



Tuberculosis

CDNA National Guidelines for Public Health Units

Version 3.0

3 March 2022

Summary of revision history

Version	Date	Revised by	Changes
3.0	October 2021	TB SoNG Working Group, National TB Advisory Committee	Updated throughout to align with the latest evidence, NTAC and other relevant policy guidance and expert recommendations Endorsed by the Public Health Laboratory Network 16 Nov 2021 Endorsed by CDNA 2 Dec 2021 Endorsed by AHPPC 16 Feb 2022
2.0	April 2015	CDNA	Updated reference to Therapeutic Guidelines: Antibiotic 2014
1.0	3 Jan 2013	Developed by TB SoNG Working Group	Endorsed by CDNA 3 Jan 2013 Endorsed by AHPPC 24 Jul 2013

The Series of National Guidelines ('the Guidelines') have been developed by the Communicable Diseases Network Australia (CDNA) and noted by the Australian Health Protection Principal Committee (AHPPC). Their purpose is to provide nationally consistent guidance to public health units (PHUs) in responding to a notifiable disease event.

These guidelines capture the knowledge of experienced professionals and provide guidance on best practice based upon the best available evidence at the time of completion.

Readers should not rely solely on the information contained within these guidelines. Guideline information is not intended to be a substitute for advice from other relevant sources including, but not limited to, the advice from a health professional. Clinical judgement and discretion may be required in the interpretation and application of these guidelines.

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Abbreviations and definitions

DR-TB:	Drug-resistant tuberculosis (DR-TB): <i>M. tuberculosis</i> strains resistant to one or more first line TB drug. Mono-resistant TB: <i>M. tuberculosis</i> strains resistant to a single first line drug. Poly-drug resistant TB (PDR-TB): <i>M. tuberculosis</i> strains resistant to more than one first line drug but not to both isoniazid and rifampicin. Rifampicin resistant TB (RR-TB): <i>M. tuberculosis</i> strains resistant to rifampicin by either phenotypic or genotypic methodology which may be in any of the above patterns of resistance. Multidrug resistant TB (MDR-TB): resistant at least to BOTH isoniazid and rifampicin (low level isoniazid resistance is considered simply as “resistant”). Pre-Extensively Drug Resistant TB (Pre-XDR TB): <i>M. tuberculosis</i> strains that fulfil the definition of multidrug resistant or rifampicin-resistant TB (MDR/RR-TB) and which are also resistant to any fluoroquinolone. Extensively drug resistant TB (XDR-TB): <i>M. tuberculosis</i> strains that fulfil the definition of MDR/RR-TB and which are also resistant to any fluoroquinolone and at least one additional WHO endorsed Group A drug (bedaquiline and/or linezolid) (WHO 2021 updated definition). The definition prior to 2021 was MDR/RR-TB which was also resistant to a fluoroquinolone and at least one of the second line injectable agents (amikacin, kanamycin, or capreomycin).
CXR	Chest X-ray (radiograph)
DOT	Directly observed therapy
DST	Drug susceptibility testing
FDC	Fixed-dose combination (medicines)
HIV	Human immunodeficiency virus
HRZ(E)	Isoniazid–rifampicin–pyrazinamide- (ethambutol). The use of brackets indicates that the use of the agent (ethambutol) is conditional.
IGRA	Interferon gamma release assay
Index Case	The case with suspected or confirmed TB that triggered contact investigation
LPA	Line probe assay
LTBI	Latent tuberculosis infection – <i>M. tuberculosis</i> complex infection without active disease (i.e. a dormant infection not able to be transmitted); asymptomatic.
Migrant	International Organization for Migration defines a migrant as any person who is moving or has moved across an international border or within a State away from his/her habitual place of residence, regardless of (1) the person’s legal status; (2) whether the movement is voluntary or involuntary; (3) what the causes for the movement are; or (4) what the length of the stay is.
PPD	Tuberculin Purified Protein Derivative
SAE	Serious adverse event
SAT	Self-administered treatment or unsupervised treatment
Source case	The case most likely to have transmitted TB to the index case, and/or a wider group of people.
TB	Tuberculosis
TST	Tuberculin skin test
WHO	World Health Organization

Contents

Summary of revision history	2
Abbreviations and definitions	3
1. Summary	6
Public health priority	6
Case management	6
Contact management	6
2. The disease	7
Infectious agents	7
Reservoir	7
Mode of transmission.....	7
Incubation period	7
Infectious period	7
Clinical presentation and outcome	8
Persons at increased risk of TB	8
Disease occurrence and public health significance	9
3. Routine prevention activities	10
TB Program activities.....	10
Migration screening	10
Vaccination	12
When BCG vaccine is not available	12
Overseas travellers.....	12
4. Surveillance objectives	13
5. Data management	13
6. Communications	13
7. Case definition	14
Reporting.....	14
Confirmed case	14
Laboratory definitive evidence	14
Clinical evidence.....	14
8. Laboratory testing	14
Testing guidelines.....	14
Pulmonary TB.....	15
Infection control requirements for sputum collection	15
Extra-pulmonary TB.....	15
Microscopy and culture.....	15
Drug susceptibility testing (DST).....	16
Nucleic acid amplification tests (NAAT)/PCR.....	16

Genotyping - including whole genome sequencing of M. tuberculosis	17
List of Reference Laboratories	17
9. Case management	18
Response times	18
Response procedure	18
Case treatment	19
Education	20
Isolation and restriction	21
10. Environmental evaluation	22
11. Contact management	22
Identification of contacts	22
Contact definition & exposure risk classification of contacts	22
Management of identified contacts	24
Education	24
Isolation and restriction	25
12. Special situations	25
Drug Resistant TB	25
TB-HIV coinfection	26
TB in children	26
TB in healthcare facilities	26
TB in other institutional settings	27
Airline contact tracing of TB cases	27
13. References and additional sources of information	29
14. Appendices	32
15. Jurisdiction specific issues	32

1. Summary

This guideline focuses on the public health aspects of the management of tuberculosis (TB) in Australia. The most important priorities for TB control and prevention are:

- The timely identification and treatment of persons with active TB; including those with drug-resistant TB (DR-TB).
- The detection and management of infection in contacts of TB cases.
- Detection and prevention of TB in populations:
 - With latent TB infection (LTBI), and
 - High-risk groups (e.g. migrants).

Public health priority

- High for pulmonary (including laryngeal) TB cases; with urgency to assess likelihood and consequences of infectiousness and to determine drug resistance profile; follow up and treatment for a smear positive pulmonary TB case should commence within one working day.
- Routine for extrapulmonary cases and people with latent TB infection (LTBI).

Case management

- Notify microbiologically confirmed or clinically diagnosed TB cases in accordance with state public and environmental health laws; unless otherwise stated (e.g. laboratory mandated notification), it is the responsibility of the diagnosing medical officer to ensure notification occurs.
- Assess infectiousness of the case.
- Ensure appropriate infection control precautions have been implemented: airborne precautions are indicated for all potentially infectious cases.
- The attending medical officer is to implement appropriate treatment in a timely manner with clinical resources and patient support provided by public health/TB services.
- Ensure treatment regimen and duration is appropriate considering site of disease, comorbidities and any antimicrobial resistance detected.
- Ensure microbiological and clinical response to treatment is monitored.
- Exclude from congregated settings, for example workplaces, educational and childcare settings for as long as the case is assessed as likely infectious.
- Report treatment outcomes to Public Health authorities.

Contact management

- Conduct an investigation to:
 - Determine the source of infection for the index case.
 - Screen contacts for TB disease and infection, with persons in prolonged close contact with pulmonary cases as first priority.
- Any contacts with symptoms suspicious of TB should be referred immediately for medical review.
- Any asymptomatic contacts with likely recent infection (positive tuberculin skin test (TST) and/or interferon gamma release assay (IGRA)) should be referred to a clinician experienced in TB to exclude active disease and consider preventive treatment.
- A chest radiograph reviewed by a medical officer is an essential tool in the assessment of both symptomatic TB contacts and those with a positive test for latent infection.

- An evaluation of results of contact tracing in each risk group should be carried out to determine if contact management activity should be extended or ceased.

2. The disease

Infectious agents

TB is caused by any of the *Mycobacterium tuberculosis* complex bacilli. *M. tuberculosis* is responsible for most cases. *M. bovis*, *M. africanum*, *M. canettii*, *M. caprae* and other species very rarely cause TB disease in Australia. Bacille Calmette-Guerin (BCG) variant of *M. bovis* may be isolated following vaccination or use as adjuvant therapy for bladder cancer; BCG is not nationally notifiable or considered to be a TB case.

Reservoir

Humans are the primary reservoir for *M. tuberculosis*, but it can infect other animals (1). *M. bovis* is characteristically found in cattle and other mammals.

Mode of transmission

- TB is primarily transmitted by inhalation of infectious aerosols produced by persons with pulmonary or laryngeal TB during coughing, laughing, speaking, singing or sneezing.
- Transmission can occur from potentially high-risk procedures including sputum induction, treatment using a nebuliser, bronchoscopy, drainage of an open abscess (especially if irrigation of a cavity), autopsy or any procedure in which an aerosol containing *M. tuberculosis* is generated.
- Invasion of *M. tuberculosis* may occur through mucous membranes (e.g. ingestion) or damaged skin.
- Extra-pulmonary TB, other than laryngeal, is generally not infectious, but can co-exist with infectious pulmonary TB.
- Laboratory acquisition via aerosolization of specimen or culture material or by inoculation, may occur in the absence of adequate biocontainment practices.

Australia was declared free of bovine TB in December 1997. Human disease may still occur due to a long latency period or due to exposure in countries where *M. bovis* is prevalent in cattle or other animals.

- *M. bovis* TB results mainly from ingestion of unpasteurised milk and dairy products.
- Aerosol transmission of *M. bovis* has been reported among abattoir and dairy workers and other workers butchering or cutting infected animals (e.g. cattlemen, veterinarians).

Incubation period

The time from infection to the primary lesion or measurable significant immunological reaction, positive TST (or positive IGRA test), can vary from 2–10 weeks (1). In the immunocompetent host, subsequent progression to active TB occurs in only 5–10% of those infected, although progression in up to 14.5% has been estimated in an Australian setting (2). This progression can occur from weeks to decades later – although most will occur within 2 years from initial or re-infection. Asymptomatic infection with *M. tuberculosis*, often referred to as LTBI or TB immunoreactivity, can persist for a lifetime (3).

Infectious period

A person is infectious when viable bacilli are aerosolised. In practice, the greatest risk of transmitting infection is in the period prior to diagnosis, before effective treatment is initiated. Persons with pulmonary/laryngeal TB may be infectious up to three months prior to symptom

onset ([TB Contact Investigation Interviewing Skills Course | Guides & Toolkits | Publications & Products | TB | CDC](#)). The risk of transmitting infection declines within days of commencing effective TB treatment, which emphasises the public health importance of rapidly ruling out drug resistance in all infectious cases.

The likelihood that TB will be transmitted to others (excluding host factors) is determined by the

- a. degree of infectiousness:
 - number of bacilli discharged (greater when acid fast bacilli detected on sputum smear microscopy and highest with laryngeal and cavitating pulmonary TB),
 - viability of bacilli,
- b. capacity for aerosolization (patient induced e.g. coughing, or, by medical intervention),
- c. persistence/survival in aerosol (adequacy of ventilation; sun or UV light exposure),
- d. intimacy and duration of exposure.

Clinical presentation and outcome

Approximately two thirds of all cases in Australia present with pulmonary TB (disease involving the lungs) and can have the following common symptoms:

- Fever and night sweats.
- Unintended loss of weight.
- Feeling generally tired and unwell.
- Cough of any duration but especially lasting greater than 2 weeks.
- Haemoptysis.

Symptom onset may be more acute in children. Clinical suspicion of TB should be high in any person with possible TB exposure and a respiratory infection unresponsive to standard treatments, or an unexplained non-respiratory illness.

Extra-pulmonary TB (disease involving organs other than lungs) can present with a wide range of symptoms dependant on the site of disease and is often accompanied by intermittent fever or weight loss. Patients with extra-pulmonary TB may also have co-existent pulmonary TB.

Some patients with microbiological proven TB may be asymptomatic and only diagnosed by active case finding activities e.g. migrant screening.

A person with LTBI has no symptoms or signs and is not infectious.

The use of standardised TB treatment for an appropriate period of time results in cure rates over 98% in drug susceptible TB (4). Deaths from TB in the Australian setting should be a rare occurrence in the absence of significant co-morbidities; delayed or missed diagnosis is the most important risk factor. The success of treatment requires optimal therapeutic selection (i.e. the right dose, drug combination and duration) delivered without interruption (ensuring uninterrupted drug supply and patient adherence). TB disease does not confer reliable protective immunity and future relapse or reinfection remain a risk.

Persons at increased risk of TB

Those with increased TB exposure risk include:

- Close contacts with an infectious TB case (especially household members).
- Healthcare workers (HCW) who were born or have worked in countries with a high incidence of TB (defined as a TB incidence of ≥ 40 per 100,000). A list of current high TB incidence countries is available on the NSW Health website: [High TB incidence countries \(nsw.gov.au\)](#).

- Migrants (especially arriving in Australia in the preceding 24 months) from high TB incidence countries.
- Recently returned travellers from high TB incidence countries, especially those that have spent a prolonged period of time there, with the risk increasing with the duration of travel.
- People living in overcrowded conditions where TB cases are known to occur (e.g. some Australian Aboriginal and Torres Strait Islander communities or correctional facilities).

HCWs who have worked with TB patients or in TB laboratories in Australia have a modest increase in exposure risk. HCWs who have worked in high TB incidence settings have a high risk of previous TB exposure/infection.

Some groups are more susceptible to progression to TB disease following infection. These include people with recent primary or re-infection (especially within 2 years post exposure but declining with time), immunocompromised individuals or young children with immature immune systems (5). High-risk groups include:

- Children <5 years of age (especially those <2yrs of age where risk of progression is highest).
- Elderly people.
- People with severe malnourishment.
- People living with HIV, poorly controlled diabetes, renal failure, or any immunocompromising disease.
- Patients receiving immunomodulating therapies, e.g. high dose corticosteroids, anti-TNF inhibitors, organ rejection drugs or cancer chemotherapy.

Persons with a past history of treated TB or radiological evidence of past untreated TB (e.g. fibrotic areas, apical scarring or blunted costo-phrenic angles) are at heightened risk of re-presenting with TB (relapse/reactivation and re-infection), especially if they become immune compromised.

Aboriginal and Torres Strait Islander peoples in some parts of Australia are at increased risk of TB due to a combination of TB exposure and other adverse factors. These include high rates of chronic non-communicable disease, which both increase the risk of TB reactivation and may confound the diagnosis (e.g. presence of chronic lung disease) (6).

Disease occurrence and public health significance

The World Health Organization (WHO) estimated the global burden of TB in 2019 at 10 million incident cases (130 cases per 100,000 population per year). Of these the South-East Asia and Western Pacific regions accounted for approximately 44% and 18% respectively. Approximately 8.2% of the incident TB cases were among people living with HIV. There were an associated 1.2 million deaths in HIV negative people with an additional 208,000 in the HIV positive, most of which occurred in Asia and Africa (7).

In Australia, the incidence of TB has remained low, with rates varying between 5.0 and 6.0 per 100,000 for many years (6, 8). These rates compare favourably with other developed countries (7) but show no trend of further decrease. Significantly higher rates of disease occur in specific subgroups, such as persons born overseas and Aboriginal and Torres Strait Islander peoples compared to non-Indigenous Australian born (6, 9).

Drug resistant TB has emerged globally and represents an ongoing concern in Australia given that 85–90% of TB notifications are in persons born overseas. Previous tracking of drug-resistance primarily focused on multi-drug resistant TB (MDR-TB). Globally, there were an estimated 378,000 incident cases of MDR-TB in 2018, and an additional 106,000 cases resistant to rifampicin. Of the total burden, an estimated 3.4% (95% confidence interval [CI]: 2.5–4.4%) of

new cases and 18% (95% CI: 7.6–31%) of previously treated cases were MDR/RR-TB (7). In Australia, approximately 2–4% of incident cases are MDR-TB (10).

The proportion of MDR-TB cases that are XDR-TB (using pre-2021 WHO definition of XDR-TB) based on global surveillance and survey data was 6.2% (95% CI: 4.4–8.2%) (7). XDR-TB is rare in Australia. While recent WHO treatment guidelines have de-escalated the importance of injectable agents, of growing concern is the proportion of MDR/RR-TB cases with resistance to a fluoroquinolone. Available surveillance data from high burden countries reported a proportion of 20.8% (95% CI: 16.3–25.8%) (7).

The prevalence of R/M/XDR-TB often reflects programmatic weaknesses in the countries where the disease was acquired. Compared to the treatment of drug-susceptible (DS)-TB, the treatment of R/M/XDR-TB is longer (up to 2 years to complete), requires agents likely to be associated with adverse effects and treatment success rates are inferior.

For the latest on world TB notifications and drug resistance refer to the WHO Global Tuberculosis Report [TB reports \(who.int\)](https://www.who.int/tb-reports) and for Australia, refer to the annual reports available on the Department of Health website: [Department of Health | Tuberculosis notifications in Australia annual reports](https://www.health.gov.au/health-conditions/communicable-diseases/tuberculosis).

3. Routine prevention activities

TB Program activities

The most effective means of preventing transmission of TB is early diagnosis and prompt effective treatment. Case management and contact screening undertaken by TB services are important public health measures in minimising transmission of infection and preventing emergence of drug resistance.

Migration screening

Pre-migration

In order to be granted a visa, all permanent visa applicants and some temporary visa applicants must undertake pre-migration health screening, through the Immigration Medical Examination (IME). An IME generally includes a medical examination and a chest X-ray (CXR) to screen for TB where the applicant is aged 11 years and over.

Children aged two years to under 11 years of age that satisfy higher TB risk criteria or applying for a refugee or humanitarian visa must undertake either an Interferon Gamma Release Assay (IGRA) or a Tuberculin Skin Test (TST) in lieu of a CXR. If the TST is >10mm or there is a positive IGRA, a CXR is then required. If the CXR has abnormal findings, further investigation is undertaken. Children treated for TB or evidence of LTBI are referred for a post-migration assessment (health undertaking) (11).

Temporary visa applicants only undertake an IME if they are from a higher TB risk country and intend to stay in Australia for six months or more, unless special circumstances apply. An IME is not required for temporary visa applicants from lower risk countries who intend to stay for less than six months, unless special circumstances apply. Special circumstances include where the applicant:

- makes a declaration of previous TB or declares a close household contact with TB within the past five years.
- is working as, or studying to be, a doctor, dentist, nurse, or paramedic.
- is from a high TB burden country and likely to enter a health care or hospital environment.
- is going to be working in a childcare centre.

- is pregnant, from a high-risk country, and intends to deliver the baby in Australia.

If CXR findings are recorded as “strongly suspicious of active TB”, panel physicians refer the applicant for further investigation. All cases with abnormal CXR findings are reviewed by Australian-based Medical Officers of the Commonwealth (MOCs), who may request further investigation and review. These health cases are deferred and the visa application is put on hold while further investigations are undertaken. In such cases, sputum specimens are collected under direct observation over three consecutive mornings and sent for smear and culture investigations.

IMEs are conducted in Australia (onshore) and overseas (offshore). Cases of active TB identified onshore are notified through the National Notifiable Diseases Surveillance System (NNDSS) as is required for other cases of TB diagnosed in Australia. Cases of active TB identified offshore are ordinarily referred for management through the national TB program in the country of residence.

If an applicant is found to have active TB, they must demonstrate that they have satisfactorily completed a full course of treatment and a MOC must be satisfied that they are not a threat to public health before they can be considered for the grant of a visa.

Post-migration

An offshore visa applicant, who intends to stay in Australia greater than 12 months, is placed on a health undertaking for post-migration health assessment as a condition of the grant of their visa if they:

- are diagnosed with TB and subsequently treated prior to migration
- have had any previous TB treatment in the past five years
- have an abnormal CXR suspicious of TB but unlikely active TB on cultures
- have a positive IGRA or TST result
- are a higher risk applicant such as a health care worker or immunocompromised person with CXR findings
- are not fully screened (e.g. due to pregnancy for protection visa applicants).

A health undertaking is a mandatory agreement an applicant makes with the Australian Government to attend a medical follow up for a specific condition with a State or Territory health clinic after arrival in Australia. Applicants do not meet the health requirement for their visa if they do not accept the undertaking agreement. Health undertakings are carried out in conjunction with jurisdictional TB Prevention and Control Services.

Testing for and treatment of LTBI post-arrival is recommended in migrants most likely to benefit (12). Priority should be given to LTBI testing and treating migrants from countries with TB incidence of ≥ 100 cases per 100,000 population where age is less than 35* or age is >35 with associated risk factors for disease progression or any migrant with a history of TB contact in the preceding 2 years, as outlined in the NTAC national position statement on the management of latent tuberculosis: [Department of Health | National position statement for the management of latent tuberculosis infection](#). LTBI assessment of migrants from countries with lesser incidence of TB (40–99 per 100,000) should be considered as resourcing permits, especially where comorbid conditions raise the likelihood of disease progression.

* Age cut off less important where a non-isoniazid containing regimen is used for treating LTBI.

For further information on immigration screening and health undertakings, refer to the:

- Department of Home Affairs website: [Health \(homeaffairs.gov.au\)](http://www.health.gov.au)

- NTAC Policy recommendation on LTBI screening and treatment in children in immigration detention: [Department of Health | Policy recommendation: latent tuberculosis infection screening and treatment in children in immigration detention](#)
- ASID Refugee Guidelines 2016: [Refugee Guidelines 2016 - Australasian Society for Infectious Diseases \(ASID\) Limited](#).

Vaccination

Bacille Calmette-Guerin (BCG) vaccination is an effective vaccine in reducing the risk of TB meningitis and disseminated disease in children aged <5 years in countries of high TB prevalence (1). However, it has limited application in countries where the incidence of TB is low and is not recommended for general use in Australia as its overall efficacy is low. Further information is contained in the current edition of the Australian Immunisation Handbook(13). It is only recommended for specific paediatric groups considered to be at high-risk for TB (14, 15).

When BCG vaccine is not available

During periods of BCG vaccine shortage, jurisdictional health authorities may opt to adopt one or more of the following strategies:

- Ration available vaccine supplies.
- Maintain a registry/list of children to receive catch-up vaccination as and when supply becomes available.
- Source an alternative BCG product (consult your jurisdictional TB services).

Offer pre and/or post-exposure TST or IGRA screening to children travelling to countries with high rates of TB based on a risk assessment.

Where required, TST or IGRA screening may be offered. Screening should only be recommended for children under 5 years of age travelling to countries with a high incidence of TB. For children aged 6 months and over, where possible pre-departure screening should be considered with testing again 2–3 months after returning from travel. Healthy babies under 6 months of age may be assumed negative and only screened 2–3 months after returning to Australia.

Children detected as having been exposed to/infected by TB while overseas should be referred to a specialist physician with experience in managing TB to prevent progression to active disease.

Overseas travellers

While the overall risk of TB to travellers is low in most overseas settings, it is important for practitioners giving advice to travellers to evaluate the individual's risks (16). Briefly, risk mitigation steps include the following:

Pre-travel assessment, including:

- Assessment of risk by considering the up-to-date information on the destination, the individual's risk of progression to active disease if infected, and other personal circumstances that may predispose them to infection (e.g. visiting friends and relatives, working in healthcare or humanitarian aid settings).
- Tailored education to groups at increased risk on their likelihood of exposure, risk reduction measures, and seeking medical care in the event of prolonged respiratory illness.
- BCG vaccination where previously recommended (see [Vaccination](#) above).

- For persons with risk factors for progressing to active disease (e.g. immunosuppressed, children aged <5 years who have not received BCG), consider pre-travel LTBI testing and referral for treatment (before/after) travel if positive.
- It may be necessary to alter travel plans or not travel to the stated destination for persons assessed as being at very high risk of progression to severe TB disease, especially if the risk of acquisition of DR-TB is also high.

During travel risk reduction measures:

- Generally, travellers should avoid close contact or prolonged time with unwell people (known TB patients, persons with productive cough), particularly in confined or crowded areas, and avoid high-risk settings (e.g. clinics, hospitals, prisons or homeless shelters).
- Healthcare workers and similar personnel should undertake best practice infection control precautions, giving prior consideration to resources available at destinations, and noting that infection control practices can vary widely.

Post-travel:

- Generally routine follow-up is not needed for travellers without risk factors for progression to active disease, unless direct contact with TB is known to have occurred.
- For individuals with risk factors for progressing to active disease, repeat LTBI test if baseline negative, and consider LTBI treatment if positive.
- Individuals who develop symptoms consistent with TB during or post-travel should be investigated for active disease.

4. Surveillance objectives

- To monitor the epidemiology of TB in Australia including risk factors to better inform prevention strategies.
- To identify infected contacts and reduce their risk of developing active TB.
- To provide evidence of Australia's progress against national and international strategic disease control targets.
- To monitor drug resistance.

5. Data management

All cases fulfilling the TB case definition are to be notified and data entered onto jurisdictional disease databases. Each year's core and enhanced data is to be completed by May of the following year. Outcome data for cases needs to be updated by May following the end of the notification year for drug susceptible cases from the previous year, and MDR-TB cases from two years prior.

Core and enhanced de-identified surveillance data on all confirmed cases of TB are reported to the Commonwealth via the National Notifiable Disease Surveillance System (NNDSS). Enhanced data includes risk factor information, clinical presentation, diagnostic information, and treatment outcomes.

Data on TB cases in Australia are reported to the WHO annually.

6. Communications

While all cases of tuberculosis require formal notification, there are certain scenarios where prompt communication to senior Public Health personnel is indicated. Each jurisdiction will specify what such scenarios are, who to notify, and what timeframe is required. Examples include MDR/XDR-TB, TB likely acquired in a healthcare setting, where large numbers of people

require contact screening, where widespread transmission becomes apparent and where prolonged presence of an infectious person on an airplane has occurred (usually an international flight). Any case where there is likely to be media interest is usually required to be communicated. Further reporting of cases and need for contact tracing within or between jurisdictions is made by the jurisdictional TB staff of the index case, on a case-by-case basis, in accordance with jurisdictional protocols which may also require notification of the Communicable Diseases department.

7. Case definition

Reporting

Only **confirmed cases** should be notified.

Confirmed case

A confirmed case requires a diagnosis accepted by the Director of Tuberculosis Control (or equivalent) in the relevant jurisdiction, based on either:

1. Laboratory definitive evidence

OR

2. Clinical evidence

Laboratory definitive evidence

1. Isolation of *M. tuberculosis* complex (excluding *M. bovis* var BCG*) by culture (Note that *M. bovis* var BCG isolated from any site in those who have received BCG vaccine or therapeutic BCG bladder instillation for bladder cancer treatment are excluded as cases, but should be notified as vaccine or medication related adverse events).

OR

2. Detection of *M. tuberculosis* complex by nucleic acid amplification testing (NAAT) EXCEPT where this is likely to be due to previously treated or inactive disease.

Clinical evidence

A clinician experienced in TB makes a clinical diagnosis of TB, including clinical follow-up assessment to ensure a consistent clinical course.

Case definitions can be found on the Department of Health website: [Department of Health | Australian national notifiable diseases and case definitions.](#)

8. Laboratory testing

Testing guidelines

Laboratory testing for TB is indicated in people with a clinically compatible illness, particularly if they are at increased risk of TB. Every effort should be made to collect adequate laboratory specimens from pulmonary and extrapulmonary sites in order to establish a microbiological diagnosis. Detection of *M. tuberculosis* complex DNA by NAAT enables a rapid diagnosis. Where Xpert MTB/RIF (Xpert® MTB/RIF) and Xpert MTB/RIF Ultra (Xpert® Ultra) assays are used, the presence of rifampicin resistance conferring mutations can also be detected directly from samples. Detection of TB by culture remains the most sensitive method for detecting *M. tuberculosis* complex and also enables drug susceptibility testing and genetic typing to be performed. Further guidance can be found in the following NTAC documents:

- a. Revised Guidelines for Australian Laboratories performing mycobacteriology (17)

b. Defining a tuberculosis cluster or outbreak (18)

Pulmonary TB

- The clinical service and/or laboratory should provide an instruction form to the patient describing the method of producing a good sputum specimen, the timing of the collection, and the handling of the specimen (e.g. refrigeration at 4o - 8oC pending submission to the laboratory).
- Sputum should be collected on 3 separate occasions (at least one early-morning specimen).
- Sputum induction (using nebulised hypertonic saline) or gastric aspirate (children) should be utilised where a patient is unable to expectorate.
- Sputum samples should be collected in sterile, wide-mouth containers with a leak-proof screw-cap lid; samples must be appropriately labelled.

Infection control requirements for sputum collection

Sputum collection from a coughing patient or by nebulized saline induction will generate infectious aerosols if the patient has pulmonary TB. It is important that sputum collection is performed in the appropriate clinical or laboratory environment with engineering designed to prevent potential transmission of TB beyond the collection area. The sputum collection area should be under negative pressure in keeping with NTAC guidance (17) and the Australian standard (46). Where this is not possible, sputum collection should be performed in a well-ventilated area without shared airflow to other areas. For ambulant patients, sputum collection in an external area away from others is appropriate.

If a healthcare worker needs to be in attendance during collection of a sputum sample, personal protective equipment for prevention of airborne transmission, including a P2/N95 respirator mask, should be used.

Extra-pulmonary TB

The investigation of extra-pulmonary TB requires the collection of samples from normally sterile sites (e.g. cerebral spinal fluid (CSF), bone, lymph node, peritoneum etc) using invasive procedures often facilitated by radiological guidance, or during an operation. Mycobacterial culture of early morning urine on 3 consecutive mornings can be used in the investigation of renal tract TB.

Surgeons and operating room staff must be specifically directed to place specimens in saline and NOT formalin so that culture and drug susceptibility testing are possible.

Microscopy and culture

Only about 60% of culture-positive respiratory specimens will be smear-positive for acid-fast bacilli (AFB). Additionally, smear microscopy cannot reliably differentiate *M. tuberculosis* bacilli from non-tuberculous mycobacteria (NTM). Microscopy therefore lacks sensitivity (so a negative result does not exclude TB) and specificity (“false-positive” results may occur due to the presence of NTMs). Smear positive cases should be treated as TB until proven otherwise.

Smear results should be available within 24-48 hours of specimen receipt even on weekends if the specimen is deemed urgent after consultation between the treating clinician and the laboratory. Microscopy provides a measure of the infectivity of the patient (i.e. smear-positive cases have a heavy burden of acid-fast bacilli (AFB) in their sputa that can be transmitted by coughing, singing, etc.).

Culture remains the definitive “gold standard” investigation for TB and in contrast to microscopy, culture is highly sensitive and specific.

The initial culture and identification of *M. tuberculosis* complex takes an average of 10–21 days with the subsequent susceptibility results expected within 15–30 days of specimen receipt. Within 24 hours of culture positivity, all TB culture laboratories should be able to perform an immunochromatogenic test (detection of MPT64 antigen) or a molecular assay for rapid identification of *M. tuberculosis* complex. Rarely, strains of *M. tuberculosis* complex may be MPT64 negative.

Some cases of TB (which respond appropriately to therapy) might be found to be negative by microscopy, NAAT and culture. About 15% of TB cases each year in Australia are not laboratory-confirmed (6). Rarely, culture is open to laboratory cross-contamination of AFBs from a “strong-positive” sample to a “true-negative” sample. Clinicians should discuss with the laboratory any cases of TB which lack clinical plausibility in order that the laboratory can investigate the possibility of cross-contamination.

Drug susceptibility testing (DST)

The NTAC Revised Guidelines for Australian Laboratories Performing Mycobacteriology Testing stipulate that drug susceptibility testing (DST) should be performed on:

- All initial isolates of *M. tuberculosis* (isoniazid, rifampicin, ethambutol and pyrazinamide).
- Isolates from patients who remain culture-positive after 3 months of treatment.
- Isolates from patients who are clinically failing treatment.
- An initial isolate from a patient relapsing after previously successful TB treatment.

Where there is resistance to rifampicin, second line agents should also be tested where a WHO endorsed method is available. Recommendations on grouping of second line antimicrobial agents and critical concentrations for DST have been published in WHO operational handbook for drug-resistant tuberculosis treatments (19). Where resistance to isoniazid but not rifampicin is detected, fluoroquinolone DST should also be performed (20, 21). A specialist in the treatment of TB should be consulted regarding the appropriate therapeutic regimen and dosages for treatment. Recommendations for treatment of drug susceptible TB in Australia can also be found in the electronic Therapeutic Guidelines ([Therapeutic guidelines > eTG complete | Therapeutic Guidelines](#)).

Nucleic acid amplification tests (NAAT)/PCR

NAAT has a sensitivity intermediate between that of microscopy and culture for TB detection. Commercial NAAT assays have a high sensitivity (>95%) in smear-positive sputum specimens, but lower sensitivity in smear-negative specimens and therefore a negative result does not exclude TB. The NTAC Guidelines for Australian Mycobacteriology Laboratories includes principles for the use of NAAT (17).

The Xpert MTB/RIF and Xpert Ultra assays (Cepheid, Sunnyvale, Calif) detect both *M. tuberculosis* complex and rifampicin resistance (an indicator for probable MDR-TB). The assays are endorsed by WHO for use on pulmonary and selective extra-pulmonary samples. Xpert Ultra has greater sensitivity and is the preferred test for paucibacillary samples, especially CSF. Xpert MTB/RIF or Xpert Ultra should be performed on smear positive sputum respiratory samples to confirm TB and assess rifampicin susceptibility as soon as possible. When *M. tuberculosis* is detected in very low concentrations with the Xpert Ultra assay, defined as ‘TRACE’, the possible explanations include true infection, a false positive result or past treated infection. It is recommended a second positive detection with the same assay (including a repeat ‘trace’ call) before considering as a true positive result from sputum samples. For extrapulmonary and bronchoscopic samples, or samples collected in children with pauci-bacillary disease, a second sample is not required to further investigate a ‘TRACE’ call but final diagnosis should consider all information including pre-test probability, TB history and results of TB culture.

Where TB is detected in TRACE amount, the assay will not report on rifampicin susceptibility and this will be reported as “indeterminant”.

Xpert Ultra takes a little over an hour to run, while other NAAT may take a few hours and results are usually available within a day. Some NAAT tests may only be validated and licenced for use on sputum samples. Use on extrapulmonary samples is possible where specified by the manufacturer and validated by the testing laboratory.

Where rifampicin resistance is detected, rapid detection of second line drug resistance, especially to fluoroquinolones can be important in determining which MDR/RR-TB regimen is appropriate. Line probe assays (MTBDRsl) and the recently released Xpert MTB/XDR assay can both provide such information.

NAAT does not replace culture as in addition to improved sensitivity, the latter remains essential for comprehensive phenotypic DST and genotyping.

Genotyping - including whole genome sequencing of *M. tuberculosis*

The Australian Mycobacterium Reference Laboratory Network (MRLN) performs molecular epidemiological typing on the initial isolate from every newly diagnosed culture positive TB patient. Mycobacterial interspersed repetitive-unit–variable-number tandem repeat (MIRU-VNTR) remains in widespread use, but is confounded by poor differentiation of selected common strains (e.g. the “Beijing” strain).

Whole genome sequencing provides a high degree of discrimination for genotyping and is a valuable tool in delineating recent transmission events. Furthermore, resistance conferring mutations can be rapidly identified. At the time of writing, several Australian jurisdictions are routinely using whole genome sequencing (WGS) on all new *M. tuberculosis* complex strains with other jurisdictions employing (or referring for) WGS on a selective basis. At the current time, a cultured isolate is still required for reliable WGS.

List of Reference Laboratories

The Australian MRLN comprises the mycobacteriology laboratories at the following institutions:

- Institute of Clinical Pathology and Medical Research, NSW Health Pathology, Westmead, New South Wales.
- PathWest Laboratory Medicine Western Australia – Queen Elizabeth II Medical Centre, Hospital Avenue, Nedlands, Western Australia.
- Pathology Queensland, Royal Brisbane and Women’s Hospital Campus, Herston, Queensland.
- SA Pathology, Adelaide, South Australia.
- Victorian Infectious Diseases Reference Laboratory, North Melbourne, Victoria.

For further information on laboratory testing, refer to:

- The Public Health Laboratory Network (PHLN) laboratory case definitions website: [Department of Health | Tuberculosis Laboratory Case Definition \(LCD\)](#)
- National Tuberculosis Advisory Committee, Revised guidelines for Australian laboratories performing mycobacteriology (17).

9. Case management

Response times

Follow up of sputum smear positive pulmonary TB notifications for appropriate infection control (if not already in place), and treatment should begin within 1 working day of receipt of notification. All other cases should begin follow up within 3 working days. Where drug resistance is suspected or proven, initiation of antimicrobial therapy may be delayed pending further DST results if clinically safe to do so.

Response procedure

Case investigation

Generally, investigation of TB cases is undertaken by TB services staff, in collaboration with the case's healthcare providers, using a disease investigation form (see example in [Appendix 1](#)). Wherever possible, seek the treating doctor's consent; however, where this cannot happen in a timely fashion, follow-up should proceed. Essential actions are:

- Confirm the onset date and symptoms of the illness.
- Document the time of first contact with healthcare for symptoms.
- Review results of relevant laboratory tests, and/or recommend that tests be done to confirm the diagnosis of TB and/or the detection of rifampicin resistance by rapid NAAT.
- Interview the case (or carer) and obtain history to inform the contact management plan (including possible exposures e.g. occupational, recreational, recent travel and identifying contacts).
- If the index case is a child, identify the possible source case as a matter of priority, given that children act as 'sentinels' of recent local transmission.
- Smear negative/culture positive pulmonary TB cases should have sputum collected when culture positivity is reported to see if the case has progressed to smear positive.
- Extra-pulmonary TB cases have a CXR and sputum samples collected to determine co-existing pulmonary involvement.
- Review case and contact management ensuring relevant respiratory isolation and infection control strategies are in place.
- Ensure infection control professionals are notified where appropriate (e.g. in hospital).
- Ensure (or confirm) with the TB staff that an appropriate treatment plan is in place.

As part of the case investigation, an assessment is made regarding the infectiousness of the case based on clinical, radiological and laboratory findings. The degree of infectiousness is categorised as follows (Table 1):

Table 1. Infectiousness of TB cases based on clinical, radiological and laboratory findings

Degree of infectiousness of case	Clinical, radiological and laboratory findings
Negligible	Extrapulmonary TB Sputum smear negative & culture negative pulmonary TB
Lower	Sputum or bronchial washings smear negative & culture positive (no cavitation on CXR)
Higher	Sputum smear positive & [culture positive or PCR positive] Cavitation on CXR regardless of smear status but PCR or culture positive Bronchial washings smear positive & [culture positive or PCR positive] Laryngeal TB

Cavitation evident on CT scanning but NOT on CXR is of uncertain significance regarding infectivity. Decision making should be based on the CXR appearance in this setting.

Case treatment

Unless drug resistance is proven or suspected, new cases of pulmonary TB should commence on standard 4 drug therapy (isoniazid, rifampicin, ethambutol and pyrazinamide). Dosing should be daily. Once the strain is confirmed as fully drug susceptible to these first line agents, ethambutol can usually be omitted from the regimen and pyrazinamide is routinely ceased after 8 weeks, representing the standard duration of the intensive phase. A continuation phase follows with a minimum total duration of therapy of six months for fully susceptible *M. tuberculosis* disease. For detailed information on therapeutic agents including dosing and use in extrapulmonary TB see the relevant jurisdictional guidance or the current edition of Therapeutic Guidelines: Antibiotics (22). Outcomes with intermittent dosing are considered inferior although thrice weekly dosing in the continuation phase may be utilised in carefully selected cases (e.g. in low burden of disease) where there are barriers to delivery of daily therapy and should always be administered as directly observed therapy (DOT). Twice weekly regimens should never be used. Pyrazinamide, combination tablets and many second line agents are not registered with the Therapeutic Goods Administration (TGA) in Australia and need to be procured using the TGA special access scheme.

Jurisdictional TB experts should be consulted regarding the management of drug resistant TB including all forms of multidrug resistant TB.

Treating physicians are responsible for implementing appropriate treatment strategies in individual cases with support provided by public health/TB services. Given the complexity and long duration of TB treatment regimes, it is crucial that a patient-centred approach is taken when developing an individualised case management plan. It is important to balance patient rights and public safety by applying least restrictive public health interventions that are effective in achieving adherence, and involving patients in a meaningful way in making decisions concerning their treatment supervision and overall care (23, 24). Key aspects when developing a case management plan include:

- Improving treatment literacy (see [Education](#) below).
- Identifying and addressing individual needs and barriers.

- Assessing for likely adherence to treatment and reviewing strategies of adherence support.
- Discussing plans for assessing response to therapy.

Several strategies are available for improving adherence. The strategies applied for cases are decided by local jurisdictional public health authorities/TB services and the treating physician, and may consider use of:

- A comprehensive case management approach – providing a team of personnel responsible for continuity of care, management and follow-up, which is coordinated by an assigned case manager.
- Selective DOT for at-risk patients – see below.
- Enablers and/or incentives – e.g. providing assistance with transport and other costs, convenient clinic hours and (decentralised) locations, assistance in accessing social services, reminders and follow-up of missed appointments, staff who can overcome language and cultural barriers, integration of care with other conditions, etc.
- Fixed-dose combination (FDC) therapy to simplify treatment where appropriate.
- Hospitalisation – see below (24-27).

DOT has been promoted as the standard of practice to minimise the development of initial or further drug resistance, the recurrence of disease related to non-adherence or inappropriate TB treatment, to assist the patient in achieving cure and to document successful treatment completion. Systematic reviews comparing DOT to self-administered therapy (SAT), however, did not find any significant differences on several outcomes of interest (including mortality, treatment completion and relapse); although, DOT was significantly associated with improved treatment success and increased sputum smear conversion during treatment (28). DOT delivered in the community has shown favourable treatment success rates when compared to DOT delivered at a fixed health clinic (29, 30). A Victorian study comparing family-based DOT with supervised but non-observed therapy found there was no significant difference in relation to treatment completion or non-adherence (31).

Decisions regarding use and mode of DOT should be based on local and individual patient circumstances. In certain situations, DOT is strongly encouraged, e.g. smear positive cavitary TB, any retreatment case or a case with any drug resistance and where factors are present predicting likely non-adherence. Thrice weekly therapy is not a preferred method but may be considered very occasionally (e.g. in low burden of disease) and should always be administered as DOT.

Many patients can be treated on an outpatient basis. Hospitalisation may be required if:

- Investigations are required to establish the diagnosis
- There is a need for continuous in-patient care due to complications from TB or other co-morbid conditions
- It is necessary to monitor adherence and tolerance of drug therapy
- The patient is likely to be a public health risk or if social circumstances in the place of residence necessitate admission.

Education

Education about the disease process and transmission of infection is provided to patients and household contacts using a qualified interpreter as appropriate. The importance of adherence to treatment is reinforced and further information provided about medications and possible side effects of drug therapy. Effective communication and provision of clear information is a high priority for patient management. It is important to emphasise that TB is a curable and

preventable disease. Unfortunately, there is still much stigma associated with the disease. Support and reassurance are required. If patients are treated at home for smear positive pulmonary TB, they must be instructed to remain there without visitors coming into the house until they are assessed as not being infectious. Language specific fact sheets about TB and drug treatment should be provided to all patients and are available from jurisdictional TB units.

Isolation and restriction

It is recommended that patients with suspected or confirmed pulmonary TB who are admitted to hospital should remain isolated in a negative pressure room with airborne precautions applied. A smear positive patient who tests negative for TB by Xpert MTB/RIF Ultra may generally be released from airborne precautions unless very strong clinical suspicion remains, in which case a second Xpert test can be performed. For further guidance on infection control measures, see:

- [Section 12. Special Situations: TB in healthcare settings](#)
- NTAC's Infection control guideline for the management of patients with suspected or confirmed pulmonary TB in healthcare settings (32): [Department of Health | Infection control guidelines for the management of patients with suspected or confirmed pulmonary tuberculosis in healthcare settings](#)

Infection control precautions should be maintained until discharge criteria are met. In principle these criteria include:

- A reduction in or absence of cough with or without other symptoms.
- Reduced smear burden or smear negativity.
- Assured treatment by direct observation.
- An appropriate discharge plan and referral to TB services.

If drug resistance is suspected, cases should remain in isolation with airborne precautions in place until susceptibility results are confirmed. If sputum remains smear positive, a decision about discharge should be made in consultation with a specialist physician who has experience in managing TB and taking into account the social circumstances at home, such as the potential to expose new contacts and the presence of children <5 years of age.

Patients with pulmonary TB who are managed at home should be isolated until assessed as being at minimal risk of transmitting infection in consultation with local TB services. Adequate social support and supervised therapy is essential in the home environment to maintain home isolation. Assessment of other family members should be undertaken as a matter of priority to determine their status and also the possible need for preventive therapy in any children <5 years of age with no initial evidence of infection. The patient and family must also be provided with appropriate education and counselling about minimising the risk of transmission of infection; i.e. cough hygiene, avoiding new contacts and restricting movements away from home.

There are no restrictions on the movement of patients with extra-pulmonary disease, who have had pulmonary TB excluded or those with negative sputum smears on adequate therapy.

Cases must be excluded from educational facilities and children's services (including childcare, family day care, kindergartens, after school care) as required under jurisdictional regulations.

A restriction order may be issued to a person with pulmonary TB who does not comply with prescribed treatment and is not willing to limit their movement within the community (see [Section 15: Jurisdiction specific issues](#) for links to relevant legislation). Enactment of an isolation order is a last resort that follows extensive consultation between the treating clinicians and TB services, patient counselling, psychological assessment and use of alternative strategies to enhance adherence, including incentives and enablers.

10. Environmental evaluation

To assist in the identification of contacts at risk of infection, an environmental assessment should be undertaken of the settings that the patient has been spending time while infectious. Factors to consider include:

- Ventilation.
- Room size.
- Proximity to the case.
- Duration of contact – while 8 hours cumulative contact is often used as a minimum time to acquire TB infection, a lower threshold should be considered where more susceptible people are involved or people participate in a high-risk medical procedure without appropriate personal protective equipment: (induced coughing/intubation) or are in a high-risk setting (post-mortem of an undiagnosed TB case where airborne precautions were not implemented).

11. Contact management

Identification of contacts

The aims of contact tracing are to:

- Identify the source case.
- Identify further cases of active TB among those in contact with the disease (co-prevalent cases).
- Identify people who may have become infected following contact with a person found to have active TB, especially vulnerable young children (<5 years of age).
- Counsel people found to have LTBI and refer them for assessment and preventive therapy.

The estimated risk of transmission should guide the priority, rapidity and thoroughness of the contact investigation.

Jurisdictional public health legislation will determine who has authority to carry out contact tracing.

The following steps should be undertaken by or in conjunction with the TB services:

1. Categorise the case according to the likely degree of infectiousness (see [Section 9: Case management](#)).
2. Obtain a list of contacts and categorise the contacts according to their estimated risk of exposure to TB (see [Contact definition](#) below).
3. Assess all high-risk contacts of suspected or confirmed pulmonary and laryngeal TB cases first.
4. Consider examination of medium risk contacts (see [Contact definition](#) below) of pulmonary or laryngeal TB cases if there is evidence of transmission in high-risk contacts.

Contact definition & exposure risk classification of contacts

The exposure risk for individual contacts is determined by the intensity, frequency and cumulative duration of time they spent with the index case during the infectious period. Contacts should be classified into high, medium and low exposure risk to assist prioritisation of screening activities (Table 2). Individual circumstances and risk may vary amongst groups of contacts.

Additional information may become available so these classifications should be reassessed throughout the investigation.

Table 2. Contact exposure risk classification

Exposure risk classification	Example groups
<p>High exposure risk</p> <p>Frequent, prolonged and close contact with the index case (cumulatively ≥8 hours*)</p> <p>OR</p> <p>Unprotected exposure to aerosol generating medical procedures[^]</p>	<ul style="list-style-type: none"> All people living in the same household or dwelling as the index case (including household-like settings such as patients sharing a hospital room), Non-household close contacts who shared an enclosed space, such as a social gathering place, workplace or educational setting, for extended periods, Contact during other high-risk social activities such as singing in enclosed settings or sharing smoking implements (e.g. bongos/water pipes), Contacts exposed during high-risk medical procedures without adequate personal protective equipment.
<p>Medium exposure risk</p> <p>Frequent but less intense contact with the index case (cumulatively 4-8 hours*)</p>	<ul style="list-style-type: none"> Other close relatives, friends, students in the same classroom, work colleagues, and neighbours who are not included in the high-risk group.
<p>Low exposure risk</p> <p>Casual contact with the index case (cumulatively <4 hours*)</p>	<ul style="list-style-type: none"> Other contacts at school, in the workplace, in medical environments, or extended family and friends who were seen occasionally, and others not included in high or medium risk groups.

*Timeframes provide a rough guide to risk. Theoretically, no amount of exposure to TB is absolutely without risk, and the threshold for significant risk has not been adequately quantified (33-35).

[^]Procedures likely to generate aerosolised particles containing M. tuberculosis as outlined in [mode of transmission](#).

Each contact tracing activity needs to be developed and evaluated on an individual basis. After contact tracing has been carried out in each risk group, an evaluation of the results should be carried out to determine if transmission has occurred. As a guide, if the majority of the closest contacts have been tested and all are TST and/or IGRA negative and remain negative at 3 months post contact, testing of more remote contacts is usually unnecessary.

Initiate screening within:

- 7 days of index case diagnosis for high-risk contacts of higher infectious cases and high-risk susceptible contacts.
- 14 days of index case diagnosis for high-risk contacts of cases of lower infectiousness.

Screening of contacts of cases with negligible infectiousness should be considered amongst closest contacts in order to identify a source case, especially when the index case is a child. Only if there is evidence of transmission in the initially screened contacts group should screening progress to the lower risk groups.

All contact tracing services should be provided free of charge.

Management of identified contacts

Contact investigation requires close co-ordinated management between nursing and medical personnel. Initial assessment includes a careful history and a test for LTBI (TST or IGRA). Medical assessment including a CXR is indicated if the contact is symptomatic of TB, has either a positive TST or IGRA test or is considered particularly vulnerable (e.g. child <5 years, immunosuppressed person).

Either TST or IGRA may be used for the investigation of LTBI in most circumstances. Neither test should be used in the investigation of active TB disease (though TST and/or IGRA may be used as supplementary tests in paediatric cases, but not as a 'rule-out' test). Further information on the use of IGRA tests has been published by NTAC [Department of Health | Position statement on interferon-γ release assays for the detection of latent tuberculosis infection](#) (36).

Information on the drug susceptibility pattern of the isolate from the source case should be pursued as this information will determine which antimicrobial agents are likely to be effective for preventive therapy in contacts.

Management decisions should be made by clinicians experienced in the diagnosis and management of tuberculosis. Recommendations to guide the management of identified contacts include:

- All contacts with a positive TST or IGRA must have active TB excluded, by clinical assessment, CXR, and other investigations including sputum culture as indicated.
- All contacts with a positive TST or IGRA where active TB has been excluded should be considered for preventive therapy for LTBI.
- Children <5 years of age should be considered for commencement of preventive therapy (window prophylaxis) regardless of the initial TST or IGRA result (if performed within 8 weeks of last exposure), especially if under 2 years of age. If follow up screening is negative at 8-12 weeks following exposure then in most circumstances window prophylaxis would be ceased, unless there is considerable concern about the child's immune competence and the reliability of the test result.
- If the TST or IGRA is negative at the initial examination, the test should be repeated 8–12 weeks after the last exposure to the case and/or since treatment was commenced and the case considered no longer infectious.
- If preventive therapy is not given because of a medical contraindication or the patient declines, the individual should remain under clinical and radiological surveillance for at least one year in children under 5 years of age and at least 2 years in older children and adults.

Education

Contacts should be advised about the nature of TB infection and disease, its mode of transmission and the importance of adhering to follow up plans and treatment for LTBI (if prescribed) using a qualified interpreter as appropriate. Recognising there are many misconceptions about TB, effective communication and provision of clear information is a high priority. It is important to emphasise that TB is a curable and preventable disease. Counselling about the risks of reactivation of latent infection and awareness of symptoms must be provided to those with a positive TST or IGRA and not treated. Language specific fact sheets about TB and drug treatment, and about LTBI and treatment or follow up, should be provided to all patients and are available from jurisdictional TB units.

Isolation and restriction

Contacts should not be isolated or restricted unless they have symptoms consistent with pulmonary TB. Such TB suspects should be isolated until active TB is excluded (see [Section 9: Case management](#)).

12. Special situations

Drug Resistant TB

Prevention of drug resistant TB (DR-TB) through good management of both drug susceptible and drug resistant TB and effective implementation of infection control remains paramount.

Early and accurate detection of DR-TB is crucial. This will depend on a high index of clinical suspicion in the first instance and use of molecular diagnostic assays (e.g. Xpert MTB/RIF) and conventional culture and DST.

Isoniazid resistant (but rifampicin susceptible) TB is the most common form of drug resistant TB and estimated globally at about 11% of cases (7). New guidance on the treatment of isoniazid resistant TB recommending the addition of the fluoroquinolone, levofloxacin, to first line treatment for 6 months was released by the WHO in 2018 (37). Management of these cases should be undertaken in consultation with clinicians with TB expertise.

Management (clinical, laboratory and public health) of MDR-TB cases in Australia should be multidisciplinary and co-ordinated by those with TB expertise.

The treatment regimen used is based on the results of molecular and phenotypic DST and a detailed history of any previous treatment. The treatment implemented should adhere to the following principles (38):

- All patients should be appropriately counselled about the available treatment options to enable informed and participatory decision making.
- Social support is very important to ensure a patient-centred approach to the delivery of care and adherence to treatment (directly observed treatment strongly recommended).
- Active TB drug safety monitoring and management is essential.

WHO endorsed treatment regimens for MDR-TB have changed substantially in recent years in both composition and duration. Considering variables such as confirmation of fluoroquinolone susceptibility, site of disease and previous TB drug exposure either a shorter 9 month or a longer 18-20 month regimen may be appropriate. Bedaquiline is a key agent in either regimen and has allowed the omission of aminoglycosides from most MDR-TB regimens (19). The final regimen choice will depend on DST results, and clinical and patient factors, including drug penetration to site of disease (e.g. CSF penetration of agents to treat TB meningitis).

Other key considerations include infection control and regular monitoring to provide ongoing patient support, assess clinical progress and monitor side effects. Following completion of MDR-TB treatment, patients should be reviewed for at least 2 years (39).

The approach to identifying infected contacts of a drug resistant case is the same as set out in [Section 11: Contact management](#). The risk of infection in contacts of an infectious MDR-TB case is not different than for contacts of drug susceptible cases; however, the management of infected contacts lacks international consensus as there is no proven preventive treatment. A number of randomised controlled trials are currently in process, but pending their outcome international consensus favours a fluoroquinolone with or without a second drug for those most at risk (40). Consultation with jurisdiction TB programme experts should occur before preventive therapy for MDR-TB contacts is initiated.

TB-HIV coinfection

Globally, TB is the most important opportunistic infection complicating HIV infection and is the leading cause of AIDS-related deaths (41). In Australia, dual infection with HIV and TB is much less common than in developing countries with approximately 2% of TB cases with a known HIV test outcome testing positive for HIV (6). The interaction between HIV and TB infection is bidirectional. People with HIV infection are predisposed to reactivation of LTBI as well as rapid progression of recently acquired infection. The rate of progression from LTBI to active TB is as high as 5–10% per year compared to 5–15% over a lifetime in those without HIV infection (42). TB also impacts on the course of HIV infection.

TB can be the initial manifestation of unrecognised HIV infection. All patients with newly diagnosed TB should be tested for HIV. The care of TB-HIV coinfecting cases should be referred to an HIV specialist with TB experience. Drug-drug interactions require careful consideration. The public health management of these cases is essentially the same as outlined in [Section 9: Case management](#) and [Section 11: Contact management](#).

TB in children

TB in children is different to adult TB in the following ways:

1. Infection is more likely to progress to active TB, especially in infants and young children (<5 years of age). The younger the child when infected, the greater the risk of disease progression. The vast majority of cases will present within 1 year after primary infection.
2. Infection is more likely to result in disseminated disease and so extra-pulmonary TB is relatively more common in young children. BCG reduces the risk of severe forms of disseminated disease such as TB meningitis.
3. Childhood TB is usually paucibacillary and rarely contagious, unless lung cavities develop, which is common in adolescents. Adolescents are at increased risk of TB compared to other children (except where < 5 years of age) and usually present with disease similar to adults.
4. Diagnosis of TB in children can be more difficult to confirm bacteriologically, because it is usually paucibacillary and it can be challenging to obtain adequate respiratory specimens for laboratory examination from young children. Bacteriological confirmation should always be pursued by collecting appropriate specimens, especially for evaluation by Xpert Ultra and/or culture, but treatment initiation should not be delayed until all results are known.

The care of a child suspected of having TB should involve a clinician experienced in the management of TB in children. The public health management is essentially the same as outlined in [Section 9: Case management](#) and [Section 11: Contact management](#), with the recognition that contact tracing of children is mainly done to identify the source case. Treating children with LTBI is indicated to reduce the risk of developing disease, both immediately after acquiring the infection (particularly in children <5 years of age) and to reduce their lifelong risk of developing future disease reactivation.

TB in healthcare facilities

Nosocomial transmission of TB can occur, particularly when diagnosis is delayed. Early detection is the most effective measure to control TB in healthcare settings. It is important that a high index of suspicion for TB is maintained, particularly in patients with respiratory symptoms and belonging to a high-risk group for TB, such as new arrivals and recently returned travellers from high incidence countries, contacts of an active case within the past 5 years, those with a history of previous TB treatment, Aboriginal and Torres Strait Islander persons in localised areas

(e.g. in parts of the Northern Territory and Queensland), patients with HIV or other immunocompromised states, and elderly Australians (32).

Airborne precautions (in conjunction with standard precautions) and other infection control measures should be applied for all suspected or confirmed cases of pulmonary TB. NTAC has issued detailed guidance on this topic: [Department of Health | Infection control guidelines for the management of patients with suspected or confirmed pulmonary tuberculosis in healthcare settings](#).

In the event a HCW is exposed to an undiagnosed case of TB, appropriate contact tracing and screening measures must be implemented. The index case may also be a HCW. Investigation and management will be the same as outlined in contact management (see [Section 11: Contact management](#)).

Healthcare facilities are required to have protocols and guidelines for routine TB prevention and management, including for healthcare workers. For detailed guidance please refer to the NTAC document, "Management of Tuberculosis Risk in Healthcare Workers in Australia": [Department of Health | National Tuberculosis Advisory Committee Guideline: Management of Tuberculosis Risk in Healthcare Workers in Australia](#).

TB in other institutional settings

Although contact identification and investigation follow the same principles as general contact tracing, clients in institutional settings (including educational facilities, childcare settings, special schools, community residential facilities and prisons), may be more vulnerable to infection, at increased risk for progression to disease or give rise to needless anxiety in settings with limited understanding or stigma surrounding the disease. In addition, an index case in these settings will lead to increased family, staff and community anxiety and stress. Key messages to be communicated include the relatively low communicability of TB, the lack of risk for contacts to transmit infection and reassurance about standard public health policy to identify and investigate contacts for evidence of infection.

Airline contact tracing of TB cases

The risk of acquiring TB during airline travel is considered to be very low (43). To date, there are no published cases of active TB demonstrated to have been acquired during plane travel. A recent systematic review (44) highlighted that in the majority of publications assessed, there was no evidence of transmission, even when the index case was AFB smear positive. Only a single study provided substantial evidence that TB infection (without disease) had been transmitted during air travel (45).

Despite the low risk, where a patient who is infectious has undertaken air travel, tracing of airline passengers may be required. This is more likely if the:

- Patient was symptomatic at the time of travel.
- Sputum specimens are found to be direct smear positive for AFB.
- Time on the aircraft was 8 hours or more.
- Time elapsed between flight and notification of case is within 3 months.

The National Incident Room should be advised if airline contact tracing is considered indicated to alert international health authorities if the flight was outbound or to co-ordinate jurisdictional notification if the flight was inbound.

Passengers who travelled in the same row, 2 rows in front and 2 rows behind the index case should be advised, in writing, of their possible exposure to TB and offered appropriate assessment and screening. Screening should be arranged at 8–12 weeks after the flight to

coincide with the optimum time for TST (or IGRA) conversion if infection has occurred. If the index case is a member of the aeroplane crew, passengers are unlikely to be at increased risk of infection but crew members should be assessed using the same principles of contact management as outlined above. (see [Section 11: Contact management](#)).

13. References and additional sources of information

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TB information and fact sheets are available on state and territory websites:

- Australian Capital Territory: [Tuberculosis \(health.act.gov.au\)](http://health.act.gov.au)
- Victoria: [Tuberculosis \(health.vic.gov.au\)](http://health.vic.gov.au)
- New South Wales: [Tuberculosis \(health.nsw.gov.au\)](http://health.nsw.gov.au)
- Queensland: [Tuberculosis \(health.qld.gov.au\)](http://health.qld.gov.au)
- Northern Territory: [Tuberculosis \(health.nt.gov.au\)](http://health.nt.gov.au)
- Western Australia: [Tuberculosis \(health.wa.gov.au\)](http://health.wa.gov.au)
- South Australia: [Tuberculosis \(www.sahealth.sa.gov.au\)](http://www.sahealth.sa.gov.au)

National Tuberculosis Advisory Committee website:

- Department of Health NTAC: [Department of Health | About the National Tuberculosis Advisory Committee \(NTAC\)](http://www.health.gov.au/about-the-national-tuberculosis-advisory-committee)

14. Appendices

Appendix 1: Example of TB Investigation form - *If you need help accessing this document, please contact CDNA.SoNG@health.gov.au.*

- [Tuberculosis-Case-Form-Aug13.pdf \(health.gov.au\)](http://health.gov.au)
- [Tuberculosis Case Investigation Form - Word 71 KB](http://health.gov.au)

15. Jurisdiction specific issues

Links to State and Territory Public Health Legislation, the *Biosecurity Act 2015* and the *National Health Security Act 2007*: [Department of Health | Links to State and Territory Public Health Legislation, the Biosecurity Act, and the National Health Security Act 2007](http://www.health.gov.au)