With grateful thanks to all the people who have contributed to this manual. You will also be thanked unconsciously by those patients and their families who remain alive and well, because of the high standards of care which will be implemented as a result of this manual.

Constructive suggestions for improving or updating this Manual would always be gratefully received.

This Manual was designed and produced at the National Tuberculosis Control Programme, Dept. of Communicable Disease Surveillance & Control, Directorate General of Health Affairs, Ministry of Health.
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PREFACE

Tuberculosis ranks among the top three infectious diseases, as a cause of disease burden in the world. The unprecedented scale of the epidemic (due to Multi-drug resistance and HIV/AIDS) and the human rights approach to TB, demand an urgent and effective action now. This has resulted in the WHO in 2005, coming out with a Global Plan of Action for its control, under the heading of, “Action for life towards a World free of Tuberculosis”. This Global Plan to Stop TB sets out what needs to be done over the next 10 years, from 2006-2015 and what can be achieved. The strategies are based on a clear vision of, “A World free of Tuberculosis”.

Oman has had the plan towards the elimination of TB since 1996 when we introduced the DOTS programme. With the help of the International Community, we believe that, the day when the World is free of TB, is near. We also believe that the plans for implementation of TB control for the period 2005-2015, are ambitious, realistic and shaped to the Individual Country needs.

This update to the third edition has considered the recommendations made by the WHO, after the review of the TB programme in October 2005. We have tried giving solutions, to the difficulties and the problems we have faced in the last ten years.

Moreover the additions to this updated edition include Combined Treatment which has Emphasis placed on Latent TB Infection treatment among contacts and high-risk groups, as a strategy, (by screening and follow up of contacts for 2 years) and the addition of a separate chapter on Pediatric TB.

I hope these additions, to the TB Manual, will help in achieving the goal of further reduction and transmission of TB in Oman.

In recognition of the efforts extended in having this update realized, the Ministry of Health would like to express its thanks and gratitude to all the contributors and editors of this Manual.

H.E. Dr Ali Jaffer Mohamed
Advisor of Health Affairs, Supevising of DG HA
### TB - glossary

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFB</td>
<td>Acid Fast Bacilli</td>
</tr>
<tr>
<td>AAFB</td>
<td>Acid &amp; Alcohol Fast Bacilli</td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired Immunodeficiency Syndrome</td>
</tr>
<tr>
<td>ATT</td>
<td>Anti Tubercular Therapy</td>
</tr>
<tr>
<td>BCG</td>
<td>Bacilli Calmette Guerin</td>
</tr>
<tr>
<td>CSF</td>
<td>Cerebrospinal fluid</td>
</tr>
<tr>
<td>DOTS</td>
<td>Directly Observed Treatment, Short-course</td>
</tr>
<tr>
<td>DGPA&amp;DC</td>
<td>Directorate General of Pharmaceutical Affairs &amp; Drug Control</td>
</tr>
<tr>
<td>DCDS&amp;C</td>
<td>Department of Communicable Disease Surveillance &amp; Control</td>
</tr>
<tr>
<td>EP</td>
<td>Extra-pulmonary</td>
</tr>
<tr>
<td>EPI</td>
<td>Expanded Programme on Immunization</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>IUATLD</td>
<td>International Union against Tuberculosis &amp; Lung Diseases</td>
</tr>
<tr>
<td>LFT</td>
<td>Liver Function Test</td>
</tr>
<tr>
<td>LTBI</td>
<td>Latent Tuberculosis Infection</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MDR</td>
<td>Multiple Drug Resistance</td>
</tr>
<tr>
<td>MT</td>
<td>Mantoux-Test</td>
</tr>
<tr>
<td>NTP</td>
<td>National Tuberculosis Programme</td>
</tr>
<tr>
<td>NRL</td>
<td>National Reference Laboratory</td>
</tr>
<tr>
<td>OPD</td>
<td>Out Patient Department</td>
</tr>
<tr>
<td>PCM</td>
<td>Protein-calorie Malnutrition</td>
</tr>
<tr>
<td>PHC</td>
<td>Primary Health Care</td>
</tr>
<tr>
<td>QCP</td>
<td>Quality Control Programme</td>
</tr>
<tr>
<td>RFT</td>
<td>Renal Function Test</td>
</tr>
<tr>
<td>SCC</td>
<td>Short Course Chemotherapy</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>TBCP</td>
<td>Tuberculosis Control Programme</td>
</tr>
<tr>
<td>TB/HIV</td>
<td>TB and HIV co-infection</td>
</tr>
<tr>
<td>TBP</td>
<td>Pulmonary Tuberculosis</td>
</tr>
<tr>
<td>UNICEF</td>
<td>United Nations Children's Fund</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>ZN</td>
<td>Ziehl-Nelsen</td>
</tr>
</tbody>
</table>
INTRODUCTION

Global TB burden

Despite the great achievement in diagnosis and treatment, TB remains a major health problem of public health concern worldwide. In the year 1993, the World Health Organization (WHO) declared TB as a global public health emergency. It is estimated that around one third of the world’s population is infected with Mycobacterium tuberculosis. In the year 2004, around 9 million individuals developed active TB disease worldwide. Despite the availability of cost-effective treatment 1.7 million TB deaths were reported in the year 2004, putting TB as the second cause of death, after HIV/AIDS, among infectious diseases in the world. Furthermore, the global incidence rate of TB is increasing by approximately 0.6% every year.

Medications used against TB have been cost effective in curing TB for more than 50 years. However, some Mycobacterium tuberculosis strains have developed resistance against one or more of TB medications. Resistance to more than one drug, known as Multiple Drug Resistances (MDR), is life threatening and 100 times more expensive to treat. Along with MDR, HIV infection has contributed to the resurgence of TB worldwide.

Situation in Oman

National Tuberculosis Program (NTP) in Oman was initiated in 1981. Reported TB cases dramatically reduced by more than 75% from 928 in 1981 to 212 in 2005. The incidence rate of TB sputum positive has also declined from 21/100,000 in 1981 to 6.4/100,000 in 2006. Though Oman is a low incidence country now, the notification of the sputum positive TB has stagnated around 5/100,000 population for the last 7 years without any noticeable further decline.

Objectives of the Tuberculosis Control Program

- To reduce mortality, morbidity and transmission of disease through implementation of “DOTS” strategy and other strategies (e.g. Latent TB Treatment in high risk patients) until TB stops to be a public health problem.
- To achieve 1/100,000 or less incidence rate of new smear positive TB cases by year 2015.
Disease information
Tuberculosis is an infectious disease caused by Mycobacterium tuberculosis. Mycobacteria that cause tuberculosis are: M. Tuberculosis, M. bovis and M. africanum. The disease is highly contagious and can infect any person exposed to the causative bacilli.

Routes of infection
• Tuberculosis is caused by the entry of the tubercle bacilli into the body when the host factors are favorable to its development.
• Tubercle bacilli usually gain entrance into the body through the respiratory system by inhalation but it can also enter through gastro-intestinal tract by drinking un-pasteurized milk.
• Tuberculosis can spread from primary lung lesion to other parts of the body by various means; bacilli can be spread by haematogenous, lymphatic or bronchial route. Direct spread sometime occurs and any organ or tissue may thus become infected.

Tuberculosis in adults
• Pulmonary Tuberculosis: Tuberculosis of the lungs or hilar lymph nodes. Tuberculosis affects the lungs in more than 80% of the cases. Pulmonary TB patients are either sputum positive or sputum negative with X-ray evidence of the disease.
• Extra-pulmonary (EP) tuberculosis: Extra-pulmonary tuberculosis affects various organs, such as lymph nodes, bones & joints, pleura, genito-urinary tract, nervous system (e.g. meningitis), intestines and other organs of the body. Patients with extra-pulmonary tuberculosis are rarely infectious.

Mycobacterium Other Than Tuberculosis (MOTT)
• Cases of MOTT viz M. Kansasi, M. fortuitum complex, M. avium complex, M. xenopi, M. chelonei etc treated with ATT should NOT be included as TB cases. The disease is not infectious hence patient should not be isolated. Ministry of health policy for TB registration, case finding and contact tracing should not be applied in these patients. However, for treatment and follow-up of case(s) of MOTT, consult TB Specialist at Referral Chest Clinic, Al Rahma Hospital in Muscat Governorate.
Chapter 1

MOH POLICY
MOH POLICY

General

• All communicable disease are subject to the law on control of infectious diseases (Issued by the Royal Decree No. 73/92) Annex 1

• TB is a notifiable disease under groups A & B i.e. all cases of TB (pulmonary and extra pulmonary) must be reported, pulmonary cases within 24 hrs of diagnosis (group A) and for extra pulmonary cases within a week of diagnosis(group B), to NTP in the Dept of Communicable Disease Surveillance & Control (DCDSC) M O H.

• DOTS, is the strategy adopted to control TB in the country. During the intensive phase it is mandatory to hospitalize all sputum positive patients for 2 months.

• Latent TB infection 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.

• Passive case finding i.e. sputum microscopy should be performed with chest X-ray for diagnosis of the symptomatic cases attending the health institutions.

• In order to rule out TB in a suspect, TB culture should be performed for all Muntux positive.

• Short-Course Chemotherapy (SCC), contained in this manual should be strictly adhered to all cases, except in cases of proven drug resistance to regimen. Such cases should be referred to the Referral Chest Clinic, Al-Rahma Hospital, Muscat.

• At the primary health care level, the health centers should be involved in case finding, case-holding, ensuring regular drug supply, diagnostic materials and follow up of the cases.

• NTP staff consolidates and monitors monthly and annual reports from all reporting institutions in the country. Feedback comments after monitoring individual reports will be sent for information and necessary corrective action.

• NTP staff will carry out training of TB Focal Points whenever needed

• In case of complication or uncertain diagnosis, patient is referred to regional medical/Chest Clinic for admission or expert opinion.

• The management of the TB case is free of charge to Nationals & Non-Nationals.

Private sectors:–

• Must adhere to the Ministry of Health policy

• Private Hospitals/ Clinics should neither treat TB cases nor prescribe anti-tuberculous drugs.

• If a private practitioner suspects/ diagnoses that a patient has TB, the patient should be referred to the nearest M O H Hospital/ Health Center. In addition, notification should be sent to regional TB focal point or NTP.

• For Muscat region, the Referral Chest Clinic is Al-Rahma hospital.

• Non-compliance would be subjected to the Royal Decree No. 73/92 and to Article No. (27) Of the law on the practice of Medicine and Dentistry NO. 9/1973.

• Private pharmacies are banned from selling anti-tuberculous drugs including Rifampicin to private clinics or individuals.

• All M O H and non-M O H institutions should carry on using these standardized procedures and reporting system in all their health facilities.

• No TB cases, especially sputum positive cases, should default from treatment. Sputum positive
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’.

- All TB patients should be screened for HIV infection. Similarly all HIV cases should be screened to exclude tuberculosis (Active or Latent).
- All close family household contacts with a positive Mantoux test of an indexed patient will be put on IPT as per guidelines given in this manual.
- The follow-up of TB contacts will be for two years once every six months.
- In order to monitor the MDR in the community, National Reference Laboratory (NRL) and NTP should coordinate to conduct drug resistance surveillance of anti-tuberculous drugs.
- Contact tracing and defaulter retrieval should be done and followed up by the health centre in the catchments area where the patient lives.

**NTP Responsibilities**

**National Tuberculosis Programme (NTP) responsibilities**

- Maintaining a master register and cross-indexing all reported cases of TB.
- 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.
- Report to the WHO (EMRO).

**Regional / sub-regional hospitals:**

**TB case finding**

- All doctors are requested to suspect and detect TB cases among OPD patient
- It is the responsibilities of Doctors and TB focal point in the 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 TB Focal point should ensure that the drugs on the collecting day are taken under their observation on the day of collection; the remaining drugs are taken home.

**The regional epidemiologist**

- Should monitor Sputum examinations monthly for suspect and patient
- To ensure that contacts screening of known TB cases (sputum smear positive, sputum smear negative and extra pulmonary) is started within one week of diagnosis.
- Treatment of all cases is according to the standardized treatment schedule contained in this manual.
- All the records are updated
- Training of the new focal point in the region
- Follow up and coordination with other governmental organization to bring back the
defaulters and patient's who refuse admissions and treatment

- Study and analyses of the TB cases and put up activities that assist to 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

- **Wilayat Health Directors or Superintendents**
  - Wilayat Health Directors or Superintendents are responsible for the supervision and conduct of the program activities at wilayat level.
  - Follow up the administrative issues with the other governmental organization or private sectors.

**Reporting responsibilities**

**Local reporting**
The local public health inspector must be informed regarding defaulters and TB contact for the follow up action.

**National reporting**

- **TB Monthly Report:** 'NIL' monthly report is also to be submitted from all health institutions.
- **Tuberculin Tests Report:** monthly, only if something to be reported.
- **Contact Tracing Report:** monthly, for new case(s) / follow up of the old contact.
- **Epidemiological investigation report:** for new case(s) (Nationals & Non National).

**Health Centre Responsibilities:**

- The health centers are responsible for appropriately investigating and diagnosing a patient with symptoms suggestive of tuberculosis.
- Health centers lacking of the diagnostic facilities (e.g. sputum microscopy, chest X-ray) may refer the patient to a health center 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 center for screening for 2 years (every 6 months). Contact addresses and names should be maintained in the health center where the follow up is done. The result of the test should be sent to the NTP every six months.
- **Defaulter retrieval and health education:** The health center should locate, treat and ensure that defaulter re-attend to the health center to collect and consumes their medications under supervision in health institution or at home. Such patient may be admitted (even by force) if necessary.
Case-finding & Diagnosis

Terminology Definitions

The following case-definitions were developed for surveillance purposes and adopted as guidelines.

Pulmonary Tuberculosis

Smear positive patient:
A patient with at least two sputum specimens positive for Acid Fast Bacilli (AFB) by microscopy OR Patients with one AFB sputum positive specimen plus radiographic abnormalities, consistent with active pulmonary tuberculosis OR A patient with at least one sputum AFB smear positive and culture positive for Mycobacterium tuberculosis.

Smear negative patient:
Patients with at least two sputum specimens negative for AFB but radiographic abnormalities consistent with active pulmonary tuberculosis. Plus decision by a physician to treat with a full course of antituberculosis treatment OR patients with AFB smear-negative sputum, that is culture positive for Mycobacterium tuberculosis.

Extra-pulmonary tuberculosis

• A patient with confirmed diagnosis either by, histopathology and/or culture of tissue fluid for AFB and/or specialized radiological investigations and/or clinical evidence consistent with active tuberculosis. Plus decision by a physician to treat with a full course of anti-tuberculosis treatment.

Epidemiological objective of “tuberculosis case finding’

The epidemiological aim of controlling tuberculosis is to prevent the spread of infection, and to identify the sources of infection in a community. The TB case-finding is the responsibility of All Health Care Workers. It is mandatory to “Think TB” whenever we examine a person complaining of a persistent cough for 2 weeks or more with / without other signs and symptoms of TB. Sputum examination, chest-X ray and sputum culture should be sent for investigation.
Classification of the TB

For operational convenience, the following disease classification has been adopted:

<table>
<thead>
<tr>
<th>New Bacillary Case-index</th>
<th>B - 00001</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Sputum smear positive on direct microscopy)</td>
<td></td>
</tr>
</tbody>
</table>

- **New X-ray case-index**
  Sputum negative but X-ray positive, AAFB culture positive, Pleural effusion, Bronchial washing positive etc)
  X - 00001

- **New Extra-pulmonary case-index**
  (Extra-pulmonary TB cases)
  E - 00001

- A patient diagnosed with both pulmonary & extra-pulmonary TB should be classified as a case of **pulmonary tuberculosis**
- Tuberculous pleural effusion and pleurisy alone should be classified as **extra-pulmonary tuberculosis**
Chapter 2

DIAGNOSIS AND TREATMENT
TB Diagnosis Schedule

**Pulmonary Tuberculosis**

Pulmonary TB should be suspected in the following

- **Adults**: persistent cough for two weeks or more, with or without expectoration.
- **Children**: persistent cough for three weeks or more, with or without expectoration (see chapter 4)
- Haemoptysis.
- Fever, night sweats or shortness of breath.
- Loss of appetite and weight.
- Chest-pain especially of the pleuritic type.

**Extra-Pulmonary TB**

The symptoms of the Extra-pulmonary TB depend on the organ involved.

- Plural effusion start at birth, chest discomfort on the affected side
- Swelling of lymph nodes in TB lymphadenitis.
- Abdominal pain, nausea, vomiting, diarrhea alternating with constipation or ascites in latent TB.
- Pain and swelling of joints in TB of the joints.
- Stiffness of spine, painful on movement, local tenderness, kyphotic deformity and gibbus formation due to Tuberculosis of the spine.
- Pain in lumbar region, frequency of micturition, usually painless haematuria in renal TB.
- Headache, fever, stiffness of the neck and mental confusion in TB meningitis.
- Amenorrhea or irregular menstruation, infertility in genital TB

**Investigations**

- Sputum microscopy for AFB X 3 times (see annex: 3)
- Sputum culture (see annex 4)
- Chest X-ray
- Mantoux test (see annex 2)
- CBC, ESR

**Sputum Induction:**

If the patient is unable to cough out sputum

- Check sputum microscopy on induced sputum (sputum induction is done with 5 ml of 3 percent saline given through nebulizer)
- Order for a sputum culture
- If induced sputum microscopy negative and chest X-Ray suggestive of TB refer the patient to chest specialist for possible bronchoscopy and expert opinion.

**Bronchoscopy**

When the suspicion for Pulmonary TB is high especially in the presence of abnormal chest x-ray; and even the induced sputum is negative for AFB smear, bronchoscopy should be done for bronchial washing test for AFB smear and culture.
Extra-Pulmonary TB
1. Appropriate investigation should be done for the diagnosis of TB in an organ e.g. biopsy.
2. Refer the patient for opinion from appropriate specialist e.g. surgeon for Lymph node biopsy

Laboratory Diagnosis

Level I
Almost all Health Care Institutions in the MOH perform sputum microscopy for AFB. (See Annex-3)

Level II
TB cultures are carried out in all regions public health laboratories (except Haïma where TB culture facilities will be made available shortly). In Muscat region TB cultures are carried out in the Central Public Health Laboratories, Darseit (see annex -4)

Level III
The isolates from TB culture are referred to the Central Public Health Laboratories where the isolates are identified and anti-microbial susceptibility tests are carried out. (see annex - 6)

Collection of Sputum specimens
Sputum should be collected in sterile universal container or wide mouthed screw-capped containers. Before collecting the specimen’s patients should be instructed to obtain proper sputum and not saliva or nasal discharge.
Three sputum specimens should be sent for microscopy and culture. One specimen should be collected on spot and remaining two at intervals on the same day. If patient is unable to provide sputum, nebulized specimen should be collected and should be mention as nebulized sputum.

Storage and transportation
The sputum specimen should be sent to the laboratory as soon as possible. If a delay is unavoidable it should be stored in a refrigerator until sent to the laboratory in a cool box.

Monitoring Sputum examination
For all smear positive tuberculosis patients smear examination should be done every two weeks until they become sputum smear negative. However the reporting of the smear examination results to the NTP should be done only as follows:

<table>
<thead>
<tr>
<th>Sputum smear examination</th>
<th>Six months regimen</th>
<th>Eighth months regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>At the end of initial phase</td>
<td>End of second month</td>
<td>End of second month</td>
</tr>
<tr>
<td>In continuation phase</td>
<td>End of fourth month</td>
<td>End of fifth month</td>
</tr>
<tr>
<td>At the end of treatment</td>
<td>End of sixth month</td>
<td>End of eighth month</td>
</tr>
</tbody>
</table>
Quality Control (QC) Programme in AFB smear microscopy

- The MOIC from each institution should collect all positive slides and randomly select 5% of the negative slides (QC of negative slides is as important as for positive slides) from institutional laboratories and should be sent to Department of Public Health Laboratories. Feedback comments are sent on the quality of smear, presence or absence of tubercle bacilli and score the slides as ‘good’, ‘satisfactory’ or unsatisfactory. Thus errors, poor performance can be identified and steps can be taken to improve microscopy, re-training of workers who have done poorly, institutions with poor performances can be identified and above all reading errors for slides labeled ‘positive’ or ‘negative’ (under or over-reading) can be done.
- It must be clear that the selection of the slide should not be done by Lab. Technician preparing the AFB slide.

TB Treatment Schedule

Directly Observed Treatment, Short-course (“DOTS”) STRATEGY

As per H.E. the Undersecretary of Health Affairs circular (MH/2/C/4/D/1687 dated November 15, 1995) on revitalization of National Tuberculosis Control Programme in Oman, all *Sputum Positive* TB patients must be admitted for the initial intensive phase of 2 months for “DOTS” — (Directly Observed Treatment, Short-course). Under “DOTS” strategy, the patients are directly observed, swallowing and recording of their medicines, by a health worker. The TB patient must be counseled, educated and motivated during the hospitalization.

The allocation of DOTS responsibilities in the region is as follows:

<table>
<thead>
<tr>
<th>Region</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Muscat Governorate</td>
<td>Al-Rahma Hospital,</td>
</tr>
<tr>
<td>Dhofar Governorate</td>
<td>Sultan Qaboos Hospital, Salalah</td>
</tr>
<tr>
<td>Buraimi Governorate</td>
<td>Buraimi Hospital</td>
</tr>
<tr>
<td>Musandam Governorate</td>
<td>Khasab Hospital</td>
</tr>
<tr>
<td>Al Dhakilyah Region</td>
<td>Nizwa, Samail &amp; Bahla Hospital</td>
</tr>
<tr>
<td>North Sharqiyah Region</td>
<td>Ibra &amp; Sinaw Hospital</td>
</tr>
<tr>
<td>South Sharqiyah Region</td>
<td>Sur, BBBA &amp; BBBH Hospital</td>
</tr>
<tr>
<td>North Batinah Region</td>
<td>Sohar &amp; Saham Hospital</td>
</tr>
<tr>
<td>South Batinah Region</td>
<td>Rustaq Hospital</td>
</tr>
<tr>
<td>Al Dhahirah Region</td>
<td>Ibra Hospital</td>
</tr>
<tr>
<td>Al Wusta Region</td>
<td>Haima Hospital</td>
</tr>
</tbody>
</table>
**Baseline Investigations**

Liver Function test (LFT) and Renal function test (RFT) should be done in all patients before starting treatment (ATT). These tests should be repeated on a monthly basis in the first 2 months of treatment and thereafter monthly in the continuation phase.

**Choice of regimens**

The regimen recommended and developed by IUATLD and WHO are being followed nationally with effect from 1st January 1996.

<table>
<thead>
<tr>
<th>R - Rifampicin</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>E - Ethambutol</td>
<td></td>
</tr>
<tr>
<td>H - Isoniazid (INH)</td>
<td></td>
</tr>
<tr>
<td>S - Streptomycin</td>
<td></td>
</tr>
<tr>
<td>Z - Pyrazinamide</td>
<td></td>
</tr>
</tbody>
</table>

**Category - I**

New cases of smear-positive pulmonary tuberculosis and other newly diagnosed seriously ill patients with severe forms of tuberculosis, (E.g. TB meningitis, disseminated tuberculosis, tuberculous pericarditis, peritonitis, bilateral or extensive pleurisy, spinal disease with neurological complications, smear-negative pulmonary tuberculosis with extensive parenchymal involvement, intestinal, genito-urinary tuberculosis etc).

**Initial phase: (2 HRZS (E))**

| Isoniazid, Rifampicin, Pyrazinamide and either Streptomycin or Ethambutol given daily | 2 months (8 weeks) |

When the patient has completed the initial phase of treatment and the sputum is smear negative, the continuation phase is started. However, if the sputum smear is positive at 8 weeks, the initial phase of therapy should be extended for another 4 weeks then the continuation phase is started, regardless of sputum test results. In case of resistance a TB specialist should be consulted.

**Continuation phase: (4 HR)**

| Isoniazid and Rifampicin given daily | 4 months (16 weeks) |

For patients with tuberculous meningitis, disseminated tuberculosis or spinal disease with neurological complications INH and Rifampicin should be given daily for 7 months (i.e. a total of 9 months of therapy).
**Category - II**

Relapse and treatment failure (smear-positive)

**Initial phase: (2 HRZES) + (1HRZE)**

<table>
<thead>
<tr>
<th>Meds</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid, Rifampicin, Pyrazinamide, Ethambutol and Streptomycin given daily</td>
<td>2 months (8 weeks)</td>
</tr>
</tbody>
</table>

**Followed by**

<table>
<thead>
<tr>
<th>Meds</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid, Rifampicin, Pyrazinamide, Ethambutol given daily</td>
<td>1 month (4 weeks)</td>
</tr>
</tbody>
</table>

By the end of the initial phase, the total duration 3 months (12 weeks)

The result of sputum for mycobacterial culture and sensitivity must be reviewed by the end of the initial phase. If the sputum smear remains **positive** and the mycobacteria is sensitive to all drugs continue treatment for 4 weeks more. If sputum smears, remain **positive** at the end of the 4 months and/ or if there is, evidence of drug resistance, consult a TB specialist in AL- Rahma hospital.

At the same time, the result of the sputum for the mycobacterium culture and sensitivity should be reviewed. Full details of the patient who developed resistance should be faxed to the TB program manager.

**Continuation phase: (5 HRE)**

<table>
<thead>
<tr>
<th>Meds</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid, Rifampicin and Ethambutol given daily</td>
<td>5 months (20 weeks)</td>
</tr>
</tbody>
</table>

If the patient remains smear- **positive** after the completion of continuation phase, he/ she is no longer eligible for the re-treatment regimen. However, patient should be referred to a TB Specialist.

**Category - III**

Pulmonary smear-negative TB with limited parenchymal involvement and less severe forms of extra pulmonary tuberculosis.

**Initial phase: (2 HRZE)**

<table>
<thead>
<tr>
<th>Meds</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid, Rifampicin, Pyrazinamide, Ethambutol given daily</td>
<td>2 months (8 weeks)</td>
</tr>
</tbody>
</table>

**Continuation phase: (4 HR)**

<table>
<thead>
<tr>
<th>Meds</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid and Rifampicin given daily</td>
<td>4 months (16 weeks)</td>
</tr>
</tbody>
</table>
Category – IV – according to sensitivity & 2nd line drugs

Chronic and Multi Drug Resistant-Tuberculosis

Patients with chronic tuberculosis have a high likelihood of multi-drug resistant tuberculosis and even with optimal therapy; cure may be possible in only half of such cases. Second line and experimental drugs are very expensive, more toxic and significantly less effective. Initially such patients must be admitted and managed only at AL-Rahma Hospital.

Total duration of the treatment

Total duration of the treatment as specified in the various categories should be strictly adhered to by Physicians / Consultants. If any case requires treatment, beyond the stipulated duration the opinion of the TB specialist should be sought and / or transferred to the Referral Chest Clinic, AL-Rahma Hospital.
### ADULT DOSAGE, SCHEDULE & ROUTE

<table>
<thead>
<tr>
<th>Drug (Strength)</th>
<th>Doses (Per day)</th>
<th>Adult Dose (Per day)</th>
<th>Adverse reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid INH (100 mg)</td>
<td>1</td>
<td>5 mg / Kg (Maximum 300 mg)</td>
<td>Mild of AST/ALT, hepatitis, peripheral neuritis, hypersensitivity. With dose &gt; 10 mg/ kg/ d, and concomitant use of Rifampicin, the incidence of hepatotoxicity increases. Skin rash, Lupus syndrome (Rare), Encephalopathy (rare)</td>
</tr>
<tr>
<td>Rifampicin (a) (150 &amp; 300 mg)</td>
<td>1</td>
<td>10 mg/ Kg (Max. 600 mg) if Body weight &lt;50 Kgs = 450 mg, Body Weight &gt;50 Kgs = 600 mg</td>
<td>Orange discoloration of urine or secretions, staining of contact lenses, vomiting, hepatitis, influenza like reaction, thrombocytopenia; pruritus, oral contraceptives may be ineffective</td>
</tr>
<tr>
<td>Ethambutol (b) (400 mg)</td>
<td>1</td>
<td>25 mg/ Kg for not more than 2 months; 15 mg/ Kg if longer than 2 months</td>
<td>Optic neuritis (usually reversible), decreased red-green color discrimination, GIT disturbances, hypersensitivity</td>
</tr>
<tr>
<td>Pyrazinamide (500 mg)</td>
<td>1</td>
<td>25 mg / Kg (first 2 months only)</td>
<td>Hepatotoxicity, hyperuricemia, arthralgia, GI upset, hyperuricemia (gout)</td>
</tr>
<tr>
<td>Streptomycin (c)</td>
<td>1</td>
<td>15 mg / Kg</td>
<td>Auditory and vestibular toxicity, nephrotoxicity, rash</td>
</tr>
</tbody>
</table>

(a) Dose of Rifampicin should be taken as early as possible in the morning, on an empty stomach  
(b) Children below 6 years should not be given Ethambutol.  
(c) Streptomycin should not be used in elderly patients (55+) and in pregnancy

### Fixed Dose Combination regimen for Category I and III

<table>
<thead>
<tr>
<th>Sample regimens with fixed-dose combinations of anti-tuberculosis drugs in adults</th>
<th>Weight in KG</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>30-39</td>
</tr>
<tr>
<td>Initial phase – Daily HRZE (75mg +150 mg+400mg+275 mg)</td>
<td>2</td>
</tr>
<tr>
<td>Continuation phase Daily RH (150Mg + 150 mg)</td>
<td>2</td>
</tr>
</tbody>
</table>

**Note:**  
1) All toxic/ side-effects of TB drugs should recorded in the treatment-card of the patient  
2) Seek TB Specialist’s opinion for management of case(s) or for transferring the patient to the Muscat Governorate, for admission
**Drug challenge**

The process of drug challenging is done to identify the drug responsible for the reaction. Drug challenge starts with the anti-tuberculous drug least likely to be responsible for the reaction (e.g., isoniazid). The dose is gradually increased over three days. The procedure is repeated, adding in one drug at a time. The table below shows the standard approach to re-introducing ATT after a cutaneous drug reaction.

If the drug responsible for the reaction is pyrazinamide, ethambutol or streptomycin, ATT is resumed without the offending drug. The offending drug is replaced with another drug. **It may be necessary to extend the treatment regimen.**

<table>
<thead>
<tr>
<th>DRUGS (in sequence)</th>
<th>Likelihood of causing a cutaneous reaction</th>
<th>CHALLENGE DOSES</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td><strong>DAY 1</strong></td>
</tr>
<tr>
<td>Isoniazid</td>
<td>Least likely</td>
<td>50 mg</td>
</tr>
<tr>
<td>Rifampicin</td>
<td></td>
<td>150 mg</td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td></td>
<td>250 mg</td>
</tr>
<tr>
<td>Ethambutol</td>
<td></td>
<td>100 mg</td>
</tr>
<tr>
<td>Streptomycin</td>
<td>Most likely</td>
<td>125 mg</td>
</tr>
</tbody>
</table>

**Management of drug-induced hepatitis**

**Drug-induced hepatitis**

Drug-induced hepatitis, the most serious common adverse effect, is defined as a serum AST level more than three times the upper limit of normal in the presence of symptoms, or more than five times the upper limit of normal in the absence of symptoms. If hepatitis occurs, INH, RIF, and PZA, all potential causes of hepatic injury, should be stopped immediately and the patient questioned carefully regarding exposure to other possible hepatotoxins.

Two or more anti-tuberculosis medications without hepatotoxicity, such as EMB, SM, amikacin/kanamycin, capreomycin, or a fluoroquinolone (e.g. ciprofloxacin) may be used until the cause of the hepatitis is identified. Once the AST level decreases to less than two times the upper limit of normal and symptoms have significantly improved, the first-line medications should be restarted in sequential fashion. Close monitoring, with repeat measurements of serum AST and bilirubin and symptom review, is essential in managing these patients.

**Reference:** Treatment of Tuberculosis: June 20, 2003 / 52(RR11):1-77

**Second Line Drugs**

- Second line anti-tubercular drugs e.g. D-cycloserine, Prothionamide and Capreomycin Inj. are available at the Referral Chest Clinic, AI Rahma Hospital.
- However, when TB patients in whom treatment was started with these drugs is subsequently transferred to peripheral institution, the receiving institution can request small quantities of these drugs, for continuation of the regime.
**Second Line Anti-tuberculosis drugs**

<table>
<thead>
<tr>
<th>DRUG STRENGTH</th>
<th>ROUTE</th>
<th>USUAL DOSE</th>
<th>MAXIMUM DOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-Cycloserine (250 mg)</td>
<td>Oral</td>
<td>500-750 mg (divided)</td>
<td>15 - 20 mg/ kg.</td>
</tr>
<tr>
<td>Prothionamide (250 mg)</td>
<td>Oral</td>
<td>500 mg - 1 gm (divided)</td>
<td>15 - 20 mg/ kg or 1 gm</td>
</tr>
<tr>
<td>Capreomycin (1g vial)</td>
<td>1.M.</td>
<td>Up to 1g single dose</td>
<td>20 mg/ kg</td>
</tr>
<tr>
<td>Ciprofloxacin 250 mg</td>
<td>Oral</td>
<td>1000 - 1500 mg (divided)</td>
<td>-</td>
</tr>
<tr>
<td>PAS (Tablet : 0.5 g)</td>
<td>Oral</td>
<td>8 g/ day</td>
<td>150 mg/ kg/ day</td>
</tr>
<tr>
<td>(Granules: 4 g pkt)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Treatment of Tuberculosis in Special Situations**

1. **Treatment of Tuberculosis in Pregnancy**
   - It is important to ask a woman before the start of ATT if she is pregnant. First line ATT is safe for use in pregnant women with the exception of ‘streptomycin’; which is oto-toxic to the fetus. **It should not be used in pregnancy, and can be replaced by Ethambutol.** It is important to explain to a pregnant woman that successful treatment of TB with the recommended regimen is important for a successful outcome of pregnancy.
   
   - In the last trimester, there is a small risk that Rifampicin may cause fetal/neonatal bleeding. Therefore, pregnant women receiving ATT should be encouraged to deliver in hospital and the staff attending them should be aware of this possible but rare complication.

2. **Treatment for women taking the oral contraceptive pill**
   - ‘Rifampicin’ interacts with the oral contraceptive pill, with a risk of decreased protective efficacy against pregnancy. Women on oral contraceptive pill in consultation with her physician, could take an oral contraceptive pill containing a higher dose of oestrogen (50 mcg), or alternatively use another form of contraception.
Algorithm for the Treatment of TB

Directorate General of Health Affairs,
National Tuberculosis Control Programme

Treatment of TB

Adult

Children

Special situation

1st attach
Initial-2 HRZS(E)
Cont-4 HR

Initial- (2 HRZ)
Cont-4 HR

Pregnancy
1st line ATT safe
exception
"Streptomycin"
should not be given

Relapse & treatment
failure

Int-(2 HRZES +
(1HRZE)
Cont-5 HRE

New born Sp.
Positive mothers
All ATT are
compatible

Chronic Tuberculosis
& MDR
Al Rahma Hospital

Women takin OCP
'Rifampicin' interacts
with oral OCP

Defaulters
If Neg. continue
ATT
If positive treatment
restarted

HIV
General it is the
same as for the
other patient
Latent TB infection (LTBI)

LTBI is the presence of M. tuberculosis organisms (positive Mantoux test) without symptoms or radiographic evidence of TB disease.

The prevalence of TB disease in Oman is currently among the lowest in the world. DOTS strategy alone may not be sufficient for further reduction of disease. Hence a strategy of detection and treatment of LTBI would help in elimination of the disease.

Terminology:
Treatment of “latent TB infection” replaces the terms “preventive therapy” and “chemoprophylaxis” to promote greater understanding of the concept for both patients and providers.

Reporting

Recording and reporting, refer chapter 6.

Treatment Regimens

The LTBI treatment regime was based on experience and trials in countries with a low prevalence TB infection, the regimen is as follow.

<table>
<thead>
<tr>
<th>Drug/Dose</th>
<th>Frequency/Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid</td>
<td>Daily x 9 months</td>
</tr>
<tr>
<td>Adult: 5 mg/ kg</td>
<td></td>
</tr>
<tr>
<td>Children: 10-20 mg/ kg</td>
<td></td>
</tr>
<tr>
<td>Maximum dose 300 mg</td>
<td></td>
</tr>
</tbody>
</table>

LTBI treatment should be given to high risk groups among the contacts, immuno-compromized patient children under 5 years of age. Prior to treatment TB disease should be ruled out and baseline investigation must be done especially for adults more than 35 yrs.

Target group
• Close contact
• Immunoocomprised

Known patient of Mantoux negative converted to Mantoux positive in 2 years

Algorithm LTBI (see page 22)
Algorithm of LTBI treatment

Criteria for Administering Latent Tuberculosis Infection Treatment (LTBI)

A close household contact of TB Patient

Mantoux test

<10 mm

Repeat at 3 months tuberculin test

<10 mm

Follow-up at 6 months

≤10 mm

Continue LTBI treatment for 9 months

Mantoux test

≤10 mm

Start LTBI treatment INH (5mg / Kg) daily x 9 months

Has symptoms

Follow guidelines for investigation & treatment as given in TB Manual

Please note that if patient HIV contact Mantoux test ≤ 5 mm continue LTBI treatment
Chapter 3

CHILDHOOD TUBERCULOSIS
**Tuberculosis in child**

- There are major differences between tuberculosis and the other diseases covered by EPI. BCG in children does not give much protection against TB infection, its main role is protection against TB meningitis, and moreover the vaccine efficacy decreases with time.

- A child is infected from a person who is coughing up the tubercle bacilli. When the child is less than five years of age, that person is usually within the household or very close to it.

- Infection can be in one or both lungs. From there bacilli quickly reach the hilar lymph nodes. These lymph nodes enlarge as the tuberculous process develops. The lung lesion and the enlarged nodes together form the "primary complex".

- If the infection is caused by contaminated milk, the primary focus is usually in the intestinal tract with nodes in the mesentery. Occasionally a focus in the pharynx causes regional nodes in the upper part of the neck.

- Whether in lung or abdomen, bacilli from the "primary complex" may spread throughout the body causing small "seedings" in other tissues such as bones or brain.

- In most cases, these events occur without any clinical illness but if nutrition is poor or resistance is low, the primary complex or the "seedings" may extend and illness follows. When this happens the illness usually comes on slowly over weeks rather than days as extension in the lung or spread in the blood overcomes the body defenses.

- Clinical illness is most likely to occur within a year after infection, the chance will be more if resistance is low. It may also follow any acute infective illness but particularly measles or whooping cough.

- Common symptoms are low-grade fever, cough for 1-2 months, loss of weight or breathlessness which may or may not be present. The tuberculin test is positive and chest x-ray may show hilar enlargement or primary-complex. Segmental collapse or lobar consolidation in younger or pleural effusion in older children may develop shortly after primary infection.

- Common symptoms in 'miliary tuberculosis' are fever and sweating. This may be associated with cough, lymphadenopathy and splenomegaly. The clinical picture is similar to that of typhoid fever or malaria. In children with protein energy malnutrition (PEM) there may be no symptoms suggestive of tuberculosis. The tuberculin test may occasionally be negative in those with miliary tuberculosis and diagnosis has to be based on typical x-ray findings.

- The presentation in 'Tuberculous Meningitis' is similar to that of any meningitis, though the onset is often slower. Fever, cough, vomiting and behavioral changes may be seen early in the disease, followed by signs of meningitis e.g. neck stiffness and epileptic fits. Examination of the CSF reveals clear fluid (clear or faintly ground-glass) with increase in cells (mainly lymphocytes) and proteins and lowered sugar levels. The tuberculin test is often positive and chest x-ray is often abnormal. CSF culture for TB bacilli may be positive.
**Introduction to pediatric tuberculosis infection**

The terminologies used to describe the stages of childhood tuberculosis have been a source of confusion, but its meaning and implications can be simplified when the terms used are those that follow the pathophysiology related to the organ. There are three basic stages of childhood tuberculosis, **EXPOSURE, INFECTION and DISEASE**.

**Exposed person** refers to a person who has had recent contact with a contagious pulmonary TB case (suspected or confirmed), is Mantoux negative, has no clinical features or chest X-ray findings suggestive of TB.

**Latent tuberculosis infection (LTBI): Only positive** Mantoux test / Elispot, no physical findings of TB disease, and chest x-ray findings that are normal or reveal evidence of healed TB infection. The term LTBI has replaced the term “chemoprophylaxis of tuberculosis”. Untreated infants with LTBI have up to a 40% likelihood of developing TB disease; the risk decreases gradually through childhood.

**Tuberculosis disease:** Person with TB infection in whom symptoms, signs, or radiographic findings are apparent. Disease may be pulmonary, extra pulmonary or both.

**Suspect of Tuberculosis**

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

1. Persistent fever of 3 weeks or more with or without cough
2. Persistent cough of 3 weeks or more with or without fever
3. Loss of appetite and / or weight loss
4. Hemoptysis, chest pain, or shortness of breath
5. A positive family history of contact with a sputum positive / contagious TB case
6. Significant Cervical lymph node enlargement
7. Acquired deformity of the spine, especially kyphosis / gibbus
8. Pain and / or swelling of joint(s), which cannot be explained clinically by any other specific disease entity.
9. Clinical features suspicious of tuberculous meningitis:

**Diagnosis of Tuberculosis in children**

The diagnosis of tuberculosis in children is neither easy nor straightforward most of the time. Although isolation of AFB on direct smears / culture is the gold standard, negative cultures never exclude the diagnosis of tuberculosis in a child. For most children, the presence of a positive TST (Mantoux test), an abnormal chest x-ray consistent with tuberculosis, and history of exposure to an adult with infectious tuberculosis is adequate proof that the disease is present.

Laboratory investigation of Tuberculosis in children is often disappointing because of the low sensitivity and specificity. Bactec Radiometric culture technique allows early detection as well as to be distinguish between the major groups. Other laboratory techniques like DNA Probes, Serological tests to look for antigen and antibodies, chromatographic techniques to look for bacterial products and PCR are also used though their value is limited in the diagnosis of childhood Tuberculosis.
The Diagnostic workup of Tuberculosis includes the following:

1. Mantoux test (see annex-2)
2. Chest x-ray
3. Gastric aspirate for AFB (direct smear and culture) for 3 consecutive days, collected through nasogastric tube early in the morning, before ambulation or feeding.
4. Sputum / induced sputum culture. Sputum can be induced in children older than 5 years of age by administration of Nebulized hypertonic saline. Collect 3 specimens on consecutive days. This technique should be done with appropriate infection control precautions.
5. CBC, ESR
6. Culture of other specimens: pleural fluid, lymph node, CSF, synovial biopsy specimen etc. Whenever a biopsy is done for TB, the specimen should be sent for both histology and mycobacterial stain and culture. Swabs should never be sent for mycobiological stain or culture.

**Chest x-ray findings suggestive of childhood pulmonary tuberculosis**

- Primary pulmonary complex with a subpleural parenchymal focus and regional lymph adenopathy  (rarely we see a parenchymal focus in Primary TB)
- Hilar / para tracheal / carinal / mediastinal lymphadenopathy
- Focal hyperinflation
- Atelectasis
- Pleural effusion
- Miliary tuberculosis
- Non resolving pneumonia
- Pericardial effusion that cannot be explained otherwise
- Rarely cavitating lung lesion which are usually seen in immune compromised patients

**Bacterial isolation and culture**

Isolation of M. tuberculosis by culture from specimens of gastric aspirates, sputum, bronchial washings, pleural fluid, CSF, urine, or a biopsy specimen establishes the diagnosis. Even in the best centres, the yield of AFB culture results is < 50 %. Therefore, a negative culture never excludes a diagnosis of tuberculosis in children.

**Gastric aspirate for AFB**

This is done for those who can not give a sputum specimen, or in those older children who have non productive or absent cough. Fluorescent staining methods for gastric aspirate smears are more sensitive and, if available, are preferred. 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 tube before the child arises and peristalsis empties the stomach of the respiratory secretions swallowed overnight. Three consecutive morning gastric aspirates yield M.Tuberculosis only in 30-50% of cases, although the yield can be as high as 70% in infants with severe form of TB. All efforts should be made to obtain sufficient volume gastric aspirate.

**Biopsy specimens of lymph node / other tissues**: The biopsied tissue specimen should be sent for histopathology, AFB microscopy + culture, and bacterial cultures.
Treatment of Childhood Tuberculosis

Table 3 outlines the guidelines for the management of various forms of childhood tuberculosis. Table 4 outlines the doses of anti-tubercular drugs available in Ministry of Health, Sultanate of Oman. It is not necessary for the radiological findings to disappear completely by the time therapy is completed. Proper and adequate follow up of patients treated for tuberculosis is important.

Indications of corticosteroids in childhood tuberculosis

Under any one of the following circumstances, a 4-6 weeks course of prednisolone (2 mg/ kg/ day, up to a maximum of 60 mg/ day), followed by tapering, may be indicated. Steroids should be started under the cover of anti-tuberculous therapy (ATT).

1. Tuberculous meningitis
2. Severe miliary disease
3. Tuberculous pleural / pericardial effusion
4. Endobronchial tuberculosis
5. Abdominal tuberculosis

Management of the newborn whose mother / other household contact has Tuberculosis disease

Management of the newborn infant is based on categorization of the maternal (or other household contact) infection. Although protection of the infant from tuberculosis disease is of paramount importance, separation of the infant from mother should be avoided when possible. Management guidelines are outlined in table 5.

Indications for referral of Childhood Tuberculosis to Infectious diseases / TB Consultant

• Tuberculosis in HIV infected children / TB in immuno-compromised
• Multi drug resistant tuberculosis
• Congenital tuberculosis
• Any other / atypical case.

BCG Lymphadenitis / BCG adenitis

BCG lymphadenitis / BCG adenitis, defined as the development of ipsilateral regional lymph node enlargement after BCG vaccination, is the most common complication resulting from this vaccination. In its natural course, BCG lymphadenitis either undergoes spontaneous regression, or enlarges progressively and become suppurative.

Though BCG lymphadenitis may develop as early as 2 weeks after vaccination, most of the cases appear within 6 months, and almost all cases occur within 2 years. Ipsilateral axillary lymph nodes are involved in more than 95 % of cases, though supraclavicular or cervical glands may be enlarged in isolation, or in association with enlarged axillary glands. In majority of the cases there are only 1 or 2 enlarged nodes, though multiple glands may be palpated in some cases.
**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. In some cases, it may progress to suppurative form.

2. **Suppurative BCG adenitis**: nodes become fluctuant with edema and erythema of the overlying skin, followed by spontaneous discharge and sinus formation. Healing eventually takes place by cicatrization and closure of the sinus, but the whole process may take several months, 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.

**Diagnosis of BCG adenitis**

Diagnosis of this condition is essentially clinical.

1. Isolated (L) axillary (or supraclavicular / cervical) lymph node enlargement
2. History of BCG vaccination on same side
3. Absence of fever and other constitutional symptoms.
4. Chest x-ray, Mantoux test, and CBC are not helpful.

**Treatment of BCG adenitis**

Treatment of this condition remains controversial. Treatment depends on the stage of the condition.

Treatment of non-suppurative (simple BCG adenitis)

This stage is best managed by expectant follow-up only. There is no role of antibiotics or anti tubercular drugs because they neither hasten the resolution process nor prevent development of suppuration.

**Treatment of suppurative BCG adenitis**

1. **Medical**: results from the controlled trials have indicated that antibiotics and ATT neither reduce the risk of suppuration nor shorten the duration of healing. Hence there is no role of medical therapy.

2. **Needle aspiration**: is recommended because it prevents discharge and associated complications, shortens the duration of healing, and is safe. Usually one aspiration is effective, but multiple aspirations may be needed. Aspiration using a wide bore needle with site of entry at the maximum point away from the lesion

3. **Surgical excision**: is indicated in cases with
   - Failed needle aspiration
   - Multiloculated or matted lymph nodes
   - When suppurative nodes have already drained with sinus formation

Surgical excision is curative but exposes the patient to the risk of general anesthesia. There is no indication to give ATT after surgical excision. Surgical incision is contraindicated.
Non-Tuberculous Mycobacterial Infection

The non-tuberculous mycobacteria are ubiquitous environmental organisms that exist in soil and water. Infections with this group of organisms are being identified with increasing frequency. Unlike Mycobacterium Tuberculosis these organisms are rarely transmitted by human-to-human contact although any organ in the body can be affected by these organisms the common sites of infection in the order of frequency are lymph nodes, otological infections, skin and soft tissue infection, catheter associated infection and pulmonary infection.

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 1-5 yrs. They usually presents 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 non-tuberculous mycobacterial 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, rifampicin or ethambutol is recommended.
## Table-3: Recommended treatment regimens for childhood tuberculosis

<table>
<thead>
<tr>
<th>Infection / Disease category</th>
<th>REGIMEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>LTBI (Positive Mantoux test, no clinical features, normal chest x-ray, AFB not isolated)</td>
<td>INH daily for 9 months</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>(2HRZ) daily for 2 months, followed by (4HR) daily; or (2HRZ) daily for 2 months, followed by (4HR) twice a week (DOT). Treat HIV infected cases for 12 months (2 months +10 months) Replace Rif by rifabutin in patients on protease inhibitor.</td>
</tr>
<tr>
<td>Extra-Pulmonary</td>
<td>(2HRZ) daily for 2 months, followed by (4HR) daily for 4 mo; or (2HRZ) daily for 2 months, followed by (4HR) twice a week (DOT) for 4 months.</td>
</tr>
<tr>
<td>Miliary / disseminated / meningeal / bone &amp; joint tuberculosis</td>
<td>(2HRZS) or (2HRZE) / (2HRZEd) daily for 2 months, followed by (10HR) daily for 10 months (total 12 months); or (2HRZ+S/E/Ed) daily for 2 months, followed by (10HR) twice weekly for 10 months (DOT), total of 12 months therapy</td>
</tr>
<tr>
<td>LTBI or pulmonary / lymph node Tuberculosis disease in immune compromised children</td>
<td>Total duration of treatment is at least 12 months. The treatment regimen is followed according to the infection or disease category.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dosage forms</th>
<th>Daily dose (mg/ kg/ day)</th>
<th>Twice weekly dosage (mg/ kg/ dose)</th>
<th>Maximum dose</th>
<th>Adverse reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid (H)</td>
<td>Scored tablets 100 mg, 300 mg Syp 10 mg/ ml</td>
<td>10-15</td>
<td>20-30</td>
<td>Daily, 300 mg Twice weekly, 900 mg</td>
<td>Mild of AST/ ALT, hepatitis, peripheral neuritis, hypersensitivity. With dose &gt; 10 mg / kg / d, and concomitant use of Rifampicin, the incidence of hepatotoxicity increases.</td>
</tr>
<tr>
<td>Rifampicin (R)</td>
<td>Capsules 150 mg, 300 mg Syp 10,15,25 mg/ ml</td>
<td>10-20</td>
<td>10-20</td>
<td>600 mg</td>
<td>Orange discoloration of urine or secretions, staining of contact lenses, vomiting, hepatitis, influenza like reaction, thrombocytopenia; pruritus, oral contraceptives may be ineffective</td>
</tr>
<tr>
<td>Pyrazinamide (Z)</td>
<td>Scored tablets 500 mg Oral suspension: 10, 100 mg/ ml</td>
<td>20-40</td>
<td>40-60</td>
<td>2 g</td>
<td>Hepatotoxicity, hyperuricemia, arthralgia, GI upset</td>
</tr>
<tr>
<td>Streptomycin (S)</td>
<td>Vials 1 g, 4 g</td>
<td>20-40</td>
<td>1 g</td>
<td>1 g</td>
<td>Auditory and vestibular toxicity, nephrotoxicity, rash</td>
</tr>
<tr>
<td>Ethambutol (E)</td>
<td>Tablets 100 mg, 400 mg</td>
<td>15-25</td>
<td>50</td>
<td>2.5 g</td>
<td>Optic neuritis (usually reversible), decreased red-green color discrimination, GIT disturbances, hypersensitivity</td>
</tr>
</tbody>
</table>
### Management of newborn infant whose mother / other household contact has TB Disease

<table>
<thead>
<tr>
<th>Maternal disease category</th>
<th>MANAGEMENT</th>
</tr>
</thead>
</table>
| Mother has AFB positive TB disease | • Mother is treated aggressively with ATT  
• Mother should wear mask & take infection control measures as advised by hospital infection control committee, can breast feed / give expressed breast milk; separation should be avoided.  
• Examine the placenta carefully for evidence of tuberculosis, send placenta for histopathology  
• Examine the baby for evidence of congenital tuberculosis (pallor, icterus, hepatosplenomegaly, feeding problems, fever, poor weight gain / low birth weight, tachypnea, dyspnoea, seizures etc)  
• **Investigations on the baby:** CBC, ESR, chest x-ray, gastric aspirate for AFB for 3 days. Other investigations depending on the clinical condition of the baby.  
• **Start the baby on INH and do not give BCG at birth.** Continue INH for 3-4 months if congenital tuberculosis is excluded on monthly follow up evaluation. At 3-4 month ages, do Mantoux test, CBC, ESR, chest x-ray, and gastric aspirate for AFB for 3 days. If Mantoux test is positive, but there is no evidence of tuberculosis disease, treat as LTBI with daily INH for 9 months. If Mantoux test is negative and the mother has become AFB negative (non contagious), INH is discontinued, BCG is given and monthly follow up is arranged.  
• If the baby has evidence of **congenital tuberculosis**, start the baby on H+R+Z+S as an inpatient care.  
• Contact survey (Mantoux test, chest x-ray, and sputum / gastric aspirate for AFB x 3 samples) for all household / close contacts |
| Mother has AFB negative TB disease / is on ATT for more than 2 weeks | • **Mother:** ATT is continued. Investigate mother for active disease if symptomatic. Separation is avoided, continue breast feeding, or give expressed breast milk  
• **Start the baby on INH and do not give BCG at birth.** Continue INH for 3-4 months if congenital tuberculosis is excluded on monthly follow up evaluation. At 3-4 month ages, do Mantoux test (and tests for TB disease if clinically indicated). If Mantoux test is positive, but there is no evidence of tuberculosis disease, treat as LTBI with daily INH for 9 months. If Mantoux test is negative and the mother has become AFB negative (non contagious), INH is discontinued, BCG is given and monthly follow up is arranged. |
Chapter 4

Tuberculosis / HIV
**HIV Infection and Tuberculosis**

**Epidemiology of TB and HIV co-infection**

Approximately one-third of the world population is carrier with latent TB. By the end of 2006 forty million people were estimated to have HIV infection. 11.5 million of the HIV-infected people worldwide were confirmed to be infected with M. tuberculosis. The risk of active TB with latent infection is increased 10 times by HIV infection. Primary TB is also common and account for one third of cases.

**Pattern of HIV-related TB**

TB can occur at any point in the course of the progression of HIV infection. However as HIV infection progresses, CD4 lymphocytes decline in number and function, worsening the immune status and the risk of developing TB rises sharply.

**Pulmonary TB**

Even in HIV-infected patients, Pulmonary TB is still the commonest form of TB. The presentation depends on the degree of immunosuppression. The table below shows how the clinical picture, sputum smear result and chest X-ray present in early and late HIV infection.

**How pulmonary TB differs in early and late HIV infection**

<table>
<thead>
<tr>
<th>Features of Pulmonary TB</th>
<th>STAGE OF HIV INFECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Early (asymptomatic)</td>
</tr>
<tr>
<td>Clinical picture</td>
<td>Often resembles</td>
</tr>
<tr>
<td></td>
<td>Post-primary pulmonaryTB</td>
</tr>
<tr>
<td>Sputum smear result</td>
<td>Often positive</td>
</tr>
<tr>
<td>Chest X-ray appearance</td>
<td>Often cavities</td>
</tr>
</tbody>
</table>

**Extra-pulmonary TB**

The commonest forms are the following: lymphadenopathy, pleural effusion, pericardial disease, miliary disease, meningitis.

**HIV-related TB in children**

As in adults, the natural history of TB in a child infected with HIV depends on the stage of HIV disease. Early stage of HIV infection, when immunity is good, the signs of TB are similar to those in a child without HIV infection. As HIV infection progresses and immunity declines, dissemination of TB becomes more common. Tuberculous meningitis, miliary TB, and widespread tuberculous lymphadenopathy occur.
Anti-TB treatment in HIV-infected TB patients

First-level facility TB management in HIV

Patient already on ART

If patient already on ART when positive TB sputum's or suspect TB, refer to district ARV clinician for treatment plan. Do not start TB treatment at first-level facility.

Patient not on ART and CD4 not available

<table>
<thead>
<tr>
<th>Patient clinical status</th>
<th>How to manage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Smear-positive pulmonary TB only</strong> (no other signs) and patient is gaining weight on treatment</td>
<td>Start and complete TB treatment according to TB guidelines then start first-line ART regimen</td>
</tr>
<tr>
<td><strong>Smear-negative pulmonary TB only</strong> (no other signs 3 or 4) and patient is gaining weight on treatment</td>
<td>Continue TB treatment and consult / refer to district medical officer for TB/ ART treatment plan. (smear negative TB requires medical officer diagnosis)</td>
</tr>
<tr>
<td>Pulmonary TB and patient has or develops signs of clinical stage 4 or thrush, pyomyositis, recurrent pneumonia, persistent diarrhea, new prolonged fever, or losing weight on treatment</td>
<td>Continue TB treatment and refer to district ART medical officer for decision on co-treatment. If patient has already completed TB treatment, start first-line ART after managing OIs.</td>
</tr>
<tr>
<td>Extra-pulmonary TB</td>
<td>If current: continue TB treatment and refer to district medical officer for decision on co-treatment. If completed extra-pulmonary TB treatment in last year and no new complications or signs, start first-line ART</td>
</tr>
</tbody>
</table>

Patient not on ART and CD4 is available

<table>
<thead>
<tr>
<th>CD4</th>
<th>How to manage</th>
</tr>
</thead>
<tbody>
<tr>
<td>If CD4 &lt; 200 / mm3</td>
<td>Start TB treatment. Start ART co-treatment as soon as TB treatment is tolerated (between 2 weeks and 2 months)</td>
</tr>
<tr>
<td>If CD4 between 200 - 350/ mm3</td>
<td>Start TB treatment. Start ART co-treatment after initial phase (unless severely compromised)</td>
</tr>
<tr>
<td>If CD4 &gt;350 / mm3</td>
<td>Give TB treatment. Defer ART unless non-TB stage 4 conditions are present</td>
</tr>
</tbody>
</table>
Response of HIV-infected TB patients to anti-TB treatment

Case fatality
The case fatality of TB/ HIV patients 1 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. Case fatality is less in TB/ HIV patients treated with SCC than with the old standard regimen. This is partly because SCC is a more effective anti-TB treatment. Also, rifampicin has broad-spectrum anti-microbial activity as well as anti-TB activity. This may decrease deaths due to HIV-related bacterial infections during anti-TB treatment.

Response in survivors
Several studies have assessed the clinical, radiological and microbiological response to SCC in HIV-positive and HIV-negative TB patients. Excluding patients who died, response rates were similar in HIV-positive and HIV-negative TB patients.

Recurrence of TB after completing anti-TB treatment
When TB recurs after previous cure, there are 2 possibilities:
   a) True relapse (reactivation of thepersisters not killed by anti-TB drugs)
   b) Re-infection (due to re-exposure to another source of the infection)
The risk of re-infection depends on the intensity of exposure to TB transmission.

Introduce Isoniazid preventive therapy
Isoniazid is given to individuals with latent Mycobacterium Tuberculosis in order to prevent progression to active disease. Exclusion of active tuberculosis is critically important before this therapy is started. Isoniazid is given daily as self administered therapy for six months. Since HIV-infected people could develop tuberculosis before antiretroviral is indicated, and as there is no evidence contraindicating combined use, use of antiretroviral drugs does not preclude the use of Isoniazid preventive therapy.
HIV has to be reviewed for TB status in all patients on each visit

HIV / TB Patient

Suspect TB

Sputum Negative

Patient on ART
Refer to HIV Clinic for treatment plan

Sputum Positive

Patient not on ART
Start TB treatment

Active TB

New Sputum positive

On treatment

HIV / TB Patient

Suspect TB

Sputum Negative

Patient on ART
Refer to HIV Clinic for treatment plan

Sputum Positive

Patient not on ART
Start TB treatment

Active TB

New Sputum positive

On treatment
Recording & Reporting
The picture of the TB case finding will not be completed without a good recording and reporting system. A good record will provide the health system with a reliable source of information. A good reporting will help to build up the surveillance of TB and good epidemiological analysis of data will help in the elimination of TB.

Reports include primarily NTP Case-index, Treatment-card and monthly TB report. These reflect the service provided to the community and helps in the preparation of the National Tuberculosis Programme Report. The recording and reporting system utilizes the WHO standardized system, and consists of the following:

- TB Register & Contact Tracing (Annex-10 & 11)
- TB Treatment-card (Annex-9)
- Patient Identity card
- Laboratory Register for TB Diagnostic work (Annex 12 & 13)

TB Address Taking
Why is address taking important?
The address of a TB patient is an ESSENTIAL part of the Physician's responsibility and it is as important as making a proper diagnosis. The reason is that, full address will be the proper tool to find a defaulter or other cases/contacts.

In Oman a full address consists of the following

For Omani Nationals
- Patient's full name: i.e. his/her own name, father's name, and grandfather's name.
- Patient's tribe:
- Patient's wilayat, village and Sub-division of the village: e.g. wilayat 'Bid Bid', village 'Fanja Safala'.
- Patient's house number, street or sika and landmark: e.g. house number 47, street 223 or sika 4114 near the Sultan Qaboos Mosque at Ruwi.
- Telephone: Office: ---------- Residence: -------- mobile--------Fax
- Patient's sheikh: (three names and the tribe)

Notes:
1) It is of no use writing address like Ruwi or Nizwa as the village? Because they are very large places and detailed information is required to enable the Public Health Staff to find the house. In Arabic the proper names for the 'suburbs' of a town or village are "hella" or "hara".

2) It is of no use putting near the mosque if there are 3 or 5 or 10 mosques in that village

For Expatriates
- Name of the Sponsor or Private Company.
- P O Box N o. Postal Code:
- Telephone: Office: _____ Residence: _____ mobile: _____ Fax: ______
- Resident card N o. and keep a photocopy of the same, if possible.
- Passport N o.
- Date of Last medical check up
Defaulter retrieval & health education

Vital role of defaulter retrieval

• TB patients cannot be 'cured' if they do not complete their treatment.
• Defaulters who were sputum positive when initially diagnosed and were subsequently converted to negative - may relapse to sputum positive again if they fail to take their treatment for the prescribed period.
• Such patients are not only endangering themselves by defaulting from their treatment but they are also endangering the public, especially their close family contacts. **In short, they are a potential public health threat.**
• This explains why defaulter retrieval is a vital part of a successful TB control programme. Indeed from the public health point of view it is even more important than TB contact tracing.

Defaulter retrieval mechanism

On receiving the notification for defaulter retrieval the respective public health staff should visit the address of the defaulter immediately. Their task is to:

• **Locate** the defaulter.
• **Persuade** him/her to re-visit the hospital for re-assessment/treatment.
• **Health Education**: explain to the defaulter the importance of COMPLETING the course of treatment, even if the patient feels better).
• **Re-visit if necessary**: if the defaulter fails to attend for treatment, he/she should be visited again (and again) until he/she finally attends. If required involve community support group, Sheikh, the Wali and the Royal O man Police.

Priorities for Defaulter Retrieval

Priorities for defaulter retrieval are according to the risk that defaulter poses to the public. Therefore, defaulters are categorized as follows:

| Priority 1 | Defaulters who are now or recently (1 or 2 months ago) sputum positive. | These are dangerous to the public and must be visited immediately |
| Priority 2 | Defaulters who were originally sputum positive but converted to sputum negative more than 2 months ago | These are a less dangerous to the public and must be visited as soon as possible |
| Priority 3 | Defaulters who were never sputum positive and/or have extra pulmonary TB. These defaulters are usually not a threat to anyone but to themselves | They are not a public health problem but should be monitored to take and complete their treatment |

Contact-tracing & Health Education

Vital role of contact tracing

TB is a disease that is transmitted from person to person by close personal contact. If we break the cycle of transmission we reduce and ultimately eliminate the occurrence of new cases. Therefore, it is obvious that vigorous and efficient tracing of all contacts of TB patient is the main task of public health staff with respect to the TB activities.
“Visit the contact”

On receiving the notification for contact tracing, the respective public health staff should visit the House of the TB patient. The contacts are asked to visit the H.C. once every 6-month for the next two years i.e. total of four visits. Their tasks are to:

- **Confirm the list of contacts**: given to them by the hospital where the patient was diagnosed.
- **Screen All contacts in the Health Center (symptomatic and asymptomatic)**

**Look especially for:**

- Cough with or without expectoration.
- Fever or chest-pain of 2 weeks or more duration.
- Hemoptysis with or without any symptoms irrespective of its duration.
- Enlarged Lymph nodes
- Investigations should include Sputum microscopy, Chest X ray, Montoux test and sputum culture.

- **Health Education**: It should be stressed strongly to the contacts that
  - Why they must be screened
  - How important it is that they are screened.
  - Health education pamphlets available should be distributed to them.
  - All contact must be educated regarding the investigation during the period of the two years (every 6 month).

### Extended Contact screening and Follow-up for 2 years

<table>
<thead>
<tr>
<th>Visit Type</th>
<th>Time Period</th>
<th>Investigation Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st visit</td>
<td>0 month</td>
<td>Clinical examination &amp; all investigation like sputum, X-ray, Mantoux &amp; sputum culture for contacts. If necessary investigation for casual contacts</td>
</tr>
<tr>
<td>2nd visit</td>
<td>6 months</td>
<td>Clinical examination for contacts + Mantoux test if any suspicion, investigate i.e. X-ray, sputum microscopy &amp; culture</td>
</tr>
<tr>
<td>3rd visit</td>
<td>12 months</td>
<td>Clinical examination, if needed investigation</td>
</tr>
<tr>
<td>4th visit</td>
<td>18 months</td>
<td>Clinical examination of contacts, if needed investigation</td>
</tr>
<tr>
<td>5th visit</td>
<td>24 months</td>
<td>Clinical examination and if needed investigation</td>
</tr>
</tbody>
</table>

### Recording registers

**Tuberculosis contact Register** *(Annex - 10 & 11)*

Each reporting institution should maintain a NEW TB Register. New TB register includes information about the case and contacts.

**Tuberculosis Treatment Card** *(Annex - 9)*

This card gives all the particulars of the TB patient required to identify him/her easily, how the diagnosis was arrived at, the treatment prescribed and to make relevant entries at different times during the course of treatment.

The treatment card is kept at every health institution at where treatment is given. It is kept for each patient under treatment. Filling of the individual boxes of the treatment-card is self-explanatory.
Patient's Identity Card:
This card is kept by the patient and should contain the following:

- Name, Age, Sex & Address of the patient.
- I.P. No., Index Number.
- Regime used.
- Space for dates of appointments.
- Remarks

Laboratory Register for TB Diagnostic work: (Annex - 12 & 13)
All laboratories in the country should maintain a register for TB diagnostic work

Latent TB infection treatment (Annex - 14)

Monthly Report on Tuberculosis: (Annex - 8)
Monthly report will include all cases from the institution. The preparation and submission of monthly report in time (first week of the following month) increases the reliability of the reporting system for tuberculosis.

- a) Tuberculosis Monthly Report - (2 copies) and A ‘Nil’ reports is also to be submitted from all health institutes
- b) Tuberculin Test Report (single copy)
- c) Contact-screening Report (New, the Follow up mid year and at the end of the year)
- d) Defaulter-retrieval Action Report (single copy)
- e) Epidemiological Investigation Report (single copy)
- f) Sputum Examinations Summary, Target/ Region (single copy)
- g) Report on IPT (single copy)
- h) MDR-TB Report (single copy)

NTBPM in turn prepares monthly & annual reports on the basis of reports received from the regions. A feedback is provided to the region every month.

Monitoring
Monitoring of all regional chest clinics in the country is carried out from the consolidated monthly and annual reports from all the institutions of the region. NTP sends comments after monitoring individual reports to the focal point of the region for information and necessary corrective action. When monitoring indicates the need for a supervisory visit, it is undertaken by the Programme Manager.

Cohort analysis of treatment
Regular cohort analysis of treatment i.e. conversion and cure rates are compiled on a quarterly basis. Cohort analysis is the key management tool used to evaluate the effectiveness of TB control programme delivery. It enables the identification of problems, so that the Programme Manager can make decision on appropriate corrective measures to overcome those problems and improve programme performance.

Supervision
Supervision of the health institutions within the region will be the responsibility of the Regional Focal Point. NTP staff will however, coordinate with the physicians of the Regional chest clinic (RCC). Suitable technical guidance will be provided on the spot and any administrative actions required will be recommended to the Director General of Health Affairs.
Annexures
Annex - 1

LAW ON CONTROL OF INFECTIOUS DISEASES
(Issued by the Royal Decree No. 73/92)

Articles translated from the original in Arabic

Article 1: Every disease listed in the table attached to this law is considered an infectious disease.

Article 2: If a person falls ill or is suspected of being ill with one of the infectious diseases or is a carrier of Agents of these diseases, the person should be reported to the nearest health institution according to the form issued by the decree by the Minister of Health and during the following period: 24 hours for diseases of the first section of the table (One week) for diseases of the second section of the table (30 days) for diseases of the third section of the table.

Article 3: The ones responsible for the reporting mentioned in the previous article are by order:
   a) The physician who examined the patient.
   b) The responsible person in the health institution where the disease occurred.
   c) The person in-charge of the laboratory where the sample indicating the presence of the disease was examined.
   d) The head of the patient's family or the one who is taking care of him.
   e) The owner or responsible director if the illness occurred in an industrial or commercial institution or public shops.
   f) The one in-charge of the transport vehicle if the disease occurred or was suspected in a patient during his presence in it.
   g) The representative of the administrative authority (the Wali, the Sheikh or the police).

Article 4: The reporting of the patient or the suspected patient should include his/her triple name, his/her address and occupation in a way that will make it possible for health authorities to reach him/her.

Article 5: Zoonotic disease mentioned in the attached table should be reported and the ones responsible for that are by order:
   a) The Vets or their assistants who examined the sick animal.
   b) The technical director responsible for the farm, the stable or the place where the case occurred.
   c) The owner of the diseased animal.

Reporting in such a condition should be to the relevant authority of veterinary affairs and this authority will report to the relevant health centre within the period defined by the Minister of Health. The centre will take the necessary preventive measures in this condition.
Article 6: Every person ill or suspect of being ill with one of the infectious diseases mentioned in the first section of the table attached to this law is to be isolated in the hospital or the place determined by the Ministry of Health. Isolation is done by a decision of the relevant physician.

Article 7: The Ministry of Health is permitted to isolate contacts of patients affected by infectious diseases mentioned in the first section of the table attached to this law. Isolation is done in the places determined by the Ministry for that purpose according to the decision of the relevant health physician and for the period he sees necessary.

Article 8: The Ministry of Health will put contacts of patients with infectious diseases under surveillance. These contacts shall present themselves to the related health centers for medical examination according to the time schedule determined by the Ministry for that reason. It is allowed to isolate contacts of infectious disease patients if by the nature of their disease or occupation they may expose others to infection.

Article 9: In cases where the health physician deems it possible to treat a patient suffering from one of the infectious diseases mentioned in the second and third sections of the table attached to the law, at his dwelling, the related health officials shall take necessary measures to protect his contacts from contracting the disease and put them under surveillance for the proper time.

Article 10: The relevant health authorities can exclude patients of an infectious diseases or carriers of its microbe from any job related to the spread of infection such as preparation, selling or transportation of food materials or drinks of any kind or any other job. Anybody excluded accordingly is not allowed to return to any of these jobs except by a permission of these authorities. The owner or director of the job is also held responsible if he permits a person excluded, as mentioned above, to continue to work in any of the mentioned jobs.

Article 11: Transport of patients ill with one of the infectious diseases mentioned in the first section of the table attached to this law, and who have been isolated is not allowed without a permission of the Ministry of Health and the transport should occur by the means prepared by the Ministry. Transport or hiding of clothes, bedding, instruments or furniture or others by which infection may spread. The Ministry of Health may order the destruction of such clothes, bedding, instrument or furniture or it may order its sterilization or disinfection.

Article 12: The Ministry of Health has the right to take the necessary sample from patients suffering from one of the infectious diseases listed in the table attached to this law or from their contacts so it can be tested in the laboratory until it is verified that they are free from pathogenic microbes.
Article 13: Physicians of the Ministry of Health or its agents are allowed to vaccinate with the protective vaccine the persons dwelling with a patient affected by one of the infectious diseases mentioned in the table attached to this law and the Communicable disease surveillance and control persons who might have had a contact with him/her or has been exposed to infection by any means.

Article 14: The Minister of Health may decide compulsory vaccination against any infectious disease to protect newborns or any specific groups of population or the whole population, according to public health interest and this decree will determine the times and measures to be followed in such conditions.

Article 15: Taking into consideration the provisions of current laws and regulations, agents of the Ministry of Health authorized by it are allowed to enter houses, if deemed necessary, to search for patients with infectious diseases, or to implement necessary measures of disinfection or vaccination, or examine contacts, or for the purpose of controlling insects and rodents, and they have to present a verification of their identity before entering houses. In order to do this duty they can ask the help of the relevant authorities.

Article 16: The Minister of Health can restrict the treatment of some cases of the infectious diseases mentioned in the table attached to this law to governmental treating institutions and prevent its treatment in private clinics and hospitals.

Article 17: During burial, transfer or transport of cadavers of persons dead from one of the diseases mentioned in the table attached to this law and defined by a decree of the Minister of Health, the preventive measures decided by the Ministry of Health shall be considered.

Article 18: In the case of occurrence of any epidemic disease that endangers the public health, the Minister of Health or the one whom he delegates, has exceptional authorities to protect the country from the spread of the epidemic with due collaboration (agreement) with the relevant authorities.

Article 19: Every person who does not report an infectious disease according to the provisions of the articles (2, 3, and 5) of this law is punished by imprisonment for a period not exceeding six months and a duty of 100 Omani Rails or by one of these punishments. This is not to substitute any severer punishment stated in another law.

Article 20: With due consideration to article (19) of this law, a punishment of not less than 20 Omani Rails and not more than 50 Omani Rails is due on every person who does not comply with any of the articles of this law or the Ministerial decrees implementing it.
Annex - 2

Tuberculin Testing

- Tuberculin test is done to identify whether an individual is infected with TB bacilli, but not to diagnose TB disease. A positive tuberculin test is rarely followed by disease and a negative test does not entirely exclude TB. The test can be one of the criteria in determining the diagnosis in cases of those who are not sputum positive (especially in children who have been in contact with an infectious case of TB and to determine if the contact were at risk or not).
- The standard Tuberculin Test recommended employs the intradermal ‘Mantoux-test’. 2 TU + Tween 80 (0.1 ml).
- The area of induration (not erythema) is recorded in millimeters. An induration of “10 mm or more” (transverse diameter) should be taken as a positive reaction.
- NTP recommends that the ‘Mantoux-test’ be performed, interpreted and recorded by the same TBFP or Staff Nurse.
- The test should produce a wheal 6 to 10 mm in diameter (record the No.). However, if the injection was subcutaneous instead of intradermal, it can be repeated in the same arm 2 inches away from initial site or in the other arm.
- A proper test if not interpreted at the appropriate time can be repeated only after 6-8 weeks.

- Inject 0.1 ml of 2 TU PPD tuberculin solution intradermally on volar surface of lower arm using a 27-gauge needle
- Measure reaction in 48 to 72 hours
- Measure induration, not erythema
- Record reaction in millimeters, not “negative” or “positive”
- Ensure trained health care professional measures and interprets the TST
**Definition of a positive Mantoux test result for Adult**

| Induration ≥ 5 mm | • HIV infection or with immune deficiency states receiving immunosuppressive therapy, including immuno-suppressive doses of corticosteroids (≥15 mg prednisolone / day for 1 month or more), and anti neoplastic agents.  
  • For Children see pediatric chapter 3. |
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<tbody>
<tr>
<td>Induration ≥ 10 mm</td>
<td>TB infection should ruled out before starting LTBI treatment</td>
</tr>
</tbody>
</table>

**Definition of a positive Mantoux test result in infants and children**

| Induration ≥5 mm | • Children in close contact with known / suspected contagious cases of TB  
  • Children suspected to have tuberculosis disease:  
    - findings on chest x-ray consistent with active / previously active TB  
    - Clinical evidence of tuberculosis disease  
      Children with HIV infection or with immune deficiency states  
      Children receiving immunosuppressive therapy, including immuno-suppressive doses of corticosteroids (≥15 mg prednisolone / day for 1 month or more), and anti neoplastic agents |
|------------------|----------------------------------------------------------------------------------|
| Induration ≥10 mm | • Children with frequent exposure to adults at high risk  
  • Birth or recent immigration (<5 yrs) from a high prevalence country  
  • Children with travel to or exposure to visitors from high prevalence Countries  
  • Children with PEM / chronic renal failure / diabetes mellitus / lymphoma |

Whenever in doubt consult Paediatric Infectious Disease Consultant

**Causes of falsely negative Mantoux test / decreased tuberculin sensitivity**

**Host related factors**
- Infections: measles, rubella, chicken pox, influenza, pertussis, brucellosis, typhoid fever, overwhelming tuberculosis (e.g. miliary, meningeal etc)
- Very young age
- PEM, chronic renal failure, HIV infection, leukemia, lymphoma, immune deficiency states
- Drugs: corticosteroids, anti neo-plastic agents
- Stress: surgery, burns, mental illness

**Tuberculin related factors**
- Improper storage (exposure to light or heat)
- Contamination
- Adsorption to glass or plastic

**Administration related factors**
- Delayed administration after loading the syringe
- Subcutaneous injection
- Wrong technique
Annex - 3 - Algorithm for the TB laboratory diagnosis at Primary Level

Directorate General of Health Affairs

Specimen

Pulmonary specimens
(To be processed at the primary level TB laboratory)

Sputum

Nebulized Sputum, bronchial wash etc

Centrifuge at 3000 rpm x 15 minutes

Deposit

Microscopy

Make two smears, Air dry

Heat fix, cool & Do ZN Stain

Examine & Report to Physician
If AFB Positive, notify to TBCP

Extra-pulmonary Specimens
(To be sent to CPHL)

Enter the details in the laboratory register and send specimens to the Central Public Health Laboratory, Darseit for microscopy and culture

After smears are made send sputum / deposit to the public health laboratory with request form for culture
Protocol for Sputum Culture

Specimen for TB Diagnosis

Pulmonary specimens
- Make smears
- Stain one by ZN, Report AFB
- Perform TB culture (petroff’s concentration)
- Examine twice in the first week and later every week upto 9 weeks
- Suspected mycobacterial colonies grown
  - Prepare a smear to look for acid fast bacilli and morphology
  - If mycobacteria grown, send all positive slants to CPHL
- If culture is negative, report: No Mycobacteria Isolated

Extra-pulmonary Specimens
- Refer specimen to the CPHL
- Examine twice in the first week and later every week upto 9 weeks
- If no mycobacterial colonies grown
  - Continue incubation for 4 weeks more if specimen is biopsy, smear positive case or specimen was collected while patient on ATT

Specimen for TB Diagnosis

Protocol for Sputum Culture

Specimen for TB Diagnosis

Pulmonary specimens
- Make smears
- Stain one by ZN, Report AFB
- Perform TB culture (petroff’s concentration)
- Examine twice in the first week and later every week upto 9 weeks
- Suspected mycobacterial colonies grown
  - Prepare a smear to look for acid fast bacilli and morphology
  - If mycobacteria grown, send all positive slants to CPHL
- If culture is negative, report: No Mycobacteria Isolated

Extra-pulmonary Specimens
- Refer specimen to the CPHL
- Examine twice in the first week and later every week upto 9 weeks
- If no mycobacterial colonies grown
  - Continue incubation for 4 weeks more if specimen is biopsy, smear positive case or specimen was collected while patient on ATT

If mycobacteria grown, send all positive slants to CPHL

Send deposit to CPHL for re-culture

If contaminants have grown

If culture is negative, report: No Mycobacteria Isolated
Flow chart for ZN staining procedure

1. Prepare sputum smear, air dry, heat fix
2. Cover the slide with filtered carbol fuchsin stain. Heat the bottom of the slide till fumes arise. Leave for 5 minutes to stain. Wash off stain in running water Drain out
3. Decolorize with 3% acid alcohol for 3 minutes. Wash in running water
4. Drain out water and counterstain with 0.2% malachite green or 0.3% methylene blue
5. Wash, drain, dry in air and examine under oil immersion lens

Results:
Acid Fast Bacilli will be found red in color against blue / green background

Reporting:

<table>
<thead>
<tr>
<th>Observation</th>
<th>Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>No AFB seen in 200 fields</td>
<td>No AFB seen</td>
</tr>
<tr>
<td>1 - 9 AFB seen in 100 fields</td>
<td>Confirm by another smear. If the finding is</td>
</tr>
<tr>
<td></td>
<td>same, report the exact number of AFB seen /</td>
</tr>
<tr>
<td></td>
<td>100 fields</td>
</tr>
<tr>
<td></td>
<td>e.g. AFB seen (3 AFB seen / 100 fields)</td>
</tr>
<tr>
<td>10 - 99 AFB seen in 100 fields</td>
<td>AFB seen +</td>
</tr>
<tr>
<td>100 - 999 AFB seen in 100 fields</td>
<td>AFB seen + +</td>
</tr>
<tr>
<td>&gt; 999 AFB seen in 100 fields</td>
<td>AFB seen + + +</td>
</tr>
</tbody>
</table>
Annex-6 - Algorithm for TB Lab. Diagnosis in the CPHL (Tertiary level)

Flow chart for TB laboratory diagnosis

Culture

- Petroff's method
  - Inoculate on L-J media
  - Check the Morphology of Bacilli & colonies, rate of growth, Pigmentation, Niacin test, Nitrate test
- Make 2 smears
  - Z - N Stain
  - Auramine Stain
- NALC / NaOH method (Automated system)
  - Inoculate into liquid media
  - Morphology of bacilli
  - Purity
  - PNB or NAP test ABS test

Make 2 smears

- If positive inform physician
- Culture Negative (42 days)
  - No growth after 9 weeks
  - Report "No Mycobacteria Isolated"

If growth present

- Mycobacterium TB complex
  - Perform ABST
  - Nitrate / Niacin Positive
  - MOTT
  - M. TB complex
  - Pyrazinamide / Pyrazinamidase test
  - Cycloserine susceptibility and TCH. Read results & identity
  - Pyrazinamide
  - Pyrazinamidase test
  - Cycloserine susceptibility and TCH. Read results & identity

- Nitrate / Niacin Negative
  - M. avium, BCG, M. malhonom
  - Mycobacterium tuberculosis
  - Pyrazinamide
  - Pyrazinamidase test
  - Cycloserine susceptibility and TCH. Read results & identity

- If PNB or NAP resistant
  - M. TB complex
  - Perform identification
  - MOTT
  - M. TB complex
  - Pyrazinamide
  - Pyrazinamidase test
  - Cycloserine susceptibility and TCH. Read results & identity
  - Pyrazinamide
  - Pyrazinamidase test
  - Cycloserine susceptibility and TCH. Read results & identity

- If PNB or NAP susceptible
  - Mycobacterium tuberculosis
  - Pyrazinamide
  - Pyrazinamidase test
  - Cycloserine susceptibility and TCH. Read results & identity
  - Pyrazinamide
  - Pyrazinamidase test
  - Cycloserine susceptibility and TCH. Read results & identity

- Report to physician & NTCP
  - Niacin nitrate positive
  - Niacin nitrate negative
  - M. TB complex
  - MOTT
  - M. TB complex
  - Pyrazinamide
  - Pyrazinamidase test
  - Cycloserine susceptibility and TCH. Read results & identity
  - Pyrazinamide
  - Pyrazinamidase test
  - Cycloserine susceptibility and TCH. Read results & identity

- Mycobacterium tuberculosis
  - Pyrazinamide
  - Pyrazinamidase test
  - Cycloserine susceptibility and TCH. Read results & identity
  - Pyrazinamide
  - Pyrazinamidase test
  - Cycloserine susceptibility and TCH. Read results & identity

- M. avium
  - Pyrazinamide
  - Pyrazinamidase test
  - Cycloserine susceptibility and TCH. Read results & identity
  - Pyrazinamide
  - Pyrazinamidase test
  - Cycloserine susceptibility and TCH. Read results & identity

Report to physician & NTCP

Report to physician & NTCP

Report to physician & NTCP
Annex - 7- Request for Bacteriological examination of TB specimens

Request for Bacteriological Examination of TB Specimens

For the laboratory diagnosis of pulmonary TB, three sputum specimens, 3-5 ml each should be sent for microscopy & culture. One specimen should be collected on spot and the remaining two at any intervals on the same day. If patient is unable to collect sputum, nebulized specimen should be collected. For each specimen a duly filled set of forms should be sent to the laboratory. After performing microscopy, the remaining specimen should be stored in a refrigerator and sent to the nearest public health laboratory along with request form. Specimens other than sputum e.g. body fluids, urine, biopsies and CSF should be sent to the CPHL, Dar es Salaam through your laboratory for microscopy and culture.

<table>
<thead>
<tr>
<th>1st name of patient</th>
<th>2nd name</th>
<th>3rd name</th>
<th>Tribe</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Nationality</th>
<th>Wilayat</th>
<th>Region</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Name of institution</th>
<th>Registration No.</th>
<th>Hosp. Lab No.</th>
<th>TB Index no. (if known)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Type of specimen</th>
<th>Date of collection</th>
<th>Nebulized</th>
<th>Yes / No</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Type of TB patient / ATT status</th>
</tr>
</thead>
</table>

- ☐ TB Suspect
- ☐ Known case
- ☐ On ATT
- ☐ Non on ATT
- ☐ Relapse case
- ☐ Defaulter

Relevant clinical particulars

Name of Physician & Tel. No., Fax No.

For Laboratory use only

Date of receiving specimen

Laboratory No.

Results of TB serology

Microscopy result

Date of reporting microscopy

Culture result

Date of reporting culture result

Sensitivity Results

First line drugs

Second line drugs

Streptomycin

Capreomycin

Isoniazid

Cycloserine

Rifampicin

Ethionamide

Ethambutol

<table>
<thead>
<tr>
<th>Date of reporting sensitivity results</th>
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</thead>
</table>

Pyrazinamide

<table>
<thead>
<tr>
<th>Date of reporting sensitivity results</th>
</tr>
</thead>
</table>

Remarks

Microbiologist

Date

Director of Laboratory
Tuberculosis Monthly Report (Part - 1)

From (Institution):

Month & Year:

Name of Recorder:

To: National TB Control Programme

<table>
<thead>
<tr>
<th>Total out-patients</th>
<th>Total Chest X-rays</th>
<th>Sputum Examination</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Old*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sputum Positive</th>
<th>Sputum Negative</th>
<th>Extra pulmonary</th>
</tr>
</thead>
</table>

1 Number of TB patients on treatment in previous month
2 New cases pur on treatment during this month
3 Transferred - in - cases (Please give name of institution(s) and index no.)
4 Re-treatment cases (give Index No.)
5 Transferred - out - cases (Please give name of institution(s) and index no.)
6 Lost cases (give Index No.)
7 Repatriated Transferred -out of Oman (give name of the country and Index No.)
8 Cured cases (give Index No.)
9 Treatment completed cases (give Index No.)
10 Dead cases (give cause of death & Index No.)
11 Number of TB patients on treatment at end of this month
12 Number of patients collected TB drugs during this month (Regular Patients)
13 Patients whose visit awaited ie. Inside the 10 day grace period
14 Defaulters (during this month)

Note:
* New OP’s should exclude all specialty clinics statistics, ie. include only GOP’s, MOP’s & A&E
* Please write the ‘TB Index Number’ of case (s) on treatment in column no. 12 or attach a separate sheet
* Please note that: 1+2+3+4+5 - 6 - 7 - 8 - 9 - 10 = 11
* 2 - copies of the report, should reach NTCP on or before the 10th of the following month
* Please fill in all the grey boxes

Signature & Stamp of MOIC
# Annex - 8 - TB Monthly Report (Part - II)

## Tuberculosis Notification Form of Follow-up

### Omani / Non-Omani

<table>
<thead>
<tr>
<th>Index No.</th>
<th>Institution:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Diagnosis:</td>
<td>Region</td>
</tr>
<tr>
<td>Name of recorder:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Full Name:</th>
<th>Tribe:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex: M / F</td>
<td>Age:</td>
</tr>
<tr>
<td>Occupation:</td>
<td>Nationality:</td>
</tr>
<tr>
<td>Village:</td>
<td>Marital status</td>
</tr>
<tr>
<td>Sheikhs/Sponsor Name:</td>
<td>Way No.</td>
</tr>
<tr>
<td>Address (P.O. Box, Postal Code):</td>
<td>Landmark:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For Expatriate only</th>
<th>Date of Left the country</th>
<th>Date of return to Oman</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Last Medical checkup</td>
<td>Date of Return to the country</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of onset</th>
<th>Date of Admission</th>
<th>OPD No.:</th>
<th>IPD No.:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Referred to</td>
<td>Date:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Transferred to</td>
<td>Date:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of specimen:</th>
<th>Date collected:</th>
<th>Date results reported:</th>
<th>Results:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopsy (Histopathology):</td>
<td>Culture:</td>
<td>HIV status:</td>
<td>Date of HIV status:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If extra-pulmonary (site of organ)</th>
<th>DOTS completed on (Date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOTS Starts on (Date)</td>
<td>Date of sputum collected</td>
</tr>
<tr>
<td>Date of First Visits: (End of 2 months)</td>
<td>Date of Results:</td>
</tr>
<tr>
<td>Date of First Visits: (End of 4 months)</td>
<td>Results:</td>
</tr>
<tr>
<td>Date of First Visits: (End of 6 months)</td>
<td>Results:</td>
</tr>
</tbody>
</table>

### Treatment

<table>
<thead>
<tr>
<th>Date of REporting:</th>
<th>Signature &amp; Stamp:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final outcome: Cured / Completed / Died / Repatriated / Transfer out of Oman</td>
<td>Date:</td>
</tr>
</tbody>
</table>

### Note:

a) Please specify, no. of smears positive / negative; if smear negative whether CXR is highly suggestive of TB or AAFB culture positive.
b) Attach copy of biopsy, culture or histopathology report in extra-pulmonary TB cases.

dispatch forms as below:

- White copy - National Focal Point, TB control Program
- Green copy - retain with treatment card
- Pink copy - send to focal point of the region
- Photocopy of the notification should send along with monthly report.
## TREATMENT CARD

<table>
<thead>
<tr>
<th>Full Name:</th>
<th>Index No.</th>
<th>Gov. Region</th>
<th>Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tribe:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Results of sputum examination

<table>
<thead>
<tr>
<th>Month</th>
<th>Local Laboratory</th>
<th>Reference Laboratory</th>
<th>Weight (Kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Results of sputum examiniation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Date</td>
<td>Smear</td>
<td>Date</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Nationality: Omani / Non-Omani .................

### Place of Diagnosis:

### Place of Treatment:

### HIV Status: Positive □ Negative □

### Mantoux-test: Positive □ Negative □ Not Read □ mm

### BCG: No Scar □ Scar seen □ Scar Dubious □

### I. Initial Intensive Phase: (Prescribed regimen & dosage)

<table>
<thead>
<tr>
<th>CAT 1</th>
<th>CAT 2</th>
<th>CAT 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>S(E)</td>
<td>H</td>
<td>R</td>
</tr>
<tr>
<td>Z</td>
<td>H</td>
<td>R</td>
</tr>
<tr>
<td>Z</td>
<td>E</td>
<td>S</td>
</tr>
<tr>
<td>H</td>
<td>R</td>
<td>Z</td>
</tr>
</tbody>
</table>

### II. Continuation Phase: (Prescribed regimen & dosage)

<table>
<thead>
<tr>
<th>CAT 1</th>
<th>CAT 2</th>
<th>CAT 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>H</td>
<td>R</td>
<td>E</td>
</tr>
<tr>
<td>H</td>
<td>R</td>
<td>Z</td>
</tr>
</tbody>
</table>

### Notes:

1) Tick the appropriate box and indicate daily number of tablets and dosage of S in grams
2) H=Isoniazid, R=Rifampicin, S=Streptomycin, E=Ethambutol and Z=Pyrazinamide

### Disease Classification

<table>
<thead>
<tr>
<th>Pulmonary □</th>
<th>Extra-pulmonary □</th>
</tr>
</thead>
</table>

### Site: 

Biopsy: Positive □ Negative □

### Other (specify)

New: □ Relapse □

Transfer-in: □ Other (specify) □

Treatment after default: .........
### TB Patient's Personal Information

<table>
<thead>
<tr>
<th>Index No.</th>
<th>Full Name</th>
<th>Tribe</th>
<th>Age</th>
<th>Sex</th>
</tr>
</thead>
</table>

### TB Treatment Card

<table>
<thead>
<tr>
<th>Date of Diagnosis</th>
<th>Treatment after default (D)</th>
<th>Type of Patient (T)</th>
<th>Transfer-in</th>
<th>Transfer-out</th>
<th>Date of Relapse (R)</th>
</tr>
</thead>
</table>

### Spuim Examination

| Sputum Examination | 
|--------------------|-----------------------------|

<table>
<thead>
<tr>
<th>Pretreatment</th>
<th>End of 2nd month</th>
<th>End of 3rd month</th>
</tr>
</thead>
</table>

|---------------|-------------|-----|-----|-----|-----|-------------|-----|-----|-----|

### Sputum Examination

|---------------|-------------|-----|-----|-----|-----|-------------|-----|-----|-----|

### Patient's House-hold Contacts

<table>
<thead>
<tr>
<th>S. No</th>
<th>Name of Contact</th>
<th>Relation</th>
<th>Sex</th>
<th>Age</th>
<th>Date of Examination</th>
</tr>
</thead>
</table>

### Asymptomatic/ Symptomatic

<table>
<thead>
<tr>
<th><strong>BCG Scar</strong></th>
<th><strong>Mantoux Test</strong></th>
<th><strong>ESR</strong></th>
<th><strong>AFB / Culture</strong></th>
<th><strong>X-Ray</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Present/Absent</td>
<td>(........ MM)</td>
<td>MM</td>
<td>Result</td>
<td>Result</td>
</tr>
</tbody>
</table>

### Date of Follow-up

<table>
<thead>
<tr>
<th>First visits</th>
<th>Follow-up</th>
<th>Second visits</th>
<th>Follow-up</th>
<th>Third visits</th>
<th>Follow-up</th>
</tr>
</thead>
</table>

### Mantoux ESR AFB Culture X-ray results

<table>
<thead>
<tr>
<th>Mantoux</th>
<th>ESR</th>
<th>AFB</th>
<th>Culture</th>
<th>X-ray</th>
</tr>
</thead>
</table>

### Conclusion

- **End of 3rd month**
- **Ref. Lab. No.**
- **Sensitivity**
- **L.S.**
- **S.L.**
- **S.L.**
- **S.L.**
### Patient's House-Holder Contacts

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Name of contacts</th>
<th>Sex</th>
<th>Age</th>
<th>Relation</th>
<th>Date of examination</th>
<th>Asymptomatic / Symptomatic</th>
<th>BCG Scar Present / Absent</th>
<th>Mantoux Test (mm)</th>
<th>ESR</th>
<th>AFB / Culture Results</th>
<th>X-Ray Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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LABORATORY REGISTER FOR T.B. DIAGNOSTIC WORK

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Year : .......................................................... Page No. ........................

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## Latent TB Infection Treatment Monthly Report

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<th>Date LTBI treatment started</th>
<th>Remarks (Yes/No) (Continue LTBI trt for 9 months)</th>
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**Treatment:**

Mantoux test ≥ 10 mm start LTBI treatment INH (5 mg/Kg) daily for 8-10 weeks. At 10 weeks repeat Mantoux test (results ≥ 10 mm) continue LTBI treatment for 9 months. If results less than 10 mm stop treatment.

*On the day of drug collection the dose should be given under direct observation in presence of the TB nurse*

**Note:**

On completion of the investigation report retain the original with treatment card of the patient. One copy of the report is to be sent to National TB control programme.
GLOSSARY OF TERMS

BCG adenitis

BCG lymphadenitis / BCG adenitis, defined as the development of ipsilateral regional lymph node enlargement after BCG vaccination, is the most common complication resulting from this vaccination. In its natural course, BCG lymphadenitis either undergoes spontaneous regression, or enlarges progressively and become suppurative.

Chronic excreter of tubercle bacilli

Chronic excreter is one who remains sputum positive after the completion of re-treatment regimen (category 2 in WHO regimen) if a patient is smear positive for more than 2 years, if he has not completed re-treatment regimen, he will not be categorised as chronic.

Codes for comparison of X-ray films.

C - Complete Clearance
I - Improved
S - Stationary
D - Deteriorated

Codes used in X-ray reading

N - Normal
NT - Non-Tubercular Conditions
TBP - Pulmonary Tuberculosis
TBPLEF - Tubercular Pleural Effusion
TBHA - Tubercular Hilar Adenitis
TI - Technically Inadequate
OBS - Observation

Cohort of TB patients

All the TB patients diagnosed during a specified period, each one of them having had an equal chance of completing the same period of observation.

Completed treatment

The number of cases, who were sputum smear positive, completed treatment, with negative smears at the end of the initial phase, but with no or only one negative sputum examination in the continuation phase and none prior to stopping ATT.
**Cured**
The numbers of patients who were initially smear positive, who completed treatment and had at least 2 negative sputum smear results during the continuation phase, one of which was prior to stopping ATT.

**Contact**
Any person who has been in close association with an active TB cases. For our program, we will define contact as anyone living in the same house, (uses the same kitchen) as the person with active TB.

**Defaulter action**
Action taken to bring a defaulter back on treatment (retrieval).

**DOTS**
Directly Observed Treatment, Short-course. In accordance with “DOTS” strategy, it has been decided that all sputum positive pulmonary TB cases will be mandatory admitted for the initial intensive phase of 2 months during which the TB medicines will be given daily under the supervision of a trained health worker.

**Drug Sensitivity test**
A culture procedure to determine whether growth of tubercle bacilli is inhibited by certain drug. Bacilli which do not grow when incubated on a medium containing a given drug are said to be sensitive to that drug; bacilli that grow despite the presence of a given drug in the culture medium, are said to be resistant to that drug. Sensitivity tests should be carried out under standardised conditions in a Tuberculosis Reference Laboratory. They are relatively unimportant when new patients are started on treatment but are of considerable value in the treatment of relapses and failure case.

**Drug tolerance**
The occurrence of unpleasant but not life-threatening side effects of a certain drug. Examples of drug intolerance: nausea and gastrointestinal disturbances due to thiacetazone, attacks of gout due to pyrazinamide, flu syndrome due to Rifampicin, etc.

**Extra-pulmonary (EP) Tuberculosis**
A patient with tuberculosis of organs other than the lung. TB of the pleura (TB pleurisy), of peripheral lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, tubercular meningitis etc. Any patient diagnosed with both TBP and EP should be classified as a case of pulmonary tuberculosis.
**Failure case**
The numbers of smear positive cases who remained or became again smear positive 5 months or later after starting treatment.

**First-line chemotherapy**
The therapy which has been selected in a certain programme for the treatment of new cases. The term is used in contrast with second-line chemotherapy i.e. the therapy selected for retreatment of relapse or failure case.

**Follow-up**
Re-examination of TB patients either during the course of treatment or anytime afterwards.

**Follow-up visits**
After completion of treatment, the patient attends four follow-up visits, as follows:
- After 3 months (First follow-up visit)
- After 3 months (Second follow-up visit)
- After 6 months (Third follow-up visit)
- After 1 year (Fourth follow-up visit)

**Incidence**
Tuberculosis incidence indicates the number of new cases of tuberculosis, which develop within a specified period of time, usually one year. It is usually expressed as a rate per 100,000 general populations. In most cases, the time of onset of the tuberculous disease cannot be determined. The expression ‘incidence’ is therefore usually replaced by the term ‘newly notified’ or ‘newly discovered’ or ‘newly reported’ cases of tuberculosis per 100,000 general populations.

**Latent TB Infection**
Once infected by the tubercle, a person remains tuberculin positive and can at any time during his life become sick with active TB, even if he never again comes in contact with a TB case.

**Initial defaulter**
A TB patient who fails to start treatment after diagnosis.

**Initial motivation**
Motivation done at the time of initiation of anti-tubercular treatment.
Lost-case (Treatment interrupted / default)
Patients who at any time after registration did not collect the anti-tuberculosis drugs for 2 months or more.

Mantoux-test
There are several types of tuberculin-tests, but the accepted standard one, is the Mantoux test. The TBCP recommends that the above test be used as an aid to diagnosis and not as a routine. It may be useful in paediatric case up to the age of 5 years in whom sputum examination is difficult and chances of getting a good X-ray are remote.

Motivation
The effort made to convince TB patients that it is in their interest to take treatment as prescribed by the doctor.

New Smear-positive case of pulmonary tuberculosis
A patient who never received treatment for tuberculosis or has taken ATT for less than 4 weeks and who has one of the following:
• At least 2 initial sputum smear examinations (direct smear microscopy) positive for AAFB.
• One sputum specimen positive for AAFB and radiological evidence consistent with active pulmonary TB.
• One sputum specimen positive for AAFB and one sputum culture positive for AAFB.

New Smear-negative case of pulmonary tuberculosis
A patient with symptoms suggestive of tuberculosis and at least 2 sputum smears negative for AAFB, and radiological abnormalities consistent with active pulmonary tuberculosis or patient with AFB smear-negative sputum and culture positive for M. tuberculosis.

Outpatients
Persons attending a health institution for relief of their symptoms or for preventive measures but not admitted in the institution.

Prevalence
Tuberculosis prevalence gives the number of cases of tuberculosis present (new + old) in a defined population at a particular date per 100,000 general population.

Relapse (Re-started Treatment)
A patient declared cured in the past who again has active tuberculosis.
Re-motivation
Motivation done by the doctor/drug distributor at the time of retreatment.

Re-treatment (smear-positive cases only)
Patients previously treated (for at least 4 weeks), including failures, relapses, defaulters who return to the health service with a positive sputum smear.

Resumed treatment: Treatment after interruption (TAI)

Sputum conversion
The process whereby initially smear-positive patients become sputum AFB-negative while on adequate chemotherapy.

Sputum specimen
Material brought out on coughing to be used for bacteriological examination. Spot specimen is produced under supervision at the health institution on request while collected specimen is brought from home by the patient.

Subsequent motivation
Motivation done at the time of subsequent drug collection or during a home-visit.

Surveillance period
After completion of ATT, the patient is kept under surveillance for a period of two years.

TB beds
Nearly 10% of the cases only require hospitalization and this should be made available primarily for serious emergencies, advanced tuberculosis cases, tuberculosis with concomitant disease(s), resistant type of cases, those requiring surgery and on sociological grounds.

TB Deaths
Patients dead during treatment, regardless of cause.

Toxicity
Serious disturbances in the human metabolism caused by a certain drug, which may cause irreversible damage or endanger the patient’s life, which require immediate medical intervention. Examples of toxicity: deafness due to streptomycin, hepatitis due to INH or Rifampicin, exfoliative dermatitis due to thiacetazone.
**Transferred-in case**
When a treatment-card of a TB patient is transferred from another institution to a particular institution, the said case is considered as a ‘transferred-in case’ at the new institution.

**Transferred-out case**
When a treatment-card of a TB patient is transferred out to another institution either due to convenience or transfer of residence etc. such cases are considered as ‘transferred-out cases’ by the earlier institution and the new institution includes them as ‘transferred-in cases’.

**Transfer of treatment**
The principle underlying transfer of treatment is that TB patients should collect ATT from the institution that is most convenient to them; as this might ensure better treatment regularity and continuity. The same should be explained to the patient and his/ her consent is obtained before transfer of his/ her treatment-card.

**Treatment**
It is recommended to fully supervise the daily drug intake during the initial phase.

**Uninfected**
Tuberculin negative (Susceptible).

**Visit – awaited period**
Patients who do not turn up to take their ATT drug supplies at the appointed time should be immediately traced and put back on treatment.
### TB Focal Point and Important Telephone Numbers

<table>
<thead>
<tr>
<th>Full Name</th>
<th>Designation</th>
<th>Institution</th>
<th>Tel. / Mobile No.</th>
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<tbody>
<tr>
<td>Dr. Hassan Al Tuhami</td>
<td>Head of Epidemiology, National TB program</td>
<td>Dept. of Comm. Disease Surv. &amp; control</td>
<td>24607082 / 95208040</td>
<td>24699809</td>
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<tr>
<td>Dr. Ali Ba Omer,</td>
<td>Head of HIV/AID's section</td>
<td>Dept. of Comm. Disease Surv. &amp; control</td>
<td>24607082</td>
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<tr>
<td>Mr. Islam Al Bulushi</td>
<td>P.H. Specialist</td>
<td>National TB program</td>
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<tr>
<td>Mr. Mohammed Shaikhan Al Maahi</td>
<td>Sr. Health Superintendent</td>
<td>National TB program</td>
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#### Muscat Region

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MOIC  
Al Rahma Hosp  
Tel.: 99358212, 24814881/24815132  
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Ms. Naqeya Nasib Abdulla Al Shahi  
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**Al-Ameerat**

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Fax: 24877686

Dr. Ghada Mohammed Abdullah Al Lawati  
Medical Officer  
Al-Ameerat HC  
Tel.: 24876512  
Fax: 24877519

Ms. Sharifa Salim Saif Al Ghammari  
Staff Nurse  
Al-Ameerat HC  
Tel.: 24876512  
Fax: 24877519

**Quriyat**

Dr. Ibrahim Gad Abdel Hai  
MOIC  
Quriyat Hosp  
Tel.: 24845002/249203455  
Fax: 24845001

Ms. Shamsa Mohd Halls Al-Malki  
Staff Nurse  
Quriyat Hosp  
Tel.: 24843340/24845933  
Fax: 24845001

Mr. Badr Youosf Salim Al Ghusaini  
Sanitary Inspector  
Quriyat Hosp  
Tel.: 24845003  
Fax: 24845001

**Sister Institutions**

Dr. Mohd Saif Al-Hosni (BL.162)  
Sr. Consultant (Paed)  
Royal Hosp  
Tel.: 24599000/99474441  
Fax: 24599319

Dr. Nasser Hamed Salem Al-Busaidy  
Sr. Consultant (Phy)  
Royal Hosp  
Tel.: 24599253/249370625  
Fax: 24599966

Ms. Fatma Masoud Al-Busaidy (BL.176)  
Staff Nurse  
Royal Hosp  
Tel.: 24599000  
Fax: 24599383/99411271

**Sultan Qaboos University Hosp**

Dr. Abdallah Balkhair  
Sr. Consultant (Phy)  
SQU Hosp  
Tel.: 24141177  
Fax: 24141009

Ms. Wafaa Al Hadhrami  
Inf. Control Nurse  
SQU Hosp  
Tel.: 24141691/95502500  
Fax: 24141780

**Armed Forces Hospital**

Dr. Said Al-Abri  
Sr. Consultant  
AF Hospital  
Tel.: 24331023/99333052  
Fax: 24331951

Ms. Wahida Said Talib Al-Kharusi  
Inf. Control. NO  
AF Hospital  
Tel.: 24331981  
Fax: 24331197

**Royal Oman Police Hospital**

Dr. Renchi Mathew  
Sr. Specialist  
ROP Hosp  
Tel.: 24603988  
Fax: 24699113
## TB Focal Point and important Telephone Numbers

### Dhofar Governorate

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### North Sharqiyah Region Focal Point and Important Telephone Numbers

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<td>Dr. Mostafa Farid Mohd Saad</td>
<td>Physician</td>
<td>Ibra Hospital</td>
<td>25570022</td>
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<tr>
<td>Ms. Nasra Salem Rashid Al Amri</td>
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<td>Mr. Dawood Dadin Al Baluchi</td>
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### MUDHAI BI Focal Point and Important Telephone Numbers

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<td>Dr. Abdul Hakin Labib</td>
<td>Physician</td>
<td>Sinaw Hospital</td>
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<td>Ms. Hasina Sulyam Saloom Al Abri</td>
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<td>Mr. Hameed Said Al Wahebi</td>
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### South Sharqiyah Region Focal Point and Important Telephone Numbers

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<td>Dr. Essam</td>
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<td>Dr. Goal Ahmed Abdul Satar</td>
<td>Med. Officer (Med)</td>
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<td>Ms. Jameela Essa Baqool Al Baloooshi</td>
<td>Staff Nurse</td>
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<td>Mr. Khalfan Salim Ali Al Busaidi</td>
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<td>Ms. Mariam Mohd Amo Al Rashdi</td>
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<td>Ms. Magda Sulaiman Abdulla Al Kamski</td>
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## South Batinah Region

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## BARKA, NAKHAL & WADI MAAWEL

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## TB Focal Point and important Telephone Numbers

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