lab must neutralize the stomach acid with bicarbonate within a half hour.

- If less than 5–10 cc of mucous returns, re-position the tube and/or the child in order to look for the pool of mucous.

- If < 5–10 cc of gastric contents have still been aspirated; Prepare to instil water into the tube. Instil 20–30 cc of sterile water into the tube then quickly re-aspirate the contents.

Step 5:

- Put all yield in sterile cup or tube.

- Immediately transport to lab to neutralize.

OR

– Neutralize at bedside. (Bicarbonate for neutralization -2.5 grams $NaHCO_3$ dissolved in 100 cc deionized water. Filter the solution through a 45 mm filter. Use 1.5 cc for each specimen. Lab should monitor and correct the pH).

- Order AFB smear and culture.

- Transport the specimen carefully and promptly to the lab.

Reference:

https://npin.cdc.gov/publication/paediatric-tuberculosis-guide-gastric-aspirate-ga-procedure.

Chapter 7

Treatment of drug resistant TB

7.1 Drug resistant forms of TB

Mono-resistant TB: MTB that is resistant to a single anti-tuberculous agent.

Poly-resistant TB: MTB that is resistant to two or more anti-tuberculous agents (rather than INH and RIF).

MDR-TB: MTB that is resistant to INH and RIF.

7.1.1 Mono-resistant TB

A.INH monoresistance:

If the patient is tolerating pyrazinamide, then to give the following regimen for six months (or four months after culture conversion)

1- RIF

2- Ethambutol

3- Levofloxacin or moxifloxacin

4- Pyrazinamide (the duration of pyrazinamide may be shortened to two months in select circumstances (noncavitary disease, relatively low burden of disease, pyrazinamide toxicity))

If the patient is not tolerating pyrazinamide or pyrazinamide toxicity, then use the following regimen for 9–12 months:

1- RIF

2- Ethambutol

3-Levofloxacin or moxifloxacin

Note: for central nervous system and bone TB, the duration of ATT is minimal of 12 months.

B. RIF monoresistance:

Patient with RIF monoresistance should be managed as MDR-TB. RR is usually rare.

C. Pyrazinamide monoresistance:

Patients with pyrazinamide monoresistance should be treated with INH, RIF (with or without ethambutol) for nine months.

D. Other agents:

resistance to other agent apart from above list is not significant and should be treated with as drug sensitive TB.

7.1.2 Poly-resistant TB

The treatment strategy should consider the following principles:

1- The treatment should contain as many first-line agents as possible.

2- The duration should be individualized to the rapidity of culture conversion to negative and consideration given to a longer duration for patients with extensive disease.

Table 15. Choice of agents in specific poly-resistant TB

Drug resistance	Treatment regimen	Duration
INH and ethambutol	RIF, pyrazinamide and a fluoroquinolone (levofloxacin or moxifloxacin)	6–9 months
INH and pyrazinamide	RIF, pyrazinamide, and a fluoroquinolone (levofloxacin or moxifloxacin)	9–12 months
INH, ethambutol and pyrazinamide	RIF, a fluoroquinolone (levofloxacin or moxifloxacin) and one or two additional oral agents to which the isolate is susceptible (possible additional agents include, linezolid, or clofazimine; use of bedaquiline with a RIF is contraindicated)	9–12 months

7.1.3 MDR-TB

The management of MDR-TB should be referred to an infectious disease service or TB programme.

There are two recommend regimens:

1- Long duration regimen

2- Short duration regimen

A long-term regimen is mandatory in the following situations:

1- Disseminated, meningeal or central nervous system disease.

2- Extrapulmonary disease in HIV patient.

3- Pregnancy.

4- Patient preference for an all-oral regimen.

5- Prior exposure to one or more drugs in the shorter regimen for more than one month (unless susceptibility to these drugs is confirmed).

6- Confirmed resistance or suspected ineffectiveness to a drug in the shortened regimen (except INH resistance).

7- Intolerance to a drug in the shortened regimen, or risk of toxicity due to drug–drug interactions.

8- One or more drugs in the shortened regimen is not available.

LONGER, INDIVIDUALIZED REGIMEN

Intensive phase: number of drugs – The American Thoracic Society (ATS)/Centers for Disease Control and Prevention (CDC)/ European Respiratory Society (ERS)/Infectious Diseases Society of America (IDSA) favours at least five drugs; the WHO favours at least four drugs.

- Intensive phase: duration – The ATS/CDC/ERS/IDSA favours 5 to 7 months following sputum culture conversion; the WHO favours at least 6 months.
- Continuation phase: number of drugs – The ATS/CDC/ERS/IDSA favours four drugs; the WHO favours three drugs.
- Total duration of therapy – The ATS/CDC/ERS/IDSA favours 15 to 21 months beyond culture conversion; the WHO favours 15 to 17 months beyond culture conversion.

Methods of choice MDR-TB drug regimen (minimal five drugs of intensive phase, four for continuation phase)

1- Choose one of fluoroquinolone (levofloxacin or moxifloxacin)

2- Choose both bedaquiline (if available) and linezolid

3- Choose both clofazimine and cycloserine

4- If regimen still not completed, then use of one of these drugs: amikacin, streptomycin

5- If still more agents are needed use the following agents in order

a. Delamanid

b. Pyrazinamide

c. Ethambutol

d. Ethionamide or prothionamide

e. Meropenem and clavulanate

f. Azithromycin and clarithromycin

Regimens should be tailored to the drug susceptibility results when available and to drug side- effects and toxicities.

SHORTER, STANDARDIZED REGIMEN

If the patient is fit for short duration regimen (see above), then management of MDR-TB should proceed as follows:

Intensive phase – Four months (daily) of seven drugs:

1- High-dose INH (15 to 20 mg/kg/day)

2- Ethambutol

3- Pyrazinamide

4- Moxifloxacin

5- Kanamycin (it could be replaced by bedaquiline by expert opinion)

6- Prothionamide

7-Clofazimine

The duration of the intensive phase is extended to six months for patients with positive sputum AFB microscopy and culture performed two months after initiation of therapy.

Continuation phase – five months (daily) of four drugs:

1. Ethambutol
2. Pyrazinamide
3. Moxifloxacin
4. Clofazimine

Patients who do not respond to the shortened regimen or develop intolerance to a component drug should be treated with the longer regimen.

7.2 References

1- WHO treatment guidelines for multidrug- and rifampicin-resistant tuberculosis, 2018 update. Geneva: World Health Organization; 2018. (https://www.who.int/tb/publications/2018/WH0.2018.MDR-TB.Rx.Guidelines.prefinal.text.pdf, accessed 14 January 2019).

2- Rapid Communication: Key changes to treatment of multidrug- and rifampicin-resistant tuberculosis (MDR/RR-TB). Geneva: World Health Organization; 2018. (http://www.who.int/tb/publications/2018/WHO_RapidCommunicationMDRTB.pdf?ua=1, accessed 24 February 2022).

3- Nahid P, Mase SR, Migliori GB, et al. Treatment of drug-resistant tuberculosis. An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline. Am J Respir Crit Care Med. 2019;200:e93.

7.3 MDR-TB treatment in children

7.3.1 INH-resistant TB

RIF, ethambutol, pyrazinamide and levofloxacin for six months for both HIV-positive or negative. It may extend to nine months for cavitary or positive culture after two months.

7.3.2 RR or multidrug resistant (MDR-TB) (second-line drug treatment)

- In MDR/RR-TB patients on longer regimens, all three Group A agents if available and at least one Group B.
- Agent should be included to ensure that treatment starts with at least four TB agents likely to be effective. If only one or two Group A agents are used, both Group B agents are to be included.
- If the regimen cannot be composed with agents from Groups A and B alone, Group C agents are added to complete it.

7.3.3 A standard longer regimens (20 months)

- Intensive phase: eight months ≥ five effective anti-TB (three from group A and two from group B) drugs.
- Maintenance phase: 12 months ≥ four effective anti-TB drugs.

7.3.4 A shorter RR/MDR-TB treatment (9–12 months)

- Intensive phase: four months (five drugs): this is recommended including pyrazinamide and four of second-line anti-TB. May be further strengthened with high-dose INH and/or ethambutol.
- Maintains phase: five months ≥ four effective anti-TB.

7.3.5 MDR-TB short duration to be avoided for

- Exposure to second-line medicines in the shorter MDR-TB regimen for >one month (unless susceptibility to these second-line medicines is confirmed).
- Pregnancy.
- Disseminated CNS TB.
- Any extrapulmonary disease in HIV.

Table 16. Recommended treatment of drug resistant TB

Groups and steps	Medicine
Group A: Include all three medicines	Levofloxacin OR moxifloxacin
	Bedaquiline (currently not available/NA)
	Linezolid
Group B: Add one or both medicines	Clofazimine
	Cycloserine OR terizidone
Group C: Add to complete the regimen and when medicines from Groups A and B cannot be used	Ethambutol
	Delamanid (currently not available/NA)
	Pyrazinamide
	Imipenem–cilastatin OR meropenem
	Amikacin
	Ethionamide OR Prothionamide aminosalicylic acid

1- Delamanid may be used in children above three years of age.

2- Evidence on the safety and effectiveness of bedaquiline use below the age of six years was insufficient.

3- Inadequate evidence on the combination use of bedaquiline and delamanid.

4- Use of linezolid for at least six months was shown to increase effectiveness, although toxicity may limit use. The analysis suggested that using linezolid for the whole duration of treatment would optimize its effect (about 70% of patients).

5- Pyrazinamide is counted as an effective agent only when drug sensitivity test confirm susceptibility.

6- Kanamycin and capreomycin are no longer recommended for use in MDR-TB regimens. These agents showed effectiveness only in regimens without bedaquiline, linezolid, clofazimine or delamanid, and are thus proposed only when other options to compose a regimen are not possible.

Chapter 8

Direct Observation Treatment (DOT)

8.1 DOT

WHO defines DOT as any person observing the patient taking medication in real time. The treatment observer does not need to be a health care worker and could be a friend, a relative or a layperson who works as a treatment supervisor or supporter under supervision of a health care worker. Observed treatment may also be achieved with real time video recording, which is called video observed treatment (VOT).

This ensures that a TB patient takes the right drugs, in the right doses, at the right intervals. DOT is recommended in the initial phase of treatment with FDCs, at least for all bacteriologically confirmed cases, and in the continuation phase of RIF-containing regimens. Patients' and health workers' compliance are key factors in treatment success.

8.1.1 Community DOT

Community based TB activities in general are the activities conducted outside the premises of formal health facilities (e.g. hospitals and clinics) in community based structures (e.g. schools, homes and places of worship). Community health workers and community volunteers carry out community based TB activities.

Community DOT is the process of continuing the TB treatment under DOT for patients with uncomplicated pulmonary TB that do not have any risk factors or comorbidities that require prolonged inpatient admission where the patient will be assessed by a case management team at hospital and assign a community based treatment option.

8.1.2 Video DOT (VOT)

VOT is the use of a videophone or other video/computer equipment to observe the TB patients taking their medications at a remote location from the health care worker.

The following need to be considered for VOT:

- Video picture must be sufficiently clear to discern the shape, colour and size of the pills.
- Viewer must have the ability to visually evaluate the patient's general health in real time.
- Patients receiving VOT must have the capability to use and maintain the equipment;
- Patient must be motivated to take their medications.
- Trial period of health centre based DOT for an initial period before instituting VOT.

8.1.3 Case management team

Case management team is a team that consists of clinical and public health personnel who will discuss the clinical and public health aspects of each patient based on clinical and socioeconomic backgrounds, social constraints, adherence to counselling and appropriate treatment and follow-up to decide on the type of DOT assigned to the patient.

The case management team consists of:

- Treating physician (infectious disease /pulmonologist/TBFP physician).
- Director/In charge of communicable disease Department at Directorate General of Health Services (DGHS).
- TBFP nurse at treating institute.
- Social worker (at hospital).
- FAMCO/Head of Health Centre at the catchment area health centre.
- Governorate Focal Point Pharmacist.

Main responsibilities of the team at the hospital level:

- Carry out detail clinical assessment of patient including all important laboratory investigations and decide type of DOTS category assigned to patient.
- Reporting of case – TB notification by e-notification through tarassud platform to the Department of Communicable Disease at the DGHS in the respective governorate which is simultaneously received by TB and Acute Respiratory Diseases Section at the Department of Communicable Disease at the DGDSC. All information must be filled (See the notification form, Figure 9).
- Maintenance of TB treatment card (See Figure 10).
- Counselling of the patient for isolation.
- Counselling of importance of adherence to treatment (DOTS).
- Discussion of public health aspects of each patient based on clinical and socioeconomic background, social constraints, adherent to counselling and appropriate treatment and follow-up with public health team.
- Regular assessment of progress of patient while on treatment and appropriate investigation to be carried out.

Responsibilities of team at discharge:

- Make decision jointly by clinical and public health team (case management team).
- Discuss the indications for discharge and review criteria of checklist (see Figure 11).
- Decide on the plan of collecting medicine and investigation (Treatment institute or catchment area health centre).
- Assign TBFP at the health centre for follow-up of CB DOT.
- Assign community health staff or other DOT provider based on risk assessment for follow-up of CB DOTS.
- Direct access to the regional focal point to discuss any issues regarding management or follow-up in catchment area.

8.2 DOT delivery options

8.2.1 Health centre based

It is the most preferred method of DOT. For patients who live close to a health facility, the best treatment supporter would be one of the staff in the health facility, if it is convenient to the patient.

8.2.2 Community nurse based

It is the preferred method for those who cannot attend health care facility.

8.2.3 Community support group (volunteers especially trained in CB DOTS)

Community support groups are groups of volunteers who work as links between the community and the health system to promote health. Such volunteers can be trained to be a DOT provider (any person who is willing and is acceptable to the patient, while also easily approachable and answerable to the health system can be a treatment supporter, e.g. a cured TB patient, member of Oman women associations, etc.). These volunteers will be under the supervision of the TBFP at the catchment area health centre.

8.2.4 Public health inspector

A public health inspector can participate in community DOT including patients who are difficult to reach or migrants.

8.2.5 Family member based

A highly committed and cooperative family member who can be trained in DOT under the supervision of the TBFP at the catchment area health centre.

8.2.5 VOT

VOT is the use of a videophone or other video/computer equipment to observe the TB patients taking their medications at a remote location from the health care worker.

8.2.6 DOT settings

- Health centres in the catchment area.
- Home.
- Workplaces.
- Schools/colleges/university clinics.
- Private institutions (upon approval of public-private mix policy and certifying the participating institute as a DOT provider).

8.3 DOT protocol

- Once a patient is notified as pulmonary TB, the case is admitted in the inpatient facility (regional or tertiary hospital) and the initial phase of treatment is introduced.
- Case management team, which consist of clinical team, and public health team will assess the clinical and socioeconomic background, social constraints, adherence to counselling and appropriate treatment and follow-up, etc. for the patient and assign him/her for the appropriate type of DOT.

8.3.1 Consider discharging from hospital patients:

- Who do not have a continuing clinical or public health need for admission with pulmonary TB.
- who are being confirmed as RR-negative on NAAT or culture or do not have risk factors for multidrug resistance.

8.3.2 The patient should meet the following before discharge:

- At least 2 weeks of adequate treatment (under DOT) have being completed.
- The patient is showing tolerance to the prescribed treatment.
- There is resolution of cough and clinical improvement on treatment; for example, remaining afebrile for a week.
- There is agreement to adhere to treatment.
- There are not immunocompromised people, such as transplant recipients, people with HIV and those on anti-tumour necrosis factor alpha or other biologics, in the same accommodation*.
- The patient's initial smear grade was two or less.
- There is no extensive pulmonary involvement, including cavitation.
- There is no laryngeal TB.
- Contact screening and people at risk such as children under five years are already placed on preventive therapy.
- Adequate home settings in terms of proper isolation room and ventilation should be ensured.
- Patient should be advised not to travel during the first weeks of treatment (until having sputum microscopy conversion).
- *If the patient is transferred to areas, where they may come into contact with HIV-positive or immunocompromised patients, three negative sputum microscopy smears taken on separate occasions over a minimum of 14 days must be obtained in addition to above.

8.3.3 Public health team notification

Clinical team MUST notify the Department of Communicable Disease at the DGHS about the discharge date of the patient in order for the arrangement to be set for the chosen type of DOT.

- All cases should undergo proper counselling, which should be documented, that is performed by the designated staff nurse who has undergone training for the same in the hospital.

The counselling will be on the following aspects:

- General information on the transmission of the disease.
- Information on the adverse effects of the medications.
- General infection control measures (mainly isolation, use of masks and limited visitors).

- Encouragement to maintain a good lifestyle (proper diet and exercise).
- Defaulter retrieval policy and other crucial information that is to be imparted depending on the characteristics of individual cases.
- The process has to be recorded and the counselling checklist (see figure 11) will be prepared for documentation for each patient. Educational material for patients and caregivers will be made for this use.
- A consenting process will be introduced for the index case and a family member who will be responsible for the case. A consent form should be signed by the patient and counselling nurse (see figure 12).
- For non-Omani TB patients enrolled in community DOT, a consent form should be signed by the sponsor and the patient prior to discharge.
- The patient and family will be introduced to the TBFP of the community team/nurse according to the chosen DOT method and communication established.
- TBFP at hospital should send all the patients documents to the health centre at patient's catchment area.
- Case will be referred to the health centre at the patient's catchment area with all necessary referral and documents that has to be maintained in the health centre.
- The TBFP at the health centre will receive the patient and introduce him or her to community staff/community supporter volunteer with all the required documents that have to be used for recording during the staff visits based on treatment plan.
- The community nurse should follow symptom, signs and side-effects of the patient started on community DOTS and register any findings on follow-up checklist.
- The TBFP physician/treating physician should perform treatment outcome evaluations in their clinical unit at regular time intervals (e.g. quarterly).
- The DOT provider must inform TBFP at the patient's catchment area health centre for missed doses or adverse drug reactions.
- The regional TB team will inform the national TBFP in case of patient defaulting or other constraints.
- The retrieval process will be followed according to the defaulter retrieval policy.

8.3.4 Patient's criteria for continuing in-hospital treatment

TB patients should continue to receive in-hospital treatment in the following circumstances:

- Condition is critical and not suitable for outpatient treatment;
- Comorbidities require inpatient treatment;
- Inability to attend daily DOT treatment;
- Severe adverse drug reactions require inpatient monitoring.
- Substance or alcohol abuse which increase the risk of defaulting treatment under ambulatory DOT.
- Poor family support.

8.4 Roles and responsibilities

8.4.1 TB clinical team

The TB clinical team which consist of treating physician, infectious disease specialist, pulmonologist, TBFP physician, TBFP nurse and preferably social worker who are responsible for clinical management, to assess severity of the case and need for extended hospitalization and the readiness for community DOT.

8.4.2 DOT providers.

DOT provider is a person who works as a treatment supervisor or supporter, which includes HCW such as community nurse/public health inspector, community supporter (volunteer), highly committed family member. The following roles and responsibilities under the supervision of the TBFP at the patient's catchment area health centre are expected.

- Provide TB medication through DOT and documenting swallowing the medicine in the treatment card.
- Report promptly to the TBFP at the health centre any individuals who are missing doses of anti-TB medication, and any adherence issues.
- Report promptly to the TBFP at the health centre any individuals who show signs or symptoms of side-effects to the anti-TB medication.
- Maintain patient confidentially with all encounters.
- Participate in the TB education within the community.
- Document and update the contact list.
- submitted recorded sheet to the TBFP of the health centre weekly.
- Follow the same process for both the phases of treatment.

8.4.3 TBFP of the health centre

- The TBFP will be responsible for collecting the weekly-recorded forms
- These forms should be forwarded to regional TBFP at the governorates on a monthly basis unless otherwise informed.

8.4.4 Governorate TBFP

The governorate TBFP shall:

- Update the information of the individual patients in the records and maintain one soft copy and hard copy at the hospital.
- Liaise with the TBFP at the health centre and overviewing the patient placed on different DOT.
- Ensure arrangement of anti-TB medication with TBFP at health centre and regional pharmacist to ensure adequate supply at health centre for the patient started on community DOT.
- Attend monthly review meetings with the epidemiologist regarding each case on DOTS treatment. The meeting will be recorded and documented.

8.4.5 Community support group DOT provider

Under supervision of the TBFP at the health centre, the community supporter group DOT provider has the following responsibilities:

- Provide TB medication through DOT and documenting swallowing the medicine in the treatment card.
- Report promptly to the TBFP at the health centre any individuals who are missing doses of anti-TB medication, and any adherence issues.
- Report promptly to the TBFP at the health centre any individuals who show signs or symptoms of side-effects to the anti-TB medication.
- Maintain patient confidentially with all encounters.
- Participate in TB education within the community.
- Document and update the contact list.
- Requirement for the community support group.
- Education: high school diploma at a minimum.
- Knowledge: become familiar with medical terminology.
- Skills: to read, write and speak Arabic, English and preferably other language, e.g. Urdu.
- Have good communication skills.

They should be able to:

- Conduct interview related to supporting the TB treatment with the patient and his/her contacts.
- Work effectively with people from various economic, cultural and social backgrounds;
- Communicate issues promptly and accurately such as adverse drug reactions and non-adherence.
- Assist patients in accepting the required medical care and treatment.
- Work with special needs of diverse populations such as immigrants.

8.5 Procedures

Registration and treatment initiation:

- Once diagnosed patient should be notified electronically by e-notification through tarassud platform.
- All patient information, contact tracing, and LTBI results should be entered in the e-notification system
- Treatment card should be filled with date and initials of DOT provider on daily basis.
- The patient and TBFP should sign community DOT TB treatment consent form.
- A copy of the following documents should be sent along with the patient upon referring the patient to the health centre at the patient's catchment (Discharge summary, TB notification form, Treatment card, Community DOT consent form and DOT follow-up checklist).
- Anti-TB medication treatment kit labelled with patient details should be sent to catchment area health centre upon discharge.

8.6 Follow-up

8.6.1 Monitoring of TB patients during the treatment

Monitoring of TB patients on treatment include:

- Bacteriological monitoring for pulmonary TB cases by examination of sputum smears at 2, 3, 5 and 6 months of treatment.
- Clinical monitoring by symptomatic improvement and weight gain including patients who are clinically diagnosed pulmonary TB.
- Monitoring the drug intake during intensive phase and drug collection during the continuation phase by reviewing the treatment cards.
- Patient weight should be monitored each month and dosage should be adjusted if weight changes.
- Adverse events: should be monitored and recorded for all medications given, along with bacteriological response.

Requirements for DOT implementation:

- Patient treatment support team;
- Counselling training for HCW involved in DOT implementation;
- Primary health care staff training workshop for management of TB and adverse effects;
- Training for HCW for implementation of the DOT guideline including a mechanism of follow-up for patient on DOT;
- Strict regulation for retained expatriate.

Figure 9. TB notification form

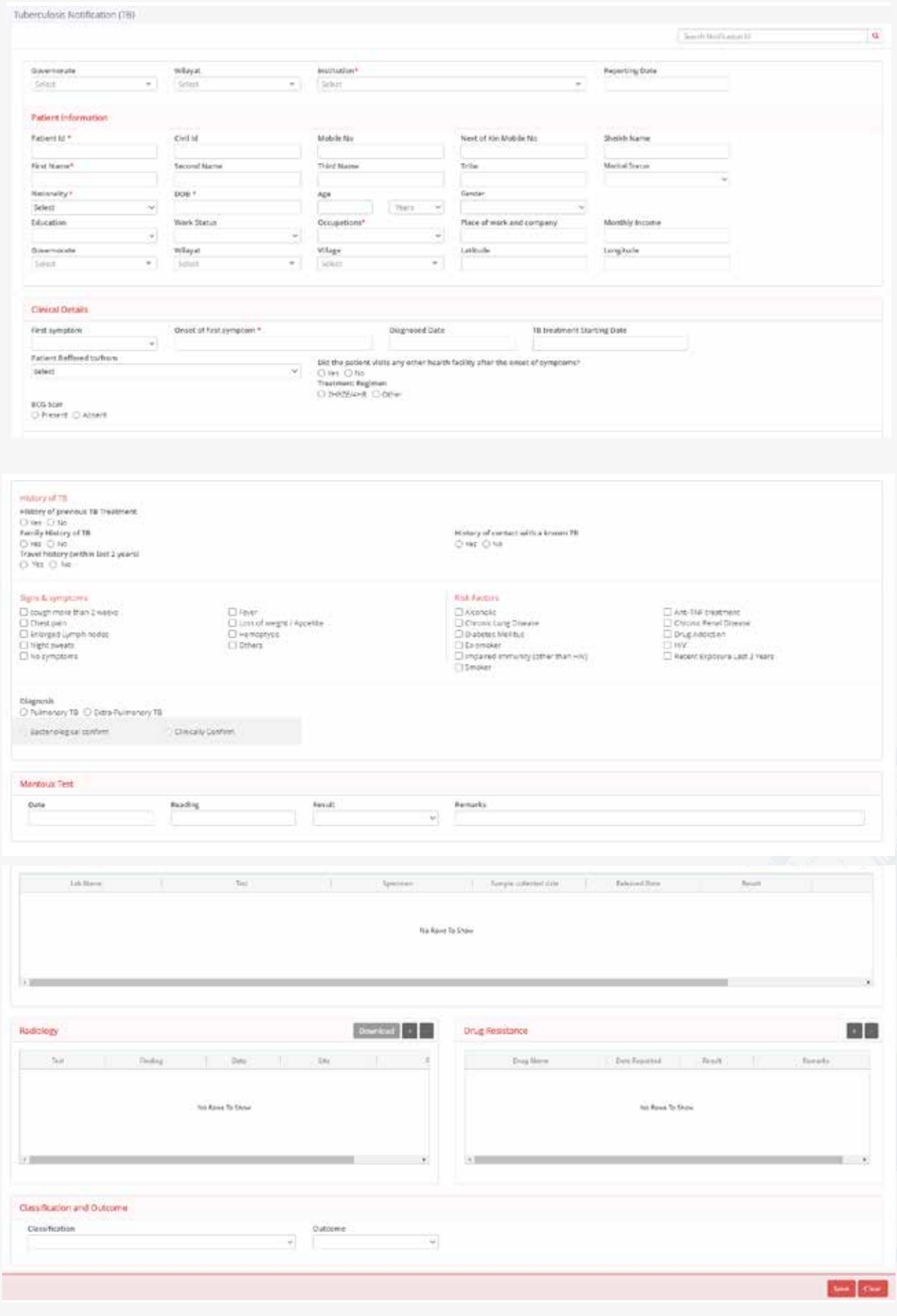


Figure 10. TB TREATMENT CARD

معاً للقضاء على السل

Sultanate of Oman
Ministry of Health
Directorate General for Disease Surveillance and Control
Department of Communicable Disease
TB & Acute Respiratory Diseases Section

مرض السل يمكن الوقاية
منه وعلاجه والشفاء منه

TUBERCULOSIS TREATMENT CARD

PATIENT INFORMATION

NAME		SEX	
INDEX NO		AGE	
NATIONALITY		WEIGHT	
REGION		ADDRESS	
TREATMENT INSTITUTION			
TRANSFER TO			
DATE OF DIAGNOSIS			
DATE OF DOTS START			

DISEASE SITE

PULM	Bactorolo-gical Confirmed	MTB/RIF	
		SMEAR POSITIVE	
		SMEAR NEGATIVE	
	CLINICALLY DIAGNOSED		
EXTRA-PULMONARY, SPECIFY ( )			

TYPE OF PATIENT

NEW	
RELAPSE	
PREVIOUSLY TREATED	

TB/HIV

HIV TEST	
DONE	
NOT DONE	

SPUTUM EXAMINATION / SENSITIVITY / WEIGHT (KG)

MONTH	DATE	LAB NO.	RESULT	CULTURE	S	I	R	E	Z	WEIGHT (KG)
0										
2										
3										
5										
6										
END OF TREATMENT										

I. INITIAL PHASE

2HRZE	INH 300 MG	INH 150 MG	RIF 300 MG	RIF 150 MG	PZA 500 MG	EMB 400 MG	STREP 1 G

DAY / MONTH	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

II. CONTINUATION PHASE

4 RH	5 RH	6 RH

DAY / MONTH	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

SIDE EFFECTS: ☐ NAUSEA ☐ JAUNDICE ☐ FATIGUE ☐ BLURRED VISION ☐ LOSS OF APPETITE ☐ VOMITING ☐ HEADACHE ☐ RASH ☐ BODY ACHES ☐ LOSS OF SENSATION ☐ OTHERS

TREATMENT OUTCOME: DATE ☐ CURED ☐ TREATMENT COMPLETED ☐ DIED ☐ TREATMENT FAILURE ☐ DEFAULTER ☐ NOT EVALUATED

REMARKS

CDOTS Provider		Contact No	
Sponser (Expatriate)		Contact No	
Name and Signature of staff filling card			

Figure 11. Checklist for discharging TB patient

Directorate General for Disease Surveillance and Control
Department of Communicable Diseases
Tuberculosis & Acute Respiratory Diseases Section

Checklist for discharging TB patient from Hospital

The patient should achieve the following before discharge:

- □ At least 2 weeks of adequate treatment (under DOT) have been completed.
- □ The patient is showing tolerance to the prescribed treatment.
- □ There is resolution of cough.
- □ There is definite clinical improvement on treatment for example remaining afebrile for a week.
- □ There is agreement to adhere to treatment.
- □ There are no immunocompromised people such as transplant receipts, people with HIV and those on antitumor necrosis factor alpha or other biologics in the same accommodation*
- □ *If patients are transferring to area where they may come into contact with HIV positive or immunocompromised patient, they must have at least three negative sputum microscopy smears taken on separate occasion over a minimum 14 days in addition to above.
- □ The patient's initial smear grade was not high; for example, 2 or less.
- □ There is no extensive pulmonary involvement, including cavitation.
- □ There is no laryngeal TB.
- □ Contact screening and people at risk such as a children < 5 years are already placed on preventive therapy.
- □ The patient has a negative rifampicin resistance on Nucleic Acid Amplification Test (NAAT) or culture.

Figure 11. continued

Directorate General for Disease Surveillance and Control
Department of Communicable Disease
Tuberculosis & Acute Respiratory Diseases Section

- □ Adequate home setting in terms of room for isolation and ventilation.
- □ Patient should advise not to travel during the first weeks of treatment (until having bacteriological conversion).
- □ Public health team has been informed about discharge plan.
- □ The appropriate type of DOT has been decided as per criteria mentioned in the text.
- □ Counselling has been done by the designated staff on the following aspects :
  - o General information on the transmission of the disease.
  - o Information on the adverse effects of the disease.
  - o General infection control measures.
  - o Proper diet and exercise.
- □ The patient doesn't have contraindication for outpatient treatment.
- □ Critical condition which is not suitable for outpatient treatment:
  - o Having co-morbidities that require inpatient treatment.
  - o Unable to attend daily DOT treatment.
  - o Having severe adverse drug reactions require in patient monitoring.
  - o Having complications of the disease.
  - o Substance or alcohol abuse which increase the risk of defaulting treatment under ambulatory DOT.
  - o Poor family support.

Figure 12. Sponsor consent visa for conditional release

Director General for Disease Surveillance & Control

المديرية العامة لمراقبة ومكافحة الأمراض

Sultanate of Oman Ministry of Health

Consent of Sponsor undertaking responsibility of employee for Visa Medical Conditional Release

تعهد كفيل بتحمل مسؤولية الحالة الصحية بعد فحص اللياقة البدنية لموظف

Employee Name:
……
Civil ID: ……
Nationality: ……
Passport Number: ……
Expiry Date: / /

I (Name)……
being the sponsor of above employee / as representative of the (Name of Organization)
……
After understanding the policies and procedures of MOH regarding medical fitness of employee& conditional fitness certify and accept the following:

- I undertake to follow the directions of MOH in providing proper treatment and sufficient care to the employee.
- I will be responsible for ensuring that the employee adheres to the instructions given for the treatment of the condition from MOH institutions or such other institutions as stipulated by law.
- I undertake to cooperate with authorities who will be verifying or inspecting for checking adherence to steps as directed by MOH.
- I undertake to cooperate with concerned authorities for legal action and repatriation in case employee is non -compliant to treatment.
- I undertake to provide and support adequate financial resources as per labor laws in Sultanate of Oman for the employee treatment and support.
- I understand that if I don't comply with the provisions of this undertaking I am acting against Public Health Law.

Name of Sponsor:
Civil ID:
Telephone Number:
Signature:
Date: / /
Copy of ID of sponsor to be attached

إسم الموظف:
.....
رقم بطاقة المقيم: .....
الجنسية : .....
رقم جواز السفر: .....
تاريخ الانتهاء: / /

أتعهد أنا /.....
كوني كفيلا للموظف المذكور أعلاه/ أو ممثلا عن المؤسسة التابع لها الموظف (اسم المؤسسة)
.....
أتعهد بالآتي فيما يخص صحة الموظف المذكور أعلاه، ووفقا لسياسات وإجراءات وزارة الصحة فيما يتعلق باللياقة البدنية:

- اتباع توجيهات وزارة الصحة في توفير العلاج المناسب والرعاية اللازمة للموظف المذكور
- أكون مسؤولاً عن ضمان التزام الموظف المذكور بالتعليمات المقدمة إليه من مؤسسات وزارة الصحة أو غير ذلك من المؤسسات التي ينص عليها القانون.
- أتعهد بالتعاون مع السلطات المختصة عن قيامها بالتحقق من مدى الالتزام بالخطوات المتبعة للعلاج والرعاية الصحية والوقائية وفقا لتوجيهات وزارة الصحة.
- أتعهد بالتعاون مع السلطات المعنية لاتخاذ الإجراءات القانونية وإعادة الموظف المذكور إلى وطنه في حالة عدم امتثاله للعلاج.
- أتعهد بتقديم المساعدة والموارد المالية لعلاج ودعم الموظف المذكور وفقًا لقوانين العمل في سلطنة عمان.
- إذا لم ألتزم بهذا التعهد أكون قد خالفت قانون الصحة العامة

إسم الكفيل :
الرقم المدني :
رقم الهاتف :
التوقيع :
التاريخ : / /
الرجاء إرفاق صورة من بطاقة الكفيل

Chapter 9

TB prevention

9.1 BCG vaccination

BCG is a live attenuated vaccine made from Mycobacterium bovis. It protects young children against developing complications of primary infection, such as TB meningitis and miliary TB. However, it has no impact on the transmission of TB in the community as it does not provide protection against development of post primary TB. In Oman, BCG vaccine given for all new-borns at birth.

9.2 Contact investigations

The investigation of people exposed to patients with infectious TB is one of the priorities of the TB control programme. Close contacts of people with active pulmonary TB are at increased risk of acquiring infection, developing active disease and spreading it. Timely identification and adequate treatment of those with active pulmonary TB reduces the risk of exposure of community members. As a result, the incidence of TB will be diminished, as the prevalence of infection with MTB declines over time.

The objectives of contact investigation are as follows:

- To reduce morbidity and fatality due to TB by early identification and adequate treatment of further cases of active TB among contacts of index cases with active TB.
- To arrest further transmission by early detection of possible (secondary) cases.
- To prevent future cases of TB in the population by detection and preventive therapy of infected high-risk contacts (children, immune compromised individuals) of index cases with active TB

The aims of contact tracing of a single index patient of drug-susceptible TB are:

- To identify contacts with active TB disease and initiate treatment early
- To identify those at high risk of developing active TB/severe outcomes, i.e. young children and immune compromised persons.
- To prevent the development of TB by providing TPT
- To provide individual/family education on infection control and counselling.

For close contact of MDR/XDR-TB index patient the aim is:

- To identify all close household contacts of MDR/XDR-TB, without active disease for monitoring for two years after disease onset in index patient
- To provide consultation for treatment initiation as per national guideline contact tracing policy was introduced in 1995 and included the following groups
- Close contact of TB disease patients any type

- Children under five years who are household contacts of people with bacteriologically confirmed pulmonary TB
- Newly diagnosed HIV and those who return to the programme after defaulter.
- Health care workers as part of pre-employment screening policy
- Migrants from high endemic countries as part of medical fitness screening for visa application
- Other risk groups to be enrolled in programmatic screening are: renal dialysis, patient on tumour necrosis factor treatment and pre-transplant recipient.

9.3 Types of contacts

Close contacts

- Household contacts – a person who shared the same enclosed living space for one or more nights or for frequent or extended periods during the day with the index case during the 3 months before commencement of the current treatment episode.
- Non-household contact – a person who is not in the household but shared an enclosed space, such as a social gathering place, workplace or facility, for extended periods during the day with the index case during the three months before commencement of the current treatment episode.

Casual contact

A contact who does not belong to above categories. Close contacts of all TB patients (adults and children above five years) irrespective of sputum findings should be screened for symptoms of TB. Those who have symptoms suggestive of TB should be investigated with sputum smears, CXR or other relevant investigation (e.g. in EPTB) irrespective of the duration of the symptoms.

- All children under the age of five years should be screened for symptoms and undergo thorough examination and samples to be collected for TB diagnosis if any symptoms found. Chest X-ray should be done for all for detailed management.

9.4 Management of LTBI

LTBI is defined as a state of persistent immune response to stimulation by MTB antigens without evidence of clinically manifested active TB. As there is no “gold standard” test for LTBI, the global burden is not known with certainty; however, up to one third of the world’s population is estimated to be infected with MTB. The vast majority of infected persons have no signs or symptoms of TB disease and are not infectious, but they are

at risk for developing active TB disease and becoming infectious with the lifetime risk of developing the disease is 5–10 % (10% every year in HIV patients).

The management of LTBI requires a comprehensive package of interventions that includes: identifying and testing those individuals who should be tested, delivering effective and safe treatment in a way that the majority of those starting a treatment regimen will complete it with no or minimal risk of adverse events, and ensuring M&E of the process.

9.5 Investigation of TB contacts

For a confirmed TB patient, a contact list for investigations should be established to identify the index case of TB. Index case, or index patient, is the initially identified case of new or recurrent TB in a person of any age, in a specific household or other comparable setting in which others may have been exposed. An index case is the case on which a contact investigation is centred but is not necessarily the source case. This systematic evaluation aims to identify active or LTBI in the contacts.

9.6 Determining the infectious period

Determining the infectious period of TB case focuses on the investigation of the contacts who are most likely to be at risk to catch the infection and this sets the time frame for testing contacts. The start of the infectious period cannot be predicated and determined with precision by available methods, a practical estimation is necessary.

An assigned start is three months before a TB diagnosis is recommended. Definite details should be taken in consideration such as the approximate dates when TB symptoms were noticed, mycobacteriology results and extent of disease (especially the presence of large lung cavities, which imply prolonged illness and infectiousness).

Table 17. Guidelines for estimating the beginning of the period of infectiousness of persons with TB, by index case characteristic

Characacterstic			
TB symptoms	AFB* sputum Smear positive	Cavitary Chest radiograph	Recommended minimum beginning of likely period of infectiousness
Yes	No	No	3 months before symptom onset or first positive finding (e.g.. abnormal chest radiograph)consistent with TB disease, whichever is longer
Yes	Yes	Yes	3 months before symptom onset or first positive finding consistent with TB disease, whichever is longer
No	No	No	4 weeks before date of suspected diagnosis
No	Yes	Yes	3 months before first positive finding consistent with TB

SOURCE: California Department of Health Services Tuberculosis Control Branch; California Tuberculosis Controllers Association. Contact investigation guidelines. Berkeley, CA: California Department of Health Services; 1998. * Acid-fast bacilli.

9.7 Testing for LTBI

9.7.1 TST

Administration

- The Mantoux TST is administered by injecting 0.1 ml of 5 IU of purified protein derivative (PPD) solution intradermal into the volar surface of the forearm using a 27-gauge needle with a tuberculin syringe.
- Avoid areas of skin with veins, rashes or excess hair. Clean the area with alcohol swab, allow area to dry, and inject all antigen just below the surface of the skin on the volar surface of the forearm, forming a 6–10 mm weal (a pale, raised area with distinct edges; has orange-peel appearance and does not disappear immediately).
- If no weal forms (immediately after intradermal injection of the PPD), or if a weal forms that is less than 6 mm of induration, the test should be repeated immediately, approximately 5 cm from original site or on the other arm.
- If minor bleeding occurs, dab the injection site with a cotton swab. Avoid covering the area with a bandage or applying pressure to the injection site.
- Record the date, time and location of TST. Instruct patient not to scratch the site, but to use cool compress to relieve any itching or swelling.
- Inform patient of the importance of returning for a reading of the TST within 48–72 hours.

- Give written appointment card for TST reading.
- Provide written information about TST (pamphlet or brochure).

Measurement

- Measure the induration (hard bump) rather than erythema.
- Palpate area with fingertips, measuring the diameter of induration perpendicular to the long axis of the arm.
- Use ballpoint pen to mark edges of induration.
- Use a TST ruler or ruler with millimetres to measure the distance between the two points.

Recording

- Record date TST was administered. Record the brand name of the PPD solution, lot number, manufacturer and expiration date on the patient record.
- Record results in millimetres of induration (0 mm if there is no induration) rather than as positive or negative.
- Record date and time of reading and name of person reading TST.
- Provide written documentation to patient and ordering health care provider.

Interpretation

Interpretation of TST results is based on the measurement of the reaction in millimetres,

Table 18. Risk stratification of reaction to TST

TST reaction	Risk group
≥ 5mm	• HIV-infected persons • Recent contacts of a person with infectious TB disease • Persons with fibrotic changes on chest radiograph consistent with prior TB • Patients with organ transplants and other immunosuppressed patients (including patients taking the equivalent of ≥15 mg/day of prednisone for 1 month or more or those taking tumour necrosis factor -antagonists).
≥ 10 mm	• Recent arrivals from high-prevalence areas • Injection drug users • Residents or employees of high-risk congregate settings (e.g. hospitals and other health care facilities) • Mycobacteriology laboratory personnel • Persons with clinical conditions that increase the risk for progression to TB disease • Children younger than 5 years of age • Infants, children, and adolescents exposed to adults in high-risk categories of acquiring TB disease.
≥ 15 mm	• Persons with no known risk factors for TB.

- the person's risk of acquiring TB infection, or the risk of progression to disease if infected (Table 18).

Storage and handling

- PPD solution must be kept refrigerated at 2.2°– 7.8° C.
- Avoid fluctuations in temperature; do not store on the refrigerator door.
- Syringes must be filled immediately prior to administration.
- Store and transport the tuberculin in the dark as much as possible; avoid exposure to light.
- Tuberculin testing solution should not be stored with other vials, such as T-dap, that could be mistaken for PPD.

9.7.2 IGRA

IGRA is in vitro blood tests of cell-mediated immune response. They are used to determine if a person is infected with MTB by measuring the immune response to TB proteins in whole blood. Specimens are mixed with peptides that simulate antigens derived from MTB and controls. In a person infected with MTB, the test measures T cell release of interferon gamma following stimulation by antigens specific to MTB the results are based on the amount of interferon-γ released.

The test available in Oman is QuantiFERON®-TB Gold Plus (QFT-Plus).

Priority at-risk group for testing using IGRA:

- Contacts of TB cases
- HIV patients
- Health care workers
- Immunocompromised patients
- Those who are expected not to return back for TST reading
- Those who are coming from high endemic countries

Routine testing with both TST and IGRAs is not recommended; however, there are certain situations where results from both tests may be useful, such as:

- When the initial test is negative and the risk for infection, progression to disease, and/or a poor outcome is high (e.g., HIV-infected persons or children under five years of age who are exposed to a person with infectious TB).
- When the initial IGRA result is indeterminate, borderline, or invalid and a reason for testing persists in which repeating an IGRA or performing a TST might be useful.
- When the initial test is positive, and evidence is required to encourage acceptance and adherence to treatment or role out false positive results.

9.8 Diagnostic algorithms of LTBI in children and adults

The following figures (13–16) show the diagnostic algorithm in the investigation of LTBI in children and adults who came into contact with a TB case.

Figure 13. Neonate (4 weeks) perinatal *or postnatal exposure (Algorithm 1)

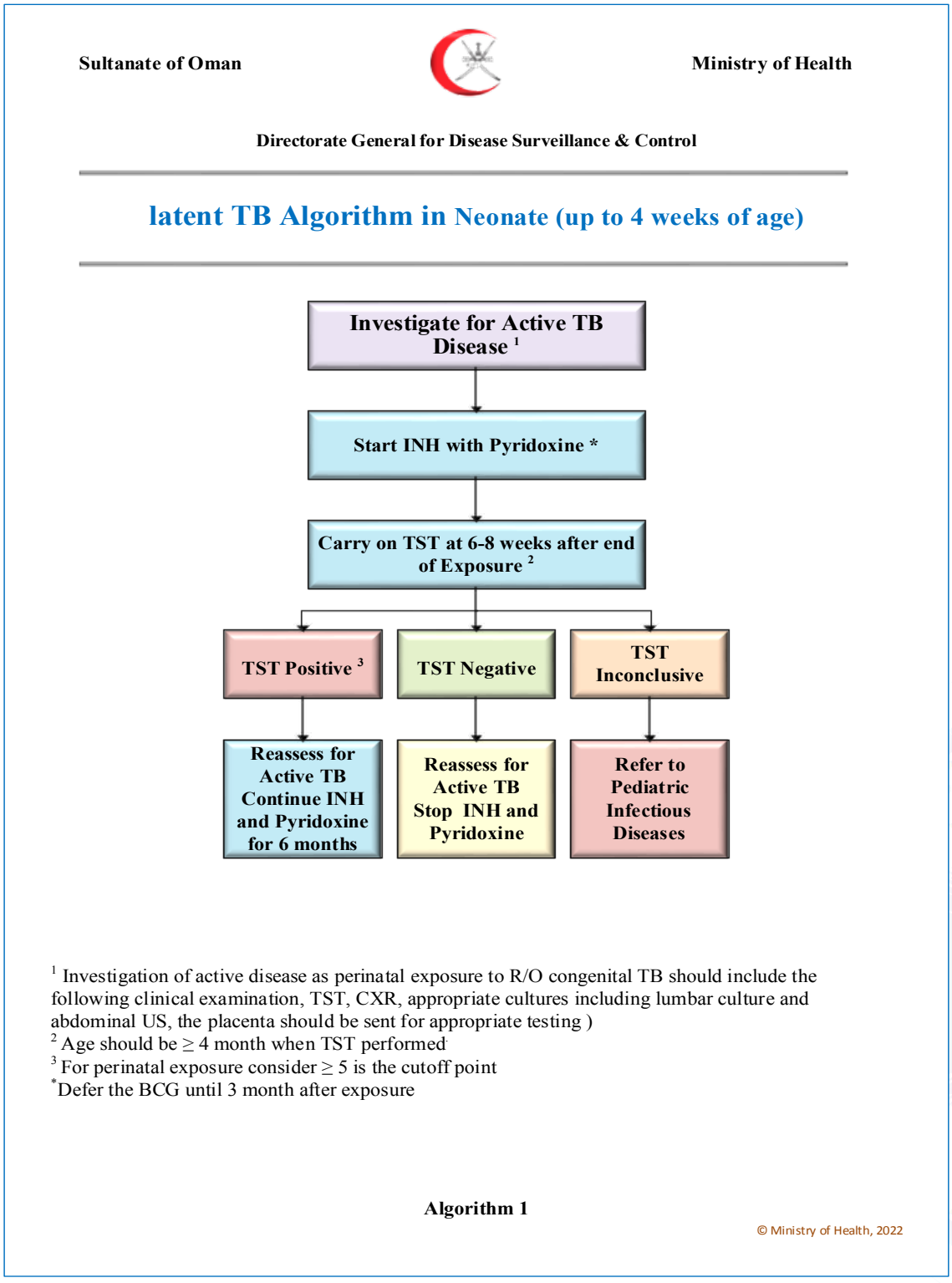


Figure 14. Children aged less than five years (Algorithm 2)

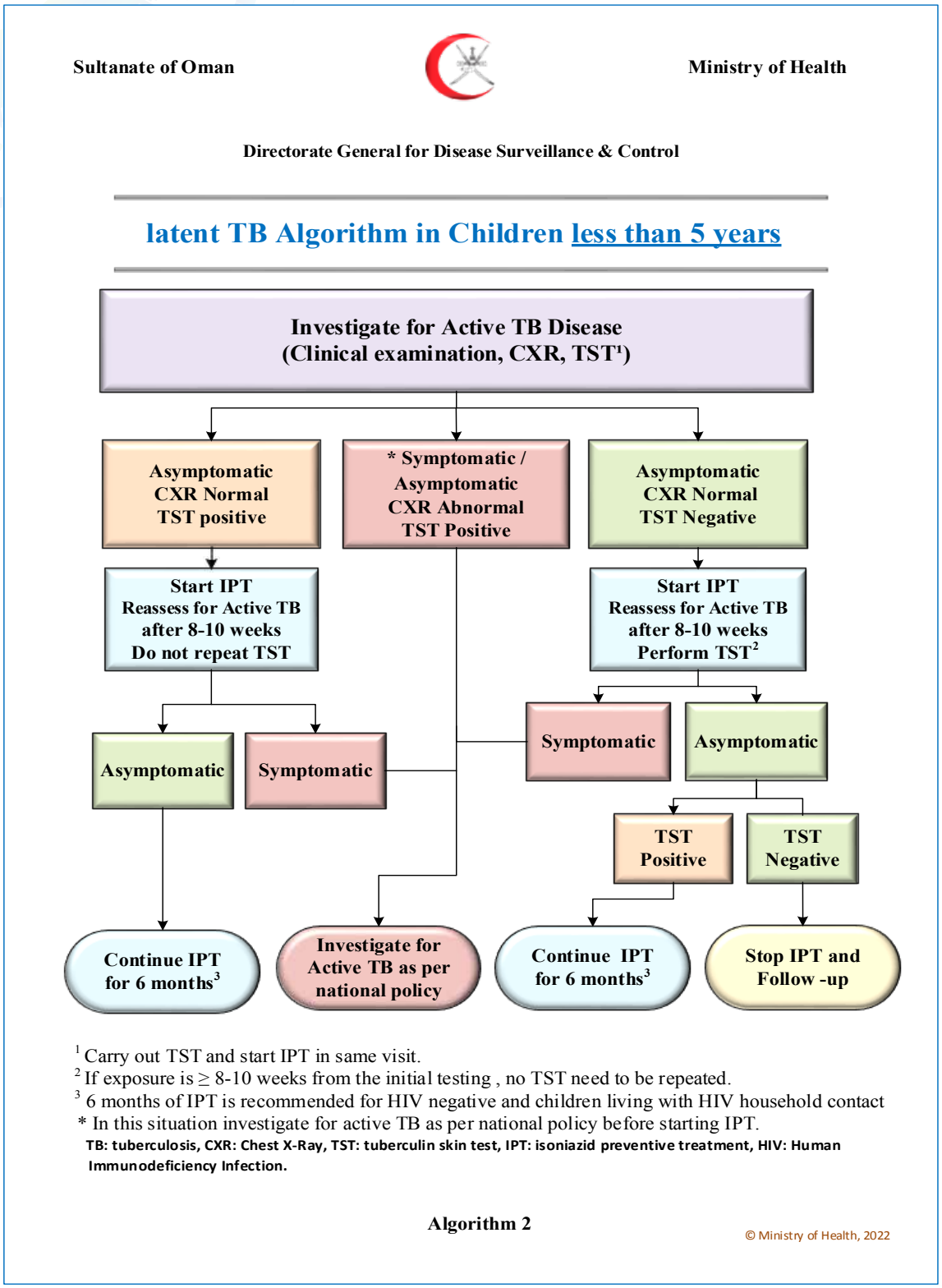
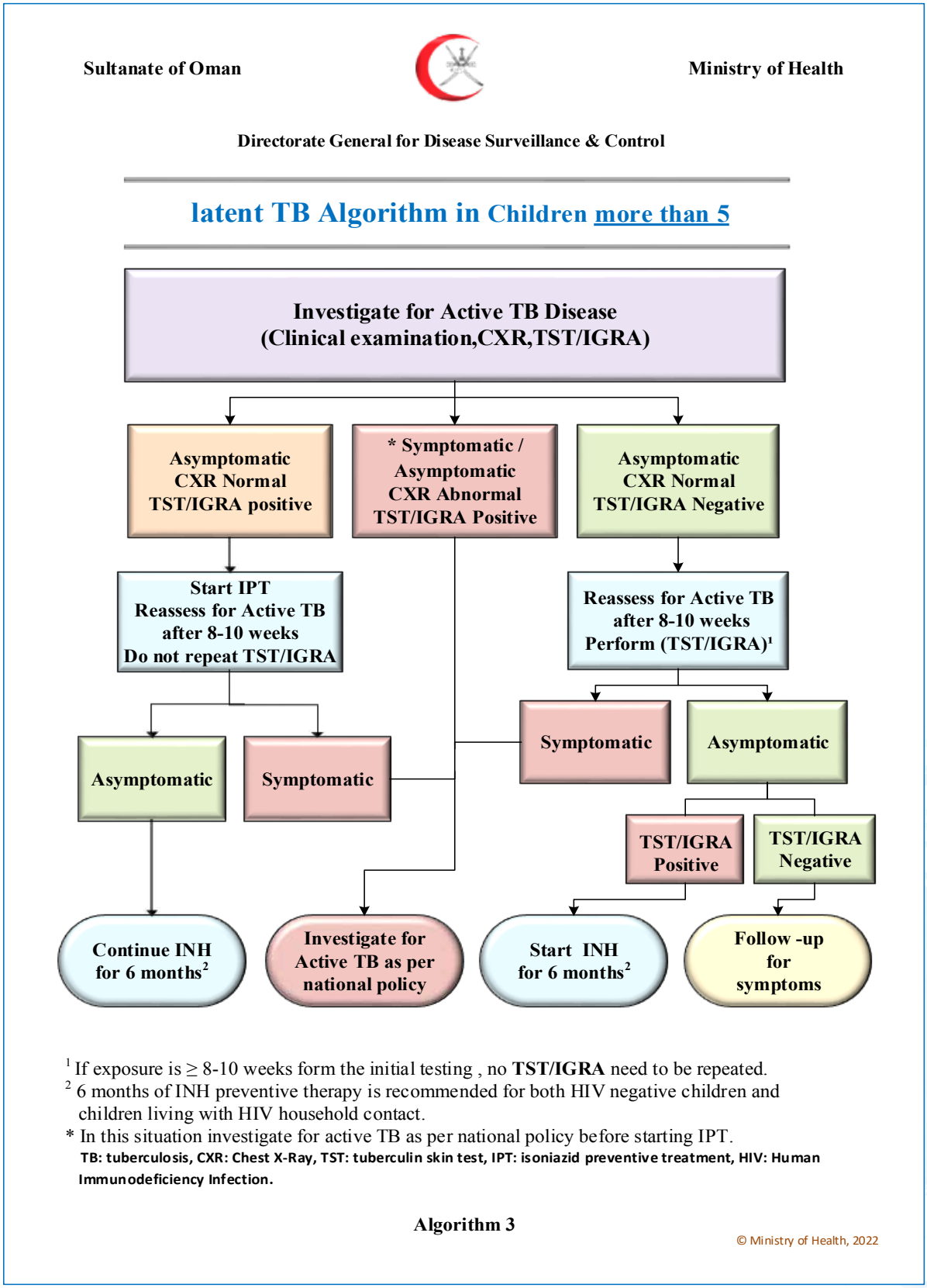


Figure 15. Children aged more than five years (Algorithm 3)



[1] If exposure is ≥ 8-10 weeks form the initial testing , no **TST/IGRA** need to be repeated.
[2] 6 months of INH preventive therapy is recommended for both HIV negative children and children living with HIV household contact.
* In this situation investigate for active TB as per national policy before starting IPT.

TB: tuberculosis, CXR: Chest X-Ray, TST: tuberculin skin test, IPT: isoniazid preventive treatment, HIV: Human Immunodeficiency Infection.

Algorithm 3

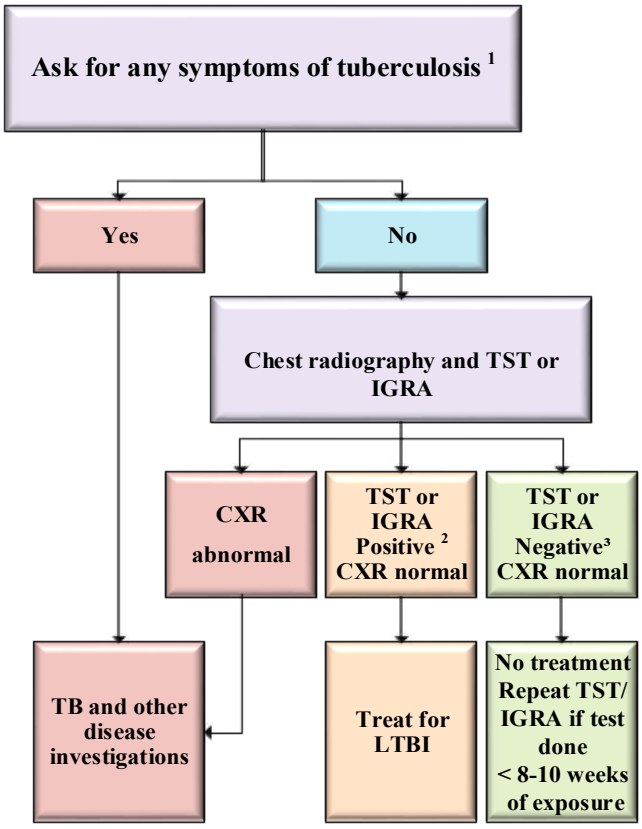
Figure 16. Adults (Algorithm 4)

Sultanate of Oman

Ministry of Health

Directorate General for Disease Surveillance & Control

latent TB Algorithm in Adult



[1] Symptoms of TB include any one of the following: cough, hemoptysis, fever, night sweats, weight loss, fatigue, shortness of breath.
[2] Refer to TST classification section for interpretation TST result in infants, children and adults.
[3] Clients for whom LTBI is not indicated should be provided with information about TB including the importance of seeking care if symptoms of TB develop.
[4] National TB guideline should be followed in investigating TB.

Algorithm 4

9.9 Treatment regimen options

TB preventive treatment (TPT) broadly falls into two categories: INH monotherapy for six or nine months or rifamycin-based shorter terms as alternatives to six months of INH. The 2020 update of WHO's guidelines recommends several shorter rifamycin-based regimens.

The following options are recommended for the treatment of LTBI as alternative options that can be used in all settings and target populations, including PLHIV.

9.9.1 INH regimen

There are two options for treatment with INH:

- Nine-month regimen
- Six-month regimen

Six months' daily monotherapy with INH is the standard treatment for both adults and children living in countries with either high or low TB incidence as per recent WHO recommendation. Several systematic reviews have demonstrated its preventive efficacy.

9.9.2 12-dose (INH and RPT) regimen

The directly observed 12-dose once-weekly regimen of INH and RPT is recommended as an alternative option equal to the standard INH nine-month daily regimen for treating LTBI in otherwise healthy people, 12 years of age and older.

The use of this regimen in other than these indications should be discussed with TB specialist on an individual basis.

The 12-dose regimen is not recommended for the following individuals:

- People presumed to be infected with INH or RIF-resistant MTB
- Pregnant women, or women expecting to become pregnant while taking this regimen

9.9.3 RIF regimen

A four-month regimen of RIF can be considered for persons who cannot tolerate INH or who have been exposed to INH-resistant TB. It should not be used to treat HIV-infected persons taking some combinations of ART. Starting this regimen need to be approved by TB specialist.

The choice of TPT will depend on the following:

- Availability of appropriate formulations
- Considerations for age, safety and drug–drug interactions
- Adherence

Important consideration:

- Proper counselling regarding the rationale and the importance of completing the treatment, follow-up procedure, symptoms of possible drug reactions is a must before commencing the 12 weeks regimen to ensure proper compliance.
- INH-RPT should be discontinued if the serum aminotransferase concentration is five or more times the upper limit of normal level even in the absence of symptoms or three or more times the upper limit of normal in the presence of symptoms.
- Women using hormonal contraceptives should be advised to consider an alternative method of contraception (e.g., a barrier method).

9.9.4 INH and RIF regimen

- This regimen considered only if RPT–INH combination is not available and by recommendation by a specialist.

Table 19. Summary of available preventive treatment options

	6H	3HP	4R	3HR
Medicines	Isoniazid	Isoniazid + rifapentine	Rifampicin	Isoniazid + rifampecin
Duration (months)	6	3	4	3
Interval	Daily	Weekly	Daily	Daily
Doses	182	12	120	84
Pill burden per dose (total number of pills for average adult) [a]	1 (182)	9 singles (108) 3 with FDC (36)	2 (240)	3 (252)
Children	All ages; child-friendly (dispersible) formulation available; preferred in HIV+ children on LPV-RTV, NVP, or DTG	≥ 2 years; no child-friendly formulation available	All ages; no child-friendly formulation available, no formulation available for infants < 8 kg weight	All ages; no child-friendly formulation available and recommended up to 25 kg weight
Pregnant women	Safe for use [c]	Not known	May be safe, although no safety or efficacy data available specifically in this population [d]	Safe for use [c,d]

Table 19. Continued

	6H	3HP	4R	3HR
Interactions with ART[b]	No restriction	**Contraindicated:** All PIs, NVP/ NNRTIs, TAF **Use:** TDF, EFV (600 mg), DTG[e], RAL[e]	**Contraindicated:** All PIs, NVP/most NNRTIs, TAF **Adjust dose:** DTG, RAL **Use:** TDF, EFV (600 mg)	**Contraindicated:** All PIs, NVP/most NNRTIs Use with caution: TAF **Adjust dose:** DTG, RAL **Use:** TDF, EFV (600 mg)
Toxicity	Hepatotoxicity (more), peripheral neuropathy, rash, gastrointestinal (GI) upset	Flu-like syndrome, hypersensitivity reactions, GI upset, orange discolouration of body fluids, rash, hepatotoxicity (less)	Rash, GI upset, hepatotoxicity (less), hypoprothrombinaemia, orange discolouration of body fluids	Hypersensitivity reactions, hepatotoxicity (less), rash, GI upset, hypoprothrombinaemia, orange discolouration of body fluids
Absorption	Best absorbed on an empty stomach; up to 50% reduction in peak concentration with a fatty meal	Oral rifapentine bioavailability is 70% (not HP); peak concentration increased if given with a meal	Rifampicin absorption is rapid but may be delayed or decreased by high-fat meals	

Note: DTG = dolutegravir, EFV = efavirenz, H = Isoniazid, LPV–RTV = lopinavir-ritonavir, NNRTI = non-nucleoside reverse transcriptase inhibitors, NVP = nevirapine, P = rifapentine, PIs = protease inhibitors, R = rifampicin, RAL = raltegravir, TAF = tenofovir alafenamide, TDF = tenofovir disoproxil fumarate.

[a] Average available adult formulations: H-300 mg, R-300 mg/150 mg, P-150 mg.

[b] For women living with HIV (as well as HIV-negative) receiving rifamycin-based TPT and oral contraceptives, consider additional barrier contraception methods to prevent pregnancy.

[c] One randomized trial has shown increased risk of poor birth outcomes for mothers taking isoniazid during pregnancy; however, several other studies have shown benefits of TPT; hence caution is required.

[d] Bleeding attributed to hypoprothrombinaemia has been reported in infants and mothers following the use of rifampicin in late pregnancy. Vitamin K is recommended for both the mother and the infant postpartum if rifampicin is used in the last few weeks of pregnancy (FDA).

[e] Indicates that drug interaction has been studied in adults and not children; applies to adults taking DTG or RAL only.

Table 20. Summary of recommended dosages of medicines for TPT

<table>
<tr><th>Regimen</th><th>Dose by age and weight band</th></tr>
<tr><td>6 or 9 months of daily isoniazid monotherapy (6H, 9H)a</td><td>Age 10 years & older: 5 mg/kg/day
Age < 10 years: 10 mg/kg/day (range, 7–15 mg)</td></tr>
<tr><td>Four months of daily rifampicin (4R)</td><td>Age 10 years & older: 10 mg/kg/day
Age < 10 years: 15 mg/kg/day (range, 10–20 mg)</td></tr>
<tr><td>Three months of daily rifampicin plus isoniazid (3HR)</td><td>Isoniazid:
Age 10 years & older: 5 mg/kg/day
Age < 10 years: 10 mg/kg/day (range, 7–15 mg)
Rifampicin:
Age 10 years & older: 10 mg/kg/day
Age < 10 years: 15 mg/kg/day (range, 10–20 mg)
<table><tr><td>Weight band</td><td>4–7 kg</td><td>8–11 kg</td><td>12–15 kg</td><td>16–24 kg</td><td>> 25 kg</td></tr><tr><td>RH 75/50 mg (FDC)</td><td>1</td><td>2</td><td>3</td><td>4</td><td>Use adult formulation</td></tr></table></td></tr>
<tr><th>Regimen</th><th>Dose by age and weight band</th></tr>
<tr><td rowspan="11">Three months of rifapentine plus high dose isoniazid weekly (12 doses) (3HP)</td><td colspan="6">Age 2–14 years[d]</td></tr>
<tr><td>Medicine, formulation</td><td>10–15 kg</td><td>16–23 kg</td><td>24–30 kg</td><td>31–34 kg</td><td>> 34 kg</td></tr>
<tr><td>Isoniazid 100 mg[b]</td><td>3</td><td>5</td><td>6</td><td>7</td><td>7</td></tr>
<tr><td>Rifapentine 150 mg</td><td>2</td><td>3</td><td>4</td><td>5</td><td>5</td></tr>
<tr><td>Isoniazid + rifapentine FDC (150 mg/150 mg)[c] (Not Available)</td><td>2</td><td>3</td><td>4</td><td>5</td><td>5</td></tr>
<tr><td colspan="6">Age > 14 years[d]</td></tr>
<tr><td>Medicine, formulation</td><td>30–35 kg</td><td>36–45 kg</td><td>46–55 kg</td><td>56–70 kg</td><td>> 70 kg</td></tr>
<tr><td>Isoniazid 300 mg</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td></tr>
<tr><td>Rifapentine 150 mg</td><td>6</td><td>6</td><td>6</td><td>6</td><td>6</td></tr>
<tr><td>Isoniazid + rifapentine FDC (300 mg/300 mg)[c]</td><td>3</td><td>3</td><td>3</td><td>3</td><td>3</td></tr>
</table>

[a] A triple pill combination containing isoniazid 300 mg + pyridoxine 25 mg + sulfamethoxazole 800 mg + trimethoprim 160 mg (scored) is the preferred alternative regimen for PLHIV being considered for isoniazid monotherapy (1 pill daily for adults, half pill for children 5 years and older of age and quarter for children < 5 years of age).

- [b] 300 mg formulation can be used to reduce the pill burden.
- [c] Expected to become available in a near future.
- [d] Dosage may differ among adults and children in overlapping weight-bands.

9.10 Management of treatment interruptions

Currently, no evidence based recommendations exists on how to manage interruption of TPT, i.e. how many missed doses can be made up for by prolonging treatment without compromising efficacy. Table 21 summarizes suggested actions to manage preventive treatment interruptions.

In addition to monitoring treatment completion, a number of triggers should be monitored that necessitate a review of case management and, in some instances, changes to treatment:

- Failed – development of TB disease any time while on TPT.
- Died – death for any reason while on TPT.
- Lost to follow-up – TPT interrupted by person for eight consecutive weeks or more for 6H, four consecutive weeks or more for 3HP, 3HR and 4R.
- TPT discontinuation due to toxicity – by clinician due to adverse events or drug–drug interactions, with or without restart or switching of regimen.
- Not evaluated – such as records lost, transfer to another health facility with record of TPT completion.

Table 21. Management of missed doses

TPT regimen	Duration of treatment interruption	Next step	Suggested actions
3HR, 4R, 6H	Less than 2 weeks	• Resume preventive treatment immediately upon return. • Add the number of days of missed doses to the total treatment duration. • Do not change the scheduled date of the next follow-up visit but the last follow-up visit will be postponed by the number of extra days to compensate for missed doses (e.g., if an adult on 4R missed 3 days of treatment, continue preventive treatment for a total duration of 4 months + 3 days from the date of start).	• Address the reason for interruption. • Counsel the person on TPT and the caregiver on the importance of adherence to preventive treatment. • Review and agree with the person on TPT and the caregiver about the best ways to improve adherence.
	More than 2 weeks	• If treatment interruption occurred after more than 80% of doses expected in the regimen were taken, no action is required. • Continue and complete the remaining treatment as per original plan. • If less than 80% of doses expected in the regimen were taken, and the treatment course can still be completed within the expected time for completion, i.e. treatment duration + 33% additional time, no action is required. Continue and complete the remaining treatment as per original plan. • If less than 80% of doses expected in the regimen were taken, and the treatment course cannot be completed within the expected time for completion, consider restarting the full TPT course.	
3HP	Weekly schedule of one dose missed	• If the missed dose is remembered within the next 2 days, the person can take the dose immediately. • Continue the schedule as originally planned (i.e. continue to take remaining doses following the same schedule). • If the missed dose is remembered more than 2 days later, the person can take the missed dose immediately and change the schedule for weekly intake to the day the missed dose was taken until treatment completion. This will avoid 2 weekly doses being taken less than 4 days apart.	
	More than one weekly doses of 3HP missed	• If between 1–3 weekly doses are missed, treatment is continued until all 12 doses are taken, thus prolonging the treatment duration to a maximum of 16 weeks. • If, however, four or more weekly doses are missed, consider restarting the full TPT course. • If adherence to a weekly routine is not possible, consider discontinuing 3HP and offering an alternative (daily) regimen.	

9.10.1 Adherence

Adherence to the TPT course and treatment completion are important determinants of clinical benefit, both at the individual and population levels (Table 22). Irregular or inadequate treatment reduces the preventive effectiveness of the TPT system. Moreover, poor adherence or early discontinuation of TPT can increase an individual's risk of developing TB including drug resistant TB (although not supported by existing evidence from the research settings). The efficacy of TPT is known to be greater if at least 80% of the doses are taken during the regimen period as well as the total number of doses.

The Table below summarizes all recommended regimens and suggested criteria to assess the completion of different regimen.

Table 22. Preventive TB treatment completion

	Total duration (months)	Expected number of doses	80% of recommended doses (days)	Extended time for treatment completion (days) (treatment duration +33% additional time)
6H (daily)	6	182	146	239
3HP (weekly)	3	12	11[a]	120
4R (daily)	4	120	96	160
3HR (daily)	3	64	84	120

[a] **90% of recommended number of doses**

9.10.2. How to improve adherence

- Counsel the person on TPT and the caregiver on the importance of adherence to preventive treatment.
- Collaboration between primary health care and governorate public health team to ensure availability of treatment, referrals for consultation and management of side effects.
- DOT, if patient is high risk (e.g., HIV infected, child etc..).
- DOT should be provided with the 12-dose regimen if the patient illegible.
- Case management to coordinate care and service.
- Provide patient education and instructions in patient's primary language at every visit.
- Ensure confidentiality.

- Provide patient reminders such as SMS messages or use of other artificial intelligence tools.
- Rewards for adherence (incentives).
- Enablers to overcome barriers such as free transportation.

9.10.3. Patient education

- Explain the disease process and rationale for medication in the absence of symptoms or radiographic abnormalities.
- Review the importance of completing treatment for LTBI.
- **Discuss possible side effects of LTBI medications that may include:**
- Fever
- Unexplained anorexia
- Dark urine (color of coffee or cola) Icterus
- Rash
- Persistent paresthesia of hands and feet
- Persistent fatigue or weakness lasting 3 or more days
- Easy bruising or bleeding
- Arthralgia
- Nausea
- Vomiting
- **Discuss management of common side effects and the need to report to health care provider.**

9.11. Monitoring

Clinical Monitoring

- **Monthly visit to health center to assess the following:**
- Signs of hepatitis.
- Adherence to medication regimen.
- Symptoms of possible adverse drug reactions or interactions.
- In case of occurrence of adverse reactions, the patient should be advised to stop medication and consult the TB focal point at their local HC immediately.
- At the end of the treatment the outcome should be registered either as complete or stopped (reason should be included in remarks).
- Follow up the patient for 2 years after the exposure.
- For children: check the weight and provide monthly refills adjusted for current weight.

9.11.2. TPT monitoring guide

Table 1. Rifampcin Regimen- summary of baseline testing and monitoring for individual on 4R/3HR LTBI treatment

Medical evaluation	Baseline	Month 1	Month 2	Month 3	Month 4
Clinical assessment	√	√ ©	√ ©	√ ©	√ ©
Adherent assessment		√	√	√	√
Chest X-ray	√				
Weight	√	Monthly monitoring for children < 5 years			
LFT (AST, Bilirubin) & CBC (Note : for children < 14 years testing as per pediatrician recommendation)					
0-14 years	√				
14-50 years	√	√			
> 50 years	√	√	√	√	√
Any age with risk factors for drug induced hepatitis	√	√	√	√	√

© Monthly physical examination and Liver Function Test (LFT) is indicated for individuals with liver toxicity, thrombocytopenia and /or signs/symptoms of TB

Table. Isoniazid Regimen- summary of baseline testing and monitoring for individual on INH LTBI treatment

Medical evaluation	Baseline	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7-9*
Clinical assessment	√	√ ©	√ ©	√ ©	√ ©	√ ©	√ ©	√ ©
Adherent		√	√	√	√	√	√	√
Chest X-ray	√							
Weight	√	Monthly monitoring for children < 5 years						
LFT (AST, Bilirubin) & CBC (Note : for children < 14 years testing as per pediatrician recommendation)								
0-14 years	√							
14-50 years	√	√						
> 50 years	√	√	√	√	√	√	√	√
Any age with risk factors for drug induced hepatitis	√	√	√	√	√	√	√	√

© Monthly physical examination and Liver Function Test (LFT) is indicated for individuals with liver toxicity, thrombocytopenia and /or signs/symptoms of TB

Table3. Isoniazid (INH) and Rifapentine (RPT) Regimen- summary of baseline testing and monitoring for individual on INT-RPT LTBI treatme

Medical evaluation	Baseline	week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Week 11	Week 12
Clinical assessment	√	√	√	√	√	√	√	√	√	√	√	√	√
Adherent assessment		√	√	√	√	√	√	√	√	√	√	√	√
Chest X-ray	√												
Weight	√	Monthly monitoring for children < 5 years											
LFT (AST, Bilirubin) & CBC	√				√				√				√

Chapter 10

Infection Prevention and Control (IPC)

Guideline for IPC of TB within health care facilities

10.1 Transmission of TB

TB is transmitted via infectious aerosols that are generated when an ill person sneezes, coughs or speaks. The infectiousness of a TB patient is directly related to the number of droplet nuclei carrying MTB (tubercle bacilli) that are expelled into the air. Depending on the environment, these tiny particles can remain suspended in the air for several hours. Infection occurs when a person inhales droplet nuclei containing MTB, and the droplet nuclei travels to the mouth or nasal passages, upper respiratory tract and bronchi to reach the alveoli of the lungs.

Persons with EPTB disease may have concurrent unsuspected pulmonary or laryngeal TB disease. Except for laryngeal TB disease, EPTB disease is rarely infectious; however, transmission from extrapulmonary sites has been reported to occur during aerosol-producing procedures such as autopsies and tissue irrigation.

In general, young children with pulmonary TB disease are less likely than adults to be infectious, because children are sometimes unable to produce sputum when they cough or may have paucibacillary TB. However, it is still possible for children to transmit MTB to others if they have infectious characteristics, such as a positive AFB smear or cavity on a chest radiograph.

10.2 TB infection versus disease

A positive TST or IGRA test indicates that the person has been exposed to the TB bacteria. The test confirms that the body recognizes the TB antigen. The person may have LTBI or active TB disease.

Persons who have had BCG vaccine may also have a positive TST but not IGRA that is why this later screening test is more specific for TB infection. However, even the TB skin reactions due to BCG tend to wane over time and in countries where the vaccine is given at birth, it is unlikely that an adult positive Mantoux test is a reaction from BCG.

10.3 Prevention of TB transmission in health care

MTB can be transmitted in virtually any setting. The household contacts are the most susceptible, but those sharing the same airspace in close quarters, (e.g. in airplanes, theatres) are also at increased risk of infection. Clinicians should be aware that transmission has been documented in health care settings where HCWs and patients come in contact with persons with infectious TB who:

- Have unsuspected TB disease or
- Have not received adequate or appropriate treatment or
- Have not been separated from others.

Table 23. Infectiousness of people known to have or suspected of having TB disease

Factors Associated with Noninfectiousness	Factors Associated with Infectiousness
No cough	Presence of cough
No cavity in the lung	Cavity in the lung
No acid-fast bacilli on the sputum smear	Acid-fast bacilli on the sputum smear
Extrapulmonary (non-pulmonary)TB disease	TB disease of the lung, airway, or larynx
Receiving adequate treatment for 2 weeks or longer	**Not** receiving adequate treatment
Not undergoing cough-inducing procedures	Undergoing cough-inducing procedures (e.g. bronchoscopy, sputum induction, and administration of aerosolized medications)
Negative sputum cultures	Positive sputum cultures

* Infectiousness depends on a variety of factors. Clinician should consider all of these factors when Determining whether a patient should be considered infectious.

Health care settings in this context include clinics, hospitals, emergency medical services, rehabilitation facilities, home-based health care and outreach settings. People who work or receive care in health care settings are at higher risk for becoming infected with MTB.

10.4 TB infection control plan

An effective TB IPC plan should be part of a general infection control programme of every health care facility and should be annually evaluated. The plan designed to ensure implementing measures for reducing the spread of TB that are appropriate to the risk of a particular setting including:

- Periodic TB risk assessment for the facility,
- Proper hazard communication,
- Ensuring implementation of three-level hierarchy infection control measures based on risk assessment of facility (administrative, environmental, and respiratory protection)
  - » Prompt detection of TB and including it in triage procedure for respiratory infections
  - » Procedures to follow to separate persons with suspected or confirmed infectious TB disease from other persons in the setting until the time of admission to isolation room/ transfer to another facility
  - » Implementation of airborne precautions once TB suspected.
- Training of staff periodically on infection control measures

- Periodic TB screening (TST, IGRA) for high-risk staff
- Ensuring prompt reporting of cases/exposure events and contact tracing in coordination with the DGHS department of disease surveillance and control in the governorate.

10.5 TB risk assessment

The infection control team of each health care facility should include TB risk assessment in their annual health care associated risk assessment. This will be mainly based of reported infectious TB cases seen within facility currently (extrapulmonary cases not included) and comparing it to previous trend in past five years. Based on risk assessment, the overall and specific areas within the organization risk will be determined and different interventions, including assessment of need for periodic screening of staff, will be determined and included in the plan.

10.6 Hazard/risk communication

The hazard or risk communication for TB within health care facilities should include:

- HCW training in the organization on prevention and management of TB exposure within the facility.
- Respiratory protection competency to be evaluated especially for HCWs at high risk of airborne pathogen exposure.
- Providing training sessions to ensure that all employees with tasks that have potential for occupational exposure to TB are informed of the hazard and take proper precautions to reduce the chance of exposure to TB.
- Outside contractors who provide temporary or contract employees who may incur occupational exposure must inform the contractor or contract employees of potential TB exposures. The contractor shall provide documentation that contract employees have received training about precautions to reduce the chance of exposure to TB.
- **Airborne pathogen hazard signs should be posted at entrance of:**

» Area or room where patient is isolated with suspected or confirmed TB.

» Area or room where a procedure is performed for a patient with suspected or confirmed TB.

» Laboratories dealing with clinical or research specimens of MTB.

» Mortuaries, especially where autopsies done for cases suspected or confirmed with TB.

- Warning labels (e.g. contaminated air – respiratory protection required) wherever duct can be accessed with risk of occupational exposure to infected TB aerosols (prior to passing through a high-efficiency particulate air (HEPA) filtration system, at fans and at the discharge outlets of non-HEPA filtered direct discharge systems).

10.7 Hierarchy of infection control measures

The following IPC measures are recommended to reduce MTB transmission to health workers, persons attending health care facilities or other persons in settings with a risk of transmission. Implementing these guidelines requires an understanding of the interdependence of the three-level hierarchy of IPC, giving prominence to the administrative controls. The second are environmental controls, which focus on preventing the spread and reducing the concentration of infectious droplet nuclei in the air. The third is personal respiratory protection, which may provide additional protection for HCWs in high-risk settings such as isolation rooms and cough-inducing or aerosol-generating suites.

10.7.1 Administrative controls

These sets of activities primarily aim at early identification, isolation and appropriate treatment of infectious patients.

- Presence of TB infection control plan
- Assign responsibility to a specific person for designing, implementing, evaluating, and maintaining a TB infection control programme for that facility (usually infection preventionist or TBFP)
- Conduct a risk assessment – the risk level of a particular facility will affect the extent of all other activities and will result in each facility having a different plan.
- Develop, implement and enforce policies and procedures to ensure early identification, evaluation and treatment of infectious cases of TB.
- Provide prompt triage and management in the outpatient settings of patients who may have infectious TB.
- Initiate promptly and maintain TB isolation for persons who may have infectious TB and are admitted to an inpatient setting.
- Plan effectively for the discharge of the patient, coordinating between the local public health team and the health care provider.
- Implement environmental controls.
- Develop, install, maintain and evaluate the effectiveness of engineering controls.

- Implement a respiratory protection programme. Develop, initiate, install, maintain and evaluate the effectiveness of the respiratory protection programme.
- Implement precautions for cough-inducing procedures. Develop, implement and enforce policies and procedures to ensure adequate precautions when performing cough-inducing procedures.
- Educate and train HCWs about TB.
- Develop and implement counselling and screening programme for HCWs about TB disease and LTBI.
- TB screening is required for the following groups/situations as per national policy:

» Pre-employment for all HCW.

» Students health sciences or medical residents before enrolment to an educational health institute or colleges.

» Annually in high-risk areas – ICU, emergency department, bronchoscopy room and laboratory staff working with TB culture specimens.

» Post TB exposure.

» The following procedures are required for TB screening:

» Past history of TB (personnel and close family member).

» TST or IGRA test.

» CXR, if positive TST/IGRA or Signs and symptoms of TB.

- Evaluate promptly possible episodes of TB exposure and coordinate activities between the facility and the DGHS of governorate.

10.7.2 Environmental and engineering controls

When a person with infectious TB disease coughs or sneezes, tiny particles called droplet nuclei that contain MTB are expelled into the air. Environmental controls are used to prevent the spread and reduce the concentration of infectious droplet nuclei. It is important to note, however, that without strong administrative controls, environmental controls are ineffective because cases would not be recognized or managed appropriately.

Ventilation:

» Controls direction of airflow to prevent contamination of air in areas surrounding a person with infectious TB.

» Dilutes and removes contaminated air.

» Exhausts contaminated air to the outside.

- **Supplementary controls:**
  - » HEPA filtration which cleans the air of infectious droplet nuclei.
  - » Ultraviolet germicidal irradiation which kills or inactivates TB bacilli in the air.
- **Providing AIIR:**
  - » It should be with negative air pressure relative to the hall,
  - » The air exchanges ≥ 6–12 per hour (ACH), of which at least two exchanges are outside air.
  - » External air exhaustion.
  - » HEPA filtration system .
- **Engineering controls, maintenance schedules and records:**
  - » Negative pressure areas occupied by a patient on airborne isolation are qualitatively demonstrated daily by using smoke trails or by computerized room pressure monitoring procedures.
  - » Facility engineering department monitors negative pressure rooms and reports are sent to hospital IPC team and IPC committee quarterly.Whenever HEPA filters are changed, the system is inspected, and its performance monitored in accordance with international standards.
  - » HEPA filters in contained air exhaust systems are inspected, maintained and performance monitored every six months.
  - » Facility management performs all routine and special monitoring and maintenance of the ventilation system of airborne isolation rooms.

If there is failure in the pressure, ACH, or exhaustion system it should be reported, and a list of exposed individuals investigated and followed-up

10.7.3 Respiratory protection

Personal respiratory protection, the third level of infection control, is also used in higher risk settings. The purpose of a respirator is to reduce exposure by filtering out TB bacilli from the room air before the air is breathed into a person's lungs. The national and local infection control team should approve the respirators (N95 masks or alternatives) used for TB control. It is recommended that health care provider staff and visitors use personal respiratory protective equipment in settings that may be at higher risk for TB transmission, such as the following:

- Rooms where infectious TB patients are being isolated;
- Areas where cough-inducing or aerosol-generating procedures are performed;

- Other areas, which should be identified in the facility's risk assessment, where administrative and environmental controls are not likely to protect persons from inhaling infectious droplet nuclei It is important to note that the precise level of effectiveness (of respiratory protection) in protecting HCWs from MTB transmission in health care settings has not been determined.
- Surgical-type masks are to be used by persons who are infectious or are suspected cases of TB disease when they are out of TB respiratory isolation. The purpose of the mask is to reduce transmission by reducing the number of TB bacilli coughed out into the room air.

Figure 17. Appropriate masking protocol

Health-care worker wearing a respirator

Infectious TB patient wearing a surgical mask

Respirators

• 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.

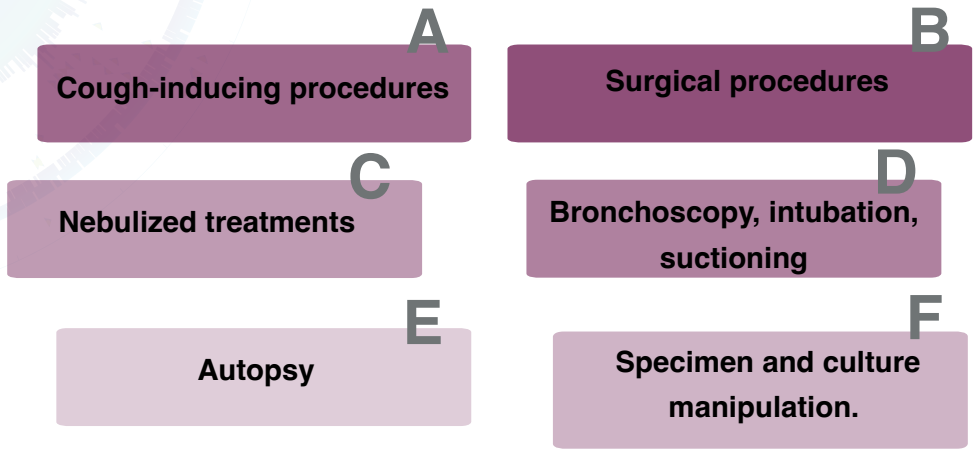
• Should NOT be worn by the patient.

Surgical masks

• Designed to stop droplet nuclei from being spread (exhaled) by the patient.

• Should NOT be worn by the health-care worker.

- The following are considered high-risk procedures where TB may be aerosolized and require special precautions to prevent/minimize occupational exposure to infectious TB including respiratory protection:



- Prior to wearing a respirator, all high-risk employees must be properly screened by IPC or occupation health and do the following:

A. N95 mask fit for all on regular bases and alternatives will be suggested for those who are not fit for available types/sizes.

B. Training and competency assessment for procedure of N95 and/or alternative powered air-purifying respirators (PAPRs) will be done including seal test.

- The IPC/occupational health team monitors PAPR airflow monthly. HEPA filters are changed whenever the airflow measurements indicate the filters need changing, or whenever filters loose integrity.
- For the care and use of PAPRs:

A. The PAPR head cover may be used repeatedly, until it is torn, the elastic is no longer taut, or it is grossly soiled.

B. Each person should keep their head cover in a bag near the PAPR filter unit. If soiled, the PAPR filter unit and breathing tube must be wiped off with an approved germicide between uses.

C. When not in use, PAPR filter units shall be plugged into battery chargers and kept in a specific area designated by each nursing unit.

D. The PAPR filter units are shared by HCWs, but each person should have their own PAPR head cover.

- The following PAPR procedures shall be conducted outside the AIIR;

A. Donning PAPR

1. Visually inspect the PAPR filter unit and breathing tube for visible damage. If any damage is noted, use a different unit and contact IPC team to report the damage.
2. Turn on the PAPR filter unit to assure that an adequate airflow is generated at the end of the breathing tube.
3. Connect the breathing tube to a PAPR head cover.
4. Check the connection to be sure that the breathing tube is seated properly.
5. Turn on the PAPR filter unit blower, place the unit around the waist, and fasten the waist belt for a comfortable fit.
6. Place the PAPR head cover over the head and check the fit by ensuring that the elastic band encircles the head. The PAPR head cover should be pulled down under the chin and should hug the face. The PAPR head cover sits just above the ears. Air flows to the front of the PAPR head cover. The protection afforded by the system may be negated if the PAPR head cover is not worn properly.

B. The PAPR system should be removed in the following manner:

1. Remove the PAPR head cover.
2. Disconnect the breathing tube from the PAPR head cover.
3. Remove the PAPR filter unit with breathing tube attached from the waist.
4. Turn off the PAPR filter unit.

C. Visually inspect the PAPR filter unit, breathing tube and PAPR head cover for any visible contamination or damage.

1. Light contamination can be removed by wiping the area with a disinfectant.
2. Grossly contaminated PAPR filter units and breathing tubes should be set aside and IPC team informed.
3. Grossly contaminated PAPR head covers should be discarded as biohazard waste.
4. Return PAPR filter units and breathing tubes to the charging location and plug the unit into the battery charger.
5. Each employee shall put their personal PAPR head cover into a plastic bag labelled with their name.

10.8 IPC common consults about TB

When being consulted about suspect or confirmed case of TB, the following are likely scenarios and proposed key questions to understand risk of transmission and advice management plan.

10.8.1 Call regarding a positive TB screening test (Mantoux and/or IGRA)

Ask:

When and why was the TB screening test preformed?

- Usually a skin test is done when someone is considered to be at high risk for TB (e.g. they have had recent contact with a person who has active infectious TB, they are from an endemic country and the test was done as a part of a routine immigration/ occupation requirement or they have symptoms suggesting active TB).
- If the person does not have any symptoms of illness (e.g. cough, fever, weight loss, night sweats or malaise) they are not likely to have active TB.

Assessment and action:

- If the TST and/or IGRA was reported by the health care provider as positive, a CXR is to be done to determine if there are any changes which might indicate active TB in the lungs.
- If the individual has symptoms suggestive of TB, they should isolate themselves from their friends, family and co-workers until active TB is ruled out.
- While TB can occur anywhere in the body, the respiratory tract is the most common location in adults.
- Only respiratory TB is infectious. EPTB does not pose a risk to others.
- If the individual does not have symptoms of TB and CXR normal they probably have LTBI and no need for isolation.

10.8.2 Call from a health care facility regarding a patient with an abnormal CXR suggestive of TB

A person with an abnormal CXR suggestive of TB must be considered to have active infectious TB until it is proven otherwise.

Ask:

- Have any other tests been carried out (e.g. sputum test)? What were the results of the tests?
- Does the person have risk factors for TB (e.g. from endemic country, or underhoused, history of previous TB, recent exposure to someone with active TB disease, and HIV positive)?
- Does the person have symptoms consistent with TB (e.g. cough, fever, night sweats, weight loss and malaise)?

Assessment and action:

- This patient needs to be in an AIIR until TB disease has been absolutely ruled out.

** Any person with suspected or confirmed TB disease of the lungs, airway or larynx needs to be isolated from others

- If respiratory isolation is not possible at the facility, recommend the patient be transferred to a setting where appropriate tests and evaluation can be carried out and meanwhile:

1. Put the patient in a separate room apart from other patients with the door closed.
2. Instruct the patient to wear a surgical or procedure mask and keep it as long they are not in an AIIR, if possible and should observe strict respiratory hygiene/cough etiquette.
3. Inform the hospital and the ambulance of the suspicion of TB so that respiratory precautions are maintain during the transfer.

10.8.3 Call in which the person states they have been in contact with someone with TB

There is still a great deal of fear and stigma associated with TB. These calls are often associated with recent cases in schools or workplaces where group panic can take hold. The most important step is to try to ascertain whether this is really an exposure.

Ask:

- Why does the person think that she/he is a contact of an active case?
- Was there communication from any Health care Facility or department? If so who, where and what instructions were given?

** Usually the instructions will advise the person to have a TST or IGRA done.

Assessment and action:

A. Reassure the person that TB is not easily transmitted. It requires close prolonged contact with someone who is infectious.

B. Explain that when someone is diagnosed with infectious TB the contacts will be notify by the responsible health authority and be advised regarding steps they have to take.

C. Recommend to the person that they contact the health centre where the exposure occurred for more information and assessment.

D. The person should be advised that there is no risk to them or others waiting until they can contact the health centre and get assessment and review the situation with them.

10.8.4 Call regarding a patient who is not taking his/her TB meds

TB medication is prescribed for both active TB disease and LTBI. If the person has been on medication for at least two weeks and no longer has symptoms, then they are not likely to be infectious to others. Medication for both LTBI and active TB disease is to be taken daily unless the person is on DOT when it may be given twice or three times a week. Persons on DOT are monitored closely by either a nurse or home visitor and all the doses of medications are observed to ensure compliance.

Ask:

- In order to determine if the person has active TB disease or LTBI, ask how many drugs they are on.
- Find out how long they have been on treatment and how long it has been since they last took their medication.
- Find out where they are currently residing and obtain a phone number where they can be reached.
- Ask if they have symptoms which will give you an idea if they are infectious or not.

Assessment and action:

- This is only an emergency if the person has active TB disease and is still infectious.
- A person with active TB disease who has been on treatment for less than two weeks and has missed taking their medication for several days should be in respiratory isolation until they can be assessed, particularly if they have symptoms such as a cough. They should not be staying in a group setting (e.g. working camps) as they may pose a risk of transmission. As a minimum, arrangements should be made for them to stay in a single room for the night and then they should be re-assessed in the morning.
- If the person is on treatment for LTBI, they cannot be required to take their medication as they do not pose a risk to others.

10.8.5 Call regarding a TB patient who needs to go to operating theatre

An admitted patient suspected or confirmed to have TB may need to be taken for surgical procedure in the operating theatre while still isolated.

Ask:

- Is there suspicion or evidence of pulmonary or laryngeal TB?
- Is the patient on appropriate anti-TB for at least two weeks?

Assessment and action:

- If there is concern about active infection with aerosols generation during intubation and/or procedure done advise the following:

1. Staff should wear N95 masks with face shield or goggles or if not N95 fit use the PAPR until patient is intubated and then those who remain in operating room can continue with surgical masks.
2. The operating theatre used needs to be equipped with HEPA filtration facility.
3. The patient recovery should be within the same OR procedure room if not going to critical care unit. Avoid placing airborne isolated patients in the usual post-anaesthesia recovery area.

- Outpatients that are suspected or known TB patients who undergo an outpatient bronchoscopy must be scheduled as the last case of the day and recovered in the procedure room, while adhering to the conscious sedation protocol.
- Elective high-hazard procedures and surgery are delayed until a patient is non-infectious for TB.

10.8.6 Call asking about procedure during transport of TB patient or relocation within same facility

Any patient under airborne isolation should not be moved outside his or her room unless it is for essential purpose.

Ask:

- What is the reason for moving the patient?
- Is there another option?
- How urgent? for how long ?

Assessment:

The following should be ensured during the process:

- The receiving facility and/or department should be informed that patient is suspected/ or confirmed TB.

- If the patient's medical status permits, the patient should wear a standard surgical mask when leaving his/her room.
- The patient will need to be placed in a single room or private waiting area with a closed door with minimum waiting time as much as possible.
- If the patient is going for a procedure, it is highly recommended that it is scheduled as least once during a working day unless it is an emergency.
- Patients must be returned to an airborne isolation room as soon as practical after completion of the procedure.

10.8.7 Call regarding an exposure event in a health care facility

The exposure of confirmed TB infectious cases within facility should be reported immediately to the IPC or occupational health team for assessment of event, number and status of exposed individuals (HCWs, patients, visitors or others).

- Procedure of TB exposure investigation and management

1. Confirm with the lab the result of TB before starting exposure investigation.
2. If exposure was to an infectious case (pulmonary or laryngeal), start the procedure in coordination with facility occupational health if available and the Department of Disease Surveillance and Control in the DGHS in the governorate.
3. Prepare a list of exposed HCWs, patients and/or visitors who attended the patient without respiratory protection.
4. Share the list with Department of Disease Surveillance and Control so all person exposed in other facilities, community and discharged patients can be notified screened and follow-up arranged.
5. Determine based on exposure risk and previous screening status of exposed HCWs the need for employee evaluation and follow-up, i.e. PPD or CXR.
6. Provide counselling to the exposed health care worker regarding the use of antimicrobial prophylaxis following an exposure.
7. Evaluated each situation on a case-by-case basis in coordination with the department of disease surveillance and control and the IPC team of the facility, governorate and central department of IPC at MoH.
8. Provide details of investigation and outcome in an exposure/incident report.

Chapter 11

Monitoring &Evaluation (M&E)

11.1 Monitoring of patient and assigning outcome

11.1.1 Monitoring of treatment response

Appropriate monitoring of the response to treatment is important for the clinical care of all categories of TB patients.

Monitoring of TB patients on treatment include:

- Bacteriological monitoring for pulmonary TB cases by examination of sputum smears at two, three, five and six months of treatment;
- Clinical monitoring by symptomatic improvement and weight gain including patients who are clinically diagnosed pulmonary TB;
- Monitoring the drug intake during intensive phase and drug collection during the continuation phase by reviewing the treatment cards;
- Patient weight should be monitored each month and dosage should be adjusted if weight changes;
- Adverse events should be monitored and recorded for all medications given, along with bacteriological response.

Response to treatment in both new and retreatment bacteriologically confirmed cases should be monitored by sputum smear examination and culture at the end of the intensive phase of treatment, end of fifth month and end of treatment (Table 24).

Table 24. Schedule for follow-up according to TB patient category

Patient category	Follow-up sputum examination for (sputum positive)
• Bacteriologically confirmed and clinically diagnosed new cases • Previously treated patients (Xpert/MTB must be done) • Relapse • Treatment after failure • Treatment after loss to follow-up • Other previously treated	End of second month# End of third month if smear positive at the end of second month End of fifth month* End of treatment

 # If smear is positive send sputum for AFB and culture

***Culture should be sent at end of fifth month**

Follow-up visits

After completion of treatment, the patient attends four follow-up visits, as follows:

- After three months (first follow-up visit)
- After three months (second follow-up visit)
- After six months (third follow-up visit)
- After one year (fourth follow-up visit)

11.1.2 Treatment outcome

Monitoring TB patients must result in establishing the outcomes of TB treatment using the standardized definitions of WHO. The treatment outcomes need to be specified for all registered and notified TB patients and LTBI cases.

Treatment outcome should be recorded in the follow-up form and REC file/e-notification quarterly and at the end of the treatment course for each patient.

Table 25. Outcome definitions for patients treated with first-line drugs

Treatment outcome	Definition
Cured	A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear- or culture-negative in the last month of treatment and on at least one previous occasion.
Treatment completed	A TB patient who completed treatment without evidence of failure but with no record to show that sputum smear or culture results in the last month of treatment.
Treatment failure	A TB patient whose sputum smear or culture is positive at the end of fifth month or later during treatment.
Died	A TB patient who dies for any reason before starting or during the course of treatment.
Lost to follow-up	A TB patient who did not start treatment or whose treatment was interrupted for two consecutive months or more.
Not evaluated	A TB patient for whom no treatment outcome is assigned. This includes cases for whom the treatment outcome is unknown to the reporting unit.

11.2 M&E

M&E is an integral part of TB programme management and provides information on the scope, quality, scale/coverage, and success of the programme.

Monitoring generally refers to the routine collection of information across time and sites in order to track a program's ongoing activities. Policy-makers use monitoring to track key health-related indicators, often without attributing change to any particular programme or set of programmes.

Evaluation involves the assessment of programme implementation in order to determine the worth or value of a programme in terms of its success in achieving predetermined outcomes/goals. Evaluation is usually achieved through a detailed analysis of the programme's process and outcomes or impacts. Evaluation lends itself to the linkage of outcomes to the programme process, as well as rule out non-programme effects on outcomes.

11.2.1 M&E framework

Adequate M&E can only be achieved through a well-defined plan incorporating a framework of the goal, service delivery areas and activities. Indicators are needed to measure the performance and progress achieved.

It is crucial that the framework indicators can be critically analysed and interpreted at all levels and corrective action taken. Guidelines and standard operating procedures for data management, analysis and quality assurance should also be developed and adhered to.

Recording and reporting forms:

- **Reporting forms:**

1. e-notification reporting system for Presumptive TB and Confirm TB cases (Tarassud)
2. e-notification for contact screening (Tarassud)
3. e-notification for Health Care Worker (Tarassud)
4. Quarterly report from Governorate to NTP
5. Annual report from Governorate to NTP
6. Annual report from NTP to MoH HQ and WHO

- **Register: (health institute)**

1. Lab TB register for presumptive TB

- **Treatment cards**

1. Electronic TB patient follow-up system (Tarassud) for patient and contacts

- **Monitoring forms:**

1. National M&E Indicator
2. Governorate M&E Indicator
3. Governorate Monitoring and Supervision Checklist for Health Institute

- **Pharmacy:**

1. Quarterly report on ATT consumption and stock from pharmacy and medical store to NTP

- **Laboratory**

1. QC related to AFB smear
2. Line list of TB PCR and culture
3. CPHL TB line list

- **TB HIV**

1. LTBI screening for PLHIV

- **Mortality**

1. Line list of TB mortality
2. Mortality report for any TB-related death from governorate

- **MDR-TB**

1. Line list of MDR-TB
2. Treatment cards for MDR-TB

- **Health Promotions**

1. Report on community health education (health education department/health institute)
2. World TB day celebrations

- **Use of GIS information for preparing spot map and assess clusters (national)**

Frequency of M&E visits:

- **National level:**

1. Minimum once a year to all governorates
2. More visits can be plan according to needs

- **Governorate level:**

1. Minimum twice a year to secondary and tertiary care hospitals
2. Minimum once a year to primary health care institutes
3. More visits can be plan according to needs

11.2.2 Programme indicators

It is important to understand that programme monitoring is not limited to indicators enlisted in this document nor should the programme managers attempt to use them all. The choice of indicators should be needs based. The overall purpose of using these indicators is to identify problem areas and find solutions to improve programme performance. But at the same time, it is necessary that the data sources for computation of these indicators are correct, complete and consistent for the indicators to act as a valid monitoring tool.

Table 26. Key performance indicators for NTP

Indicator	Target	Actual
TB treatment coverage rate (%) Number of new and relapse cases that were notified and treated divided by number of estimated incident TB cases in same year	>=90%	
TB treatment success rate (%) Percentage of notified TB cases who were successfully treated.	>=90%	
Percentage of TB-affected households that experience catastrophic cost due to TB Number of people treated for TB and their household who incur catastrophic cost. (cost >20% of annual household income)	0	
Percentage of new and relapse TB patient tested using WHO recommended rapid diagnostic at the time of diagnosis (New molecular test, e.g. TB PCR/GeneXpert)	>=90%	
LTBI treatment coverage Number of newly enrolled HIV patients, number of children < 5 years who are household contact of TB cases and TB screening test positive divided by all eligible for LTBI treatment (percentage)	>=90%	
Contact investigation coverage Number of contacts of patients with confirmed TB who are evaluated for TB divided by number of eligible (percentage)	>=90%	
DST coverage for TB patients Number of TB patient with DST results for at least rifampicin divided by total number of (New and retreatment) cases in same year (percentage) (Gene Xpert and Culture sensitivity results)	100%	

Treatment coverage for new TB drugs Number of TB patient treated with regimes that include new (Endorsed after 2010) TB drugs divided by number of patient eligible for treatment	>=90%	
Documentation of HIV status among TB patients Number of new and relapse TB patient with documented HIV status divided by number of new and relapse TB patients notified in same year (percentage)	100%	
Case fatality ratio Number of TB deaths divided by estimated number of incident TB cases in same year (percentage)	<=5%	

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