Manual for Tuberculosis Management within IOM Migration Health Assessment Programmes
The opinions expressed in the report are those of the authors and do not necessarily reflect the views of the International Organization for Migration (IOM). The designations employed and the presentation of material throughout the report do not imply expression of any opinion whatsoever on the part of IOM concerning legal status of any country, territory, city or area, or of its authorities, or concerning its frontiers or boundaries.

IOM is committed to the principle that humane and orderly migration benefits migrants and society. As an intergovernmental organization, IOM acts with its partners in the international community to: assist in meeting the operational challenges of migration; advance understanding of migration issues; encourage social and economic development through migration; and uphold the human dignity and well-being of migrants.

Note: This document was prepared to provide guidance to IOM Migration Health Physicians, Migration Health Nurses, laboratory technicians and other staff working in Migration Health Assessment Programmes as to the key components and methodologies for identifying and then managing a client with tuberculosis (TB) who has been assessed or has been referred to IOM for care or is under IOM care.

The document should be used to guide the care processes for TB, supported through local standard operating procedures and algorithms that are based on the guidance in this manual.

While this manual forms the basis for how IOM provides care based on current evidence, IOM staff should ensure first and foremost that there is adherence to the technical instructions (TIs) of the receiving countries. Where there is potential discrepancy between what is outlined in this manual and specifications in the TIs, IOM staff should adhere to the TIs from individual countries or escalate to a supervisor for clarification.

If there is no guidance in the TIs, IOM staff must abide by the directions outlined in this manual.

This report was issued without formal editing by IOM.

Publisher: 17 route des Morillons
P.O. Box 17
1211 Geneva 19
Switzerland
Tel.: +41 22 717 9111
Fax: +41 22 798 6150
Email: hq@iom.int
Website: www.iom.int

ISBN 978-92-9068-858-7 (PDF)
© 2020 International Organization for Migration (IOM)

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise without the prior written permission of the publisher.
Table of contents

List of figures ............................................................................................................................ vi
List of tables ............................................................................................................................ vi
Acronyms and abbreviations ................................................................................................. ix

Introduction ............................................................................................................................. 1

Aim ........................................................................................................................................... 2
Technical instructions ............................................................................................................ 2
Reference guidelines ............................................................................................................... 3
General principles .................................................................................................................. 4

Chapter 1. TB Case Management: Roles and Responsibilities .................................................. 7
1.1. Basic level: IOM refers for treatment without follow up and post-treatment evaluation ... 9
1.2. Monitoring level: IOM does not provide DOT, but provides monitoring throughout treatment and post-treatment evaluation ............................................................................. 10
1.3. Comprehensive level: IOM fully manages TB treatment ................................................ 12
1.4. Individual roles and responsibilities .............................................................................. 16

Chapter 2. Initiating treatment ................................................................................................. 17
2.1. Screening programmes ................................................................................................... 18
2.2. TB screening algorithm ................................................................................................ 20
2.3. Newly diagnosed cases .................................................................................................. 20
2.4. Cases of ongoing TB treatment ..................................................................................... 22
2.5. Isolation .......................................................................................................................... 23
2.6. Initial administrative requirements ............................................................................... 24
2.7. Additional administrative requirements when IOM provides treatment ..................... 25

Chapter 3. Pre-Treatment Work Up ......................................................................................... 27
3.1. Counselling ..................................................................................................................... 28
3.2. Medical history review, physical examination and vital signs ..................................... 29
3.3. Baseline investigations .................................................................................................. 29

Chapter 4. Contact Tracing and Latent TB Infection ................................................................. 33
4.1. Evaluating and managing TB contacts as part of the Migration Health Assessment and resettlement processes ......................................................................................................................... 34
4.2. Treating latent TB infection ........................................................................................... 36
4.3. Country-specific requirements for managing latent TB infection ................................. 38

Chapter 5. Treatment ............................................................................................................. 41
5.1. General treatment processes .......................................................................................... 42
5.2. Mode of TB treatment delivery: directly observed versus self-administered ............. 43
5.3. Delivering and organizing DOT .................................................................................... 44
5.4. Client-centred TB case management ............................................................................ 47
5.5. Anti-TB medicines ........................................................................................................ 48
5.6. Drug-susceptible TB ................................................................. 48
5.7. Paediatric TB cases ............................................................... 50
5.8. Treatment extensions ............................................................ 51
5.9. Treatment interruptions ......................................................... 51
5.10. Patients with TB−HIV co-infection ....................................... 52
5.11. TB treatment and hepatic disease ......................................... 54
5.12. Pre-existing hepatic disease ................................................ 54
5.13. TB treatment and renal disease or insufficiency .................... 55
5.14. TB treatment for pregnant and breastfeeding women ............ 55
5.15. Regimens for drug-resistant TB ............................................ 56
5.16. Schedules for follow-up tests for different countries ............... 57
5.17. Monitoring and managing side effects ................................. 57
5.18. Default tracing .................................................................... 57
5.19. Clinical consultations .......................................................... 58

Chapter 6. Drug-resistant TB ......................................................... 61
  6.1. Molecular testing .................................................................... 62
  6.2. Drug-susceptibility testing on liquid and solid media ............... 64
  6.3. Empiric identification ............................................................ 65
  6.4. Treatment monitoring for drug-resistant TB ............................ 65
  6.5. Treatment regimens for drug-resistant TB ............................... 65
  6.6. Building a longer treatment regimen for multidrug-resistant TB .. 67
  6.7. Using the standardized shorter regimen to treat multidrug-resistant TB ...... 69

Chapter 7. Treatment Monitoring .................................................. 71
  7.1. Monitoring adherence to treatment ....................................... 72
  7.2. Monitoring side effects ........................................................ 72
  7.3. Monitoring treatment effectiveness ...................................... 75

Chapter 8. Documentation and Reporting ...................................... 79
  8.1. Responsibility ....................................................................... 80
  8.2. Documentation ....................................................................... 80
  8.3. Data entry procedure ........................................................... 83
  8.4. Data validation and IOM internal reporting ............................. 83
  8.5. Reporting obligations .......................................................... 84

Chapter 9. Treatment completion and certification .......................... 85
  9.1. Treatment outcomes ............................................................ 86
  9.2. Certification ......................................................................... 87

Chapter 10. Psychosocial management ............................................ 89
  10.1. Background ......................................................................... 90
  10.2. Psychosocial support .......................................................... 91

Chapter 11. TB Infection Prevention and Control .............................. 95
  11.1. Administrative infection control measures ............................. 97
  11.2. Environmental infection control measures ............................ 98
  11.3. Respiratory protection measures ........................................ 99
  11.4. Measures for congregate settings ....................................... 100
Annexes ........................................................................................................................................... 101

Annex 2. Individual Staff Roles and Responsibilities for Managing TB for IOM Clients 104
Annex 3. TB Flow Process Schematic 107
Annex 4. Table of Country Screening Requirements 115
Annex 5. MiMOSA Guide for MHD Users 119

Template Forms ............................................................................................................................. 127

Template Form 1. TB Treatment Referral Summary 128
Template Form 2. Treatment Monitoring Advice for External Physicians 129
Template Form 3. National TB Programme Notification 131
Template Form 4. TB Counselling and Consent 133
Template Form 5. TB Patient Treatment Record 135
Template Form 6. TB Patient Appointment Card 138
Template Form 7. TB Treatment Compliance 139
Template Form 8. TB Side Effect Monitoring 140
Template Form 9. Form for HIV Counselling and Consent for HIV Testing for TB Patients 142
Template Form 10. Checklist for TB Monitoring 144
Template Form 11. Baseline and Routine Monitoring of MDR-TB Requirements 145
Template form 12. Sputum Results Summary 147
Template Form 13. Chest X-Ray Results Summary 149
Template Form 14. TB Treatment Certificate 150
List of figures

Figure 1. Generic TB screening algorithm for most receiving countries .................................................. 20
Figure 2. Decision tree for TB contact tracing and evaluation ................................................................. 35
Figure 3. Criteria to use when deciding if the shorter regimen to treat multidrug-resistant TB (MDR-TB) may be offered ........................................................................................................ 69
Figure 4. Screen shots of the Active TB Report and the TB Indicators Report generated using Microsoft Power BI .................................................................................................................. 83

List of table

Table 1. Potential TB culture outcomes and corresponding reporting in MiMOSA ................................. 21
Table 2. Requirements for clients receiving TB treatment from an external provider at the time of their migration health assessment, Australia and United States ............................ 23
Table 3. Drug regimens for microbiologically confirmed pulmonary TB caused by drug-susceptible organisms ................................................................................................................. 49
Table 4. Managing interruptions to TB treatment .................................................................................... 52
Table 5. World Health Organization’s groups of medicines recommended for use in treating multidrug-resistant TB ........................................................................................................ 66
Table 6. Mandatory clinical tests for specific medications ...................................................................... 73
Table 7. Laboratory tests for monitoring the side effects of TB treatment ............................................ 74
Table 8. Country-specific requirements for radiological and bacteriological testing and monitoring of treatmenta .................................................................................................................. 76
Table 9. Infection control measures for health-care facilities and clinics ............................................ 96
Acronyms and abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>aFB</td>
<td>acid-fast bacilli</td>
</tr>
<tr>
<td>ALP</td>
<td>alkaline phosphatase</td>
</tr>
<tr>
<td>ALT</td>
<td>alanine aminotransferase</td>
</tr>
<tr>
<td>AP</td>
<td>anteroposterior (CXR)</td>
</tr>
<tr>
<td>ART</td>
<td>antiretroviral therapy</td>
</tr>
<tr>
<td>ARV</td>
<td>antiretroviral</td>
</tr>
<tr>
<td>AST</td>
<td>aspartate aminotransferase</td>
</tr>
<tr>
<td>ATS</td>
<td>American Thoracic Society</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CMHO</td>
<td>Chief Migration Health Officer</td>
</tr>
<tr>
<td>CNS</td>
<td>central nervous system</td>
</tr>
<tr>
<td>CXR</td>
<td>chest X-ray</td>
</tr>
<tr>
<td>DGMQ</td>
<td>Division of Global Migration and Quarantine</td>
</tr>
<tr>
<td>DOT</td>
<td>directly observed therapy</td>
</tr>
<tr>
<td>DR-TB</td>
<td>drug-resistant tuberculosis</td>
</tr>
<tr>
<td>DST</td>
<td>drug-susceptibility testing</td>
</tr>
<tr>
<td>ECG</td>
<td>electrocardiogram</td>
</tr>
<tr>
<td>EMB</td>
<td>ethambutol</td>
</tr>
<tr>
<td>ETA</td>
<td>ethionamide</td>
</tr>
<tr>
<td>FBC</td>
<td>full blood count</td>
</tr>
<tr>
<td>FQN</td>
<td>fluoroquinolone</td>
</tr>
<tr>
<td>GUV</td>
<td>germicidal ultraviolet light</td>
</tr>
<tr>
<td>HAP</td>
<td>Health Assessment Programme (IOM)</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<tr>
<td>HR</td>
<td>isoniazid + rifampicin</td>
</tr>
<tr>
<td>HREZ</td>
<td>isoniazid + rifampicin + ethambutol + pyrazinamide</td>
</tr>
<tr>
<td>IDSA</td>
<td>Infectious Diseases Society of America</td>
</tr>
<tr>
<td>Acronyms</td>
<td>Definitions</td>
</tr>
<tr>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>IGRA</td>
<td>interferon-gamma release assay</td>
</tr>
<tr>
<td>IME</td>
<td>immigration medical examination</td>
</tr>
<tr>
<td>INH</td>
<td>isoniazid</td>
</tr>
<tr>
<td>IOM</td>
<td>International Organization for Migration</td>
</tr>
<tr>
<td>IPC</td>
<td>infection prevention and control</td>
</tr>
<tr>
<td>IRCC</td>
<td>Immigration, Refugees and Citizenship Canada</td>
</tr>
<tr>
<td>IRIS</td>
<td>immune reconstitution inflammatory syndrome</td>
</tr>
<tr>
<td>LPA</td>
<td>line probe assay</td>
</tr>
<tr>
<td>LTBI</td>
<td>latent tuberculosis infection</td>
</tr>
<tr>
<td>MAC</td>
<td>Manila Administration Centre</td>
</tr>
<tr>
<td>MDR-TB</td>
<td>multidrug-resistant tuberculosis</td>
</tr>
<tr>
<td>MHA</td>
<td>Migration Health Assessment</td>
</tr>
<tr>
<td>MHAC</td>
<td>Migration Health Assessment Centre (IOM)</td>
</tr>
<tr>
<td>MiMOSA</td>
<td>Migrant Management and Operational Systems Application (IOM)</td>
</tr>
<tr>
<td>MTB</td>
<td>Mycobacterium tuberculosis</td>
</tr>
<tr>
<td>NAAT</td>
<td>nucleic acid amplification test</td>
</tr>
<tr>
<td>NGO</td>
<td>non-governmental organization</td>
</tr>
<tr>
<td>NTM</td>
<td>nontuberculous mycobacteria</td>
</tr>
<tr>
<td>NTP</td>
<td>National Tuberculosis Programme</td>
</tr>
<tr>
<td>PA</td>
<td>posteroanterior (CXR)</td>
</tr>
<tr>
<td>PCR</td>
<td>polymerase chain reaction</td>
</tr>
<tr>
<td>PP</td>
<td>panel physician</td>
</tr>
<tr>
<td>PPE</td>
<td>personal protective equipment</td>
</tr>
<tr>
<td>PTB</td>
<td>pulmonary tuberculosis</td>
</tr>
<tr>
<td>PZA</td>
<td>pyrazinamide</td>
</tr>
<tr>
<td>RIF</td>
<td>rifampicin</td>
</tr>
<tr>
<td>RHAPC</td>
<td>Regional Health Assessment Programme Coordinator</td>
</tr>
<tr>
<td>RR</td>
<td>rifampicin resistant</td>
</tr>
<tr>
<td>SAT</td>
<td>self-administered therapy</td>
</tr>
<tr>
<td>SL-LPA</td>
<td>second-line line probe assay</td>
</tr>
<tr>
<td>Acronym</td>
<td>Full Form</td>
</tr>
<tr>
<td>---------</td>
<td>-----------</td>
</tr>
<tr>
<td>SOP</td>
<td>standard operating procedure</td>
</tr>
<tr>
<td>TB</td>
<td>tuberculosis</td>
</tr>
<tr>
<td>TI</td>
<td>Technical Instruction</td>
</tr>
<tr>
<td>TSH</td>
<td>thyroid stimulating hormone</td>
</tr>
<tr>
<td>TST</td>
<td>tuberculin skin test</td>
</tr>
<tr>
<td>UKTBDP</td>
<td>UK Tuberculosis Detection Programme</td>
</tr>
<tr>
<td>VOT</td>
<td>video-observed treatment</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>XDR-TB</td>
<td>extensively drug-resistant tuberculosis</td>
</tr>
<tr>
<td>ZN</td>
<td>Ziehl−Neelsen</td>
</tr>
</tbody>
</table>
Introduction
Aim

The management of tuberculosis (TB) by the International Organization for Migration (IOM) has two overall objectives: namely, to adequately treat and cure the infected patient, as well as to minimize the risk of transmission to other persons before, during and after migration. Both individual and public health responsibilities fall on IOM to:

• Manage public health risk, including infection control and contact tracing;
• Oversee treatment and ensure adherence to an appropriate regimen;
• Conform with the resettlement country’s technical instructions (TIs);
• Coordinate with the host country’s National TB Programme (NTP).

Quality TB management requires the consistent and diligent application of a standardized, evidence-based approach within recognized guidelines. This manual aims to support a consistent and high-quality process of TB management for IOM health assessment activities worldwide.

Receiving countries’ TIs dictate a screening algorithm for TB and a set of requirements to be fulfilled once diagnosis is made and treatment is initiated and then completed. However, TIs do not provide comprehensive operational specifics for TB management, instead, in the main, they reference external guidelines for this purpose.

This manual provides a bridge between the TIs and external guidelines by concisely defining a practically applicable process that fulfils TI requirements in harmony with the reference guidelines regardless of whether the treatment is provided directly by IOM.

This manual does not replace clinical judgment and does not prevent physicians from performing additional investigations or taking clinical action as individual cases require. A standard approach cannot cover all possibilities, meaning that exceptions occasionally arise; however, this does not undermine the importance of consistency as a foundation for quality TB management.

Technical instructions

The receiving country’s TIs form the starting point for health assessment activities and TB management, and these instructions should be adhered to in all cases as standard practice. TIs are available from:


Reference guidelines

Reference guidelines provide detail beyond the scope of this manual, which is intended for operational use and, as such, presents simplified content. The reference guidelines identified below should be consulted for more detail about matters not addressed by TIs or this manual.


- ATS–CDC–IDSA recommendations are comparable to those of the World Health Organization (WHO) and the International Union Against Tuberculosis and Lung Disease and describe the DOT (directly observed therapy) strategy. A copy of these recommendations should be available at all treatment centres. DOT is required by United States’ TIs and the guidelines of other resettlement countries.

- ATS–CDC–IDSA recommendations should be observed for all United States-bound and Australia-bound cases, as well as TB cases bound for other resettlement countries for which treatment guidelines are not otherwise provided or stipulated.


(3) New Zealand-bound cases should be managed in accordance with the Guidelines for Tuberculosis Control in New Zealand, 2019 (www.health.govt.nz/publication/guidelines-tuberculosis-control-new-zealand-2010).

(5) Guidance for the management of drug resistance is addressed in Section 7 of this manual. Further guidance is provided in the following references:


**General principles**

As outlined in the TIs of each country, while TB screening is primarily in place to identify inadmissible conditions as required under law, it also has a broader public health principle. As defined by WHO in its description of the principles and practices of systematic screening for TB,¹ the primary objective of TB screening is to ensure that active TB is detected early and that appropriate treatment is initiated promptly, with the ultimate aims of reducing the risks of poor treatment outcomes, health sequelae and the adverse social and economic consequences of TB, as well as helping to reduce TB transmission. Therefore, under this objective, this manual addresses the need for all TB screening programmes to have in place a mechanism to ensure the effective treatment of any identified active case.

As such, in addition to necessitating an effective screening process as defined by specific country TIs, quality TB management also requires the implementation and maintenance of a complementary set of activities to support good clinical practice. These include:

(1) Ongoing staff training and development;
(2) Systematic data collection and analysis;
(3) Laboratory quality assurance and management;
(4) Radiology quality assurance and management;
(5) Partnership and liaison with the NTP;
(6) Client-centric services, with appropriate counselling.

It is the responsibility of the Chief Migration Health Officer (CMHO) to ensure that these activities are optimized in their jurisdiction.

TB management of individual clients must be supervised by an IOM Migration Health Physician (MHP) even when the treating physician is an external provider. IOM MHPs should act as case managers to ensure that the requirements of treatment completion and certification, public health responsibility and external notification, as well as the resettlement needs of the client are met as per the receiving country’s TIs and host country’s NTP guidelines. Guidance relating to the monitoring and supervision of external treatment is provided in Section 3b.

For complex cases not conclusively addressed by this manual or applicable external guidelines, further guidance should be sought from senior Health Assessment Programme (HAP) staff or an appropriate representative of the receiving country, or both (see Section 7s).
CHAPTER 1

TB Case Management: Roles and Responsibilities
As outlined above, the panel physician’s (PP’s) role in TB case management is first and foremost to ensure that the client understands their TB disease status and, further, complies with and completes treatment. In this respect the prescribing physician’s role in completing therapy is fundamental: “…he/she, in the public or private sector, is carrying out a public health function with responsibility not only for prescribing an appropriate regimen but also for successful completion of therapy.”

Once the MHP is notified about a diagnosis of TB, there are two roles for IOM in further management based on whether the applicant is IOM or non-IOM (that is, referred by other PP clinics).

For IOM applicants:

(1) Make a diagnosis of TB disease based on findings elicited from routine health assessments, that is, clinical, radiological and bacteriological findings that meet the case definition for active TB disease requiring treatment.

(2) Update the Migrant Management and Operational System Application (MiMOSA) and the UK TB Detection Programme (UKTBDP) Global Software fully, with all of the information available at the time of diagnosis. The MHP will put the necessary hold in MiMOSA for TB treatment and assign an alert date, initially on a presumed 6-month treatment regimen plus 2 months to complete post-treatment investigations, that is, 8 months from the date of diagnosis. The PP must update this alert date during the course of treatment if the planned treatment regimen or duration of treatment changes. Likewise for UKTBDP cases, the MHP will proceed as “certificate refused”, with the reason being “referred for TB treatment”.

(3) Inform patients and counsel them about their TB diagnosis and the need for treatment, and provide general information regarding their treatment regimen and potential side effects, the duration of treatment and the expected way forward in reference to ongoing resettlement and migration processes.

(4) Explain to the patient the options for TB treatment that are consistent with the TIs for the receiving country, and ask the patient to make an informed decision as to whether they will register and take treatment with IOM or with another provider. The MHP must explain to patients the expected outcome and consequences of whichever decision they make.

(5) Manage any relevant contacts.

---

For non-IOM applicants (referred by other PP clinics):

1. The patient should be received by the assigned staff member, preferably an MHP or Migration Health Nurse (MHN), with briefing and counselling given during registration.

2. Once applicants give consent for TB treatment they should be registered at a Migration Health Assessment Centre (MHAC) and referred to an IOM TB treatment centre.

3. Inform the referring PP via email whether the client has been registered or chose to defer and have treatment elsewhere.

Depending on the destination country or the choice of the client, IOM may be involved in TB management in the following ways:

1. Basic level – refers for treatment to the NTP without follow up and post-treatment evaluation;

2. Monitoring level – refers for treatment elsewhere (usually the NTP) and provides regular follow up and post-treatment evaluation with certification;

3. Comprehensive level – provides the full spectrum of TB management services including initiation of treatment, DOT, follow up, post-treatment evaluation and certification.

### 1.1. Basic level: IOM refers for treatment without follow up and post-treatment evaluation

This situation is applicable mainly to the UKTBDP, and the Republic of Korea and Japan programmes, for which the main responsibility of the IOM physician is to detect TB, and if identified, refer the client for treatment. Post-treatment assessment is applicable only as part of a new health assessment and new clearance process after sufficient time has elapsed from the time of detection (not less than 6 months). While the UKTBDP TIs state that ideally clients should provide a medical report with details of their treatment, technically, even if migrants do not submit a treatment report, they are eligible for clearance provided that they have negative sputum tests and are not considered to require treatment on clinical or radiological grounds.

At this basic level of treatment, it is an ethical obligation for IOM staff to make their best efforts to promote the patient’s adherence to treatment and measures to interrupt TB transmission, although there is no requirement to take these steps, and the TIs may have limited requirements for clearance.

As such, all IOM MHACs must ensure the following basic steps are taken to assist in this.

1. Refer the client with all appropriate documentation and a referral letter (see Template Form 1, TB Treatment Referral Summary, and Template Form 2, Treatment
Monitoring Advice for External Physicians) to the nominated NTP, and notify national authorities if the client was assessed through IOM (see Template Form 3, National TB Programme Notification). The expected outcome or consequences for resettlement or migration must be reiterated to the client, and signed documentation must be obtained from the client confirming that they have understood (see Template Form 4, TB Counselling and Consent).

(2) Provide a referral letter (Template Forms 1 and 2) to the client containing the information detailed in Section 3b.

(3) Forward the referral paperwork to the IOM TB nurse in the MHAC who will follow up to confirm that the applicant has attended the NTP and is connected to care. Ideally, written notification will be requested (and should be mentioned in the referral letter) and where this is possible, the information will be forwarded to the IOM examining PP (the TB case manager) to open the TB Treatment Work-Up Module in MiMOSA. When this is not feasible, verbal confirmation of a connection to care is the minimum requirement to ascertain that the patient is on treatment: this confirmation must be sought, and the PP must immediately update MiMOSA to indicate that confirmation of a connection to care has occurred.

(4) At a minimum, the MHP or TB Focal Point should:

(a) Request the external TB treatment provider to provide a detailed end-of-treatment report based on Template Form 5, the TB Patient Treatment Record;

(b) Encourage the patient to attend for a free-of-charge follow-up visit at least at the end of the intensive phase, as well as to contact IOM if there are any questions throughout the course of treatment.

All interactions with the external treating TB service and any information shared or received should be recorded in the remark section of the UKTBDP Global Software (where applicable), as well as in MiMOSA.

### 1.2. Monitoring level: IOM does not provide DOT, but provides monitoring throughout treatment and post-treatment evaluation

IOM staff should clearly explain to the migrant the advantages of receiving treatment from IOM and the disadvantages and consequences of receiving treatment elsewhere. If migrants choose to access the NTP for treatment, they should be requested to provide contact information for the treating physician or health worker as soon as they register. The contact information should be entered into MiMOSA.

If the migrant opts to receive treatment elsewhere, all IOM MHACs must take the following intermediate steps.
(1) Advise applicants requiring TB treatment that even if they choose to have treatment outside of the prescribed TB treatment facility, they are expected to return to the IOM PP for monthly clinical review, as well as for scheduled follow-up sputum testing or chest X-rays (CXRs) as outlined in Section 9. It must be made clear that follow up without DOT by IOM will not imply clearance post treatment but, instead, information will be shared and consultation will be made with the country of resettlement or migration to obtain further advice on the way forward. In cases in which applicants live and are treated in settings that are far from IOM clinics, other alternatives might be sought, such as IOM physical or video verification of processes, and endorsement by the receiving country’s programmes for these alternatives (see Section 7c, point 2b).

(2) When the migrant chooses to receive treatment elsewhere, the IOM MHP (that is, the case manager) should prepare a referral letter to the treating physician as outlined in the information on the basic level of care in Section 3a above. The letter should contain the following information (Template Form 1, TB Treatment Referral Summary):

(a) History, symptoms and results of physical examination;
(b) Full diagnosis, including concomitant diseases;
(c) CXR report;
(d) Results of sputum tests, which must include culture and drug-susceptibility testing if positive. If all results are not available at the time of referral, pending results should be mentioned and the date by which they are expected;
(e) Results of other laboratory and clinical investigations, including results of HIV (human immunodeficiency virus) and hepatitis tests, as well as blood sugar;
(f) Recommendations for treatment in accordance with the requirements of the receiving country (instructions should be attached, if available);
(g) Any follow-up plan to be implemented by IOM;
(h) An invitation from IOM for a mutual exchange of information with the TB case manager, as outlined in Section 3a, and to collaborate on management of the patient;
(i) Request for periodic reports and an end-of-treatment report, with details of required information;
(j) Contact information for the IOM TB Focal Point;
(k) Migrant’s consent for bilateral sharing of treatment information (from IOM to the treating physician and from the treating physician to IOM) throughout the full course of treatment.

(3) Review all results related to TB treatment throughout the course of treatment and undertake a monthly clinical physical review of the patient, noting and documenting
the following aspects of the patient’s progress or lack of it in MiMOSA (see Section 9). These are the minimum requirements and, hence, any additional findings in addition to these must be documented and managed as well including:

(a) The patient’s clinical response to treatment as indicated through the resolution of signs and symptoms of TB, or the lack of response;
(b) Weight gain, loss or stability and need for dose modification as a result of weight changes;
(c) Bacteriological improvement as assessed by sputum conversion from positive to negative when relevant, or the lack of improvement;
(d) Radiological improvement assessed by comparing serial CXR images (that is, resolution or reduction of pathological lesions, or stability of the lesions, or noting and acting on any worsening of or increase in the lesions or the emergence of new lesions, suggestive of disease progression);
(e) Presence and management of any co-morbid conditions;
(f) Patient’s tolerance to medication, by noting the presence or absence of adverse side effects;
(g) Review of the drug-susceptibility results if available;
(h) Making recommendations for the way forward; this could be to continue the current plan or change a regimen or dose or refer for further investigations.

(4) Update the examination findings in the TB Treatment Work-Up Module in MiMOSA with the entry, follow-up and, eventually, the exit forms.

(5) If the patient is unable to come for monthly follow up, the reason why should be recorded in MiMOSA, and a bimonthly follow-up plan (that is, every second month) should be established. At the minimum, the patient should be seen by the IOM physician at the end of the intensive phase and at the end of treatment.

(6) Undertake a post-treatment evaluation, which should be conducted in accordance with Section 11.

1.3. Comprehensive level: IOM fully manages TB treatment

The CMHO in coordination with the Chief of Mission should ascertain whether a special permit is required for the MHAC to conduct TB treatment (that is, to provide and potentially prescribe DOT). The CMHO should refer to IN/2733 for further guidance that establishes the legal foundations of HAPs, including TB management. IOM MHACs can provide DOT and anti-TB medicines under three scenarios.

---

(1) The preferred scenario is that the NTP recognizes the MHAC as an NTP TB management site. In this situation, the NTP usually provides IOM directly with anti-TB medicines and the required NTP registration and reporting tools.

(2) The NTP recognizes the MHAC but as an independent site; in this scenario, IOM purchases the medicines.

(3) If the NTP does not recognize the MHAC as a TB management site, it is still possible for IOM to provide DOT, especially in cases in which the NTP allows self-administration of treatment. In this situation, IOM should counsel the patient, explain the benefits of DOT for both health and facilitation of the immigration process, and encourage the patient to bring anti-TB medicines received from the NTP to the MHAC to conduct DOT. Alternatively, the TB nurse could collect the medicines from the NTP. It is important that the TB Focal Point establishes contact with the NTP physician responsible for the patient’s management and regularly discusses with the physician the progress and complications of treatment, if any, and possible changes to the treatment regimen.

When the client agrees to undertake TB treatment through an IOM clinic, the following procedures apply.

(1) At the commencement of treatment:
   
   (a) The TB case manager prescribes the regimen, including doses for all medicines, and refers the patient to the IOM TB DOT clinic to register and start TB treatment.

   Note: In some situations, the IOM PP may not be the prescribing doctor; instead the NTP prescribes the medicines and provides them to the client, who then delivers them to IOM. In this case, IOM continues to supervise treatment and monitor its effectiveness. In such a situation, steps 1–12 in this section should be followed, with the exception of prescribing.

   (b) Once the client has been registered and treatment has been initiated at the TB DOT clinic, the nurse at the clinic sends the TB file to the TB case manager so that the case manager can open and update the TB Treatment Work-Up Module in MiMOSA to reflect the start of TB treatment and enter details of the treatment.

   (c) At month zero, the TB Focal Point reviews the records of all patients starting treatment to confirm the appropriateness of the regimen and doses, as well as to ensure that the file in MiMOSA is complete and correct at the commencement of treatment.

   (d) The TB nurse provides the client with the TB Patient Appointment Card (Template Form 6), which will be updated daily.
Throughout treatment the DOT nurse and the TB case manager have the following responsibilities.

(a) The DOT nurse administers treatment daily during work days (using Template Form 7, the TB Treatment Compliance record, to document treatment) and packs and dispenses medicines for self-administered therapy (SAT) over the weekend.

(b) The DOT nurse schedules baseline and follow-up tests and provides results to the examining PP for review and action if needed.

(c) The TB case manager reviews all results related to TB treatment each month in the same manner as they would for any external DOT management, as outlined in Section 3b, point 3, including:
   • Clinical response to treatment;
   • Weight changes;
   • Sputum conversion from positive to negative, if relevant, or the lack of conversion;
   • Radiological improvement;
   • Tolerance to medication;
   • Drug-susceptibility results; the PP must respond immediately in cases of drug resistance;
   • Presence and management of any co-morbid conditions;
   • Recommendation of the way forward.

(d) The TB case manager updates the examination findings in the TB Treatment Work-Up Module in MiMOSA with the entry, follow-up and, eventually, exit forms.

(e) Throughout the course of treatment, the TB case manager liaises with the DOT nurse for updates, to review results and for any further follow up that is required.

(f) At least twice during the treatment course (ideally at months 3 and 5), the country TB Focal Point undertakes the monthly clinical review of the patient (instead of the TB case manager) to provide feedback and advice to the TB case manager, as needed, regarding the extent to which the patient’s management plan is consistent with the standard operating procedures (SOPs) and TIs.

At the completion of treatment, the DOT nurse and the TB case manager have these responsibilities.

(a) The DOT nurse schedules the end-of-treatment examination and drafts a preliminary treatment completion certificate, pending culture results.
(b) The TB case manager undertakes the end-of-treatment examination and organizes end-of-treatment sputum collection for cultures.

(c) Once the culture results are available, the TB case manager reviews all results and records all necessary findings. If results are abnormal, the TB case manager recalls the applicant and undertakes further examination and assessment.

(d) If culture results show no growth and the TB case manager is satisfied that treatment has been successful, a final signed TB treatment certificate is issued to the patient, with a copy for the patient’s file, and the case is submitted to the relevant receiving country with all results.

Ensuring there is an adequate supply of quality-assured medicines is an essential component of robust TB management. The following points describe how this is best managed.

Medicines should be stored in a locked room with restricted access at the temperatures and humidity levels indicated by manufacturers. In hot and humid climates, dehumidifiers and air conditioners should be used. It is the responsibility of the TB Focal Point to restrict access to the room where medicines are stored, keep a daily log of the room temperature and organize the storage of the medicines according to the manufacturer’s instructions.

If medicines are supplied by the NTP, it is important to establish whether they were procured through the Global Drug Facility to ensure they are quality assured (see Annex 1). Enough medicines should be procured for a full course of treatment for each patient, and the medicines should be stored and labelled specifically for each patient.

NTPs usually supply anti-TB medicines as fixed-dose combinations; however, they should also be asked to supply single-drug formulations. Single-drug formulations may be needed to manage side effects produced by one or more medicines or drug resistance, as well as to adjust doses due to weight changes. If the NTP is not able to supply separate medicines, these may need to be purchased independently by IOM.

If the NTP does not supply anti-TB medicines or there is a need to purchase additional medicines, the TB Focal Point in coordination with the CMHO should ensure that the medicines purchased have been prequalified by WHO’s TB prequalification programme. IOM prefers to procure first-line medicines directly from the Global Drug Facility; however, this may require an importation permit. As such, IOM may need to negotiate with the NTP to procure medicines through the NTP or their distributors. Medicines prequalified by WHO may be available locally, which would obviate the need for importation. In case of difficulty obtaining WHO-prequalified medicines, the TB Focal Point and CMHO should

---


5 The list of medicines and pharmaceutical products prequalified by WHO is available at https://extranet.who.int/prequal/content/prequalified-lists/medicines?label=All&field_medicine_applicant=&field_medicine_pp_site_value=&search_api_aggregation_1=&field_medicine_pp_date%5Bdate%5D=&field_medicine_pp_date_1%5Bdate%5D=&field_therapeutic_area=23&field_medicine_status=&field_basis_of_listing=All.
consult the Global Procurement Unit in Manila, the Philippines, and seek advice from the regional HAP coordinator.

To procure quality assured second-line anti-TB medicines, please consult the International Dispensary Association (www.idafoundation.org/) or the regional WHO Green Light Committee.³

DOT management is outlined in Section 7.

### 1.4. Individual roles and responsibilities

Many different staff play key roles in managing TB for IOM clients. These roles may vary from strategic to supervisory or supportive or to providing hands-on care. Furthermore, depending on the size of the MHAC, the roles may be less defined, and one or more staff may share responsibilities. Key areas of responsibility for different positions in the MHAC are outlined in Annex 2. This information should be used to assist in allocating specific roles within country-level SOPs. Annex 3 provides a detailed schema for each step in the client-management process, and this may also assist in identifying all key steps that should be considered within a country-level SOP.

---

CHAPTER 2

Initiating treatment
2.1. Screening programmes

In their specific TIs, each country outlines the requirements that IOM panels must adhere to for TB screening (see Annex 4). These vary by country but follow the same basic principles.

(1) Medical history related to TB evaluation: PPs will enquire about pertinent aspects of the applicant’s prior medical history and risk factors that may indicate prior or current TB or a history of contact with someone with TB. This should include an applicant’s own history of TB; illness suggestive of TB, such as a persistent or slowly worsening cough of ≥3 weeks’ duration dyspnoea, weight loss, fever or haemoptysis; prior treatment suggestive of TB; and any prior diagnostic evaluation suggestive of TB. It should be ascertained whether there is a history of immunosuppressive illness or medication. Inquiries regarding close household or work contact with a person who has or had TB or a diagnostic evaluation suggestive of TB should be included. In taking children’s history, questions should be asked about fever, night sweats, growth delay and weight loss.

(2) Physical exam: This should include a thorough pulmonary examination, respiratory rate, heart rate, height, weight and temperature; inspection and palpation of appropriate lymph nodes; and inspection for scars of cervical lymphadenitis and prior chest or spinal surgery.

(3) Digital CXR: Although the age at which digital CXR is required varies by country, usually it is required for applicants aged ≥11 years; note that the United States requires digital CXR for those aged ≥15 years. A posteroanterior view is required as standard. Additional views may be submitted if appropriate. For children younger than 11 years, a lateral view should be performed (for the United States this is for children <10 years). The CXR must be interpreted by a designated radiologist, and the review must include the lung fields, hila, mediastinum and pleura. For all cases, the X-ray image and report must be reviewed by PPs for correlation with history and clinical findings.

(4) Use of latent TB infection (LTBI) immune response testing: LTBI testing, such as the tuberculin skin test (TST) and the interferon-gamma release assay (IGRA), is not done routinely, but it may be included as a supplement to standard testing requirements if there is a clinical indication. Note that the United States and Australia require this testing in children younger than 15 years and 11 years, respectively, who are examined in a country where the TIs classify the WHO-estimated TB incidence as high.

(5) Firm diagnosis using laboratory testing: Laboratory testing is required if the CXR is suggestive of TB that requires treatment or if signs and symptoms of TB are present, or if HIV infection is present, as specified in the TIs for certain countries; testing should include the use of acid-fast bacilli (AFB) sputum microscopy and culture.
(a) Within 7 days of an abnormal CXR, three specimens of 5–10 ml of sputum are required to be collected at least 24 hours apart, preferably on consecutive days; all three specimens must be collected within 1 week. In cases in which applicants have not completed the collection of all three specimens within 1 week, the process should be recommenced so that all three specimens are collected during the same 7-day period. Sputum collection must be directly observed in an appropriate and safe area (for example, outdoors or in a negative pressure indoor chamber). Sputum samples should be transported to the laboratory within 1 hour of collection. If it is not possible for the sample to be transported within 1 hour, the sample should be refrigerated but not frozen. Refrigerated specimens must be delivered to the laboratory within 5 days of collection, taking into account holidays and weekends. The laboratory should be informed that a specimen will be sent, and specimens received in the laboratory should be processed within 24 hours: specimens should not be sent to the laboratory on a day when it is closed. Note: For applicants to Canada, three specimens may be collected on the same day at least 1 hour apart, ideally using at least one induced specimen.

(b) Nebulized saline induction can be utilized, especially for persons from whom a satisfactory sputum specimen cannot be obtained otherwise, including children as young as 3 years. Gastric aspirate, which is preferred for children, or bronchial washings are also acceptable if sputum cannot be obtained; however, sputum is the preferred specimen from adults.

(c) For the sputum smear, either fluorescent auramine or Ziehl–Neelsen (ZN) staining can be used to investigate the presence of AFB. Fluorescent auramine stain is preferred.

(d) Molecular tests may be used for all sputum specimens or, in some programmes, only for sputum smear-positive cases, to augment (but not replace) traditional sputum culture for early identification. The Hain Lifescience GenoType® MTBDRplus (Nehren, Germany), a line probe assay (LPA), and the Cepheid Xpert® MTB/RIF assay (Sunnyvale, CA, United States), a cartridge-based nucleic acid amplification test (NAAT), may allow for faster identification of drug resistance and alteration of treatment regimens. Note that they do not replace the need for culture, and there will need to be a mechanism to deal with discordant results.

(e) IOM laboratories perform liquid and solid culture in parallel, although this is not mandatory except for applicants to the United States, and so final results are not available until 8 weeks, unless a positive result is obtained earlier. When only one type of culture can be performed, liquid culture is preferred.

(f) The first positive culture isolate for an applicant must be tested for susceptibility to first-line medicines, including isoniazid (INH), rifampicin (RIF), ethambutol (EMB) and pyrazinamide (PZA).

\(^7\) For some countries, the TIs allow pregnant women to go directly to sputum collection without having a CXR.
Monoresistance to either EMB or streptomycin does not automatically lead to drug-susceptibility testing (DST) for second-line medicines, but DST is desirable. Second-line DST must be performed if resistance to INH or RIF is identified, as well as other resistance patterns. At a minimum, DST for second-line medicines should include testing for susceptibility to fluoroquinolones (FQN)s, (for example, levofloxacin, moxifloxacin) and amikacin.

2.2. TB screening algorithm

Figure 1 presents a generic algorithm for TB screening for most receiving countries. Please refer to country-specific TIs for more detail.

Figure 1. Generic TB screening algorithm for most receiving countries

$\text{CXR}$: chest X-ray; DST: drug-susceptibility testing; LTBI: latent tuberculosis infection; MTB: Mycobacterium tuberculosis; NTP: national tuberculosis programme.

2.3. Newly diagnosed cases

To mitigate the risk of transmission of Mycobacterium tuberculosis (MTB), early treatment is paramount. As such DOT should be initiated immediately in a person diagnosed with active TB, which is defined as:

(1) One or more positive AFB smear or TB culture results (as outlined in Table 1); and/or

(2) A positive result from an automated cartridge-based NAAT, such as the Xpert MTB/RIF assay, while the results of smear and culture tests are awaited; note that all NAAT results must be confirmed by culture; and/or

(3) Symptomatic presentation that is highly consistent with pulmonary TB (PTB) disease; and/or
(4) CXR lesions that are highly consistent with active PTB disease, namely
   (a) widespread unilateral lung infiltration and/or
   (b) parenchymal cavitation and/or
   (c) pleural effusion not otherwise explained and/or
   (d) subtle presentations of the above in persons who are contacts of active cases;
   and/or
(5) Progression of CXR changes over at least two X-rays that are consistent with PTB;
   and/or
(6) A request for treatment made by health authorities of the receiving country.

Table 1. Potential TB culture outcomes and corresponding reporting in MiMOSA

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Specimen culture 1</th>
<th>Specimen culture 2</th>
<th>Specimen culture 3</th>
<th>Final culture result reported as</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive (MTB+)</td>
</tr>
<tr>
<td>2</td>
<td>Positive</td>
<td>Positive</td>
<td>NTM</td>
<td>Positive (MTB+)</td>
</tr>
<tr>
<td>3</td>
<td>Positive</td>
<td>Positive</td>
<td>Negative</td>
<td>Positive (MTB+)</td>
</tr>
<tr>
<td>4</td>
<td>Positive</td>
<td>Positive</td>
<td>Contaminated</td>
<td>Positive (MTB+)</td>
</tr>
<tr>
<td>5</td>
<td>Positive</td>
<td>NTM</td>
<td>NTM</td>
<td>Positive (MTB+)</td>
</tr>
<tr>
<td>6</td>
<td>Positive</td>
<td>NTM</td>
<td>Negative</td>
<td>Positive (MTB+)</td>
</tr>
<tr>
<td>7</td>
<td>Positive</td>
<td>NTM</td>
<td>Contaminated</td>
<td>Positive (MTB+)</td>
</tr>
<tr>
<td>8</td>
<td>Positive</td>
<td>Negative</td>
<td>Negative</td>
<td>Positive (MTB+)</td>
</tr>
<tr>
<td>9</td>
<td>Positive</td>
<td>Negative</td>
<td>Contaminated</td>
<td>Positive (MTB+)</td>
</tr>
<tr>
<td>10</td>
<td>Positive</td>
<td>Contaminated</td>
<td>Contaminated</td>
<td>Positive (MTB+)</td>
</tr>
<tr>
<td>11</td>
<td>NTM</td>
<td>NTM</td>
<td>NTM</td>
<td>NTM</td>
</tr>
<tr>
<td>12</td>
<td>NTM</td>
<td>NTM</td>
<td>Negative</td>
<td>NTM</td>
</tr>
<tr>
<td>13</td>
<td>NTM</td>
<td>NTM</td>
<td>Contaminated</td>
<td>NTM</td>
</tr>
<tr>
<td>14</td>
<td>NTM</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative (MTB−)</td>
</tr>
<tr>
<td>15</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative (MTB−)</td>
</tr>
<tr>
<td>16</td>
<td>Negative</td>
<td>Negative</td>
<td>Contaminated</td>
<td>Negative (MTB−)</td>
</tr>
<tr>
<td>17</td>
<td>NTM</td>
<td>Negative</td>
<td>Contaminated</td>
<td>Pending*</td>
</tr>
<tr>
<td>18</td>
<td>NTM</td>
<td>Contaminated</td>
<td>Contaminated</td>
<td>Pending*</td>
</tr>
<tr>
<td>19</td>
<td>Negative</td>
<td>Contaminated</td>
<td>Contaminated</td>
<td>Pending*</td>
</tr>
<tr>
<td>20</td>
<td>Contaminated</td>
<td>Contaminated</td>
<td>Contaminated</td>
<td>Pending*</td>
</tr>
</tbody>
</table>

MTB: *Mycobacterium tuberculosis*; NTM: nontuberculous mycobacteria.

* Indicates recollection required for three samples.

In the absence of positive sputum results, any intention-to-treat adult cases should be discussed with supervisors or senior HAP staff, or both, prior to starting treatment. Section 7g contains further information about paediatric TB, for which negative sputum results routinely occur.
If there is strong suspicion of TB despite negative results on sputum testing, then further investigation should occur (where available) to inform decisions about whether to treat. In cases in which suspicion is primarily radiological, additional imaging via plain views or serial CXRs may help elucidate the nature of the lesion.

Lung infiltration can occur in nontuberculous conditions, such as rheumatological conditions, and these should be considered among the differential diagnoses in sputum smear- and culture-negative cases. TST or IGRA can assist in determining whether a lesion may be TB related. These tests may also assist in cases in which extrapulmonary disease is suspected based on clinical or CXR findings, including lymphadenopathy or pleural effusion (in cases of pleural TB).

The diagnosis of persons with high clinical or radiological suspicion for TB but negative sputum smear and culture results can be assisted by the use of molecular testing (that is, polymerase chain reaction; PCR) of negative sputum samples with the Xpert-MTB/RIF assay, if available. Positive results from the Xpert MTB/RIF assay in the context of high clinical or radiological suspicion may be considered as a positive identification in sputum-negative cases, but guidance should be sought from authorities in the receiving country if the TIs do not explicitly address this issue. Further information on molecular testing appears in Section 8.

In cases with discordant NAAT results (that is, NAAT is positive but cultures are negative), advice about continuing therapy should be sought from authorities in the receiving country.

Given the invasive nature of bronchoscopy, this should not be considered as a TB diagnostic tool in the migration context unless exceptional circumstances exist. There may be a need to exclude non-TB lesions, such as carcinoma, but this should be discussed first with the client and representatives of the receiving country before such action is taken. Therefore, bronchoscopy should not be considered unless senior staff or receiving country representatives, or both, have been consulted.

### 2.4. Cases of ongoing TB treatment

Patients examined by IOM who are already on TB treatment from an external provider at the time of the migration health assessment (MHA) must have three sputum specimens collected for AFB smear and TB culture testing, as well as DST at their initial visit. A CXR taken within the past 3 months cannot be used as part of the MHA, and a new CXR should also be obtained. See Table 2 for TI requirements for the United States and Australia for clients receiving treatment from an external provider.
Table 2. Requirements for clients receiving TB treatment from an external provider at the time of their migration health assessment, Australia and United States

<table>
<thead>
<tr>
<th>Country</th>
<th>Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (for migrants from countries at high risk for TB, as notified by the Department of Home Affairs)</td>
<td>Applicants must: Complete treatment with their private physician and wait for repeat evaluation at 12 months after the end of treatment or Re-start TB treatment under a DOT programme, such as that offered by IOM.</td>
</tr>
<tr>
<td>United States</td>
<td>Applicants must: Be transferred to a DGMQ-defined DOT programme for the remainder of treatment and have the following tests: CXR plus 3 sputum specimens for smear and culture, followed by DST if culture is positive.</td>
</tr>
</tbody>
</table>

CXR: chest X-ray; DOT: directly observed therapy; DGMQ: Division of Global Migration and Quarantine (United States Centers for Disease Control and Prevention); DST: drug-susceptibility testing.

If any sputum specimens are positive on either smear or culture, the patient should be evaluated and a decision made as to whether treatment should be started from the beginning or continued with or without any adjustments, with IOM assuming responsibility for treatment at locations where it is offered by IOM; continuation is an especially relevant consideration during the first 1–2 months. If IOM does not offer treatment at the location where the MHA is performed, a full treatment summary and a new CXR report should be sent with the referral to the DOT provider.

If a patient with positive sputum results has already been on treatment for 2 months or longer, DST should be used to guide the treatment regimen if MTB culture isolate can be grown. If sputum culture is negative and LPA has not been performed on positive smear specimens, supervisors should be consulted and treatment monitored closely given the possibility of drug resistance and the potential need to alter doses or medicines, or both.

See Section 8 for further information about drug resistance.

2.5. Isolation

Isolation should be considered in facilities with the capacity to provide it for persons:

1. With symptomatic presentation that is highly consistent with PTB; and/or
2. With smear-positive PTB; and/or
3. Who are infants or immunocompromised family contacts of a person with sputum smear-positive TB; and/or
4. Requesting assistance with treatment initiation due to disability or substance abuse or other prohibitive factors; and/or
(5) With suspected or confirmed multidrug resistant (MDR) or extensively drug-resistant (XDR)-TB.

Isolation should be maintained:

(1) In the cases described in points 1–3 above until symptoms have resolved and sputum AFB smears have converted to negative;

(2) In cases described in point 4 above until treatment has been successfully initiated and the client can be managed as an outpatient;

(3) In cases described in point 5 above until symptoms have resolved and consecutive sets of sputum smears taken 1 month apart are negative and culture conversion has occurred.

In all cases, patients should be educated about the modes of transmission and the risk of infecting others. Instruction should be provided on cough etiquette, the need to stay within the isolation area, and the importance of maintaining adequate ventilation.

Face masks should be readily available to those with positive sputum smears until smear conversion occurs. Patients with MDR-TB should wear a face mask until culture conversion has been documented by negative findings on consecutive sets of sputum smears taken 1 month apart. Patients must be shown how to wear a face mask and instructed on the need to do this when outside the isolation area. Contact with visitors should be managed so that the risk of cross-infection is balanced with the patient’s need for social contact. Ideally, visitors would be received in open-air environments or other well-ventilated environments.

Where isolation facilities are not available, patients should be educated about additional means of reducing the risk of transmission, including isolating themselves within their household or using other means to minimize family or social contact.

2.6. Initial administrative requirements

Once a decision is taken to initiate treatment, in all cases:

(1) The IOM physician puts the case on hold in MiMOSA, if this has not already occurred.

(2) IOM notifies the receiving country if TIs require it, but note that Australia and the United States require this only for drug-resistant (DR) TB.

(3) The IOM physician assigns Class A (tuberculosis disease in the United States’ TIs) in MiMOSA for United States-bound clients and submits the case in eMedical for non-refugees.

(4) eMedical forms must be completed for Australia, Canada and New Zealand, graded B, and submitted to the receiving country.
(5) For United Kingdom-bound patients, the case is closed in the web application with the note “Refer for TB treatment”.

(6) The designated officer in MHAC notifies the host country NTP.

(7) The TB case manager is requested to recall the patient for counselling and work up as described in Section 5.

(8) Treatment is initiated or the patient is referred to a treatment centre.

(9) Contact tracing is initiated per the relevant TIs and NTP guidelines as described in Section 6.

2.7. Additional administrative requirements when IOM provides treatment

The TB Treatment Work-Up Module in MiMOSA must be updated. (A detailed explanation of the correct process is described in Annex 5, the MiMOSA Guide for MHD [Migration Health Division] Users). A TB treatment file must be prepared and include the:

(1) Complete immigration medical examination (IME) file with the results of relevant investigations;

(2) Patient’s TB record, including a photo (Template Form 5);

(3) Treatment compliance card (Template Form 7);

(4) Side effects monitoring sheet (Template Form 8);

(5) Patient’s appointment card (Template Form 6);

(6) Pre-treatment counselling acknowledgement and consent form (Template Form 4);

(7) Informed consent for HIV testing, if required (Template Form 9);

(8) MiMOSA TB treatment entry form.
CHAPTER 3

Pre-Treatment Work Up
Pre-treatment evaluation consists of three components:

1. Counselling and obtaining acknowledgement of information given and consent to undertake treatment;
2. Medical history review, physical examination and vital signs;
3. Baseline investigations.

### 3.1. Counselling

The aims of counselling are to educate patients and prepare them psychologically for TB treatment, to ensure treatment compliance, and to encourage behaviours that will reduce the risk of transmission. It is important to assess and address the psychological effects of diagnosis and to destigmatize the diagnosis through education. Patients should understand that their cooperation is essential for treatment to be successful and consent to treatment should be sought as documented in Template Form 4.

Patients should be advised to choose a guardian or treatment supporter to assist them throughout the treatment course. This support person should be invited to the counselling and education session.

Suggested topics to be covered in counselling delivered by trained staff (an MHN or, alternatively, an MHP) should include:

1. General background information about TB;
2. Its mode of transmission;
3. Information about the patient’s condition and rationale for treatment;
4. The need for infection control (for sputum smear-positive cases);
5. A general outline of DOT principles, the duration of treatment and information about the regimen;
6. The importance of compliance and the likelihood of a good outcome with full compliance;
7. Key side effects and the importance of promptly reporting these;
8. The need and schedule for treatment monitoring, including repeated sputum collection, CXR and clinical review;
9. The need for HIV testing, if this has not already been done;
10. The need for contact tracing, if applicable, with an invitation or referral for contacts;
11. The need for lifestyle change, if applicable, (for example, smoking cessation, dietary improvement);
(12) Treatment timelines, including isolation timelines, if applicable;

(13) The role of the guardian or treatment supporter in assisting the patient and monitoring signs of physical or psychosocial deterioration.

At the end of the session, questions should be elicited from the patient and addressed, and any educational material available should be provided (for example, brochures, literature) that is compatible with the patient's language and literacy skills (pictograms and graphics are preferable). The psychological response of patients to their diagnosis and the counselling should be noted in their file.

3.2. Medical history review, physical examination and vital signs

The patient should be re-examined and re-questioned by the PP in light of the TB diagnosis. Patients may be more forthcoming about their history and any previous diagnosis. Again, the importance of treatment compliance should be emphasized.

Areas of enquiry at the re-examination include:

(1) Signs and symptoms of TB disease, with dates of onset;
(2) Details of previous investigations or TB treatment, or both;
(3) History of known contact with TB patients;
(4) Current medical conditions and medicines;
(5) Allergies.

A general physical examination should be undertaken, with particular attention paid to respiratory and lymphatic signs. Vital signs to be obtained prior to treatment include:

(1) Weight, height, body mass index;
(2) Temperature;
(3) Respiratory rate;
(4) Blood pressure.

3.3. Baseline investigations

The local availability of diagnostic capacity may affect the pre-treatment work up; however, a number of investigations should be regarded as core requirements in all locations as part of the initial work up before referral, and these should be accompanied by request forms.
Core requirements to be undertaken in all circumstances, subject to the patient’s consent are:

(1) Full blood count (FBC), platelet count;
(2) Liver function tests;
(3) Serum creatinine;
(4) HIV testing, including diagnostic counselling and testing with informed consent (unless already performed at the IME);
(5) CXR if no recent CXR is available; in all cases of PTB, a diagnostic set of sputum tests and a CXR must be available;
(6) Fasting blood sugar;
(7) Pregnancy test for women of childbearing age (15–50 years);
(8) Testing of visual acuity and red–green colour discrimination if EMB or rifabutin are to be prescribed.

For MDR-TB, rifampicin-resistant (RR)-TB, and XDR-TB in cases in which second-line TB medicines are required, these additional baseline tests are needed:

(1) Thyroid stimulating hormone (TSH);
(2) Electrolytes (Mg2+, K+, Ca2+);
(3) Audiovestibular function testing;
(4) Other tests (for example, electrocardiogram [ECG]) as necessary, according to the prescribed treatment regimen.

The following additional investigations may be needed based on clinical indications:

(1) Hepatitis B and C serology for patients with
   (a) Risk factors for hepatitis
   (b) Elevated transaminases
   (c) HIV co-infection;
(2) Blood urea nitrogen for patients with
   (a) risk factors for renal disease
   (b) elevated creatinine;
(3) CD4 count, viral load and specialist evaluation (if this has not been done) for patients with HIV–TB co-infection.
The PP must review all baseline investigation results, provide advice on the appropriateness of treatment, make any adjustments needed, or consult the supervisor or other expert focal points if needed, or both.

Consult a supervisor if the following indicators are present as the therapeutic regimen should be reconsidered based on the pre-treatment work up:

1. Elevated alanine aminotransferase (ALT) (≥3 times above the upper limit of normal);
2. Elevated serum creatinine;
3. Known hepatic or renal disease;
4. Pregnancy (pyridoxine required).
CHAPTER 4

Contact Tracing and Latent TB Infection
4.1. Evaluating and managing TB contacts as part of the Migration Health Assessment and resettlement processes

TB contacts are people who have or have had close contact with patients with infectious TB. Contacts are at a high risk for infection and in keeping with WHO’s End TB Strategy, contacts should be investigated systematically and actively for TB infection and disease. Contact investigation contributes to the early identification of active TB, thus decreasing its severity and reducing transmission to others, and it also enables the identification of LTBI, which allows for preventive measures to be taken.

In this document a contagious (infectious) TB patient is defined as one with pulmonary or laryngeal TB disease, either confirmed or undetected, who is able to spread infectious droplet nuclei containing viable MTB when coughing, sneezing, talking or conducting any other respiratory manoeuvre.

Many studies in countries with a high incidence of TB have shown that the prevalence may reach 5 per cent or more among contacts, particularly among household members. Other data suggest that contact investigations could be particularly useful for identifying paediatric TB. Furthermore, contact investigation can help identify people who require careful follow up, such as those who were exposed to an index case with MDR-TB or XDR-TB, or people infected with HIV, whose risk for rapid progression to active TB is high.

Contact tracing should occur for any index case:

1. With symptomatic PTB; and/or
2. With positive sputum AFB smear or TB culture; or
3. Who is a child with active TB of any type.

A contact is defined as:

1. Any applicant with the same case number; and/or
2. Any household member; and/or
3. A person who has had frequent and prolonged close contact with the index case.

In summary, contacts are defined as people who have had intimate or prolonged contact with a known index case (that is, a person with sputum smear- or culture-positive PTB disease), have shared the same enclosed air space or other enclosed environment for a prolonged period (that is, days or weeks, not minutes or hours), and are likely to include family or household members. In the absence of an immunocompromising condition, occupational contact with TB is not considered to be a significant risk in the context of the IME and should not be recorded in the history.
Once contacts have been identified, PPs have the following responsibilities:

1. To notify and coordinate with local health authorities, where applicable, about the positive TB result;

2. To do household contact tracing or, if the relevant health authority carries this out, confirm that tracing activity has been undertaken. Contact tracing in the immigration setting should be focused on contact with other visa applicants who are family or household members of the index case.

As summarized in Figure 2 and detailed here, when evaluating contacts, the following should be considered.

**Figure 2. Decision tree for TB contact tracing and evaluation**

(Please refer to country-specific technical instructions for finer detail.)

CXR: chest X-ray; IGRA: interferon-gamma release assay; IME: immigration medical examination; LTBI: latent tuberculosis infection; NTP: national tuberculosis programme; TST: tuberculin skin test.

a For the United States, the grading in the United States’ TIs can be B1 Pulmonary and B3, B2 and B3, or B3 alone.

b For Canada, contacts must have sputum testing regardless of their LTBI results.

1. To determine the likelihood of infection, contact tracing should be performed by using interviews.

2. Further investigation should include a TST or IGRA test.

3. Any contact who satisfies any of the following criteria should undergo further evaluation that includes medical history, physical examination and CXR (however, if this evaluation was undertaken as part of the MHA during the previous month, no new investigation is required and evaluation of the client can move to the next phase):

   a. TST induration ≥5 mm or positive IGRA;
(b) HIV infection;
(c) Severe immunosuppression (for example, from chemotherapy);
(d) Is a child younger than 5 years or is immunosuppressed.

(4) Note that child contacts younger than 5 years and immunosuppressed contacts should commence INH preventive therapy immediately after the presence of active TB disease is excluded, irrespective of CXR result.

(5) All other applicants with a positive LTBI test (TST induration ≥5mm or positive IGRA) should be counselled about the importance of treatment and offered INH preventive therapy if eligible.

(6) Contacts with an abnormal CXR or those with symptoms or signs of TB should undergo sputum testing, as outlined in each country’s TIs. For Canada-bound contacts, all positive contacts require sputum testing irrespective of clinical or CXR findings.

(7) Contacts with a TST induration <5mm or with a negative or indeterminate IGRA who do not satisfy any of the criteria above should undergo repeat LTBI testing ≥8 weeks after exposure to the infectious contact has ended.

(8) For Australia:
(a) When applicants declare they have had a close household contact with TB within the past 5 years, the 719 LTBI test should be added in eMedical by the PP, regardless of the age of the applicant or whether a CXR has already been performed.
(b) Ensure that the nature of the relationship is reported and how long ago the contact was. If the 719 LTBI test is positive, a CXR should be added, if it has not already been performed.
(c) All cases with a close household contact, regardless of the results of the 719 LTBI test or the CXR should be graded B.

4.2. Treating latent TB infection

LTBI is a state of persistent immune response to stimulation by MTB antigens without evidence of clinically manifested active TB. Someone has LTBI if they are infected with the TB bacterium but do not have signs of active TB disease and do not feel ill. However, they can develop active TB disease in the future. LTBI is an infection with MTB without clinical, bacteriological or radiological evidence of the disease.

LTBI is diagnosed when there is a positive response to a TST or IGRA test. There is no international consensus on what constitutes TST positivity. TST interpretation may be affected by the dose of the purified protein derivative and by operator variability in both inoculation and reading, as well as by previous bacille Calmette–Guérin vaccination. To overcome the limitations of the TST, the ATS guidelines for interpreting TST were revised
to include the pre-test risk of TB infection or reactivation. An induration of ≥5 mm is considered positive in patients with a high risk of infection or reactivation (for example, recent contacts of infectious cases or people who are HIV-positive). An induration of ≥10 mm is considered positive for those with intermediate risk (for example, residents of long-term care facilities or patients with chronic diseases). For those with no risks, an induration of ≥15 mm is considered positive.

In the immigration setting, applicants are defined as having LTBI when their test results are:

1. a positive IGRA; or
2. TST induration >10 mm; or
3. TST induration >5 mm in recent contacts of infectious cases, or contacts with severe immunosuppression or who are HIV-positive.

For an asymptomatic person found to have LTBI through positive TST or IGRA results in a setting consistent with likely TB exposure, a number of regimens are available. Monotherapy is still used as standard treatment for LTBI within many receiving countries. However, WHO updated its guidelines in 2018, and these offer a range of options included two-agent therapy and short-course therapy.\(^8\)

The following treatment options are recommended for LTBI:\(^9\)

1. 6 months of INH; or
2. 9 months of INH; or
3. a 3-month regimen of weekly rifapentine plus INH; or
4. 3–4 months of INH plus RIF; or
5. 3–4 months of RIF alone.

The choice of regimen depends on the resistance pattern of the index case, if known, as well as the availability of medicines.

There are serious limitations in the evidence that prevent making any recommendations about using MDR-TB preventive therapy as a public health measure, as outlined in chapter 10 of the Curry International Tuberculosis Center’s Drug-Resistant Tuberculosis: a Survival Guide for Clinicians.\(^10\)

At a minimum, experts agree that regardless of the decision to treat or the treatment option selected, it is important to:


(1) Follow those with presumed latent MDR-TB infection at regular intervals for a minimum of 2 years following exposure;

(2) Educate patients about the signs and symptoms of TB in case they progress to TB disease.

In selected high-risk household contacts of patients with MDR-TB, preventive treatment may be considered depending on individual risk assessments and a sound clinical justification based on careful assessment of the intensity of exposure, the certainty of the identity of the source case, reliable information on the drug-resistance pattern of the source case, and potential adverse events.

When assessing the need for MDR-TB preventive treatment, the following points should be considered.

(1) MDR-TB preventive treatment should be given only to household contacts at a high risk of developing TB (for example, children, people receiving immunosuppressive therapy and people living with HIV).

(2) Medicines should be selected according to the drug-susceptibility profile of the source case.

(3) Confirmation of infection is required by LTBI test.

---

Strict clinical observation and close monitoring for the development of active TB disease for at least 2 years are required, regardless of whether preventive treatment for MDR-TB is provided.

If an applicant has known exposure to a case with MDR-TB or TB with INH resistance, advice on other preventive regimens should be sought from experts. The range of treatment options for contacts of people with MDR-TB includes monotherapy with an FQN or treatment with two medicines to which the organism is sensitive and for which the toxicity profile is acceptable. This would most likely be an FQN plus EMB.

### 4.3. Country-specific requirements for managing latent TB infection

The requirements for managing applicants with LTBI are described below.

(1) United States: Since LTBI is not infectious, LTBI testing and treatment are not required for adult immigrants to the United States, but some adults may be identified as having LTBI as a result of a required TB contact evaluation. Children aged 2–14 years living in countries where WHO has estimated the TB burden to be >20/100,000 population are required to have immune response tests undertaken as a first-stage screen to
diagnose active TB disease. Through this process, some children may be diagnosed with LTBI. The United States’ TIs require preventive therapy to be initiated overseas only for the following two categories of applicants who are known contacts of a person with TB and who have had a negative evaluation for TB disease:

(a) Children aged <4 years;
(b) Applicants with impaired immunity (for example, HIV-positive people).

These two groups should begin directly observed preventive therapy regardless of their IGRA results.

(2) Australia: In the IME setting, LTBI treatment should be undertaken after an applicant’s arrival in Australia. Contacts of active TB cases who are clinically well and have normal CXRs require no further investigation. However, close household contacts of a case with PTB in which drug resistance has not been identified and where there are expected to be lengthy delays before migration should commence treatment prior to migration in the following two situations:

(a) Children who are immunocompromised;
(b) Children aged <5 years.

(3) Canada: IGRA screening for LTBI is advised for the following five risk groups:

(a) Close contacts of cases with active, infectious PTB diagnosed within the past 5 years;
(b) Applicants who are HIV-positive or who have AIDS;
(c) Applicants with advanced chronic renal failure and end-stage renal disease with a glomerular filtration rate <30mL/minute;
(d) Applicants with a history of treatment for head or neck cancer within the past 5 years;
(e) Recipients of solid organ or bone marrow transplants who are on immunosuppressant therapy.

Note that TST screening should be performed if IGRA is not available and for clients younger than 2 years.

If LTBI is diagnosed, clients should be informed of their LTBI status and receive counselling about the test results, including information on risk reduction strategies, such as preventive therapy, and education on the signs and symptoms of active PTB.

(4) United Kingdom: The United Kingdom’s TIs require treatment only of persons with clinical, radiological or bacteriological evidence of active TB disease. No action is required in relation to LTBI.
(5) New Zealand: New Zealand requires LTBI testing at the time of the pre-departure assessment for refugee applicants younger than 11 years, with IGRA for those aged 2–10 years and TST for those younger than 2 years. Positive tests do not require further investigation or treatment and are followed up after arrival in New Zealand.
CHAPTER 5

Treatment
Chapter 5. Treatment

5.1. General treatment processes

Appropriate TB treatment benefits both the individual patient (by reducing morbidity and preventing mortality) and the community around the patient by minimizing transmission to others. Thus, the objectives of TB therapy are to:

(1) Rapidly reduce the bacillary load, thus reducing disease severity, preventing death and stopping further transmission;

(2) Eradicate persisting bacilli to prevent relapse;

(3) Prevent the development of drug resistance.

Categorizing TB patients is based on prior treatment – that is, new versus previously treated cases.

(1) A new TB case is a patient diagnosed for the first time with TB who has not previously been treated with anti-TB medicines or who has had TB therapy for less than 1 month.

(2) Previously treated patients have received anti-TB medicines for 1 month or longer in the past. These patients are further classified by the outcome of their most recent course of treatment as follows.

(a) Relapse patients have previously been treated for TB, were classified as cured or treatment completed at the end of their most recent course of treatment, and have now been diagnosed with a recurrent episode of TB, either a true relapse or a new episode of TB caused by reinfection.

(b) Patients classified as treatment after failure are those who have previously been treated for TB and whose treatment failed at the end of their most recent course.

(c) Patients classified as treatment after loss to follow up have previously been treated for TB and were categorized as being lost to follow up at the end of their most recent course of treatment. (These patients were previously known as “treatment after default.”)

(d) Other previously treated patients are those who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.

(3) Patients with unknown previous TB treatment history do not fit into any of the categories listed above – that is, they were diagnosed with TB but it is not known whether they had treatment or what kind of treatment they had.

Because DST is now more readily available, including rapid molecular tests for INH and RIF resistance, the treatment regimen for both new and retreatment cases is guided by the DST pattern. For both new and previously treated patients, in the absence of DST results, drug susceptibility is assumed, and the treatment regimen is assigned accordingly, unless
there is an epidemiological and or clinical reason to suspect drug resistance; however, it
must be noted that patients who have been treated previously are at a greater risk of
having RR-TB.

In the absence of DST results and especially for previously treated cases, consultation with
a supervisor and other expert Focal Points is needed to create an expanded regimen that
considers local resistance patterns.

5.2. Mode of TB treatment delivery: directly observed versus self-administered

There is a multiplicity of methods by which medicines can routinely be taken by patients.
However, for TB treatment, compliance is especially important to ensure that treatment
is complete and drug resistance is avoided. The following points describe these different
modalities of promoting compliance.

(1) Directly observed therapy, or DOT, is an adherence-enhancing strategy in which
a health-care worker or other trained health-care staff member watches a patient
swallow each dose of medicine in person and documents that the dose was taken. It
is the standard of care for all applicants with TB disease. While recent WHO advice
has indicated that video-observed treatment (VOT) can enhance patient compliance,
may replace DOT when the technology is available and it can be appropriately
organized and operated by health-care providers and patients, this is not supported
by receiving countries, and as such it is not recommended as routine practice by IOM.

For all applicants undertaking TB treatment through IOM DOT clinics, the IOM
standards for TB care adhere to the practice of daily DOT (usually 5 days/week)
for the entire course of treatment. If clients are referred to non-IOM clinics for
treatment, IOM will work with these centres to ensure treatment is delivered within
these guidelines.

Note: A minimum of 5 days/week of DOT is considered an
acceptable alternative to 7 days/week of DOT, and both fit
into the definition of daily dosing as outlined in the ATS−
CDC−IDSA 2016 guidelines on treating drug-susceptible TB
(www.cdc.gov/tb/publications/guidelines/pdf/clin-infect-dis.-
2016-nahid-cid_ciw376.pdf).

(2) Self-administered therapy, or SAT, means that patients take anti-TB medicines on
their own and they are not supervised; they then report back regularly to the treating
facility for review and to collect more supplies as needed. In some locations, patients
are advised to mark their patient cards to indicate that the medicines have been
taken. Note that this is not acceptable to IOM and is not recommended for migration cases.

(3) Individual partner countries’ requirements regarding DOT are summarized below.

(a) United States: According to the 2018 TIs, PPs must provide DOT treatment to applicants or identify in-country treatment programmes that follow the DOT standards defined in the TIs by the CDC. Failure to comply with these standards means that applicants cannot be cleared for travel and must wait 1 year from the date of treatment completion to repeat the medical examination. Doses that are taken but not observed for whatever reason should not be counted towards the total number of minimum required DOT doses.

(b) Australia: As of July 2018, treatment must be DOT. If applicants are unable to comply with DOT, then this must be documented in the file. Applicants must be counselled that non-adherence to DOT may lead to delays in medical clearances or visas may not be granted if it cannot be proven that they are free from TB. Further, health clearance will be deferred for a minimum period of 12 months from the end of their treatment.

(c) Canada: Although DOT is not mandatory, applicants should be informed that it is highly recommended.

(d) United Kingdom: The TIs have no position on DOT, but when possible, treatment should adhere to WHO’s guidance for programmes at the applicant’s location.

(e) New Zealand: Overseas examining physicians are to use applicable standards of practice.

(f) Other countries without specific protocols: IOM should strive to provide treatment through DOT, and when this is not possible, applicants should be referred to NTP providers who adhere to WHO protocols.

5.3. Delivering and organizing DOT

The provision of DOT requires a systematic and organized process to achieve the required numbers of observed doses.

(1) The practical aspects of achieving the minimum required 130 DOT doses for the standard 6-month treatment course for drug-susceptible TB are described in this section.

With daily dosing on the standard 6-month regimen of 2HREZ/4HR (2 months INH + RIF + EMB + PZA followed by 4 months INH + RIF), the total number of doses required is 182. However, the minimum number of DOT doses required is 130, which is equivalent to 5 days/week of DOT (40 doses in the intensive phase and 90 doses in the continuation phase). Many countries, but not all, now accept 5 days/week of DOT for 130 doses (26 weeks).
A minimum of 130 DOT doses is required and will be the preferred option if the NTP allows it. This translates to treatment with DOT 5 days/week, with no medicines to be taken over the weekend.

There are two approaches to achieve the minimum number of 130 DOT doses with a supply of 168 or 182 doses when the NTP does not provide 5 days/week of DOT treatment (that is, it provides weekend doses as part of their non-DOT regimen).

(a) Clinics that are required to administer 168 doses by the NTP should provide 6 days/week of DOT and 1 day/week as SAT. This will translate to 144 DOTs and 24 SATs. (The 6 days/week DOT administration will be continued until the minimum of 130 DOT doses is reached, which is usually at 22 weeks, and then the remaining doses will be completed as SAT). This means that staff need to be available for DOT for 1 day over the weekend.

(b) Clinics that are required to administer 182 doses should provide 5 days/week as DOT and 2 days/week (weekend) as SAT. This will translate to 130 DOTs and 52 SATs. Thus, staff will need to be available for DOT if a public holiday falls on one of the 5 working days of the week or to provide DOT on a weekend day in these situations.

(2) Considerations for organizing DOT are discussed in this section.

(a) Infection prevention and control (IPC) strategies that should be used with DOT include the following.

- DOT should take place in a well-ventilated room that is equipped with germicidal ultraviolet light (GUV) fixtures. The room and access to it, including a waiting area, should be spatially separated from the main processing area (that is, not using common areas). Patients in the initial phase of treatment and those in the continuation phase should be scheduled at different times to account for their different levels of infectiousness. It is preferable for infectious patients to be scheduled earlier to avoid them mixing with those who are not infectious and clients who are attending for MHAs. While patients’ convenience is an important consideration, IPC principles should prevail. In this document, a contagious (infectious) TB patient is defined as anyone with PTB disease who is able to spread infectious droplet nuclei containing viable MTB bacilli while coughing, sneezing, talking or conducting any other respiratory manoeuvre. Note that that TB can be infectious before it is confirmed.

- Good ventilation should be maintained in the DOT room throughout treatment administration. Ensuring natural ventilation, with windows open on opposite sides of the room, is particularly effective. If it is impossible to implement such ventilation (for example, if the weather is very cold or very hot, there is a storm), then mechanical ventilation (including exhaust fans) can be used in combination with upper room GUV. Whenever effective natural ventilation
cannot be achieved, upper room GUV should be switched on throughout the duration of treatment administration. If upper room GUV is not available, the DOT worker should switch on unshielded UV lights between groups of infectious and non-infectious patients and after the completion of DOT administration.

Infectious patients should wear surgical masks, and DOT personnel should wear N95 respirators while administering DOT. Once the patient becomes non-infectious (which is defined as completing at least 2 weeks of DOT and having a negative sputum smear and resolution of all respiratory symptoms), there is no need for the patient to wear a mask.

The DOT room should have a stock of masks, respirators and tissues and separate receptacles for infectious and non-infectious materials. Ideally, the room should have a handwashing facility. If that is not possible, hand sterilizers, such as alcohol-based gels, should be available for patients and personnel.

(b) This section describes the process of administering DOT.

At each encounter DOT personnel should:

• Confirm the identity of the patient;
• Observe the patient’s condition and, if necessary, measure vital signs and conduct a quick physical exam; if there are any concerns, refer the patient to the physician before administering DOT;
• Enquire about side effects, paying particular attention to any that were previously reported or identified;
• Enquire about symptoms of TB;
• Enquire about symptoms of any other disease that the patient may have;
• Verify the medicine that the patient will be taking by comparing it with the prescription;
• Give the medicines and observe the patient swallowing them;
• Record the doses in the DOT compliance records, and sign and date the entry;
• Record the medicines that the patient took, the side effects, if any, and any additional actions that were undertaken, including measurements and a physical examination;
• Congratulate the patient on the progress of treatment, reiterate the importance of adhering to treatment, remind the patient about upcoming monitoring tests, and invite the patient to ask questions;
• Provide food supplements or allowances for transportation, if applicable;
• Refer patients for additional tests or physician’s consultation if they are on the schedule or if the patient’s condition has changed.
Patients must be contacted every time they miss a treatment appointment. In some cases, for example when the treatment is provided in a refugee camp, DOT staff should visit the patient, clarify the reason for the no-show, provide the medicines and encourage the patient to continue DOT.

If the patient cannot visit the clinic for legitimate reasons (such as illness, trauma, sick family members) and if resources permit, home visits could be organized. If home visits are impossible, VOT can be used to avoid treatment interruptions.

For the purposes of IMEs, VOT is not considered DOT, and if the TB TIs are explicit that DOT must be provided, the period of VOT should be considered as an interruption to treatment and managed accordingly.

If neither home visits nor VOT is feasible, the patient should be provided with the medicines for SAT, but this period should be considered as a treatment interruption and managed accordingly, as outlined in Section 7i.

DOT can be administered only by clinical staff − including physicians, nurses, clinical officers, pharmacists − or other health workers, such as trained community health workers.

In the migration setting, the applicant’s friends and relatives cannot provide DOT. Under WHO and NTP guidelines, TB treatment can be administered by family members and treatment supporters who are not health-care workers. This is acceptable and considered to be community-based DOT but it is not acceptable under receiving country instructions for migrants.

5.4. Client-centred TB case management

Client-centred care aims to provide TB care that is respectful of and responsive to an individual patient’s needs, values and preferences and ensures, to the extent possible, that knowledge of the client’s needs and values guides all clinical decisions. This type of care acknowledges and respects the patient’s right to act as a partner in decisions and activities related to their diagnosis and treatment.

(1) Case management interventions: In addition to providing curative therapy, case management for patients with TB entails educating and counselling them, making field or home visits, coordinating their care with specialists, and using reminders or enablers, such as a transport allowance.

(2) Interventions to provide client-centred care: IOM staff can use the following interventions when providing client-centred care.

(a) Enablers can be provided, such as transport allowance, daily DOT services and monthly clinical reviews, interpreters when necessary, referrals to social services
for support, integration of TB care with other services for co-morbid conditions, referrals for specialized care, phone call or text reminders about appointments, a waiver of costs related to TB management, continuing education and counselling, and the use of treatment supporters.

(b) Incentives may also be provided, such as nutritional support, for example packaged milk, biscuits, eggs, vegetables or canned fish, although the specifics will vary based on local availability and logistical feasibility.

5.5. Anti-TB medicines

Historically, WHO grouped anti-TB medicines into five categories, based on efficacy, experience using the medicines, safety and class. US guidelines classify anti-TB medicines as first line, referring to the traditional core medicines used to treat drug-susceptible TB; second line, referring to medicines used to treat MDR-TB (including FQNs, aminoglycosides and polypeptides); and third-line medicines, which are also used to treat drug-resistant (DR)-TB, but are less active, have more adverse effects and less evidence to support their use as first- or second-line medicines. In 2016 WHO updated the categories, and in 2019 refined the classification further to concentrate specifically on three specific groups for MDR-TB as outlined here.

(1) Group A: These are the medicines to be prioritized – levofloxacin OR moxifloxacin plus bedaquiline and linezolid.

(2) Group B: These medicines are to be added next – clofazimine plus cycloserine OR terizidone.

(3) Group C: The medicines from this group are to be included to complete the regimens and when agents from Groups A and B cannot be used – EMB, delamanid, PZA, imipenem–cilastatin, meropenem, amikacin OR streptomycin, ethionamide (ETA) OR prothionamide, p-aminosalicylic acid.

In this manual, drug-susceptible TB (including special circumstances and situations) is covered in this section, and DR-TB (incorporating the new WHO groups of medicines and detailed guidance on building treatment regimens) is covered in Section 8.

5.6. Drug-susceptible TB

First-line anti-TB medicines are INH, RIF, EMB and PZA; these are used to treat drug-susceptible TB, which is the most common type of TB seen in IOM clinics. Pending DST results, treatment should be initiated on the basis of presumed susceptibility to all medicines. Treatment should be adjusted if drug resistance is later identified. Table 3 outlines the different regimens and their effectiveness, noting that, ideally, IOM should use only Regimen 1.
Table 3. Drug regimens for microbiologically confirmed pulmonary TB caused by drug-susceptible organisms

(As you move from Regimen 1 to 4, the effectiveness decreases. For IOM, Regimen 1 should be used.)

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Phase of treatment</th>
<th>Total No. of doses (range)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intensive</td>
<td>Continuation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Medicine</td>
<td>Medicine</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Interval and No. of doses (minimum duration)</td>
<td>Interval and No. of doses (minimum duration)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>INH RIF PZA EMB</td>
<td>7 days/week for 56 doses (8 weeks) OR 5 days/week for 40 doses (8 weeks)</td>
<td>INH RIF</td>
</tr>
<tr>
<td>2</td>
<td>INH RIF PZA EMB</td>
<td>7 days/week for 56 doses (8 weeks) OR 5 days/week for 40 doses (8 weeks)</td>
<td>INH RIF</td>
</tr>
<tr>
<td>3</td>
<td>INH RIF PZA EMB</td>
<td>3 times/week for 24 doses (8 weeks)</td>
<td>INH RIF</td>
</tr>
<tr>
<td>4</td>
<td>INH RIF PZA EMB</td>
<td>7 days/week for 14 doses then 2 times/week for 12 doses</td>
<td>INH RIF</td>
</tr>
</tbody>
</table>

DOT: directly observed therapy; EMB: ethambutol; INH: isoniazid; PTB: pulmonary TB; PZA: pyrazinamide; RIF: rifampicin; VOT: video-observed treatment.


As defined by WHO, drug-susceptible TB means that all anti-TB medicines will be effective if taken appropriately. The preferred administration schedule is once daily during both the intensive and continuation phases of treatment. Based on clinical experience, experts consider 5 days/week of DOT to be an acceptable alternative to 7 days/week of DOT; hence, both approaches are considered to be daily dosing. Pyridoxine at 25−50 mg/day should be added to all INH-containing regimens.

(1) Adults and children with drug-susceptible new or retreatment PTB or extrapulmonary TB should be treated with 2HREZ/4HR.
(a) A standard short-course 6-month chemotherapy regimen consisting of a 2-month intensive phase of treatment with INH, RIF, EMB and PZA followed by 4 months of INH and RIF is the preferred recommended regimen for adults and children with drug-susceptible TB. This is for both PTB and cases of extrapulmonary TB, with the exception of TB meningitis and skeletal TB (which occurs in bones and joints).

(b) EMB is considered safe and can be used in children in doses not exceeding 20mg/kg per day. Hence, paediatric regimens now include it as part of the intensive phase, similar to the regimen for adults.

(c) TB in patients without DST results and without prior treatment history should be treated as drug-susceptible unless there is strong epidemiological information to support DR-TB

(2) Adults and children with drug-susceptible new or retreatment TB meningitis or skeletal TB should be treated with 2HREZ/10HR.

(a) For adult and paediatric patients with new or retreatment cases of drug-susceptible TB meningitis or for skeletal TB, treatment begins with a 2-month intensive phase of INH, RIF, EMB and PZA that is followed by a 10-month continuation phase with INH and RIF; the duration of treatment ranges from 9 to 12 months.

(b) Adjunctive corticosteroid therapy with dexamethasone or prednisolone tapered down over 6–8 weeks is strongly recommended for patients with TB meningitis, according to the 2016 ATS–CDC–IDSA guidelines.11

Note that while EMB may be discontinued once DST results are available and confirm susceptibility to INH and RIF, this is not practical in most locations due to the use of fixed-dose combination medicines. In such circumstances, the patient completes the intensive phase with the four medicines in the fixed-dose combination tablet.

### 5.7. Paediatric TB cases

In children, even if parenchymal involvement is present, their lower bacillary burden means that sputum results are more likely to be negative than they are in adults. Therefore, a decision to treat should not be based solely on sputum results.

EMB, which previously was not included in paediatric regimens, is now considered safe when used at doses not exceeding 20mg/kg per day. The risk of toxicity is negligible when EMB is used at recommended doses, which range from 15–25 mg/kg per day. The risk of toxicity is related to the dose and duration of therapy. The main potential side effect is optic neuritis, which can lead to blindness. However, the data on the risk of toxicity

in children has been extensively reviewed, and much clinical experience with using it in children has accumulated.

Hence, the regimen for drug-susceptible TB in children, whether confirmed or presumed to be drug susceptible, is the standard 6-month regimen of 2HREZ/4HR for all forms of TB with the exceptions of TB meningitis and skeletal TB. Doses should be calculated as per Table 3 of the 2016 ATS−CDC−IDSA recommendations.12

5.8. Treatment extensions

Scenarios that require treatment to be extended include the following.

(1) Cavitation and positive cultures at the end of the intensive phase of treatment: Patients on a 6-month standard regimen who have cavitation on initial CXR and positive cultures at the end of the 2-month intensive phase should have the continuation phase extended by a further 3 months, thus having up to 9 months of treatment (2HREZ/7HR). Cavitation on CXR or positive cultures at month 2 have been associated with relapse rates of about 20 per cent compared with 2 per cent among those with neither of these factors.

(2) Cavitation or positive culture at month 2: If the patient has one of these two factors − that is, either cavitation or positive cultures at month 2 but not both − then consider other factors in determining whether to extend treatment. The additional factors that might extend treatment include:

(a) Weighing >10 per cent below the ideal body weight;
(b) Being an active smoker;
(c) Being diabetic;
(d) Being HIV-positive or having another immunosuppressive condition;
(e) Having extensive disease on CXR.

(3) HIV-positive patients: It is recommended that HIV-positive patients who do not receive antiretroviral therapy (ART) during TB treatment have the continuation phase extended by 3 months; thus, treatment will last for up to 9 months (2HREZ/7HR).

5.9. Treatment interruptions

When interruptions to TB treatment occur, the PP must decide whether to restart the full treatment course or continue as originally planned. When and for how long the interruption occurs are key to making this decision. The earlier in the course of treatment the interruption

occurs and the longer the duration, the more serious are the consequences and, hence, the need to restart the treatment from zero. In addition, the patient’s bacteriological status before and after the interruption are also important factors to consider. Table 4, adapted from the 2016 ATS–CDC–IDSA guidelines gives some guidance about how to make these decisions.

Table 4. Managing interruptions to TB treatment

<table>
<thead>
<tr>
<th>Phase of interruption</th>
<th>Length or time of interruption</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intensive</strong></td>
<td>Interruption is less than 14 days</td>
<td>Continue treatment as planned for total number of doses in intensive phase, ensuring that all doses are completed within 3 months.</td>
</tr>
<tr>
<td></td>
<td>Interruption is 14 days or longer</td>
<td>Restart treatment from beginning.</td>
</tr>
<tr>
<td><strong>Continuation</strong></td>
<td>Received at least 80% of doses and was AFB smear-negative on initial testing</td>
<td>Further therapy should not be necessary, depending on clinical and bacteriological assessments.</td>
</tr>
<tr>
<td></td>
<td>Received at least 80% of doses and was AFB smear-negative on initial testing</td>
<td>Continue therapy until all doses are completed (full course).</td>
</tr>
<tr>
<td></td>
<td>Received less than 80% of doses and cumulative lapse is less than 3 months</td>
<td>Continue therapy until all doses are completed (full course) unless the interruption is longer than 2 months. If treatment cannot be completed within the recommended timeframe for the regimen, then treatment must start again from the intensive phase – that is, the full course must be completed.</td>
</tr>
<tr>
<td></td>
<td>Received less than 80% of doses and cumulative lapse is more than 3 months</td>
<td>Restart course from beginning – that is, both the intensive and continuation phases must be restarted.</td>
</tr>
</tbody>
</table>

AFB: acid-fast bacilli.


5.10. Patients with TB–HIV co-infection

Co-infection with TB and HIV is relatively common, and clinicians should be aware of specific factors to consider in this situation. Patients who did not have HIV screening as part of their initial health assessment, should be tested for HIV infection, with appropriate consent, when they are diagnosed with TB during their initial pre-treatment tests (see Template Form 9).

(1) General considerations for patients with TB–HIV co-infection include knowing that the usual indicators of TB may be absent in these patients.

Macrophages and CD4 lymphocytes are the natural barriers against TB, and they are also the targets of HIV. The consequent failure of the immune system in HIV is the most powerful risk factor for TB disease. Typical indicators of TB may be absent in patients with TB–HIV co-infection.
(a) Clinical: Fever and weight loss are important symptoms; cough is less frequently a symptom or it may be absent.

(b) Bacteriological: Smear microscopy is less sensitive.

(c) Radiological: The CXR pattern is more variable, with fewer cavities and infiltrates.

(d) Site: Extrapulmonary and disseminated TB are more frequent.

(e) Diagnosis: the differential diagnosis is broad and includes NTM.

2. The TB treatment regimen, duration and drug interactions are somewhat different in patients who are co-infected with TB and HIV.

TB treatment regimens for HIV-positive patients are similar to those for HIV-negative patients. However, management entails addressing the interactions between anti-TB medicines and those used for ART, paradoxical reactions and other added toxicities. Expert consultation is needed when treating patients with TB–HIV co-infection owing to the interactions between anti-TB medicines, particularly rifamycin and those used for ART. Rifabutin is generally recommended in place of RIF.

Different countries use different regimens to treat TB and HIV, so local and national guidelines should also be consulted to determine the recommended regimens to address potential interactions that would otherwise result in negative outcomes in terms of both diseases.

The standard 6-month regimen (2HREZ/4HR) is the recommended regimen for HIV-positive patients with TB who are on ART and have drug-susceptible TB disease. However, in rare situations when the patient is not receiving ART during the course of TB treatment, extending the continuation phase by a further 3 months is recommended (2HREZ/7HR).

3. What is the best time to start anti-TB treatment and ART?

Anti-TB treatment should be started at the time of diagnosis. However, if HIV infection was not diagnosed previously, the initiation of ART (with respect to the commencement of TB treatment) is more controversial. Ideally ART should be initiated:

(a) Within the first 2 weeks of TB treatment for patients with CD4 counts <50 cells/μL except in cases of TB meningitis and HIV co-infection;

(a) Within 8 to 12 weeks TB treatment initiation for patients with CD4 counts >50 cells/μL.

4. Co-infection with TB meningitis and HIV affects the timing of starting ART.

---

For patients with TB meningitis and HIV, ART should be started after 8 weeks of anti-TB therapy regardless of the CD4 count, as immune reconstitution inflammatory syndrome (IRIS) in a patient with central nervous system (CNS) TB may cause fatal neurological complications. IRIS is a transient and paradoxical worsening of TB symptoms, signs and lesions that occurs after a patient begins anti-TB treatment and ART. IRIS associated with TB is more common at the beginning of ART and in patients with low CD4 counts (<50 cells/μL).

Management of IRIS depends on the symptoms and developing IRIS does not worsen the treatment outcome for either condition.

### 5.11. TB treatment and hepatic disease

Drug-induced hepatotoxicity is the most frequent serious adverse reaction to first-line anti-TB medicines. Among the first-line medicines, PZA, INH and RIF can all cause hepatotoxicity. An asymptomatic increase in ALT occurs in 20 per cent of patients on standard first-line regimens with four medicines, and in most cases it resolves spontaneously.

When there is elevation of liver enzymes, particularly when ALT is >3 times the upper limit of normal in the presence of hepatic symptoms or >5 times the upper limit of normal with or without symptoms, drug-induced hepatotoxicity should be suspected and all potentially hepatotoxic medicines should be stopped immediately and the patient evaluated.

Other causes of abnormal liver tests, including pre-existing hepatic disease, hepatitis B or C infection, or alcohol-induced liver disease, should be investigated and excluded before a diagnosis of drug-induced hepatotoxicity is made.

Once hepatotoxicity has been diagnosed and the medicines stopped, follow-up monitoring should include repeat liver function tests and international normalized ratios tests, and clinical review should be performed until the levels return to baseline. The frequency of the repeat testing may vary from weekly to fortnightly or monthly as needed, and expert opinion should be used to guide management.

The optimal approach to reintroducing therapy after the patient’s ALT levels return to baseline is not known, with some sources suggesting that medicines should be reintroduced sequentially, starting with the least hepatotoxic medicine, and that ALT monitoring should continue as each medicine is reintroduced.

### 5.12. Pre-existing hepatic disease

In the presence of pre-existing hepatic disease, the magnitude of drug-induced hepatotoxicity increases, and it may be severe or life threatening in patients with marginal liver reserves. Regimens with medicines that are less potentially hepatotoxic should be used in cases in which hepatotoxicity is a risk due to pre-existing hepatic disease and the baseline ALT is >3
times the upper limit of normal where this elevation is not caused by TB disease. Expert consultation is necessary, and adjustments during treatment may also be needed.

5.13. TB treatment and renal disease or insufficiency

Patients with renal insufficiency or end-stage renal disease who are on anti-TB treatment require close monitoring due to being immunocompromised and, hence, having the potential for poor outcomes. Renal or other expert specialists should be involved in the management of these patients.

Dose adjustments may be required, and caution must be taken to ensure peak serum medicine concentrations are not compromised to the extent that treatment efficacy is lost.

For patients with serum creatinine clearance of <30mL/minute or those receiving haemodialysis, the interval between doses should be increased. For patients on haemodialysis, medicines should be administered after haemodialysis to prevent their premature clearance.

When there is borderline serum creatinine clearance, 24-hour urine collection and testing should be used to better measure the degree of insufficiency and guide changes to the dosing interval. With reduced creatinine clearance but clearance that is still >30mL/minute, standard dosing can be used but the patient should be closely monitored.

(1) RIF and INH are metabolized in the liver, so standard dosing can be used in patients with renal insufficiency.

(2) PZA is metabolized in the liver, but its metabolites may accumulate in patients with renal insufficiency; EMB is approximately 80 per cent cleared by the kidney, and it may accumulate in patients with renal insufficiency. Thus, PZA and EMB should have longer dosing intervals – that is, three times weekly.

(3) Where creatinine clearance is <30mL/minute, advice should be sought from a renal specialist.

5.14. TB treatment for pregnant and breastfeeding women

Maternal TB has been associated in some studies with an increased risk of spontaneous abortion, perinatal mortality and low birth weight. Thus, untreated TB thus poses a greater risk to mother and child than does TB treatment.

The medicines used to treat TB have not been studied in pregnant women and, as such, there is some small risk of teratogenicity, as there is with any medicine, especially when given during the first trimester. Pregnant patients must be given the opportunity to make an informed and educated decision about treatment while recognizing the potential small risk as well as the likely greater benefit.
The International Union Against Tuberculosis and Lung Disease, WHO and the British Thoracic Society all endorse the use of standard first-line regimens in pregnant women who have TB. The US CDC does not specifically endorse the use of PZA during pregnancy, citing the absence of detailed teratogenicity data, but states that PZA can probably be used safely during pregnancy. An alternative 9EHR regimen is endorsed by the CDC.

Thus, for pregnant patients with drug-susceptible TB disease, except for those with TB meningitis or skeletal TB, the standard 6-month regimen or 2HREZ/4HR is recommended and can be used during any stage of pregnancy. Pyridoxine should be given to all pregnant and breastfeeding women receiving INH.

Second-line drugs should not be used in pregnant women without consulting with a TB specialist. Aminoglycosides (that is, streptomycin, amikacin and kanamycin) and the polypeptide capreomycin are known to have ototoxic and possibly teratogenic effects on the developing foetus and, therefore, should not be used during pregnancy.

Although small concentrations of anti-TB medicines are excreted in breast milk, treatment for TB is not a contraindication to breastfeeding. The concentrations of anti-TB medicines in breast milk are extremely low and they cannot be considered to be treatment for an infant with TB.

If an infant requires treatment for active disease or primary prophylaxis, the weight-based guidelines for children should be followed to select a suitable treatment regimen. In general, mothers with fully drug-susceptible PTB can continue breastfeeding their infant, providing that the infant has been given appropriate treatment for LTBI (that is, INH if there is no evidence of disease in the infant or standard anti-TB treatment if active TB disease cannot be excluded.)

5.15. Regimens for drug-resistant TB

Treatment for DR-TB should be guided by the isolate's DST pattern, which can initially be determined through rapid molecular DST, such as through second-line (SL)-LPAs. References to aid in managing cases of DR-TB include the Curry International Tuberculosis Center’s Drug-resistant Tuberculosis: a Survival Guide for Clinicians and WHO’s consolidated guidelines for managing DR-TB, 2019.14,15

See Section 8 for more detailed guidance on DR-TB.


5.16. Schedules for follow-up tests for different countries

A summary of country-specific requirements for follow-up tests based on TIs is available in Section 9. The Checklist for TB Monitoring is provided in Template Form 10.

A monitoring schedule for treating DR-TB is provided in Section 9c; it was developed from the Curry International Tuberculosis Center’s Drug-resistant Tuberculosis: a Survival Guide for Clinicians and WHO’s 2018 monitoring schedule, and it addresses the tests needed and the frequency of monitoring in MDR-TB treatment. The schedule can be found in Template Form 11.

5.17. Monitoring and managing side effects

For drug-susceptible and DR-TB other than MDR-, RR- and XDR-TB, the standard side effects form is used to document the presence and absence of side effects; enquiries should be made daily, and weekly documentation is mandatory, as outlined in Section 9b and recorded on Template Form 8.

Side effects booklets are used for patients with MDR-, RR- and XDR-TB so that more detailed notes can be recorded about side effects and actions taken to address them, including changes to the regimen, and their severity can be graded.

5.18. Default tracing

In order to enable patients who have defaulted from treatment to be found, the DOT provider should adhere to the following processes.

(1) At registration, all patients must provide their contact address, physical address and telephone number, and these must be confirmed at each review.

(2) Any patient who fails to attend for daily DOT should be telephoned at the end of that same day. If there is no response, the patient’s treatment supporter should be telephoned.

(3) If there is no response or contact from either the patient or their supporter by the second day, a physical visit should be undertaken, if possible.

(4) Where applicable, involve community leaders.

(5) If all of the preceding steps fail, the NTP should be involved because it has the prerogative to invoke the public health act and compel the patient to take the anti-TB treatment.

(6) If the default lasts for longer than 2 weeks, contact the authorities in the receiving country and determine whether any further action is required.
5.19. Clinical consultations

When physicians need assistance for complex treatments, they should seek guidance from the receiving country authority. The following information should be provided for each of these requests:

1. The name and occupation of the person making request;
2. Their contact details;
3. The country where the physician is based and the panel site;
4. Information about any previous requests made for assistance;
5. The patient’s name, date of birth and identification number (these should be provided only when sending through a secure site and never sent for United States consultations);
6. The age of the patient;
7. The specific question;
8. Whether the client is an immigrant or refugee;
9. Any relevant information, such as
   a. History of the present illness
   b. History of previous treatment for active TB or LTBI (including treatment regimens and dates)
   c. Other medical history (that is, co-morbid conditions)
   d. Any current medicines or allergies
   e. Physical exam findings
   f. Laboratory results, including culture and DST, if available
   g. Pertinent radiographic findings.

For United States-bound clients: IOM physicians should access the CDC’s TB Regional Training and Medical Consultation Centers’ clinical consultation service by using the following URL to request a consultation from the TB clinical expert − https://rtmcc.medicine.ufl.edu/panelphysicianrequest.aspx.

For Australia-bound clients: Panel members with access to the eMedical electronic health processing system should use the Contact Us tab to contact the Department of Home Affairs. Alternatively, panel members can email the department at health@homeaffairs.gov.au.

For Canada-bound clients: IRCC medical officers are responsible for making the final assessment of all IMEs. When IOM physicians need assistance with complex treatments, they should submit to the regional office the results of the IME and attach all relevant
material for review by the medical officers of the IRCC. Contact the specific regional office at one of the following MANILMC-MD@international.gc.ca; LDNMC@international.gc.ca; IRCC.MHBGPNNMUYGRMPDDGMS.IRCC@cic.gc.ca.

For United Kingdom-bound clients: For queries related to the UKTBDP send an email to phe.tbdata@nhs.net or PHE.tbssection@nhs.net. Emails containing patient identifiable information should not be sent to these address because they are not secure.

For New Zealand-bound clients: Send an email to panelphysiciansupport@mbie.govt.nz.
CHAPTER 6

Drug-resistant TB
Drug resistance can be identified by molecular testing of sputum samples or culture isolates, by DST on culture isolates, or empirically, following treatment failure. The case of any patient identified with DR-TB should be discussed with the CMHO.

### 6.1. Molecular testing

There are two main molecular methods for detecting drug resistance: LPA and the Xpert MTB/RIF assay.

1. **LPA**
   - The LPA is a PCR-based test that identifies DNA markers of MTB species and markers of INH and RIF resistance. Sensitivity for identification of MTB and RIF resistance is approximately 99 per cent, but it is lower for INH resistance (≥90%). The LPA has been validated for testing sputum smear-positive samples as well as MTB culture isolates. The LPA product used by IOM is GenoType MTBDRplus, sometimes referred to as the Hain assay. GenoType kits are also available for detecting mutations associated with resistance to FQNs and second-line injectable agents.

2. **Xpert MTB/RIF assay**
   - The Xpert MTB/RIF assay is another PCR-based test that identifies DNA markers of MTB and RIF resistance. This assay capitalizes on the strong link between RIF resistance and multidrug resistance, with RIF resistance associated with multidrug resistance in ≥95 per cent of cases. A high prevalence of multidrug resistance increases the test’s sensitivity for RIF resistance, and in studies reviewed by WHO, the sensitivity of the Xpert MTB/RIF assay for RIF resistance was ≥95 per cent. However, in areas with lower prevalence, the positive predictive value of RIF resistance drops significantly. The assay has been validated for use on sputum smear-negative samples as well as on smear-positive samples. The next-generation cartridge-based Xpert MTB/RIF Ultra assay has increased sensitivity for detecting MTB, especially among paucibacillary specimens, and it has better detection of RIF resistance. Its primary intended use is as a rapid supplement or alternative to sputum microscopy and culture in settings with a high burden of RR- and MDR-TB where these services may not be available or reliable. The cartridge format means that it can be used by persons with minimal training compared with that required for LPA, which increases its suitability for difficult operational conditions.

Further information can be found in WHO’s Xpert implementation and consultation manuals.\(^\text{16,17}\)

In cases in which results from molecular drug-resistance testing are available for INH or RIF resistance, treatment needs to be adjusted accordingly, given that treatment failure poses a greater threat to the individual’s and the public’s health than does the risk of medicine toxicity. Therefore, failure to use a medicine to which an organism is sensitive carries a

---


greater risk than prescribing a medicine to which an organism is resistant. This principle should be kept in mind whenever consideration is being given to withdrawing a first-line agent.

(1) Molecular identification of INH resistance on a sputum smear-positive specimen should lead to initiation of a treatment regimen for INH mono-resistance. Further adjustment may be required when DST results become available.

(2) Given the rarity of isolated RIF resistance, a molecular result that indicates RIF resistance should raise suspicion of multidrug resistance.

(3) If multidrug resistance is identified by LPA, a regimen that assumes resistance to only INH and RIF should be instituted unless strong epidemiological evidence suggests amplified resistance.

(a) In patients with RR-TB or MDR-TB who were not previously treated with second-line agents and in whom resistance to FQNs and second-line injectable agents has been excluded or is considered highly unlikely, a shorter MDR-TB regimen of 9–12 months may be used instead of the longer regimens.

(b) WHO’s 2019 guidelines recommend that for patients with MDR- or RR-TB who are on longer regimens, a regimen with at least four effective anti-TB medicines is required during the intensive phase. As mentioned in Section 8f, all three Group A agents and at least one Group B agent should be included to ensure that treatment starts with at least four anti-TB agents that are likely to be effective, and at least three agents should be included for the remainder of treatment after bedaquiline is stopped. If only one or two Group A agents are used, two Group B agents should be included. If the regimen cannot be composed of agents from Groups A and B alone, Group C agents should be added to complete it.

(c) Smear-positive patients with MDR-TB should be isolated where possible; they should also be provided with education to minimize transmission risk and encourage the patient’s health (for example, by providing information about nutrition).

(d) It is vital that DST results are reviewed as soon as they are available and the regimen is adjusted accordingly.

(e) Adverse effects must be monitored closely, with regimens adjusted accordingly after consultation with a supervisor.

(f) A supervisor should be notified about the case and consulted regarding the treatment regimen, and second-line DST should be arranged if a culture isolate is available.

---

6.2. Drug-susceptibility testing on liquid and solid media

Traditional DST, preferably using liquid culture medium, remains the gold standard for identifying drug resistance. However, DST can be performed only after MTB complex has been isolated, which can take many weeks. Once an isolate has been grown, DST on liquid medium can usually produce a result within 6 to 10 days, but solid medium requires 3 weeks.

If DST identifies drug resistance, the IOM physician should:

(1) Adjust therapy as per guidelines if this has not already been done on the basis of the molecular results and if the treatment is to be administered by the IOM clinic. If treatment will be provided by the NTP, the PP should coordinate closely with the programme;

(2) Obtain second-line DST (where available);

(3) Immediately discuss the management of polydrug- or multidrug-resistant cases with a supervisor;

(4) Notify cases of MDR- and XDR-TB to national authorities;

(5) Notify the appropriate authorities at the country of destination

(a) United States − notify the CDC via email to cdcqap@cdc.gov;

(b) Australia − notify the Department of Home Affairs via email to Health@homeaffairs.gov.au;

(c) Canada − notify the IRCC Regional Medical Office as well as Headquarters via email to Nat-Med-Surveillance@cic.gc.ca;

(d) New Zealand − notify Immigration New Zealand via email to panelphysiciansupport@mbie.govt.nz;

(e) United Kingdom − notify Public Health England via email to phe.tbdata@nhs.net or PHE.tbsection@nhs.net.

If resistance is limited to INH and RIF, the suggested treatment regimen is as that in Section 6.5.

However, if broader resistance is demonstrated that includes either EMB or PZA, these should be withdrawn in favour of two second-line oral agents, and the total course duration should be 24 months. Seek a supervisor’s assistance and consult the Curry International Tuberculosis Center’s Drug-resistant Tuberculosis: a Survival Guide for Clinicians or WHO’s 2019 consolidated guidelines for further information.19

If a resistance result is generated by molecular testing, but the specimen is susceptible on DST, then epidemiological and past treatment data should be reviewed. While the detection of a mutation that is highly associated with resistance should usually supersede a phenotypically susceptible result, if there is no epidemiological or history reason to suspect resistance, the re-introduction of a previously withdrawn agent or regimen may be considered. Seek guidance from a supervisor and the resettlement country and with the NTP in the country of origin.

If a specimen is susceptible on molecular testing but resistant on DST, then probable resistance has been identified. Seek prompt guidance from a supervisor and the resettlement country before withdrawing the agent.

### 6.3. Empiric identification

Drug resistance is empirically identified by treatment failure, especially in patients who are re-treatment cases. The failure of treatment in a previously untreated person raises suspicions of resistance, non-compliance or the reliability of the history. The failure of treatment in a re-treatment patient is more likely to represent multidrug resistance than monodrug or polydrug resistance.

The ATS−CDC−IDSA recommendations define treatment failure as recurrent positive cultures in a person receiving adequate chemotherapy. They define a person whose culture has remained positive after 4 months of treatment as having had treatment failure. In situations in which sputum cultures have remained positive longer than expected, DST should be repeated to determine whether additional resistance is present.

### 6.4. Treatment monitoring for drug-resistant TB

Enhanced monitoring is required for patients with MDR- and XDR-TB given the increased risk of toxicity associated with treating patients with complex regimens for an extended duration. Prolonged isolation and the duration of treatment necessitated by MDR-TB also increase the potential for stigmatization and other negative psychosocial responses to treatment.

In addition to the standard monitoring described in the next section, refer to the table in Template Form 11 for additional information about monitoring and intervals.

### 6.5. Treatment regimens for drug-resistant TB

The regimen for DR-TB should be individualized and guided by the isolate’s DST pattern. The groups of medicines used to manage DR disease are outlined in Table 5. The Curry

---

International Tuberculosis Center’s reference on DR-TB can be used as a guide to creating regimens for TB with mono- and poly-resistance, but not for MDR-, RR- and XDR-TB.

WHO has revised its groups of medicines used to treat MDR-TB into three categories and ranked them based on the latest evidence about the balance of effectiveness to safety.

1. Group A: These are the medicines to be prioritized – levofloxacin OR moxifloxacin plus bedaquiline and linezolid.

2. Group B: These are the medicines to be added next – clofazimine plus cycloserine OR terizidone.

3. Group C: The medicines from this group are to be included to complete the regimens and when agents from Groups A and B cannot be used – EMB, delamanid, PZA, imipenem–cilastatin, meropenem, amikacin OR streptomycin, ETA OR prothionamide, p-aminosalicylic acid.

Table 5. World Health Organization’s groups of medicines recommended for use in treating multi-drug-resistant TB

<table>
<thead>
<tr>
<th>Groups of anti-TB medicines and steps to be taken</th>
<th>Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A − include all three medicines</td>
<td>Levofloxacin OR moxifloxacin</td>
</tr>
<tr>
<td></td>
<td>Bedaquiline</td>
</tr>
<tr>
<td></td>
<td>Linezolid</td>
</tr>
<tr>
<td>Group B − add one or both medicines</td>
<td>Clofazimine</td>
</tr>
<tr>
<td></td>
<td>Cycloserine OR terizidone</td>
</tr>
<tr>
<td>Group C − add to complete the regimen and when medicines from Groups A and B cannot be used</td>
<td>Ethambutol</td>
</tr>
<tr>
<td></td>
<td>Delamanid</td>
</tr>
<tr>
<td></td>
<td>Pyrazinamide</td>
</tr>
<tr>
<td></td>
<td>Imipenem–cilastatin OR meropenem</td>
</tr>
<tr>
<td></td>
<td>Amikacin OR streptomycin</td>
</tr>
<tr>
<td></td>
<td>Ethionamide OR prothionamide</td>
</tr>
<tr>
<td></td>
<td>p-aminosalicylic acid</td>
</tr>
</tbody>
</table>

WHO Consolidated Guidelines on Drug-resistant Tuberculosis Treatment (2019) should also be utilized; it has combined evidence and previous recommendations for treating DR-TB, especially MDR- and XDR-TB, and also provides a stepwise guide to building a regimen for MDR-TB.

The proposed total duration of longer MDR-TB regimens is approximately 18–20 months, modified depending upon the patient’s response. The standardized, shorter MDR-TB regimen may be offered to eligible patients who agree to briefer treatment (lasting 9–12
months) that may be less effective than a longer, individualized regimen and that requires a daily injectable agent for at least 4 months.

6.6. Building a longer treatment regimen for multidrug-resistant TB

In patients with MDR- or RR-TB who are on longer regimens, all three Group A agents and at least one Group B agent should be included to ensure that treatment starts with at least four anti-TB agents that are likely to be effective, and at least three agents should be included for the remainder of treatment after bedaquiline is stopped. If only one or two Group A agents are used, two Group B agents should be included. If the regimen cannot be composed of agents from Groups A and B alone, Group C agents should be added to complete it.

Injectable agents are no longer among the medicines to be given priority when designing longer regimens to treat MDR-TB: kanamycin and capreomycin not recommended. Thus, the preferred option for most patients is a regimen comprising only oral medicines. Three medicines – FQNs (levofloxacin or moxifloxacin), bedaquiline and linezolid – are strongly recommended for use in longer regimens, and the regimen should be completed with other medicines, ranked by their relative balance of benefits to harms. For the first 6 months, most regimens include at least four agents likely to be effective, and then three agents are used thereafter.

Generally, recommendations on the composition, duration and monitoring of longer MDR-TB regimens apply to children and adults, to people living with HIV and to patients with MDR- or RR-TB who have additional resistance to FQNs or other agents, subject to the specific conditions outlined in the paragraphs below. Bedaquiline can be given to children aged ≥6 years, and delamanid can be given to children from 3 years of age. Regimens that vary substantially from the recommended composition and duration (for example, a standardized shorter MDR-TB regimen lasting 9–12 months in which the injectable agent is replaced by bedaquiline) can be used under operational research conditions.

(1) For MDR- or RR-TB alone or with additional resistance, a longer regimen is more likely to be effective if its composition is guided by reliable information about drug susceptibility. The design of longer regimens for MDR- and RR-TB patients with additional resistance (including XDR-TB) follows a logic similar to that used for other patients with MDR-TB. At a minimum, all MDR-TB patients should be tested for resistance to FQNs before starting MDR-TB treatment. If the shorter regimen is being considered or amikacin is being considered as part of the regimen, then rapid testing for resistance to second-line injectable agents should be performed. Tests for resistance to agents such as bedaquiline, delamanid, linezolid and PZA and for mutation patterns commonly associated with resistance to INH, ETA and prothionamide may help inform the choice of regimen (for example, by excluding the shorter regimen) and its composition. There is no approved rapid test for PZA resistance, and phenotypic DST may be required.
In cases of RR-TB, children and adults whose TB is not resistant to INH should be treated with a recommended MDR-TB regimen, either a longer MDR-TB regimen to which INH is added or for eligible patients, a shorter MDR-TB regimen (see Section 4. Although high-dose INH is not included in the medicines in WHO’s Groups A–C, given the rarity of its use in longer regimens for adults with MDR- or RR-TB, it may still be used in patients with confirmed susceptibility or in the presence of mutations that do not usually confer complete resistance to INH.

WHO’s recommendations on longer MDR-TB regimens apply to children as well as adults. Most medicines that are used in longer regimens have been part of MDR-TB treatment for many years, used in similar combinations, and used in both adults and children. It is recommended that bedaquiline be used in children who are aged ≥6 years and delamanid in children who are ≥3 years.

For extrapulmonary TB, WHO recommends the longer MDR-TB treatment regimen. Adjustments may be required depending upon the specific location of the disease. Treatment of MDR- and RR-TB meningitis is best guided by DST of the infecting strain and by knowledge of the properties of anti-TB medicines that cross the blood–brain barrier. Levofloxacin and moxifloxacin penetrate the CNS well, as do ETA and prothionamide, cycloserine and terizidone, linezolid and imipenem–cilastatin. High-dose INH and PZA can also reach therapeutic levels in the cerebrospinal fluid and may be useful if the strains are susceptible. p-aminosalicylic acid and EMB do not penetrate the CNS well and should not be considered effective agents for MDR-TB meningitis. Amikacin and streptomycin penetrate the CNS only in the presence of meningeal inflammation. There are few data on the CNS penetration of clofazimine, bedaquiline or delamanid.

During pregnancy, amikacin, streptomycin, prothionamide and ETA are usually contraindicated. Following changes made in the 2019 WHO guidelines update, these agents are expected to be used less frequently in longer regimens in the future. Data about the safety of bedaquiline and delamanid during pregnancy and while breastfeeding are sparse. It is recommended that in cases of MDR-TB in pregnant women, a longer regimen should be individualized to include components with a safety profile that is better established. The outcomes of treatment and pregnancy, and postpartum surveillance for congenital anomalies, should be documented to help inform future recommendations for MDR-TB treatment during pregnancy.

For HIV-positive patients, the composition of the treatment regimen for MDR-TB does not usually differ substantially from that for people who are HIV-negative. A few medicine–medicine interactions can be avoided with careful attention (for example, interactions between bedaquiline and efavirenz). Thioacetazone, which is no longer on the list of recommended medicines for TB treatment, should not be given to patients who are HIV-positive or whose HIV status is unknown because of

the risk of Stevens–Johnson syndrome and toxic epidermal necrolysis in people living with HIV. HIV infection needs to be reliably excluded in the rare instances in which thioacetazone is being considered as part of treatment.

The new recommendations signal an important departure from previous approaches to treating MDR- and RR-TB. Regimens comprising only oral medicines should be prioritized and become the preferred option for most patients; injectable agents are no longer among the priority medicines to consider when designing longer MDR-TB regimens.

6.7. Using the standardized shorter regimen to treat multidrug-resistant TB

In patients with MDR- and RR-TB who have not been previously treated for more than 1 month with the second-line medicines used in the shorter MDR-TB regimen or in whom resistance to FQNs and second-line injectable agents have been excluded, a shorter MDR-TB regimen lasting 9–12 months may be used instead of the longer regimens.

Figure 3. Criteria to use when deciding if the shorter regimen to treat multidrug-resistant TB (MDR-TB) may be offered

Are any of the following present:
- Preference of the clinician or patient for a longer MDR-TB regimen;
- Confirmed resistance to or suspected ineffectiveness of a medicine in the shorter MDR-TB regimen (except INH resistance);
- Exposure to one or more second-line medicines in the shorter MDR-TB regimen for >1 month (unless susceptibility to these second-line medicines is confirmed);
- Intolerance to medicines in the shorter MDR-TB regimen or risk of toxicity (for example, due to medicine–medicine interactions);
- Pregnancy;
- Disseminated, meningeal, or central nervous system TB;
- In HIV-positive patients, any extrapulmonary disease;
- One or more medicines in the shorter MDR-TB regimen is not available.

Offer individualized longer MDR-TB regimen

Shorter regimen failure or non-response, drug intolerance, emergence of any other exclusion criterion

Offer standardized shorter MDR-TB regimen

Ideally, strains from patients with MDR- and rifampicin-resistant (RR)-TB should be tested for resistance to fluoroquinolones and other regimen components regardless of the type of MDR-TB treatment regimen offered.
Decisions about starting newly diagnosed patients on the standard shorter MDR-TB regimen should be made according to the patient’s preference and clinical judgement as long as the patients do not have any of the following conditions (see Figure 3):

1. Resistance to or suspected ineffectiveness of a medicine in the shorter MDR-TB regimen (except INH resistance);

2. Exposure to one or more second-line medicines in the regimen for >1 month (unless susceptibility to these second-line medicines is confirmed);

3. Intolerance to any medicine in the shorter MDR-TB regimen or risk of toxicity from a medicine in the shorter regimen (for example, due to medicine–medicine interactions);

4. Pregnancy;

5. Disseminated, meningeal, or CNS TB;

6. In HIV-positive patients, any extrapulmonary disease;

7. Or in cases in which one or more of the medicines in the shorter regimen is not available.
CHAPTER 7

Treatment Monitoring
Specific information about monitoring treatment for DR-TB can be found in Section 8 and Template Form 11.

Treatment monitoring consists of the following key elements:

1. Monitoring adherence to treatment
2. Monitoring side effects
3. Monitoring the treatment’s effectiveness along with other clinical monitoring.

7.1. Monitoring adherence to treatment

Monitoring adherence to treatment is straightforward if the treatment is provided by IOM as DOT or VOT. In scenarios in which IOM is not directly providing treatment, IOM TB Focal Points should review any documentation (such as the TB treatment card, the external treating physician’s report) and interview the patient. In addition to questions requiring yes or no answers, the Focal Point should ask where the treatment was performed, who assisted or reminded the patient to take the medicines, whether there were some days when the patient forgot or did not feel well enough to take the medicines, how frequently the patients neglected to take the medicines, if there were any side effects and how they were managed, how frequently the patient was seen by the doctor, and any other questions that assist in understanding whether there were significant interruptions to the treatment.

7.2. Monitoring side effects

Before treatment starts, patients should be educated about the possible side effects of treatment, requested to report any side effects and be reassured that side effects will be managed appropriately (as outlined in Template Form 8).

The clinical monitoring of side effects is performed by DOT staff at every visit or VOT session. DOT staff should ask patients concrete questions related to possible side effects, such as “Do you have abdominal pain or nausea?”, rather than general questions, such as “Are you feeling OK?” During face-to-face DOT, staff should assess the patient’s general condition and mobility, and look for discolouration of skin and mucosa, rash, fever, disturbance of balance or coordination, muscle weakness and mood disturbance, as well as noting any deviation from the patient’s usual appearance, behaviour and functional status.

A standard chart for the weekly monitoring of side effects is available in Template Form 8. Formal, documented monitoring of side effects is recommended to occur weekly, but it may be undertaken more frequently for persons at higher medical or psychological risk. DOT nurses with frequent patient contact should be alert for any signs of physical or psychological deterioration, even on days when the side effects monitoring card is not being updated.
Any deviations from the patient’s norm should be recorded and immediately reported for further investigation to the TB case manager or Focal Point or any other IOM physician. The patient’s records should clearly reflect actions taken and whether there is a plan for additional monitoring.

Monitoring for side effects should include regular evaluation of the possible psychosocial effects of treatment and the stigma of diagnosis. Psychological counselling and support should be offered to clients in need. Any client with significant psychological symptoms should be referred for further evaluation by a physician or psychiatrist.

Vital signs should be measured and recorded at least once a month or as frequently as indicated clinically.

In addition to a general assessment, patients receiving EMB, linezolid, clofazimine, rifabutin, aminoglycosides or cycloserine should undergo the clinical tests outlined in Table 6.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Clinical test</th>
<th>Person responsible for monitoring; frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethambutol, linezolid,</td>
<td>Visual acuity and colour discrimination</td>
<td>DOT nurse; perform at baseline, then ask patients about changes in vision at every clinic visit; test monthly.</td>
</tr>
<tr>
<td>clofazimine, rifabutin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aminoglycosides</td>
<td>Clinical hearing test, audiogram, vestibular function tests</td>
<td>DOT nurse; perform a baseline audiogram, and then test monthly while on an injectable agent. Ask patients about changes in their hearing at every clinic visit, and evaluate their ability to participate in normal conversation.</td>
</tr>
<tr>
<td>Cycloserine</td>
<td>Mental health assessment</td>
<td>DOT nurse, physician; assess clinically at a baseline and then regularly; refer for a psychiatric evaluation every 2 months or as clinically indicated.</td>
</tr>
<tr>
<td>Any regimen</td>
<td>As required depending on situation</td>
<td>DOT nurse, physician; regularly assess clinically; refer for a psychiatric evaluation as needed.</td>
</tr>
</tbody>
</table>

The results of these tests should be clearly indicated on the monitoring sheets and attached to the patient’s record. Patients receiving treatment from external providers should be encouraged to contact their treating physicians or DOT providers as soon as they notice any side effects.

Laboratory monitoring of side effects should be individualized and based on each patient’s individual risk profile and condition as outlined in Table 7.
### Table 7. Laboratory tests for monitoring the side effects of TB treatment

<table>
<thead>
<tr>
<th>Laboratory test</th>
<th>Indication</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>AST, ALT, bilirubin, alkaline phosphatase</td>
<td>Abnormalities at baseline</td>
<td>As clinically indicated</td>
</tr>
<tr>
<td></td>
<td>Symptoms of hepatotoxicity</td>
<td>As clinically indicated</td>
</tr>
<tr>
<td></td>
<td>Chronic consumption of hepatotoxic substances (for example, alcohol, hepatotoxic medications)</td>
<td>Monthly</td>
</tr>
<tr>
<td></td>
<td>Viral hepatitis or chronic liver disease</td>
<td>Monthly</td>
</tr>
<tr>
<td></td>
<td>HIV-positive patient</td>
<td>Monthly</td>
</tr>
<tr>
<td></td>
<td>Bedaquiline included in regimen</td>
<td>Monthly</td>
</tr>
<tr>
<td></td>
<td>Prior medicine-induced liver toxicity</td>
<td>Monthly</td>
</tr>
<tr>
<td>Platelet count</td>
<td>Abnormalities at baseline</td>
<td>As clinically indicated</td>
</tr>
<tr>
<td>Haemoglobin and white blood cell count</td>
<td>Linezolid</td>
<td>Weekly at first, then monthly or as needed</td>
</tr>
<tr>
<td></td>
<td>HIV-positive patients on zidovudine</td>
<td>Monthly initially, then as needed</td>
</tr>
<tr>
<td>Creatinine</td>
<td>Abnormalities at baseline</td>
<td>As clinically indicated</td>
</tr>
<tr>
<td></td>
<td>Renal failure</td>
<td>Monthly</td>
</tr>
<tr>
<td></td>
<td>Aminoglycosides, capreomycin included in regimen</td>
<td>Monthly; every 1 to 3 weeks in HIV-positive patients, people with diabetes and other high-risk patients</td>
</tr>
<tr>
<td>Serum potassium</td>
<td>Aminoglycosides, capreomycin included in regimen</td>
<td>Monthly; every 1 to 3 weeks in HIV-positive patients, people with diabetes and other high-risk patients</td>
</tr>
<tr>
<td>Serum magnesium and calcium</td>
<td>Hypokalaemia</td>
<td>As clinically indicated</td>
</tr>
<tr>
<td></td>
<td>Prolonged QT interval on ECG</td>
<td>As clinically indicated</td>
</tr>
<tr>
<td></td>
<td>Bedaquiline, delamanid included in regimen</td>
<td>Monthly</td>
</tr>
<tr>
<td>Lipase</td>
<td>Abdominal pain in patients on linezolid, bedaquiline, stavudine, didanosine or zalcitabine</td>
<td>As clinically indicated to rule out pancreatitis</td>
</tr>
<tr>
<td>Lactic acid</td>
<td>Lactic acidosis in patients on linezolid or antiretroviral treatment</td>
<td>As clinically indicated</td>
</tr>
<tr>
<td>Serum glucose</td>
<td>Gatifloxacin&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Monthly</td>
</tr>
<tr>
<td>TSH</td>
<td>Ethionamide or p-aminosalicylic acid</td>
<td>Every 3 months, with clinical monitoring monthly</td>
</tr>
<tr>
<td>ECG</td>
<td>Bedaquiline, delamanid included in regimen</td>
<td>At least 2nd, 12th and 24th weeks of treatment</td>
</tr>
<tr>
<td></td>
<td>Other QT-prolonging drugs (such as moxifloxacin, clofazimine)</td>
<td>Monthly</td>
</tr>
</tbody>
</table>

ALT: alanine aminotransferase; AST: aspartate aminotransferase; ECG: electrocardiogram; TSH: thyroid stimulating hormone.

<sup>a</sup> Oral gatifloxacin has been taken off the market in several countries and should not be prescribed if alternatives are available.
7.3. Monitoring treatment effectiveness

Treatment effectiveness can be assessed based on the following main criteria:

(1) Clinical – a reduction in or disappearance of symptoms and signs, weight gain, improved functional status;
(2) Bacteriological – conversion of smears and cultures from positive to negative;
(3) Radiological – improvement seen on CXR.

Clinical monitoring should be performed monthly by both a nurse and a physician, with observations recorded on a specific form (see Template Form 10), and should include:

(1) Vital signs;
(2) Weight;
(3) Additional clinical and laboratory tests as described above;
(4) Review of symptoms;
(5) Complete physical examination.

Evaluation should occur more frequently for patients:

(1) Aged ≥ 60 years;
(2) With significant underlying chronic disease including, but not limited to,
   (a) HIV positivity;
   (b) Hepatitis B or C;
   (c) Malnourishment;
   (d) Diabetes;
   (e) Renal dysfunction;
(3) Abnormal baseline tests;
(4) Documented side effects of treatment;
(5) Regimens containing second-line agents.

Bacteriological monitoring (Template Form 12) should be conducted in accordance with the TIs of the receiving country. If the TIs do not specify the frequency of follow-up sputum tests, the United States’ TIs should be followed.

The decision about whether to use CXRs for radiological monitoring (Template Form 13) during TB treatment is a clinical one left to the judgement of the treating physician. An end-of-treatment CXR should be performed by all programmes, regardless of drug-susceptibility profile. This is explicitly stated in the US and Australian TIs and should apply
to other receiving country health assessment programmes unless they have been instructed otherwise by the immigration health authorities of the destination country.

Radiological monitoring of treatment for RR- and MDR-TB should include CXRs at 3-month intervals during the first year and then at 6-month intervals during the second year.

Country-specific monitoring should be conducted in accordance with the TIs summarized in Table 8.

Table 8. Country-specific requirements for radiological and bacteriological testing and monitoring of treatment

<table>
<thead>
<tr>
<th>Type of test</th>
<th>Country or area</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>United States</td>
</tr>
<tr>
<td>Radiological</td>
<td>No routine monitoring, but based on clinical decision; however, end-of-treatment CXR required</td>
</tr>
<tr>
<td>Baseline diagnostic</td>
<td>3 specimens for sputum smear and culture, 1/day</td>
</tr>
<tr>
<td>No DST</td>
<td></td>
</tr>
<tr>
<td>Follow up (if culture is negative or contaminated)</td>
<td>Monthly sputum smear and culture for the duration of treatment (2 samples)</td>
</tr>
<tr>
<td>End of treatment</td>
<td>3 sputum smears and cultures</td>
</tr>
</tbody>
</table>
### Drug-susceptible TB

<table>
<thead>
<tr>
<th>Follow up</th>
<th>End of treatment</th>
<th>Sputum smear and culture at months 2 and 4 (3 samples)</th>
<th>These countries do not specify microbiological monitoring of treatment; follow the United States’ guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 monthly sputum cultures until they are negative for 2 consecutive months</td>
<td>None if managed by IOM, BUT 2 sputum smears and cultures if treated elsewhere</td>
<td>None if negative on months 2 and 4, BUT 3 samples if positive at month 2 or 4</td>
<td></td>
</tr>
</tbody>
</table>

### Mono- or poly-DR, excluding RR-TB

<table>
<thead>
<tr>
<th>Follow up</th>
<th>End of treatment</th>
<th>Obtain guidance from the Regional Medical Officer</th>
<th>These countries do not specify microbiological monitoring of treatment; follow the United States’ guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 monthly sputum cultures until they are negative for 2 consecutive months</td>
<td>3 sputum smears and cultures</td>
<td>2 sputum smears and cultures</td>
<td></td>
</tr>
</tbody>
</table>

### RR- and MDR-TB

<table>
<thead>
<tr>
<th>Follow up</th>
<th>End of treatment</th>
<th>Follow the US guidelines</th>
<th>These countries do not specify microbiological monitoring of treatment; follow the United States’ guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 sputum smears and cultures monthly for the duration of treatment</td>
<td>3 sputum smears and cultures</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

CXR: chest X-ray; DR: drug resistant; DST: drug-susceptibility testing; MDR: multidrug resistant; RR: rifampicin resistant;

* When National TB Programmes have specific requirements (such as smear testing at months 5 and 6), panels will also need to abide by local guidelines.

Tools to guide the formulation of a checklist for monitoring TB treatment are available in Template Form 10.
CHAPTER 8

Documentation and Reporting
8.1. Responsibility

The responsibility for managing all TB-related patient records, whether paper or electronic, and the reports and information derived from the data in the records ultimately falls to the IOM physician managing the case, with the assistance of the TB nurse. The TB case manager should oversee the maintenance of these records, giving special attention to the physician’s progress notes and the aim of treatment certification. The TB nurse is responsible for the nursing clinical notes and for entering the results of clinical and laboratory investigations as soon as these are received, with any abnormal result immediately being brought to the attention of the TB case manager. This information must be recorded at the time of consultation or at the point of care. Depending on the mission, other Data Focal Point staff may assist in validating the recorded information. In some missions, the TB nurse or the TB case manager performs the data validation step.

8.2. Documentation

There are two types of records for each patient receiving TB treatment: paper and electronic. These two types of clinical records usually coexist.

1. Paper records: As outlined in Annex 3, paper records (or, as commonly referred to in clinical settings, the patient’s chart) must be maintained by both the TB nurse and the IOM physician managing the case.

   The TB nurse is responsible for collecting and organizing the results of investigations, and completing the treatment adherence and side effect monitoring sheets, consent forms, other monitoring sheets and the nurse’s clinical notes.

   The TB case manager is ultimately responsible for the comprehensive, logical and timely organization of the record and, specifically, for the physician’s progress notes and unambiguously recording clinical orders.

   **If treatment was undertaken by IOM, paper records as outlined in Annex 3 should contain the:**

   (a) Schedule of appointments and plan of routine investigations;
   (b) History and physical examination forms that are specifically required by the receiving country printed out from eMedical or MiMOSA;
   (c) Summary TB patient treatment record;
   (d) Side effects monitoring form;
   (e) TB drug compliance form (for the total course);
   (f) DOT log, containing date and signature or initials, entered daily by DOT staff;
   (g) Sputum smear and culture reports in chronological order, from the date of the first test to the last;
(h) DST report;
(i) Molecular testing report;
(j) Sputum result summary sheet;
(k) CXR result summary sheet;
(l) CXR reports in chronological order;
(m) Blood chemistry and haematology monitoring sheet;
(n) Copies of referral letters and related forms;
(o) Consultants’ reports and results of additional investigations (for example, ultrasound, ECG) in chronological order;
(p) Physician’s progress notes in a chronological order, printed from the TB Treatment and Work-Up Module. The physician’s notes must reflect:
   – Clinical progress (symptoms and complaints, and physical findings, including weight);
   – Radiological progress (comparative review of CXRs);
   – Bacteriological progress (review of sputum tests);
   – Tolerability of treatment, actions taken in case of side effects, and an outcome;
   – Review of follow-up investigations;
   – Review of co-morbidities;
   – Management plan (any changes in a treatment regimen should be accompanied by a narrative);
(q) Nursing notes, including notes about all interactions with the patient, both face to face as well as by phone, chat or video. The records of interactions with the patient should contain the date, time and a brief description of the interaction;
(r) Weight and vital signs monitoring sheet;
(s) For patients on aminoglycosides, the results of visual acuity, colour discrimination and vestibular function tests;
(t) Non-TB medication record;
(u) Counselling form and consent for TB treatment form;
(v) Consent for HIV testing;
(w) Records of the evaluations of household contacts.

Upon completion of treatment and the post-treatment evaluation, the treatment certificate should be printed out and become the first page of the record.
If treatment is undertaken externally, paper records should contain the:

(a) Follow-up plan to be implemented by IOM as outlined in Section 3a, which describes the IOM basic level of care;

(b) History and physical examination forms that are specifically required by the receiving country;

(c) Results of baseline investigations, grouped by type of investigation (for example, sputum tests, imaging, radiological tests, other lab tests); each group of results should be presented in chronological order, from the date of the first test to the last;

(d) Copy of the referral for treatment;

(e) Contact details of the external treating physician, if available;

(f) Reports from the external treating physician, if available;

(g) Copy of the TB treatment card;

(h) IOM Physician’s progress notes;

(i) Results of follow-up investigations (for example, CXR, sputum, laboratory tests) in chronological order;

(j) Physician’s progress notes as described above;

(k) Nurse’s notes, including notes about all interactions with the patient, both face to face as well as those conducted by phone, chat or video. The records of interactions with the patient should contain the date, time and a brief description of the interaction;

(l) Weight and vital signs monitoring sheet;

(m) For patients on aminoglycosides, the results of visual acuity, colour discrimination and vestibular function tests;

(n) Non-TB medication record;

(o) Consent to share information with the external treating physician, if this was separate from the general consent;

(p) Consent for HIV testing;

(q) Records of the evaluations of household contacts.

Upon completion of treatment and the post-treatment evaluation, the treatment certificate should be printed out and become the first page of the record.

(2) Electronic records: Digital copies of entries in the paper records of information that is relevant to TB management must be maintained in the MIMOSA TB Treatment Work-Up Module or eMedical system, depending on the data management procedure initially set forth by HAP. When results are not available in an electronic version,
missions should supplement with scanned copies of the paper records listed in the preceding part of this section. There is a plan to develop an IOM TB information system that will capture and consolidate both electronic and paper patient records.

8.3. Data entry procedure

Refer to Annex 5 in this manual (MiMOSA Guide for MHD Users) for instruction on using the MiMOSA TB Treatment Work-Up Module.

8.4. Data validation and IOM internal reporting

Each mission should ensure the timeliness and accuracy of recorded patient data. In MiMOSA, mandatory fields provide automatic checks to ensure data quality, and the file cannot be completed until they these data are entered. When applicable, MiMOSA will display a prompt or will not allow a user to proceed when data are missing or incorrect. In addition, Data Focal Points (who may be the nurse or the doctor) are mainly responsible for capturing data, correcting errors and following up with TB nurses and TB case managers to make any necessary adjustments to the data record if warranted.

Web-based tools for visualizing and reporting data, such as Microsoft Power BI, are available to aid in checking for internal consistency and internal reporting. Examples of Microsoft Power BI data validation reports include those for active TB and TB indicators. The Active TB Report mainly displays the relevant TB information for active TB cases; this information can be further stratified by the year, mission or HAP, among other variables. The TB Indicators Report, based on those required by the CDC, primarily presents information about the different TB indicators but covers all HAPs. These reports are interactive, so it is possible to create additional reports based on the data. Screen captures of these reports are shown in Figure 4 below.

Figure 4. Screen shots of the Active TB Report and the TB Indicators Report generated using Microsoft Power BI
8.5. Reporting obligations

Reports may be required regularly or on an ad hoc basis, and they are required internally to monitor programmes or assess outcomes (see Section 10d). Embassies from receiving countries may also require reports as part of an agreement or reports may be required as part of the annual global reporting by IOM. Other external reports may be mandated by the NTP.

In summary, IOM has different reporting responsibilities.

(1) At the national level, this may include country TB registry reports (referred to as NTP data reports).

(2) At the global or IOM level, this includes the CDC TB Indicator Report for US cases, the IOM Annual Report, and IOM fiscal year reports.

(3) Other reports may be requested on an ad hoc basis.
CHAPTER 9

Treatment completion and certification
Chapter 9. Treatment Completion and Certification

9.1. Treatment outcomes

Treatment outcome information should be provided for all patients with bacteriologically confirmed and clinically diagnosed drug-susceptible TB; they should be assigned an outcome from the list below. Patients with RR-TB or MDR- or XDR-TB, who are placed on a second-line drug regimen cannot be given a definitive cure and as such are defined in 2–6 below.

The outcome definitions are as follows.

(1) Cured: This describes a patient with pulmonary TB whose disease was bacteriologically confirmed at the beginning of treatment and who was smear negative or culture negative during the last month of treatment and on at least one previous occasion; patients in this category have had 130–182 doses of anti-TB medicines.

(2) Treatment completed: Patients in this category have completed treatment without evidence of failure BUT without records of negative results on sputum smear or culture during the last month of treatment and on at least one previous occasion, either because the tests were not done or because the results are unavailable. This definition also includes patients with pulmonary TB who did not have bacteriologically confirmed TB at the beginning of treatment (that is, they had a clinical diagnosis) and have completed the prescribed course of treatment without any evidence of failure.

(3) Treatment failed: This category is for TB patients whose sputum smear or culture results are positive at month 5 (that is, at end of month 4) or later during treatment.

(4) Died: This category includes TB patients who die for any reason before starting or during the course of treatment.

(5) Loss to follow up: Patients in this category either did not start treatment or had a treatment interruption lasting for 2 consecutive months or longer.

(6) Not evaluated: Use this category for TB patients for whom no treatment outcome is assigned. This includes cases that transferred out to another treatment unit, as well as cases for whom the treatment outcome is unknown to the reporting unit.

(7) Treatment success: This includes all patients in the categories cured and treatment completed.

Treatment is defined as complete when the total number of doses has been administered (and observed, for DOT), rather than when a defined period of time has elapsed.

The 2HREZ/4HR regimen translates to a range of 130 (5 days/week) to 182 (7 days/week) doses of INH and RIF and 40 to 56 doses of PZA and EMB. If these are administered daily, the course of treatment lasts 6 months. The 5 day/week regimen is accepted as effective in the ATS–CDC–IDSA clinical practice guideline on the treatment of drug-susceptible
TB, which is referenced in the United States’ TIs. Australia and Canada also refer to the 5 day/week regimen as acceptable. Therefore, allowing for DOT 5 days/week leads to an acceptable regimen that includes 130 doses. Where these guidelines are not recognized by the NTP and the NTP requires treatment 7 days/week, the total number of necessary doses is 182. IOM should aim to directly observe these doses at least 5 days/week, if possible.

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

9.2. Certification

Where treatment is undertaken by IOM and upon completion of treatment (or as close as possible to the patient receiving their last dose of treatment), the TB case manager must:

1. Clinically review the patient;
2. Obtain three sputum samples for AFB smear and culture (except for Australia-bound cases for whom this is required only at the end of treatment if the client is not managed by IOM);
3. Obtain a post-treatment CXR and compare it with previous films;
4. Complete the TB Treatment and Work-Up Module in MiMOSA:
   a. Finalize all forms;
   b. Assign an outcome and TB treatment end date;
   c. Print summary reports;
5. Forward the treatment certificate and summary forms from the treatment module to the receiving country, along with any other specific information outlined by the receiving country. The template for the standard treatment certificate appears in Template Form 14.
6. Change the MiMOSA TB treatment hold status to “complete.”

Where treatment is undertaken externally and upon receipt of the treatment completion certificate from an external provider, the TB case manager must:

1. Review doses of the anti-TB agents and results of sputum smear and culture tests;
2. Arrange for post-treatment sputum collection, if this has not already occurred;

(3) Arrange for a post-treatment CXR, if this has not already been done;
(4) Review the series of CXRs;
(5) Clinically review the patient if concerns arise about X-ray stability or sputum results;
(6) Change the patient’s status in MiMOSA from TB treatment hold to “complete”;
(7) Forward the treatment certificate and follow-up test results to the receiving country.
CHAPTER 10

Psychosocial management
Providing a timely range of psychological support services can prevent cases from being lost to follow up, increases the number of patients who complete treatment and, indirectly, reduces the incidence of TB disease. Paying insufficient attention to the psychological and social aspects of TB has a negative impact on the entire process of diagnosis and treatment. This section discusses the main points that staff should address and monitor when counselling clients and their families about TB and its treatment.

### 10.1. Background

A diagnosis of TB carries with it a risk of negative psychosocial responses related to fears about the condition, the impact it may have on perceptions of the client by others, the effects it may have on resettlement and the difficulties that treatment may present. Addressing the psychosocial impacts of TB diagnosis and treatment is an important part of TB management.

In particular, clients may be concerned that:

1. Their health is at risk;
2. The health of their family is at risk;
3. TB disease and its treatment may have an effect on pregnancy;
4. Their productivity or livelihood may be compromised;
5. They may be perceived negatively by others;
6. Travel to their receiving country may be delayed;
7. They and their family may be rejected by the receiving country;
8. They may be separated from their family;
9. They may suffer adverse effects from treatment.

A diagnosis of TB can be particularly hard to accept for persons who are asymptomatic and have no known prior contact with someone with TB. It is commonly perceived that people with TB become sick, so those who are not sick may resist the diagnosis. TB is also associated with being in a lower socioeconomic group, meaning that diagnosis may be further resisted in people who are from higher socioeconomic strata.

Isolation carries a further risk of negative psychosocial impacts, given that it removes people from their family and social supports, deprives them of freedom, and overtly signifies that they are a danger to others. Isolation should be maintained only for as long as infection control requirements demand. Requirements for psychosocial support for those in isolation, and in particular those with MDR-TB, are substantially greater than for those with drug-susceptible disease.
10.2. Psychosocial support

(1) At diagnosis, counselling should be provided to all persons identified as required TB treatment as described in Section 5a. It should be explained that a diagnosis of TB may lead to a travel delay, but it will not lead to rejection by the receiving country. A family member or friend should be identified to assist and support the patient during treatment and watch for physical or psychological deterioration. Positive health activities should be promoted, for example, by encouraging the client to improve their nutrition and diet, cease smoking or address substance abuse.

The psychological response to the need for treatment should be documented by the counsellor who could be an IOM physician or nurse. Any client with significant negative responses that are beyond the ability of the counsellor to address should be brought to the attention of a supervisor or physician. Any person with known psychological or psychiatric issues should also be brought to their attention, and psychiatric evaluation should be arranged.

Any person requiring isolation should have the need for this clearly explained, and reassurance should be given that it is only a temporary measure. When isolation is not available, it is important to enlist support from family members or a guardian, friends, community-based organizations or NGOs, or some combination of these; this support should be discussed with the patient. In all cases, ways in which patients can reduce the risk of infecting family members and other visitors should be explained as discussed in Section 4e.

(2) During treatment, DOT providers (nurses or trained health-care workers) should look for any signs of physical or psychological deterioration at any point during care. Brief questioning regarding a patient’s psychological status should be part of daily monitoring of side effects. Any signs of psychological deterioration or psychiatric symptoms should be promptly brought to the attention of a supervisor or physician. Monthly physician review should include an evaluation of the patient’s mental state.

Patients should be able to attend counselling weekly if they wish to utilize it. Counselling should address patients’ thoughts and feelings about their TB diagnosis and treatment, perceptions of stigma, and factors that may affect their adherence to treatment. Non-IOM providers of psychosocial support, such as NGO staff in camps, should be enlisted to contribute to collaborative care if possible. Home visits may assist in providing holistic care where feasible.

Patients with MDR-TB or in prolonged isolation for other reasons must be monitored closely, given their higher risk of negative psychosocial outcomes. This is additionally important with patients taking cycloserine, for which depression and psychosis are known potential side effects. All patients in isolation should be reviewed by a physician at least weekly. Isolation should be discontinued as soon as public health management needs allow, and it should not be prolonged for other reasons.
Diversionary activities should be provided as much as possible to patients who are in prolonged isolation, and family visits should be managed to ensure ongoing contact without unnecessary risks of cross-infection. Patients in prolonged isolation should be encouraged to help support one another throughout the treatment process.

Multidisciplinary staff meetings regarding TB cases should occur monthly, and they should include nurses, the psychosocial support team, the psychiatrist, TB Focal Points, PPs and support staff, as necessary. Overall patient care, including care for other relevant medical conditions, should be discussed during these meetings, and reviews of the patient’s mental state, psychosocial management and consideration of relevant family members should also be included. The importance of team effort, information sharing and coordination among staff caring for TB patients should be continually highlighted.

The CMHO should ensure that psychiatric input is available for clients who require it. If difficulties in obtaining psychiatric support are encountered, the Regional Health Assessment Programme Coordinator should be contacted to ascertain possibilities for support.

Emphasis should be put on increasing the capacity of staff to monitor a patient’s overall condition, including being able to recognize mental changes and warning signs. Staff should understand the need to listen and respond to individual patients rather than limiting interactions purely to providing medical information.

(3) Some specific circumstances and co-morbidities may require specialized counselling.

(a) Patients co-infected with HIV and TB face many stressors, including overlapping side effects from their medicines, medicine-medicine interactions, taking a high number of pills, the risk of IRIS, and issues of stigma and fear. It is critically important to work closely with the caregiver who is treating the patient for HIV to ensure appropriate treatment of both HIV and TB. The patient’s cooperation and consent for sharing information should be sought during counselling. The patient with TB–HIV co-infection will need regular, ongoing support and counselling. It is important to check what patients have understood about their co-infection and encourage them to ask questions.

(b) Some TB patients are at a higher risk for substance abuse and mental health issues. Substance abuse treatment programmes are important partners for TB clinics and providers. Similarly, the treatment of mental health disease is paramount in ensuring that patients adhere to TB therapy.

Closely monitor a patients’ success in addressing substance abuse issues or their relapse during TB treatment in order to anticipate toxicity and to avoid adherence complications. Facilitate referrals to programmes and services that can work with the patient on harm reduction. Even patients without underlying mental health issues will need significant mental health support and monitoring.
during the long and arduous treatment, especially during treatment for MDR-TB. Monitor patients for symptoms of mental health issues or substance abuse, and provide support and referral as needed.

(c) One of the major obstacles to completing TB treatment is patients’ non-adherence to the treatment regimen, which results in prolonged disease transmission and the development of resistance to the anti-TB agents. Psychological counselling improves adherence to treatment, the likelihood of successful treatment of the disease, and results in lower rates of treatment failure and loss to follow up.

The factors that increase the risk of treatment default are:

- Economic hardship due to loss of work, interruption in schooling and stigma;
- Lack of support from family or other relatives;
- Social or family duties and constraints;
- Lack of education;
- Alcohol and substance abuse;
- Co-morbidity with multiple medical conditions;
- Side effects of medications;
- Poor patient–provider relationship.

Most patients need frequent, ongoing psychosocial support to cope with these challenges. The case manager should address the potential barriers to adherence and ensure that the patient can access psychological support to express their difficulties. The case manager should provide emotional and social support by listening to and talking with the patient and their family to reduce stigma, fear, concern and misunderstandings about the disease; the case manager should also try to engage family members in the patient’s care and encourage and praise their support of the treatment plan. The patient’s social support network should be accessed and issues such as mental illness and substance abuse should be addressed; IOM staff should consider asking for support from community-based organizations, NGOs and drug and alcohol rehabilitation centres.

The development of a trusting relationship between case managers and their patients plays a key role in successfully assisting patients with these challenges.

Any patient whose non-adherence to the treatment plan is beyond the ability of the counsellor should be brought to the attention of a supervisor or physician.
CHAPTER 11

TB Infection Prevention and Control
IPC refers to the interventions required to prevent the transmission of microorganisms from infected or colonized patients to other patients, health-care workers and the public.

WHO’s guidelines on TB IPC contain recommendations for specific administrative and environmental controls, and respiratory protection measures. Moreover, these guidelines focus on interventions specific to preventing the transmission of MTB, bringing the core components of IPC to the national and acute health-care facility levels.23

IPC occurs through implementation of an integrated package of interventions. A combination of administrative controls, environmental controls and respiratory protection measures must be used to reduce the transmission of TB in health-care facilities; these controls include the use of personal protective equipment (PPE). A summary of these measures is outlined in Table 9.

Table 9. Infection control measures for health-care facilities and clinics

<table>
<thead>
<tr>
<th>Type of measure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative</td>
<td>• Promptly identify people with TB symptoms (triage).</td>
</tr>
<tr>
<td></td>
<td>• Separate infectious patients from non-infectious patients.</td>
</tr>
<tr>
<td></td>
<td>• Control the spread of pathogens (use cough etiquette and respiratory hygiene measures).</td>
</tr>
<tr>
<td></td>
<td>• Minimize the time that TB patients or patients suspected of having TB spend in health-care facilities.</td>
</tr>
<tr>
<td></td>
<td>• Provide a package of prevention and care interventions for health workers, including HIV prevention, and antiretroviral therapy and isoniazid preventive therapy for HIV-positive health workers.</td>
</tr>
<tr>
<td></td>
<td>• Implement additional administrative controls, such as reducing diagnostic delays and using the Xpert MTB/RIF assay for sputum-positive and symptomatic patients.</td>
</tr>
<tr>
<td></td>
<td>• Initiate prompt treatment or refer for treatment.</td>
</tr>
<tr>
<td></td>
<td>• Perform contact tracing as required.</td>
</tr>
<tr>
<td>Environmental</td>
<td>• Use ventilation systems, either or both natural or mechanical ventilation.</td>
</tr>
<tr>
<td></td>
<td>• Use upper-room or shielded germicidal ultraviolet light fixtures.</td>
</tr>
<tr>
<td>Personal protective equipment</td>
<td>• Use particulate respirators:</td>
</tr>
<tr>
<td></td>
<td>– N95 masks for health-care workers and</td>
</tr>
<tr>
<td></td>
<td>– Surgical masks for infectious or potentially infectious TB patients.</td>
</tr>
<tr>
<td></td>
<td>• Train staff to use personal protective equipment.</td>
</tr>
<tr>
<td></td>
<td>• Ensure that cough etiquette is used.</td>
</tr>
<tr>
<td></td>
<td>• Implement behaviour-change training for staff and educational material for clients.</td>
</tr>
</tbody>
</table>

General infection control efforts include the standard precautions (that is, cough etiquette, hand and respiratory hygiene, and the use of PPE) that should apply to all health-care facilities, as well as core interventions specifically used for health systems treating patients with TB and HIV.24


Efforts to control airborne infection include considering the placement of patients, the use of adequately ventilated areas to treat patients and the use of particulate respirators; these precautions apply to all health-care facilities that care for patients with, or who are suspected of having, airborne infections. These precautions are important because MTB is spread almost exclusively through droplet nuclei via the air.

11.1. Administrative infection control measures

A set of administrative controls is the first and most important component of any IPC strategy. These key measures comprise specific interventions aimed at reducing exposure and, therefore, reducing transmission of MTB. They include systems for triage and patient separation (that is, managing patient flow through the facility to promptly identify and separate presumptive TB cases), prompt initiation of effective treatment and implementing respiratory hygiene measures.

1. Triage of people with TB signs and symptoms or with TB disease is recommended to reduce MTB transmission to health workers, including community health workers, other persons attending health-care facilities and persons in other settings where there is a high risk of transmission.

2. Respiratory separation or isolation of people with presumed or demonstrated infectious TB is recommended to reduce MTB transmission to health workers or other persons attending health-care facilities. These people should be routed away from general client flow areas, and they should never be crowded into areas such as hallways or waiting rooms with other people who have not been determined to be at risk of having active TB (that is, non-infectious persons). Sputum collection should occur in a segregated area, as should DOT.

3. The prompt initiation of effective TB treatment for people with TB disease is recommended to reduce MTB transmission to health workers, other persons attending health-care facilities and persons in other settings where there is a high risk of transmission. Prompt initiation of DOT is an important infection control measure as it reduces the duration of infectivity of a case. The designated infection control officer should maintain or supervise the maintenance of a log of all cases of suspected TB, referrals and sputum smear results so that all infectious or potentially infectious patients are tracked. A tracking system to measure the time patients spend within the facility and the time before DOT commences should also be in place and monitored by the infection control officer.

4. Respiratory hygiene (including cough etiquette) in people with presumed or confirmed TB is recommended to reduce MTB transmission to health workers, other persons attending health-care facilities and persons in other settings where there is a high risk of transmission.

of transmission. All patients who are known or suspected to be infectious (including those for whom there is high suspicion on the basis of X-ray results prior to sputum collection) should be provided with surgical masks, shown how to correctly fit these and educated about the importance of wearing masks until they become non-infectious.

(5) Educational material on TB infection control measures should be available for all staff and patients, with signs in appropriate languages to inform people of the need for these measures. Information about cough etiquette should be displayed, along with tissues and masks for people who are coughing. Clients should be routinely asked about cough on entering the facility. Clients who are coughing should be provided with masks, separated from general client flows and prioritized for medical attention.

(6) All TB patients and their support person should be educated about transmission and methods for preventing it. All relevant staff should be trained in TB infection control and understand the mechanisms of transmission and prevention. Each site should designate an infection control staff member or group to oversee infection control measures.

11.2. Environmental infection control measures

Three principles can be used to reduced the risk of airborne transmission of MTB: dilution, filtration and disinfection. Environmental controls are aimed at reducing the concentration of infectious droplet nuclei in the air. This is achieved by using special ventilation systems to maximize airflow rates or filtration, or by using GUV systems to disinfect the air. Ventilation systems can also be used to control the direction of airflow to reduce the spread of infection, for example, through the use of exhaust fans to generate negative pressure gradients. Environmental controls are used in combination with other IPC measures to help prevent the spread of MTB.

(1) Upper-room GUV systems are recommended to reduce transmission to health workers, other persons attending health-care facilities and persons in other settings where there is a high risk of transmission.

(2) Ventilation systems (including natural, mixed-mode and mechanical ventilation, and air recirculated through high-efficiency particulate air, or HEPA, filters) are recommended to reduce transmission to health workers, other persons attending health-care facilities and persons in other settings where there is a high risk of transmission.

Two basic principles govern infection prevention by ventilation:

(a) Air exchange (or air change) refers to the replacement of contaminated air by clean air.

(a) Air mixing refers to the equal distribution of contaminated air and clean air within a space so that the overall concentration of infectious particles is reduced.
TB laboratories have sophisticated ventilation systems that produce constant air change based on negative pressure within the lab. These systems are also utilized in sputum collection booths, but they are not feasible for use in general areas.

An ideal ventilation arrangement for such areas has components of both exchange and mixing and uses natural or low-tech solutions. Outdoor settings or rooms that open to the outdoors allow air exchange to occur naturally, with air mixing also occurring naturally if a breeze is present. Signs should be in place to prevent people from inadvertently closing doors or windows that need to be open for ventilation.

Mechanical devices, such as standing electrical fans, can be used to ensure air mixing in environments where the air is still, and extractor fans can increase air exchange.

Ideally, air flow should be directed from areas of low concentration of infectious particles to areas of high concentration. Where possible, staff should position themselves upwind from patients when working.

1. To correctly dispose of waste, all contaminated materials from persons with presumptive TB or from TB patients must be immediately placed into clearly marked containers that have biohazard signage. This includes used tissues, face masks and cups used for rinsing prior to sputum collection. This waste must be incinerated either onsite or offsite by a waste contractor. If incineration occurs offsite, the designated infection control officer should inspect the site and review the disposal process at least once yearly. All areas where TB patients or presumptive patients are seen must be equipped with visual aids or posters showing proper waste disposal techniques that reflect country-specific sanitary and epidemiological standards.

11.3. Respiratory protection measures

Respiratory protection controls are designed to further reduce health workers’ risk of exposure to MTB and other airborne pathogens.

1. Particulate respirators should be used together with administrative and environmental controls in circumstances in which there are increased risks of transmission.

2. Staff working with infectious patients should wear N95 or equivalent masks at all times while in areas of potential exposure. Staff should be instructed how to correctly fit their mask and should not have facial hair that might compromise the mask’s fit. Masks should be replaced at least every 2 weeks or immediately if they become wet or damaged.

3. Gloves should be worn by staff handling infectious or potentially infectious materials, including used tissues or face masks.

4. Staff exposed to infectious or potentially infectious patients should have access to regular evaluations for TB exposure (at least yearly), and a log should be kept by the occupational health unit of any TB cases that arise among staff.
11.4. Measures for congregate settings

Congregate settings include places such as transit centres, refugee camps and other waiting areas.

(1) Managerial activities that can be taken in congregate setting include avoiding overcrowding as it leads to non-infected individuals becoming infected with TB. IPC strategies should be put in place in all congregate areas and should be part of IOM surveillance activities. Monitoring and evaluating IPC measures in congregate settings should be performed regularly, and appropriate actions should be taken to ensure that the general principles of IPC are followed. Education material on controlling the spread of TB infection should be available to all staff and clients. All staff should be given appropriate information and encouraged to undergo annual testing for TB. Each site should designate an infection control staff member or group to oversee infection control measures.

(2) Environmental controls in congregate settings include ensuring that waiting areas and transit centres comply with WHO and national norms and regulations for the ventilation of public buildings.\(^2\) The use of GUV irradiation can be considered.

(3) Respiratory protection in congregate settings includes implementing surveillance for infectious conditions in transit centres. Basic IPC controls should be applied. The same recommendations for personal infection controls apply as are used in health-care facilities.

---

Annex 1. Global Drug Facility Process

The Global Drug Facility (GDF; www.stoptb.org/gdf/) operates a unique pool procurement system that responds to the main barriers to accessing quality-assured TB medicines access by ensuring:

- Quality control – providing quality-assured products that meet WHO’s stringent standards;
- Standardization – providing blister packs for individual patients for easy administration;
- Pool procurement – offering rapid medicine delivery;
- Transparency – using web-based tracking for orders;
- Procurement and supply management – offering in-country technical support on medicine management, registration and supply issues.

The GDF has also developed a simple and quick application process. Both governments and non-governmental organizations in collaboration with their respective ministries of health are able to apply for GDF assistance. Countries simply complete an application that includes information on the anti-TB medicines needed, the National TB Programme’s strategy and a description of management of the procurement and supply chain processes.

The direct procurement service enables clients to use their own resources to procure quality-assured anti-TB medicines and diagnostic equipment through a reliable procurement agent at prices that will result in considerable savings.

Placing an order

Follow these steps to ensure timely processing of your order:

1. Complete the Procurement Request Form for Medicines (www.stoptb.org/gdf/drugsupply/procurement_forms.asp) and provide a document showing how the needed medicines were quantified (e.g. by providing the QuanTB file).

2. Send the completed Procurement Request Form and all attachments to the GDF Country Supply Officer responsible for your country. For a list of Country Supply Officers, contact gdf@stoptb.org or visit the Stop TB Partnership’s secretariat page (www.stoptb.org/about/secretariat.asp).

3. Your Country Supply Officer will provide you with a price quotation.

4. Sign the price quotation and send a scanned copy back to your Country Supply Officer.
(5) Transfer the necessary funds to the account indicated on the price quotation. Your order will then be placed with the suppliers.

(6) Once your products are ready for shipment and quality control has been carried out, you will receive an Authorization Request for shipment.

(7) Review and verify the shipping documents provided with the Authorization Request and confirm your readiness to receive the shipment.

(8) Delivery is arranged according to the agreed-upon Incoterm.

Standard lead times from final order placement (i.e. step 5) to delivery vary from 4 to 6 months. This lead time comprises production, quality control, preshipment inspection, internal processing and transport to the destination.
## Annex 2. Individual Staff Roles and Responsibilities for Managing TB for IOM Clients

<table>
<thead>
<tr>
<th>Primary responsibility</th>
<th>A. Panel physician</th>
<th>B. DOT healthcare worker</th>
<th>C. TB nurse</th>
<th>D. TB panel physician</th>
<th>E. Administrator</th>
<th>F. Lab technician</th>
<th>G. Chief Migration Health Officer</th>
<th>H. Regional TB Focal Point</th>
<th>I. Data management</th>
<th>J. Regional Health Assessment Programme Coordinator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IME and review</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB diagnosis</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Referral for TB care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB medical reviews</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB case escalation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>final IME</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case submission</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Notification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NTP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Receiving country</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Client</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Appointments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Monthly tests and follow up</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ordering</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Clinical review of results</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Updating patient record</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Side effect monitoring</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMOSA and other documentation and reports</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grading and classification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>TB hold</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>TB Treatment Work-Up Module</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Updating patient record</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Finalization trigger</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>TB finalization</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>LIMS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Primary responsibility</td>
<td>A. Panel physician</td>
<td>B. DOT healthcare worker</td>
<td>C. TB nurse</td>
<td>D. TB panel physician</td>
<td>E. Administrator</td>
<td>F. Lab technician</td>
<td>G. Chief Migration Health Officer</td>
<td>H. Regional TB Focal Point</td>
<td>I. Data management</td>
<td>J. Regional Health Assessment Programme Coordinator</td>
</tr>
<tr>
<td>-------------------------------------------------------------</td>
<td>--------------------</td>
<td>--------------------------</td>
<td>-------------</td>
<td>-----------------------</td>
<td>-----------------</td>
<td>------------------</td>
<td>-------------------------------</td>
<td>--------------------------</td>
<td>------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>TB SOPs and similar</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>TB indicators</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Monthly NTP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Medication and supplies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Prescriptions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preparation</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Administration (DOT)</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Updating patient record</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicine procurement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stock-keeping</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLV light</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PPE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IEC materials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB certification</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Determination of treatment completion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>File review</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Certificate of completion</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Counselling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Initial on diagnosis</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ongoing and reinforcement</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Specific support for continuing treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Educational materials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Failure to attend</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Patient contact</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Appointments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Scheduling</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Failure to attend</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitoring</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Country-level checklists (every 6 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Regional checklist (annual)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Primary responsibility</td>
<td>A. Panel physician</td>
<td>B. DOT healthcare worker</td>
<td>C. TB nurse</td>
<td>D. TB panel physician</td>
<td>E. Administrator</td>
<td>F. Lab technician</td>
<td>G. Chief Migration Health Officer</td>
<td>H. Regional TB Focal Point</td>
<td>I. Data management</td>
<td>J. Regional Health Assessment Programme Coordinator</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------</td>
<td>-------------------------</td>
<td>------------</td>
<td>----------------------</td>
<td>-----------------</td>
<td>-----------------</td>
<td>---------------------------</td>
<td>------------------------</td>
<td>-----------------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Annual report to SHQC</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Capacity-building</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>NTP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Webinars</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

DOT: directly observed therapy; IEC: information, education and communication; GUV: germicidal ultraviolet; IME: immigration medical examination; LIMS: Laboratory Information Management System; NTP: National Tuberculosis Programme; PPE: personal protective equipment; SOPs: standard operating procedures; SHQC: Senior Health Quality Coordinator.

* The roles of the PP and the TB PP may be done by the same person.
Annex 3. TB Flow Process Schematic

Staff codes
A: panel physician (general); B: DOT health worker; C: TB nurse; D: TB panel physician; E: customer care/administration; F: lab technician; G: Chief Migration Health Officer (CMHO); H: regional TB focal point (RFP); I: data staff; J: regional Health Assessment Programme (HAP) coordinator (RHAPC).

Abbreviations
CDC: Centers for Disease Control and Prevention (United States); CXR: chest X-ray; DOT: directly observed therapy; DST: drug-susceptibility testing; FP: Focal Point; GDF: Global Drug Facility; GPSU: Global Procurement Support Unit; GS: Global Software; IEC: information, education and communication; IME: immigration medical examination; LIMS: Laboratory Information Management System; LTBI: latent tuberculosis infection; MAC: Manila Administration Centre; MDR-TB: multidrug-resistant TB; MOU: memorandum of understanding; NGO: non-governmental organization; NTP: National Tuberculosis Programme; PE: physical examination; PP: panel physician; PPE: personal protective equipment; Rx: prescription; S/C: smear/culture; S/E: side effect; SOP: standard operating procedure; SHQC: Senior Health Quality Coordinator; TBFP: TB Focal Point; TI: technical instructions; GUV: germicidal UV light; WHO: World Health Organization.
**PRE-TREATMENT**

1. **Order and write lab request for baseline tests**
2. **Vital signs taken**
3. **History review, PE and entry form populated with prescribed regimen and doses**
4. **TB medicine treatment package retrieved from storage cabinet**
5. **Package labelled with patient ID and photo**
6. **Enrols for nutritional and transport support if required**
7. **Assign and start using TB treatment module in MiMOSA**
8. **Assessment of isolation need**
   - Those requiring special support
   - MDR-TB (if required by NTP)
9. **Fill in Patient TB record card and commence Day 1 DOT**
10. **Hospitalization if required**

- **Separate process**

- **If applicable – register and pay for TB-related costs**
PRE-TREATMENT

Fill in Patient TB record card and commence Day 1 DOT C, B

DOT requires:
- Facial recognition
- Check medicines for expiry date
- Prepare medicines as per regimen
- Give medicines and observe swallowed C, B

Notify embassy, NTP, external PP as required D

Schedule next day appointment C

Attended?

Yes

Call the patient
Call support
Visit patient C

Daily process
- DOT compliance
- Side effect assessment
- Health education C, B

No

Cannot locate

Reassure and review by physician C

S/Es present?

Yes

Mild

Moderate

Severe

Requires further management

Manageable

Resolve/adjust treatment

Treatment interruption, specialist consultation, possible regimen change C

MONTH 1 REVIEW C, D

Monthly review requires:
- Repeat sputum exam as applicable (S/C)
- Vital signs, weight
- Physical examination
- Counselling and education C, D

c) As required:
- Modify regimen
- Additional baseline tests (MDR-TB)
- Notify external panel (if needed)
- Update MiMOSA D

b) DAY 15 – Review DST results
Revise regimen if required D

a) DAY 5 – Review baseline results
Revise regimen if required D

Notify embassy, NTP, external PP as required D

Call the patient
Call support
Visit patient C

S/Es present?

No

Continue DOT C

a) As required:
- Modify regimen
- Additional baseline tests (MDR-TB)
- Notify external panel (if needed)
- Update MiMOSA D
Key messages
- CXR during treatment is undertaken only if clinically indicated
- The number of sputum samples to be collected will be guided by each country’s TIs
- Sputum collection will end as determined by each country’s TI requirements
- The monthly review remarks and conclusion must address:
  - Clinical progress
  - Weight
  - Bacteriological data
  - Tolerability of treatment/side effects
  - Any co-morbidities
  - Future plan
**FINAL ASSESSMENT**

**MONTH 6 REVIEW C, D**
- Medical history
- Physical exam
- CXR
- Refer for sputum tests D

**Refer for sputum tests D**

**Sputum test scheduled C**

**Chase and provide counselling C**

**Discharge from TB treatment if there are concerns that suggest treatment failure C**

**Review of results D**

- For United States and United Kingdom cases, triggers repeat health assessment (IME)
- Appointment made for panel physician C
- PP undertakes IME
- Puts client on hold awaiting cultures A

**Post-treatment review C**

- Does not attend?

**Sputum test scheduled C**

**Chase and provide counselling C**

**Discharge from TB treatment if there are concerns that suggest treatment failure C**

**For Australia, if smear negative provide clearance, although if S/C performed must wait for results before clearing C**

---

**If patient treated externally – contact for appointment C**
COMPLETION AND CERTIFICATION

PKTB
Print certificate from GS A

eMedical – upload and send all documents D, C

MiMOSA – finalize treatment module and outcome; update medical status to completed D

Notify patient results are ready and schedule appointment C

Culture negative?

Culture positive?

Re-evaluate with PE and further investigation D

Update MiMOSA D

Recommence process D

See slide 2 and re-treat if confirmed failure

Complete TB record, and finalize forms and treatment completion certificate D

Print certificate from GS A

Print and sign certificate and required forms C, D

Give copy of signed certificate to patient, and upload to IME C

Transmit completed IME and TB treatment for United States cases I

Move to slide 2 and complete certification

UKTB and MiMOSA – finalize treatment module and outcome; update medical status to completed D

Print certificate from GS A

MiMOSA – finalize treatment module and outcome; update medical status to completed D

Print and sign certificate and required forms C, D

Give copy of signed certificate to patient, and upload to IME C

Transmit completed IME and TB treatment for United States cases I
### Programme Support

#### Country Level
- **Checklist twice annually**
- **Report to CMHO, RFP**

#### Regional Level
- **Checklist annually**

#### Review and feedback
- **Report to SHQC**

#### Medication
- **NTP** (weekly/monthly)
- **Market – single dose**
- **Need to ensure quality (GDF, WHO, and others)**

#### Training
- **All staff involved** (nurse, doctor, DOT, lab, others)
- **NTP**
- **Address rotation and new staff**
- **Regular by TBFPs**
- **Annually RFP**

#### Knowledge Management
- **TB guidelines** (e.g. WHO)
- **TB SOPs** (global)
- **TB TIs**

#### Data Management
- **Source** – MIMOSA, LIMS
- **Person** – Country TB admin, MAC, Lab admin

#### Expert Advice
- **Focal nurse**
- **Focal doctor**
- **DOT personnel**

#### Equipment
- **GVU (regular check)**
- **Room ventilation (engineer)**
- **PPE**
- **IEC materials**

#### Mediation
- **Contact**
- **Market (WHO)**
- **NGOs**
- **Other Missions**
- **GPSU**
- **Managed by CMHO, RFP, RHAPC**

#### Communication and information

#### Contingency planning

#### Monitoring

#### Capacity-building

#### Knowledge management

#### Procurement

#### Relationship

#### Procurement
## Annex 4. Table of Country Screening Requirements

<table>
<thead>
<tr>
<th>Initial screening</th>
<th>Australia</th>
<th>Canada</th>
<th>Japan</th>
<th>Republic of Korea</th>
<th>New Zealand</th>
<th>United Kingdom</th>
<th>United States of America</th>
</tr>
</thead>
<tbody>
<tr>
<td>History</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Physical examination</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>• Symptomatic</td>
<td>Yes</td>
<td>• Doctor’s discretion (migrant)</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Abnormal CXR</td>
<td></td>
<td>• Symptomatic</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Abnormal CXR</td>
<td></td>
</tr>
<tr>
<td>CXR</td>
<td>PA</td>
<td>PA</td>
<td>PA</td>
<td>PA</td>
<td>PA</td>
<td>PA</td>
<td>PA</td>
</tr>
<tr>
<td></td>
<td>• &gt;11 years</td>
<td>• &gt;11 years</td>
<td>• &gt;15 years</td>
<td>• &gt;11 years</td>
<td>• &gt;11 years</td>
<td>• &gt;11 years</td>
<td>• &gt;11 years</td>
</tr>
<tr>
<td></td>
<td>• If &lt;11 years, AP/PA and lateral views</td>
<td>• If &lt;11 years if TB contact, positive for LTBI, with previous TB, or symptomatic</td>
<td>• &gt;15 years</td>
<td>• Children &lt;15 if positive for LTBI, with respiratory disease, or if a close contact</td>
<td>• &gt;11 years</td>
<td>• If requested by New Zealand</td>
<td>• &gt;11 years</td>
</tr>
<tr>
<td></td>
<td>• 2–10 years if positive for LTBI or with signs or symptoms of TB disease</td>
<td>• Children &lt;15 if positive for LTBI, with respiratory disease, or if a close contact</td>
<td>• &lt;15 years</td>
<td>• If requested by New Zealand</td>
<td>• &gt;11 years</td>
<td>• If requested by New Zealand</td>
<td>• 2–14 years</td>
</tr>
<tr>
<td></td>
<td>• &lt;2 years if signs or symptoms of TB, HIV-positive, or if TB contact</td>
<td>• &lt;2 years if signs or symptoms of TB, HIV-positive, or if TB contact</td>
<td>• &gt;15 years</td>
<td>• Children &lt;15 if positive for LTBI, with respiratory disease, or if a close contact</td>
<td>• &lt;11 years if TB contact, with previous TB, or symptomatic</td>
<td>• &lt;11 years if TB contact, with previous TB, or symptomatic</td>
<td>• &lt;11 years</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV testing if active TB (with consent)</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>As required by the NTP</td>
<td>Mandatory where required by the NTP</td>
<td>Mandatory where required by the NTP</td>
<td>Mandatory where required by the NTP</td>
<td>Mandatory where required by the NTP</td>
</tr>
<tr>
<td>LTBI testing</td>
<td>Children 2–10 years if TB incidence &gt;40/100,000</td>
<td>Migrating dose contacts of applicant with TB</td>
<td>Children &lt;15 years</td>
<td>Not required</td>
<td>Not required</td>
<td>Refugees, only if TB contact</td>
<td>Children 2–14 years if TB incidence &gt;20/100,000</td>
</tr>
<tr>
<td></td>
<td>• &lt;2 years if dose TB contact, symptoms of TB, or HIV-positive</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• &lt;2 years if signs or symptoms of TB disease or HIV-positive</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Sputum

<table>
<thead>
<tr>
<th>Australia</th>
<th>Canada</th>
<th>Japan</th>
<th>Republic of Korea</th>
<th>New Zealand</th>
<th>United Kingdom</th>
<th>United States of America</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Testing requirement</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• CXR highly suggestive of active TB (positive Q7 on eMedical)</td>
<td>• CXR highly suggestive of active TB (grade ≥4.6)</td>
<td>• Symptomatic</td>
<td>• Symptomatic</td>
<td>• All abnormal CXR consistent with previous or active PTB</td>
<td>• Symptomatic</td>
<td>• All abnormal CXR suggestive of TB</td>
</tr>
<tr>
<td>• Symptomatic</td>
<td>• HIV-positive</td>
<td>• Request by country</td>
<td>• Positive LTBI test in contact with TB</td>
<td>• Symptomatic</td>
<td></td>
<td>• Known HIV-positive</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Request by country</td>
<td>• HIV-positive</td>
<td>• Within 2 weeks of CXR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• HIV-positive</td>
<td>• If more than 2 weeks after CXR, PP should strongly consider testing the applicant for the presence of medicines used to treat TB disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• End of treatment</td>
<td>• Symptomatic</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Extrapulmonary TB</td>
<td>• End of TB treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Migrants − alternative to CXR in pregnancy</td>
<td>• Extrapulmonary TB</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Refugees if HIV-positive</td>
<td>• Children &lt;11 years if TB contact, previous TB, or symptomatic (option to have CXR or go directly to sputum test)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Known HIV-positive</td>
<td>• Children &lt;11 years if TB contact, previous TB, or symptomatic (option to have CXR or go directly to sputum test)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Within 2 weeks of CXR</td>
<td>• Positive LTBI test in contact with TB</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• If more than 2 weeks after CXR, PP should strongly consider testing the applicant for the presence of medicines used to treat TB disease</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Symptomatic</td>
<td>• End of treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Extrapulmonary TB</td>
<td>• Extrapulmonary TB</td>
</tr>
</tbody>
</table>

| **Collection technique** | | | | | | | |
| 3 consecutive days, supervised in the early morning with fasting | 3 specimens on the same day (1 hour apart) or 1 specimen on 3 consecutive days | 3 consecutive days, supervised in the early morning with fasting | 3 consecutive days, supervised in the early morning with fasting | 3 at least 24 hours apart, supervised in the early morning with fasting | 3 consecutive days, supervised in the early morning with fasting | 3 consecutive days, supervised in the early morning with fasting |

| **Smear** | | | | | | | |
| Fluorescent auramine (preferred) or ZN | Fluorescent auramine or ZN | Fluorescent auramine (preferred) or ZN | Fluorescent auramine (preferred) or ZN | Fluorescent auramine (preferred) or ZN | Fluorescent auramine (preferred) or ZN | Fluorescent auramine (preferred) or ZN |

| **Culture** | | | | | | | |
| Solid and liquid media | Liquid or solid | Liquid or solid | Liquid or solid | Liquid or solid | Liquid or solid | Liquid and solid |

| **DST** | | | | | | | |
| First positive culture only | First positive culture only | Mandatory | Mandatory | Mandatory | Mandatory | For first positive culture only; if there is any concern about the DST results, DST can be performed on another positive culture, if there is more than 1 |

<p>| <strong>Molecular testing (Xpert MTB/RIF assay)</strong> | Never done in place of sputum | | | | | | |
| • Mandatory for all applicants with positive smears | | | | | | | |
| • Treatment relapse | | | | | | | |
| • Suspicion of active TB | | | | | | | |
| • Suspicion during pre-treatment | | | | | | | |
| Performed on all first specimens and any positive smear | Acceptable instead of smear | Not required | Not required | Not required | Can be used additionally by PPs to inform decision about DST when there is a strong suspicion of drug resistance or for differentiation of NTM |</p>
<table>
<thead>
<tr>
<th>Country</th>
<th>Australia</th>
<th>Canada</th>
<th>Japan</th>
<th>Republic of Korea*</th>
<th>New Zealand</th>
<th>United Kingdom</th>
<th>United States of America</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TB management</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment provider</td>
<td>Approved clinic</td>
<td>PP or NTP</td>
<td>Refer to NTP</td>
<td>Refer to NTP</td>
<td>Refer to NTP</td>
<td>Refer to NTP</td>
<td>DGMQ-approved DOT centre</td>
</tr>
<tr>
<td>Non-PP clinic</td>
<td>PP must closely supervise</td>
<td>No advice</td>
<td>No advice</td>
<td>No advice</td>
<td>No advice</td>
<td>No advice</td>
<td>PP must closely supervise</td>
</tr>
<tr>
<td>DOT</td>
<td>Mandatory</td>
<td>Highly recommended</td>
<td>No advice</td>
<td>No advice</td>
<td>NTP standards, but highly recommended</td>
<td>For refugees, this is mandatory</td>
<td>For migrants, follow NTP protocols</td>
</tr>
<tr>
<td>Contact tracing</td>
<td>• Within migrating household</td>
<td>Within migrating household</td>
<td>No advice</td>
<td>As per NTP</td>
<td>• Within migrating household</td>
<td>For migrants, follow NTP protocols</td>
<td>All persons who shared same enclosed space for prolonged period (days)</td>
</tr>
<tr>
<td>Special circumstances</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Children</td>
<td>History and physical exam</td>
<td>History and physical exam</td>
<td>History and physical exam</td>
<td>History and physical exam</td>
<td>History and physical exam</td>
<td>History and physical exam</td>
<td>History and physical exam</td>
</tr>
<tr>
<td></td>
<td>• Ages 2−10 years, TST or IGRA</td>
<td>• &lt;15 years requires TST or IGRA testing</td>
<td>• History, Physical exam, if deemed necessary</td>
<td>• Refugees require history and physical exam</td>
<td>• Refugees require history and physical exam</td>
<td>• Refugees require history and physical exam</td>
<td>• History and physical exam</td>
</tr>
<tr>
<td></td>
<td>• Lateral and PA CXR if required</td>
<td>• Lateral and PA CXR if required</td>
<td>• As per NTP</td>
<td>• For migrants, history and physical exam if deemed necessary</td>
<td>• For migrants, history and physical exam if deemed necessary</td>
<td>• For migrants, history and physical exam if deemed necessary</td>
<td>• Ages 2−14 years, IGRA LTBI test</td>
</tr>
<tr>
<td></td>
<td>• &lt;2 years with TB symptoms, HIV-positive, or with TB contacts requires CXR and review by paediatrician</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• CXR, if required</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy</td>
<td>History and physical exam</td>
<td>History and physical exam</td>
<td>History and physical exam</td>
<td>History and physical exam</td>
<td>History and physical exam</td>
<td>History and physical exam</td>
<td>History and physical exam</td>
</tr>
<tr>
<td></td>
<td>• CXR after first trimester with consent and double wraparound shield</td>
<td>• CXR with consent and double wraparound shield</td>
<td>• Delay CXR until after pregnancy if do not wish CXR</td>
<td>• 3 sputum tests</td>
<td>• Delay CXR until after pregnancy if do not wish CXR</td>
<td>• 3 sputum tests</td>
<td>• CXR with consent and double wraparound shield</td>
</tr>
<tr>
<td></td>
<td>• Delay CXR until after pregnancy if do not wish CXR</td>
<td>• Delay CXR until after pregnancy if do not wish CXR</td>
<td>• If consent to CXR, use double wraparound shield</td>
<td>• or</td>
<td>• Delay CXR until after pregnancy if do not wish CXR</td>
<td>• or</td>
<td>• Delay CXR until after pregnancy if do not wish CXR</td>
</tr>
<tr>
<td></td>
<td>• In country with low TB burden, CXR not required</td>
<td>• If consent to CXR, use double wraparound shield</td>
<td></td>
<td></td>
<td>• CXR after first trimester with consent and double wraparound shield</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refugee pre-embarkation check</td>
<td>Abnormal CXR at IME</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Repeat CXR for all after 6 months</td>
<td>Repeat CXR for all after 6 months</td>
<td>Abnormal CXR at IME</td>
</tr>
<tr>
<td></td>
<td>• Symptoms of TB</td>
<td></td>
<td></td>
<td></td>
<td>• 3 smears required for abnormal CXR or HIV-positive</td>
<td></td>
<td>• Symptoms of TB</td>
</tr>
<tr>
<td></td>
<td>• HIV-positive</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• HIV-positive</td>
</tr>
</tbody>
</table>
### Annexes

<table>
<thead>
<tr>
<th>Notification</th>
<th>Australia</th>
<th>Canada</th>
<th>Japan</th>
<th>Republic of Korea*</th>
<th>New Zealand</th>
<th>United Kingdom</th>
<th>United States of America</th>
</tr>
</thead>
<tbody>
<tr>
<td>NTP</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>Not required</td>
<td>Mandatory</td>
<td>Mandatory</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Receiving country</td>
<td>• All drug-resistant TB should be reported within 3 working days (includes multi-, mono- and polydrug resistance)</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>• MDR-TB</td>
<td>• XDR-TB</td>
<td></td>
</tr>
<tr>
<td>• Treatment refusal or failure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health clearance at end of treatment</td>
<td>• If treated at approved DOT site, PP submits the documentation after end of treatment (Medical Officer of the Commonwealth provides the final opinion about whether the applicant is free of TB)</td>
<td>TB treatment records including the active TB management form to be submitted upon completion of TB treatment</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>• New medical exam to be done if client returns after 6 months with written records of treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Applicants should expect to receive health clearance in a timely manner</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Certificate to be issued at PP discretion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• If treated by external provider, health clearance will be deferred for a minimum of 12 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• If treated at DGMQ-approved DOT centre, new IME can be done after end of treatment</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**CXR:** chest X-ray; **DOT:** directly observed therapy; **DGMQ:** Division of Global Migration and Quarantine; **DST:** drug-susceptibility testing; **IGRA:** interferon-gamma release assay; **IME:** immigration medical examination; **LTBI:** latent tuberculosis infection; **MDR:** multidrug resistant; **NTM:** nontuberculous mycobacteria; **NTP:** national tuberculosis programme; **PA:** posteroanterior; **PP:** panel physician; **PTB:** pulmonary tuberculosis; **XDR:** extensively drug resistant; **TST:** tuberculin skin test; **ZN:** Ziehl–Neelsen.

Annex 5. MiMOSA Guide for MHD Users

This annex is from the MiMOSA Guide for MHD [Migration Health Division] Users.

It describes the steps used to create and populate a TB Treatment Work-Up Module in MiMOSA. The module is first created and then the data are entered. The screenshots below are from a fictional case.

Steps used to create a TB Treatment Work-Up Module in MiMOSA

The user is assumed to have basic knowledge of the MiMOSA MED application prior to creating a TB Treatment Work-Up Module. Creating the module is done mainly in four key steps:

1. Add the medical service TB Rx (for clients treated by IOM or non-IOM facilities) in the Functional Area where TB Work-Up and Treatment details are entered. The TB Rx category is valuable for tracking the progress of clients and their treatment.

2. Create the TB Treatment and Work-Up module.

3. Record data in the module.

4. Finalize the TB Rx (IOM or Non-IOM) medical service for clients seen at IOM or non-IOM facilities.

Step one: add the medical service TB Rx (for clients treated by IOM or non-IOM facilities) in the Functional Area where the TB Treatment Work-Up Module was initiated.

1. Open the case record; this will take you to the Summary tab of the Individual Details page.

2. Click on the link under the Functional Area column (for example, Health Assessment) to display all of the included medical services within the Functional Area.
(3) At the bottom of the Medical Service column, click [+ ] Add.

(4) In the ADD NEW SERVICE window, click on the Service field. This will open the Medical Services window.

In the Medical Services window, click the + next to Treatment to expand the options, then click TB Rx IOM (if the applicant will be treated by an IOM panel physician) or TB Rx Non-IOM (if the applicant will be treated externally); click Save.

Next click OK. This will add the TB Rx to the Medical Service list and will change the Functional Area Status from Completed to Hold.
Step two: create the TB Treatment Work-Up Module (TB WRx).

(1) Select the Case No. of the applicant. This will take you to the MANAGE CASE page.

(2) In the Activity section, select the Medical tab, and then select the individual case by ticking the box next to the appropriate IOM Individual No.
(3) Assign the medical services required by going to the second-level navigation menu and then selecting Medical > Assign Core Services with Appointment. This will open a window called Set Appointment.

(4) In the Set Appointment window, click on the Medical Profile drop-down and select TB WRx (TB Treatment Work-Up Module). This will automatically set the Functional Area to TB Treatment – TBRX. Then select the appropriate Screening Site. Set the Appointment Base Date, which is the date on which the client commenced treatment. Once these mandatory fields have been completed, click the OK button and you will automatically go to the SCHEDULE APPOINTMENTS page.

(5) On the SCHEDULE APPOINTMENTS page, select the No specific timeslot button. Then click Save Schedule.
(6) After saving the schedule, the screen should appear as below.

![Schedule Appointments Screen]

(7) To go back to the main record, click Return to Previous Page; on the MANAGE CASE page, select the Medical tab, then select the IOM Individual No. The page will then return to the Summary tab displaying the TB WRx Medical Profile.

Then click on the Forms tab and select ENTRY. This step will bring you to the Entry Exam Form on the TB Treatment page as part of the third phase of data entry.

Alternatively, go to MANAGE CASE-Activity and select the Medical tab; then click the TBRX-SCH link in the Medical Status column. This will directly open the TB Treatment Entry Exam Form.

**Step three:** record data in the TB Treatment Functional Area.

(1) This step involves assigning forms for each activity and then keying in data for each step of treatment as it progresses by completing the entry, follow-up, exit and CXR forms.

(2) All of the forms are created in the Summary tab of the TB Treatment Work-Up Module (TB WRx), but they can be updated only from the Forms tab.

(a) In the Summary tab, select the TB Treatment Functional Area. Under the TB WRx Medical Profile, do the following to add medical services:

(i) Create a FOLLOWUP form by clicking [+ Add] Medical Services Exam > PE TB Follow-Up > Save > OK;
(ii) Create an EXIT form by clicking [+] Add > Medical Services Exam > PE TB Exit > Save > OK;

(iii) Create a CXR form by clicking [+] Add > Medical Services Imaging > X-ray Chest > Save > OK.

(b) To update the forms, open them from the Forms tab.

(3) Treatment details (that is, the regimen) and baseline medical services (for example, lab results) are created, updated and completed from the Summary tab. The procedure for adding treatment details is similar to that for adding a medical service (see previous step in this section).
(4) Categories for sputum smears, cultures and DST are created and updated or completed from the Forms tab.

(a) In the Forms tab, click [+ ] Add.
(b) In the ADD FORM section, use the Functional Area drop-down to select TB Treatment.
(c) In the Form drop-down, select SSC-Sputum Smears and Culture.
(d) Click OK. Then click Save.

(e) To update the form, simply return to the Forms tab and click on SSC to enter results of smear and culture testing and DST.

The steps described above are best learned by entering information for actual patients.

Step four: finalize the TB Rx medical services (for clients treated by IOM or non-IOM facilities) upon completion of the TB Treatment Work-Up Module.

Once the TB Treatment Work-Up Module has been completed, return to the Functional Area where the TB Rx information was added.

(1) In the Summary tab, select the Functional Area, then select the appropriate TB Rx category (either IOM or non-IOM).

(2) Update the Status field to Completed and fill out the appropriate Outcome and Completion Date. Click OK and then Save.
This step will update not only the TB Rx status but also the Functional Area (for example, Health Assessment) status, changing it from Hold to Completed, thus finalizing the data entry.
Template Forms
**Template Form 1.**
**TB Treatment Referral Summary**

Subject: Referral for TB Treatment from IOM Panel Physician  
To: IOM/ Other *(insert name)* TB DOT Clinic in *(insert country)*  
Date:

 setName
Case No. (1st Ref. No.):  
IOM Individual No.:  
Date of Birth:  
Age/Sex:  
Address:

Dear Ms/Mr/Dr __________________________,

The person mentioned above has active infectious PTB / non-infectious PTB / extrapulmonary TB (delete as required).

**Sputum results**  
- smears  
- cultures  
- molecular studies  
- DST  

(enter results as appropriate)

**Clinical findings**

I would appreciate your assistance in providing anti-TB therapy for this patient. Please find related documents and information attached. (Tick as appropriate.)

- Medical exam form with photo for identification
- Sputum results: Smear ☐ Culture ☐ Molecular test ☐
- CXR report
- HIV results
- Consultant chest physician letter, if applicable
- Biopsy/FNA report
- DST results
- Baseline investigations
- Other relevant information regarding this patient

Attached is a monitoring protocol that is required to enable future migration, which we would be grateful if you would follow. Kindly notify us once treatment has been initiated and in case of treatment failure, default or completion. Thank you.

Referred by:

---

**IOM Medical Officer Contact Details**

Contact Number:  
Address:  
Phone:  
Email:
### Template Form 2.

**Treatment Monitoring Advice for External Physicians**

**Subject:** Treatment Monitoring Advice (non-IOM)

**To:** (insert name) TB DOT Clinic in:

**Date:**

---

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migrant’s Name:</td>
<td></td>
</tr>
<tr>
<td>Case No. (1st Ref. No., as per receiving country file):</td>
<td></td>
</tr>
<tr>
<td>IOM Individual No.:</td>
<td></td>
</tr>
<tr>
<td>Date of Birth:</td>
<td></td>
</tr>
<tr>
<td>Age/Sex:</td>
<td></td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
</tbody>
</table>

---

Dear Dr_________________________,

Thank you for accepting this patient for TB treatment on behalf of IOM. Consistent with our responsibility to the receiving country to supervise treatment, guidance is provided on the agreed minimum supervision, monitoring and certification requirements to assist with patient management and facilitate migration as prescribed by the receiving country, (Name of country........................).

**Patients should have the following investigations performed prior to commencement of TB treatment.** If the results of these investigations are not available in the attached documents, please consider the following:

- HIV serology after counselling and obtaining a signed informed consent to test;
- Chest X-ray (if most recent is more than 2 months old);
- LFTs, serum creatinine, CBC, fasting blood sugar, pregnancy test (females aged 15−50 years);
- Testing of visual acuity and red–green colour discrimination (if EMB is to be prescribed).

**Follow-up tests and clinical reviews**

It is advised that follow-up tests and reviews are done as per the attached schedule in addition to monthly clinical review (history and physical examination), addressing, among others, the patient’s weight trend, symptom resolution or otherwise, bacteriological conversion, CXR stability if CXR is performed, treatment tolerance, co-morbid conditions, if any, and a determination of the way forward.

If the requested tests cannot be done at your treatment site, please refer the patient back to IOM for these requirements to be fulfilled, as they are required by the receiving country.
IOM should be promptly notified if any of the following occur:

- Sputum smear or culture is positive on specimens collected at 2 months or thereafter;
- Radiological or clinical deterioration occurs during treatment;
- Patient defaults from treatment.

The following information is requested in a certificate to be issued on treatment completion:

- All medicines given, including the doses of individual medicines, frequency of administration, mode of administration (DOT, VOT, SAT), and start and end date for each medicine;
- Patient weight prior to, during, and at the end of treatment;
- Results of sputum tests and chest x-ray(s) done during and at the end of treatment.

Thank you,

IOM Medical Officer
### Template Form 3.
### National TB Programme Notification

#### TUBERCULOSIS CASE NOTIFICATION FORM

TO: TB UNIT / IOM

The below-named individual has been diagnosed with TB disease.

<table>
<thead>
<tr>
<th>Patient name:</th>
<th>Case No.:</th>
<th>Date of birth:</th>
<th>Sex:</th>
</tr>
</thead>
</table>

Address:

Date of diagnosis of TB illness:

Site of disease:
- Pulmonary ( )
- Extrapulmonary ( )

Specify site:

Clinical signs and symptoms: No ( ) Yes ( ) Specify:

TST/IGRA: No ( ) Yes ( ) Date: Reading:

Pre-treatment vital signs: HR: RR: BP: Temp.: °C Weight: kg

<table>
<thead>
<tr>
<th>Initial and/or diagnostic results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
</tr>
<tr>
<td>------</td>
</tr>
</tbody>
</table>

Drug-susceptibility testing (DST): Pan-susceptible ( ) Drug resistance ( ) Not done ( )

<table>
<thead>
<tr>
<th>Date</th>
<th>INH</th>
<th>RIF</th>
<th>PZA</th>
<th>ETH</th>
<th>STREP</th>
<th>OTHER</th>
</tr>
</thead>
</table>

R= Resistant; S= Sensitive.
Other diagnostic tests or consultations: Specify with dates

Treatment regimen

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Dose</th>
<th>Start date</th>
<th>Expected date of completion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rifampicin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isoniazid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethambutol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyridoxine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other comments:

IOM Officer name: ____________________ Signature: ____________________ Date: __________

Clinic contact details

Address: _____________________________
Phone/email: _________________________
Template Form 4.
TB Counselling and Consent

TB PRE-TREATMENT COUNSELLING ACKNOWLEDGMENT
AND INFORMED CONSENT FORM

I, ____________________________, by nationality _____________________, of legal age, resident of ________________, do hereby declare that I am aware that

in connection with my processing for immigration to Australia, Canada, Japan, New Zealand, the United Kingdom, the United States or another country am required to have medical treatment for tuberculosis and that I have completed the TB education course conducted by IOM staff member (name) __________________ of IOM Migration Health Assessment Centre on (date) _____________.

The following were discussed about TB disease.

(1) The pathogenesis, transmission, signs and symptoms of TB (and that absence of these may not negate the diagnosis of TB) and prevention and control.

(2) How tuberculosis is diagnosed, and the need for sputum examinations that include AFB smears, MTB cultures and drug-susceptibility testing (DST).

(3) Treatment for tuberculosis, with emphasis on the directly observed therapy (DOT) strategy, the anticipated duration of treatment and the treatment regimen that will be used.

(4) During treatment, there will be regular monitoring of side effects; monthly clinical review; weight and vital signs checks; blood tests, both at baseline and for abnormal results; sputum follow-up monitoring as per the receiving government’s technical instructions; contact evaluation of all household members, as instructed by the (insert country) National Tuberculosis Programme (NTP) as well as the receiving government’s technical instructions.

(5) I understand that I have a choice whether to take my TB treatment at the IOM DOT TB centre that is also approved by the Australian and United States’ technical instructions or at another facility. However, if I choose to have TB treatment at a non-approved facility and I am an applicant for the United States or Australia, I understand that I may not be cleared to travel and must repeat my immigration medical examination 1 year after I complete TB treatment. At that time and in that situation, I will be required to bring a written treatment summary from the treatment provider outlining the treatment provided, including the treatment record, the results of all monitoring tests, and comments from the treating doctor, which should include the treating doctor’s name, and the treating clinic’s address and physical location, all of which will be attached to my travel documents.

(6) I was also made aware that this IOM TB DOT centre is registered by the (insert country) NTP, and that TB treatment is guided by (insert country) NTP guidelines as well as the
receiving government’s technical instructions. Based on both, TB disease is a notifiable disease
and will be reported to the appropriate authorities. Likewise, non-compliance with guidelines,
including refusing treatment, will be notified to the respective authorities for further action
and guidance.

(7) I have been informed of the possible side effects of the medications, and these may include
but are not limited to fever, rashes, difficulty in breathing, tinnitus, deafness, nausea, vomiting,
yellowish discoloration of eyes and skin, arthritis, blurring of vision, colour blindness,
numbness, gastritis, seizures and kidney problems, and that the IOM TB DOT centre has
adequate equipment and supplies to treat such side effects. However, I acknowledge that such
adequate equipment and supplies are not an assurance that every side effect can be effectively
treated. I am aware that I will assume full responsibility for whatever adverse reactions or
complications may arise during TB treatment and I will not hold the IOM TB DOT centre and
its medical staff legally liable.

(8) I have also been informed that if I am pregnant and opt to undergo TB treatment, the possible
consequences may be detrimental to my fetus/baby.

(9) I may be asked to secure medical clearance from my primary physician for my underlying
chronic medical condition, if any, prior to initiation of TB treatment. ___(Specify condition)___

(10) The whole regimen of treatment is administered for at least 6 months, and it may be longer
if necessary, depending on the DST pattern or type of TB disease.

I am executing this consent on my own volition without force, threats, intimidation, or undue
influence. (Enter applicant’s name on the appropriate line below.)

I, ______________________, agree and accept to have TB treatment at IOM’s Migration
Health Assessment Centre (insert country).

I, ______________________, choose to have my TB treatment at a TB treatment
facility of my choosing not at IOM’s MHAC.

I, ______________________, refute the TB diagnosis and decline TB treatment.

If you have any inquiries related to this matter, please feel free to approach our medical staff.

I HEREBY UNDERSTAND THE ABOVE CONDITIONS.

IOM staff signature and name _________________________________ Date ________________

Applicant/Parent/Guardian signature and name____________________ Date ________________

IOM Clinic: _______________ Country Office: _______________
Address: ________________________________________________
Phone and fax: ____________________________________________
Email: ___________________; Web: _________________________
# Template Form 5.
## TB Patient Treatment Record

<table>
<thead>
<tr>
<th>Destination Country:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migrant Type: □ IMM □ REF □ OTHER</td>
</tr>
<tr>
<td>Case No. (1st Ref. No.):</td>
</tr>
<tr>
<td>IOM Individual No.:</td>
</tr>
<tr>
<td>NTP Registration No.:</td>
</tr>
<tr>
<td>Clinic Name:</td>
</tr>
<tr>
<td>Clinic Location:</td>
</tr>
<tr>
<td>Clinic Country:</td>
</tr>
<tr>
<td>Date of Registration:</td>
</tr>
<tr>
<td>Treatment Start Date:</td>
</tr>
<tr>
<td>Treatment End Date:</td>
</tr>
</tbody>
</table>

### Biographic Information

<table>
<thead>
<tr>
<th>Photo</th>
</tr>
</thead>
</table>

#### Name:  
(Family)  
(First)  
(Middle)

| Date of Birth: |
| Treatment Supporter Information |

| Age/Sex: |
| Name: |

| Nationality: |
| Relation to patient: |

| Contact No.: |
| Address: |

### Patient Classification

- □ New
- □ Retreatment
  - □ Relapse
  - □ After failure
  - □ After loss to follow up
- □ Transfer In
- □ Other

### Site of Tuberculosis Disease

- □ Pulmonary
- □ Extrapulmonary (specify site of disease):
- □ ICD code/s of TB disease:

### Reason/s for Treatment

- □ Positive smear for AFB
- □ Positive culture for MTB
- □ Molecular test result
- □ Sign or symptom consistent with TB
- □ Abnormal CXR consistent with TB
- □ Other (specify):

### HIV Test Status

- □ Negative
- □ Positive
- □ Not done

<table>
<thead>
<tr>
<th>CD4:</th>
<th>Viral load:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARV commencement:</td>
<td></td>
</tr>
</tbody>
</table>

### Other Diagnoses

- □ Diabetes mellitus
- □ Hepatitis
- □ Hypertension
- □ Kidney disease
- □ Pre-existing liver disease
- □ Pregnancy
- □ Other

### ICD Code

<table>
<thead>
<tr>
<th>ICD Code</th>
<th>Remarks</th>
</tr>
</thead>
</table>

### Pre-treatment TB Signs and Symptoms

- □ Prolonged cough
- □ Haemoptysis
- □ Fever/Sweats
- □ Anorexia
- □ Weight loss
- □ Easy fatigueability
- □ Dyspnoea

### Pre-treatment Anthropometry/Vital Signs

- □ Weight (kg):
- □ Height (m):
- □ BMI:
- □ BP:  
  - PR: 
  - RR: 
  - Temp (°C):
- □ Vision exam:
- □ Chest exam:
**Template forms**

**Nutritional support details:**

<table>
<thead>
<tr>
<th>Requirement Category</th>
<th>Drug</th>
<th>Date specimen obtained: (mm-dd-yyyy)</th>
<th>Date DST reported: (mm-dd-yyyy)</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Susceptible</td>
</tr>
<tr>
<td>For first-line DST</td>
<td>Isoniazid 0.1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Isoniazid 0.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rifampicin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ethambutol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pyrazinamide</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Streptomycin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For second-line DST</td>
<td>Levofloxacin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moxifloxacin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bedaquiline</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Linezolid</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clofazimine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Amikacin)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others (specify)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Drug-Susceptibility Result**

- Pan-susceptible
- Drug Resistant
- Not Done

**Molecular Test**

- Done
- Not done

P – positive; N – negative; ID – indeterminate; IN – invalid; MTB – *Mycobacterium tuberculosis*; NTM – Nontuberculous mycobacteria

<table>
<thead>
<tr>
<th>Test Date</th>
<th>Test Name</th>
<th>MTB complex</th>
<th>Rifampicin</th>
<th>Isoniazid</th>
<th>Fluoroquinolone</th>
<th>Kanamycin</th>
<th>Ethambutol</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>GenoXpert MTB/RIF</td>
<td></td>
<td>P N IN P N IN P N IN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Genotype MTBDRplus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Genotype MTBDRsl</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other____</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Species:**

NTM speciation

**Chest X-ray Examination Result**

<table>
<thead>
<tr>
<th>Date taken</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Test for Cell-Mediated Immunity to Tuberculosis**

- Performed?
- Yes
- No

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Date Applied/Drawn</th>
<th>Results</th>
<th>If IGRA performed, indicate which test:</th>
</tr>
</thead>
<tbody>
<tr>
<td>TST</td>
<td></td>
<td></td>
<td>Quantiferon</td>
</tr>
<tr>
<td>IGRA</td>
<td>Positive</td>
<td></td>
<td>T-Spot</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Indeterminate, Borderline, Equivocal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Treatment Regimen Details

<table>
<thead>
<tr>
<th>Regimen</th>
<th>2HREZ/4HR</th>
<th>Other (specify):</th>
</tr>
</thead>
</table>

#### Drugs and Dosage

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose (mg)</th>
<th>Start Date</th>
<th>End Date</th>
<th>Total Dose</th>
<th>Reason for Cessation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isoniazid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rifampicin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethambutol</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Opportunistic Infections Prophylaxis

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose (mg)</th>
<th>Frequency</th>
<th>Start Date</th>
<th>End Date</th>
</tr>
</thead>
</table>

#### Antiretroviral Therapy

<table>
<thead>
<tr>
<th>ART Regimen</th>
<th>Dose (mg)</th>
<th>Frequency</th>
<th>Start Date</th>
<th>End Date</th>
</tr>
</thead>
</table>

### Monitoring

#### Body weight (kg)

<table>
<thead>
<tr>
<th>Month</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Visual Acuity

| Color Vision | |
|--------------||

#### Smear/Culture Examination Result

<table>
<thead>
<tr>
<th>Month</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serial No.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smear Result</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Culture Result</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Treatment Outcome

- Cured
- Treatment completed
- Treatment failed
- Died
- Loss to follow up
- Not evaluated

#### Date of last treatment dose:

### Comments

Examining Physician:  
Signature Date:
Template Form 6.  
TB Patient Appointment Card
Template Form 7.
TB Treatment Compliance

<table>
<thead>
<tr>
<th>Drug and Dosage</th>
<th>Day</th>
<th>Month/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>H R E Z Other</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>300 600 1100 1600 - 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>11</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>12</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>13</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>14</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>15</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>16</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>17</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>18</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>19</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>20</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>21</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>22</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>23</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>24</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>25</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>26</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>27</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>28</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>29</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>30</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
<tr>
<td>31</td>
<td></td>
<td>MM YY MM YY</td>
</tr>
</tbody>
</table>

Legend marks
DOT provider to enter signature/ initials for drugs observed being taken
N – Not observed
X – Drugs not taken

Total #

Drug Abbreviations
- Am = Amikacin
- Amox/Clv = Amoxicillin/ Clavulanate
- BDQ = Bedaquiline
- Cr = Ciprofloxacin
- Cs = Clarithromycin
- Cl = Clindamycin
- Km = Kanamycin
- Lfx = Levofloxacin
- LZd = Linezolid
- Mfx = Minocycline
- H = Isoniazid
- P = Pyrazinamide
- R = Rifampicin
- PAS = Para-aminosalicylic acid
- Pto = Prothionamide
- S = Streptomycin
- Th = Thiacetazone
- Vm = Vomycin
## Template Form 8. TB Side Effect Monitoring

### Patient Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name</td>
<td>(First name Family name)</td>
</tr>
<tr>
<td>Case Number (1st Ref. No.)</td>
<td>____________________</td>
</tr>
<tr>
<td>IOM Individual No.</td>
<td>____________________</td>
</tr>
<tr>
<td>Date of Birth</td>
<td>(dd-mm-yyyy)   Age/Sex</td>
</tr>
</tbody>
</table>

### Side Effect Monitoring

- Abdominal pain
- Anorexia
- Confusion
- Convulsions
- Depression/mood changes
- Diarrhoea
- Discoloured urine
- Dizziness
- Fever

| Date | Treatment Week | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 |
|------|----------------|---|---|---|---|---|---|---|---|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
|      | Abdominal pain |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
|      | Anorexia       |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
|      | Confusion      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
|      | Convulsions    |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
|      | Depression/mood changes | |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
|      | Diarrhoea      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
|      | Discoloured urine | |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
|      | Dizziness      |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
|      | Fever          |   |   |   |   |   |   |   |   |   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |
| Date | Treatment Week | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 |
| Headache |                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Hearing loss/problems |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Itching |              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Jaundice |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Joint pain |           |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Nausea |                |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Numbness |              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Psychosis |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Skin rash |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Tiredness |              |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Vision loss |            |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Vomiting |             |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
| Others, specify below: |         |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
Template Form 9.
Form for HIV Counselling and Consent for HIV Testing for TB Patients

INFORMED CONSENT FORM FOR VOLUNTARY HIV DIAGNOSTIC COUNSELLING AND TESTING FOR IOM TB

In connection with my processing for immigration to Australia, Canada, New Zealand, the United States of America or another country, I hereby agree to the following.

(1) I understand that a TB diagnosis requires that I undertake TB treatment as prescribed by the country of examination in accordance with technical instructions of the resettlement country, and if I agree to testing, this result will be included in the medical documentation.

(2) I understand that an HIV test is necessary to rule out co-infection with TB and HIV, although an HIV test is not a mandatory test for migration to some countries.

(3) I understand that HIV is the virus that causes HIV/AIDS and that the HIV test indicates whether the blood is infected with HIV.

(4) I understand that TB makes HIV worse and HIV makes TB worse; therefore, it is necessary for both to be treated and, as such, it is important to know my HIV status for proper treatment of TB.

(5) I realize that I have the right to agree to or decline an HIV test. I understand that if I decline to have an HIV test, regardless of my declination, the IOM medical team will still treat me according to the standards for TB treatment as stipulated in the IOM TB management procedures.

(6) I understand that if I agree of my own volition to have an HIV test, it will be to my own benefit and that I have the right to ask questions and receive answers about HIV and the test.

(7) I retain the right to ask questions during the course of my treatment to enable my family and me to understand the course of my treatment.

(8) I declare that I have read and fully understand the contents of this form, and hereby sign the form of my own free will.
I, ______ (enter name) ________, agree and accept to take an HIV test as indicated above.
I, ______ (enter name) ________, decline to take an HIV test as indicated above.
Applicant/Parent/Guardian signature: ____________ Sex ___ DOB _____ Marital status
TB No. ____________________ Case No. ________________
Telephone number (include area and international codes) __________
Counsellor’s/IOM Medical staff signature and name: ______________________ Date _____

IOM Clinic: __________ Country Office: __________
Address: ________________________________
Phone and fax: __________________________
Email: _____________; Web: _______________
Template Form 10.
Checklist for TB Monitoring

CHECKLIST FOR TB MONITORING

| Patient Name:  (First name Family name) | Clinic Name: |
| Case Number: | Treatment Regimen: |
| Date of Birth:  (dd-mm-yyyy)  Age/Sex: | Treatment Start Date:  (dd-mm-yyyy) |
| Treatment Completion Date:  (dd-mm-yyyy) |

<table>
<thead>
<tr>
<th>Investigation</th>
<th>Baseline</th>
<th>Month of treatment</th>
<th>End of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>MICROBIOLOGY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sputum smears and cultures</td>
<td>☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drug-susceptibility testing</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>IMAGING</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CXR</td>
<td>☐</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>CLINICAL ASSESSMENT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Symptom and adherence review</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Vision assessment</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>LABORATORY TESTING</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AST, ALT, bilirubin, alkaline phosphatase</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Full blood count</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Creatinine</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>HIV*</td>
<td>☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hepatitis B and C screen*</td>
<td>☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes screen (fasting blood sugar)</td>
<td>☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy testing for women aged 15–50 years</td>
<td>☐</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


☐ Routine investigation
☐ If clinically indicated
* Repeat drug-susceptibility testing if patient remains culture-positive after completing 3 months of treatment.
# Testing for bloodborne viruses requires appropriate counselling and consent and does not need to be repeated if undertaken at the immigration medical examination.
Template Form 11.
Baseline and Routine Monitoring of MDR-TB Requirements

**MDR-TB MONITORING CHECKLIST**

| Patient Name: (First name Family name) | Treatment Start Date: (dd-mm-yyyy) |
| Case Number: | Treatment Regimen: |
| Date of birth: (dd-mm-yyyy) | Sex: |

<table>
<thead>
<tr>
<th>Activity</th>
<th>Baseline</th>
<th>Month of Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month</td>
<td>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18</td>
<td></td>
</tr>
<tr>
<td>CLINICAL MONITORING</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sputum smear and culture¹</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>CXR²</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Weight³</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Symptom review⁴</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>LABORATORY MONITORING FOR TOXICITY/CO-MORBIDITIES</td>
<td></td>
<td></td>
</tr>
<tr>
<td>DST⁵</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>FBC⁶</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Creatinine⁷</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>LFTs⁸</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>K+, Ca, Mg+³</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>ALT, AST (liver enzymes)¹⁰</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>TSH</td>
<td>☐</td>
<td></td>
</tr>
<tr>
<td>HIV</td>
<td></td>
<td>☐</td>
</tr>
<tr>
<td>Lipase</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lactic Acid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**MONITORING PROCEDURES**

- **Audiogram**
- **Vestibular exam**
- **Vision exam**
- **Peripheral neuropathy**
- **Arthralgias**
- **Depression**
- **ECG**

**General Monitoring Recommendations**

- Collect three AFB smear and culture specimens every 2 weeks until smear conversion, and then 2-3 specimens monthly until cultures have converted to negative. Once cultures have converted, obtain at least 1 specimen monthly throughout therapy.
- Obtain baseline CXR and monitor q 3 months during the first year and q 6 months in the second year of treatment.
- Monitor weight monthly and adjust medications as needed.
- Monitor for symptoms monthly.
- Obtain first- and second-line DST results at baseline. Repeat if patient on RIPE and remains culture positive prior to MDR-TB Rx, and again if patient fails to convert culture after 3 months on treatment.
- Obtain weekly for first month, then monthly for patients on linezolid.
- Obtain creatinine at baseline and monthly while patient is on an injectable agent. Every 1-3 weeks recommended in higher risk (e.g. HIV).
- LFTs at baseline and then monthly while patient is on PZA, ethionamide or PAS.
- K+, Ca++, and Mg++ at baseline and monthly while patient is on an injectable agent.
- At 1, 2 and 3 months when on PZA for prolonged period; anytime for those with symptoms of hepatitis; HIV recommended monthly. Bedaquiline monitor monthly. Patients with viral hepatitis every 1-4 weeks.
- Monitor TSH at baseline and every 3 months while patient is on ethionamide or PAS, and more frequently if symptoms.
- Obtain baseline HIV.
- Indicated at work up if on linezolid, or if develop abdominal pain to exclude pancreatitis.
- Indicated at work up for those on linezolid or on antiretroviral treatment.
- Perform audiogram at baseline and monthly while patient is on an injectable agent.
- Perform vestibular exam at baseline and monthly while patient is on an injectable agent.
- Perform visual acuity plus colour discrimination exams at baseline and monthly while patient is on ethambutol or linezolid.
- Monitor for peripheral neuropathy at baseline and monthly while patient is on linezolid and as clinically indicated for patients on fluoroquinolones.
- Monitor for arthralgias at baseline and monthly while patient is on PZA or fluoroquinolone.
- Monitor for depression, agitation, or mental status change at baseline and monthly while patient on cycloserine.
- Obtain ECG at baseline and at least at 2, 12, and 24 weeks for patients on bedaquiline, and at baseline and after treatment start for patients on fluoroquinolones as clinically indicated.

---

*a* Important: Monitoring recommendations may change if treatment regimen or patient status changes. A box indicates monitoring activity is recommended. Check box when activity is completed.

*b* Adapted from the World Health Organization.
## Template form 12. Sputum Results Summary

### SPUTUM RESULTS SUMMARY

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Collection 1</th>
<th>Collection 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Date of collection</td>
<td>Date of collection</td>
</tr>
<tr>
<td></td>
<td>Date reported</td>
<td>Date reported</td>
</tr>
<tr>
<td></td>
<td>Smear results</td>
<td>Smear results</td>
</tr>
<tr>
<td></td>
<td>Date reported</td>
<td>Date reported</td>
</tr>
<tr>
<td></td>
<td>Culture results</td>
<td>Culture results</td>
</tr>
<tr>
<td></td>
<td>Date reported</td>
<td>Date reported</td>
</tr>
</tbody>
</table>

- **Purpose**: Diagnostic, Treatment monitoring, Pre-departure, End of treatment
- **Lab ID**: 
- **Molecular test results**: Date reported
- **Culture results**: Date reported
- **Smear results**: Date reported
- **Date of collection**: 1, 2, 3
- **Date reported**: 1, 2, 3
- **Clinic Name**: 
- **Patient Name**: (First name Family name)
- **Case Number**: 
- **Date of birth**: (dd-mm-yyyy)
- **Sex**: 
- **Lab ID**: 
- **Molecular test results**: Date reported
- **Culture results**: Date reported
- **Smear results**: Date reported
- **Date of collection**: 1, 2, 3
- **Date reported**: 1, 2, 3
<table>
<thead>
<tr>
<th>Collection 3</th>
<th>Lab ID: ____________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Diagnostic</td>
</tr>
<tr>
<td></td>
<td>□ Treatment monitoring</td>
</tr>
<tr>
<td></td>
<td>□ End of treatment</td>
</tr>
<tr>
<td></td>
<td>□ Pre-departure</td>
</tr>
<tr>
<td>#</td>
<td>Date of collection</td>
</tr>
<tr>
<td></td>
<td>Smear results</td>
</tr>
<tr>
<td></td>
<td>Date reported</td>
</tr>
<tr>
<td></td>
<td>Culture results</td>
</tr>
<tr>
<td></td>
<td>Date reported</td>
</tr>
<tr>
<td></td>
<td>Molecular test results</td>
</tr>
<tr>
<td></td>
<td>Date reported</td>
</tr>
<tr>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Collection 4</th>
<th>Lab ID: ____________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Diagnostic</td>
</tr>
<tr>
<td></td>
<td>□ Treatment monitoring</td>
</tr>
<tr>
<td></td>
<td>□ End of treatment</td>
</tr>
<tr>
<td></td>
<td>□ Pre-departure</td>
</tr>
<tr>
<td>#</td>
<td>Date of collection</td>
</tr>
<tr>
<td></td>
<td>Smear results</td>
</tr>
<tr>
<td></td>
<td>Date reported</td>
</tr>
<tr>
<td></td>
<td>Culture results</td>
</tr>
<tr>
<td></td>
<td>Date reported</td>
</tr>
<tr>
<td></td>
<td>Molecular test results</td>
</tr>
<tr>
<td></td>
<td>Date reported</td>
</tr>
<tr>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Collection 5</th>
<th>Lab ID: ____________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purpose:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Diagnostic</td>
</tr>
<tr>
<td></td>
<td>□ Treatment monitoring</td>
</tr>
<tr>
<td></td>
<td>□ End of treatment</td>
</tr>
<tr>
<td></td>
<td>□ Pre-departure</td>
</tr>
<tr>
<td>#</td>
<td>Date of collection</td>
</tr>
<tr>
<td></td>
<td>Smear results</td>
</tr>
<tr>
<td></td>
<td>Date reported</td>
</tr>
<tr>
<td></td>
<td>Culture results</td>
</tr>
<tr>
<td></td>
<td>Date reported</td>
</tr>
<tr>
<td></td>
<td>Molecular test results</td>
</tr>
<tr>
<td></td>
<td>Date reported</td>
</tr>
<tr>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>
## Template Form 13.

**Chest X-Ray Results Summary**

<table>
<thead>
<tr>
<th>CHEST X-RAY RESULTS SUMMARY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Name:</strong> (First name Family name)</td>
</tr>
<tr>
<td><strong>Case Number:</strong></td>
</tr>
<tr>
<td><strong>Date of birth:</strong> (dd-mm-yyyy)</td>
</tr>
</tbody>
</table>

### Screening X-ray

<table>
<thead>
<tr>
<th>View(s):</th>
<th>AP/PA</th>
<th>Lateral</th>
<th>Apical</th>
<th>Oblique</th>
<th>Other (specify):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date taken</td>
<td>Radiology report</td>
<td>Panel physician comment</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiologist’s name:</th>
<th>Physician’s name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date reported:</td>
<td>Date:</td>
</tr>
</tbody>
</table>

### Additional X-ray if clinically indicated or requested

<table>
<thead>
<tr>
<th>View(s):</th>
<th>AP/PA</th>
<th>Lateral</th>
<th>Apical</th>
<th>Oblique</th>
<th>Other (specify):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date taken</td>
<td>Radiology report</td>
<td>Panel physician comment</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiologist’s name:</th>
<th>Physician’s name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date reported:</td>
<td>Date:</td>
</tr>
</tbody>
</table>

### Post-treatment X-ray

<table>
<thead>
<tr>
<th>View(s):</th>
<th>AP/PA</th>
<th>Lateral</th>
<th>Apical</th>
<th>Oblique</th>
<th>Other (specify):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date taken</td>
<td>Radiology report</td>
<td>Panel physician comment</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiologist’s name:</th>
<th>Physician’s name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date reported:</td>
<td>Date:</td>
</tr>
</tbody>
</table>
# Template Form 14.
## TB Treatment Certificate

**To:** Health Officer, Physician or Tuberculosis Control Personnel

<table>
<thead>
<tr>
<th>Patient’s Name:</th>
<th>Patient Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case No. (1st Ref. No.):</td>
<td>New</td>
</tr>
<tr>
<td>IOM Individual No.:</td>
<td>Retirement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date of Birth:</th>
<th>Relapse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age/Sex:</td>
<td>Return after loss to follow up</td>
</tr>
<tr>
<td>Place of Birth:</td>
<td>After treatment failure</td>
</tr>
<tr>
<td>Address:</td>
<td>Transfer In</td>
</tr>
</tbody>
</table>

The individual named above has been treated for:

- **Site of disease:**
  - Pulmonary
  - Extrapulmonary, specify site: _________________

**Date of diagnosis of current TB illness:** _________________

<table>
<thead>
<tr>
<th>Smear</th>
<th>Positive</th>
<th>Negative</th>
<th>Not done</th>
</tr>
</thead>
<tbody>
<tr>
<td>Culture</td>
<td>Positive</td>
<td>Negative</td>
<td>Not done</td>
</tr>
<tr>
<td>Clinical signs and symptoms</td>
<td>Yes, specify: _________________</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

Initial and follow-up laboratory and radiologic test results

- **TST**
  - Not done
  - Done
  - Date applied/drawn:
  - Reading:

- **IGRA**
  - Not done
  - Done
  - Drug Susceptibility Test

  - Pan-susceptible
  - Drug Resistant
  - Not Done

  - Test Date

<table>
<thead>
<tr>
<th>Drug-Susceptibility Test</th>
<th>First-Line DST</th>
<th>Second-Line DST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H</td>
<td>R</td>
<td>Z</td>
</tr>
<tr>
<td>0.1ug/ml</td>
<td>0.4ug/ml</td>
<td></td>
</tr>
</tbody>
</table>
### Molecular Test

<table>
<thead>
<tr>
<th>Test Date:</th>
<th>Test Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

### chest X-ray (CXR)

<table>
<thead>
<tr>
<th>Date</th>
<th>CXR Results</th>
<th>Month</th>
<th>Date</th>
<th>Smear Result</th>
<th>Culture Result</th>
<th>Weight (kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Treatment Regimen

**Pre-treatment weight (kg):**

**End of treatment weight (kg):**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Intensive Phase</th>
<th>Continuation Phase</th>
<th>Treatment Period</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dosage</td>
<td>Total Number of Doses</td>
<td>Dosage</td>
</tr>
<tr>
<td>Isoniazid</td>
<td>DOT</td>
<td>SAT</td>
<td>VOT</td>
</tr>
<tr>
<td>Rifampicin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethambutol</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyridoxine</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Treatment Outcome

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment Outcome</th>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cured</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment completed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment failed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Died</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss to follow up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not evaluated</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Nursing Officer

(First name Family Name)  
Signature:  
Date:  

### Medical Officer in Charge

(First name Family name)  
Signature:  
Date:  

### Clinic contact details

Address:  
Phone:  
Fax:  
Email:  

---

Manual for Tuberculosis Management within IOM Migration Health Assessment Programmes