Guidelines for Tuberculosis Control in New Zealand 2010
Chapter 5: Tuberculosis in Children

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## Summary

### Clinical and diagnostic differences from adult tuberculosis

- The same basic principles that apply to diagnosis and management of TB in adults apply to children. However, there are some important clinical and diagnostic differences.
- Children have a higher risk of progressing from infection to disease than adults and a higher risk of developing severe forms of disease (miliary and meningeal).
- Younger children < 5 years have a higher risk of developing extrapulmonary disease particularly miliary or meningeal TB.
- TB in children is usually an immediate complication of primary infection with a closed caseous paucibacillary lesion. Cavitatory TB is rare in children.
- Majority of TB in young children occurs within one year of infection, meaning that TB disease in a child is a marker of recent transmission of the organism.
- Most children are infected from an infectious adult within their own immediate or extended family.
- Majority of children with intrathoracic TB have minimal symptoms and signs.
- Early suspicion and diagnosis is a crucial part of detection of TB in children.
- Diagnosis of TB in children is usually based on history and examination along with a combination of positive tuberculin skin test, known contact with adult case of TB and clinical or radiological features suggestive of TB.
- Miliary TB has a high risk of meningeal involvement in over 50% of cases, so many experts would recommend all children < 5 years with miliary TB should undergo a lumbar puncture to rule out meningitis.
- Bacteriological confirmation is particularly important if an isolate from a source case is not available, if the child has HIV, if there is suspected drug resistance or known drug resistance in the probable source case, in severe disease, and if the diagnosis is unclear.
- The vast majority of children with TB are not infectious, although all new/suspected cases should be isolated initially if hospitalised.

### Basic principles of treating tuberculosis in children

For paucibacillary childhood TB, a three drug intensive phase is sufficient, if resistance is not suspected. More complicated disease requires a four drug intensive phase.

Optimal treatment regimens and dosages are not known for children, but most children using current regimens have good outcomes.
Management of tuberculosis in children

Many studies have confirmed that the regimen of 6/12 of isoniazid rifampicin, with pyrazinamide in the first two months cures over 99% cases of drug susceptible pulmonary TB.

As most cases of TB in children do not have an isolate available, the treatment regimen is based on sensitivities from source case.

Children with severe forms of TB should be hospitalised, including cases of miliary and meningeal TB, often for most of the intensive phase, as well as children with airway obstruction, some bone and joint disease and severe adverse reactions.

In most case of extrapulmonary disease excluding lymphadenopathy, 9–12 months treatment may be required.

Early discussion with a paediatric TB expert should be undertaken in cases:

- of disseminated TB
- poor or slow resolution of TB despite adequate treatment
- presence of comorbidities, especially HIV co-infection
- cases of suspected or proven drug resistance
- neonatal TB.

Monitoring

Clinical and radiological follow-up are used to evaluate a child’s response to treatment.

Clinical follow-up should include assessment of growth, symptomatology, adherence and adverse events, as well as dose adjustments for weight gains.

Chest X-ray – radiological changes usually require longer than six months to resolve. A normal CXR is not necessary for discontinuing anti-TB medication.

Adverse events are less common than in adults.

Management of neonates

Congenital TB is rare.

Transmission is most likely to occur in women with miliary TB, untreated smear positive disease or diagnosis in late pregnancy or post delivery. Greater than four months of treatment of the mother will protect foetus.

Breastfeeding does not transmit TB.

Consider TB when evaluating an unwell infant with symptoms not able to be explained by other causes and born to a mother at high risk for TB.

If the diagnosis is suspected a Mantoux test, chest X-ray, lumbar puncture and appropriate cultures should be performed.

Perinatal TB from airborne spread from an adult case including health care worker has been well documented over the years.

Management of a neonate will depend on stage of maternal disease.
Introduction

TB in children under 15 years of age accounts for approximately 5–10% of all disease in New Zealand, although this can be as high as 40% in some developing countries. (see chapter epidemiology, Shingadia 2003) This means that many clinicians in New Zealand will rarely diagnose a case of TB disease. Along with this, paediatric TB disease has some distinct characteristics, particularly in the young infant, which can make it a challenge to diagnose and treat.

Young children are more likely to develop active disease after exposure to TB and this can progress rapidly within weeks. Once disease occurs it is also more likely than in adults to progress to severe disseminated or meningeal disease, with significant morbidity and mortality. Tuberculosis in many young children may present with few or non-specific symptoms. Obtaining appropriate specimens can be difficult and other clinical investigations can also be difficult to interpret due to the paucibacillary nature of disease in young children.

An approach which includes awareness of the diagnosis, epidemiological information, clinical findings and appropriate investigations will help to make an early and accurate diagnosis. As TB in children is an indicator of recent acquisition and a marker of ongoing transmission in a community, it needs to be diagnosed early to identify source cases and prevent further transmission.\textsuperscript{1,2}

Other chapters will include details of management of exposure of a child to a case of active TB (Chapter 7), management of latent TB infection in children (see Chapter 8) and drug specifics (see Chapter 3). BCG vaccination is now covered in the Immunisation Handbook (MoH website).
1 Clinical and Diagnostic Differences from Adult Tuberculosis

The same basic principles that apply to diagnosis and management of TB in adults apply to children. However, there are some important clinical and diagnostic differences.

- Children have a higher risk of progressing from infection to disease than adults and a higher risk of developing severe forms of disease (miliary and meningeal) with high rates of disability and death. Reasons for this relate to a relative immaturity of immune function.3,4

- Younger children < 5 years have a higher risk of developing extrapulmonary disease particularly miliary or meningeal TB. A child < 1 year old has a 10–20% chance of developing disseminated TB or tuberculous meningitis compared with a child >2 years of age who has only a 0.5% chance.4

- TB in children is usually an immediate complication of primary infection with a closed caseous paucibacillary lesion. Cavitory TB is rare in children and is more likely to occur in children >10 years of age.3,4,5 Uncomplicated hilar adenopathy is the most common disease manifestation seen in children.

- Prior to the use of chemotherapy, studies found that children under 2–3 years of age with primary infection progressed to serious disease within the first 12–24 months without significant prior symptoms. This progression rarely occurred in those age 2 to 10 years, but when it did they usually had significant symptoms.6,7

- Children with HIV infection or other immunocompromising condition can have similar progression to young children.1

- The majority of TB in young children occurs within one year of infection, meaning that TB disease in a child is a marker of recent transmission of the organism. In infants the time period can be as short as a few weeks.2

- Most children are infected from an infectious adult within their own immediate or extended family.8,9

- Just over half of TB occurs in infants and children <5 years of age and a second peak again in late childhood and adolescence. TB is much less common between 5–14 years.

1.1 Signs and symptoms

- Majority of children with intrathoracic TB have minimal symptoms and signs.10 Over one-half of children will have no symptoms or signs, but have significant changes on chest x-ray. The younger the age the more likely the child will have symptoms. Non-productive, unremitting cough, mild dyspnoea and fever are the most common symptoms and young infants may have failure to thrive or lack of weight gain.11 Findings on chest examination are uncommon. The characteristic X-ray finding is lymphadenopathy with or without parenchymal involvement. A recent study from South Africa found significant limitations in interpretation of mediastinal adenopathy on chest X-ray and suggests caution in interpretation of radiographic lymphadenopathy.12 Further imaging maybe required.
- Miliary disease results from lymphohaematogenous spread and occurs early after infection within first two to six months. The clinical manifestations are variable with onset that can be insidious (malaise, anorexia, low grade fever, weight loss) and non specific or rapid and overwhelming. TB meningitis can also have an insidious onset over several weeks, but is universally fatal without treatment and delayed diagnosis can result in significant morbidity.\(^1\)

- Early suspicion and diagnosis is a crucial part of detection of TB in children. There have been a number of large outbreaks reported due to delayed diagnosis in the source case. A number of these have involved schools.\(^3,13\)

- Superficial lymph node enlargement is more commonly due to non-tuberculous mycobacteria in children in New Zealand, particularly in the under five year olds, but TB needs to be excluded particularly if overseas born or born to a family from a high prevalence country.

### 1.2 Diagnosis

- Diagnosis of TB in children is usually based on history and examination along with a combination of positive tuberculin skin test, known contact with adult case of TB and clinical or radiological features suggestive of TB. Positive cultures are uncommon in children and the above three factors are the mainstay of the diagnosis despite introduction of new diagnostic tests.\(^2,4\) The role of IGRA tests in diagnosis of active TB disease in young children is yet to be clarified\(^14\) (see Chapter 8).

- As sputum is rarely available from young children (< 7 years), alternatives are three early morning gastric aspirates on consecutive days, at least one induced sputum\(^15,16\) and bronchial secretions, preferably used in combination with gastric aspirates, from bronchoscopy if available. Bronchoscopy is invasive and should be used with caution in the unwell child with respiratory compromise but may be useful if other diagnosis are under consideration. A recent study from South Africa suggests that induced sputum can be done even in young infants, although this depends on the expertise being available and appropriate infection control precautions.\(^17\)

- Biopsy of appropriate tissue specimen for microscopy culture and PCR should be undertaken if possible, eg, pleura/CSF/lymph node. Miliary TB has a high risk of meningeal involvement in over 50% of cases, so many experts would recommend all children < 5 years with miliary TB should undergo a lumbar puncture to rule out meningitis.\(^18\)

- PCR will frequently be negative in pulmonary TB in children due to the low bacillary load, but can be very useful in diagnosis of extrapulmonary TB.\(^16\)

- Bacteriological confirmation is particularly important:
  - if an isolate from a source case is not available
  - if the child has HIV
  - if there is suspected drug resistance or known drug resistance in the probable source case
  - in severe disease
  - if the diagnosis is unclear.\(^18\)
• Even under ideal circumstances cultures are often negative in children as a result of paucibacillary disease. Negative cultures never exclude TB in a child.²

• In many cases of TB in children there will be no positive culture so a decision to treat requires careful consideration prior to initiation of a complete treatment course. Most children have smaller mycobacterial loads than adults with good treatment outcomes provided treatment is started promptly. The risk of developing drug resistance during drug treatment is less.

1.3 Isolation requirements

• It is recommended to isolate all hospitalised children with TB and their caregivers and visitors initially, as although cases are rarely infectious an undiagnosed relative may be the source case.³,⁸,¹⁴

• The vast majority of children < 10 years old with TB are not infectious. The reasons for this are that most children have no significant cough, lack tussive force necessary to spread disease; rarely produce sputum, low concentration of organisms in endobronchial secretions.¹ Any child who develops adult-type TB including upper lobe infiltrates or cavities have a higher load of organisms and can be infectious as well as acquire resistance to treatment.

• Children that require isolation include children with: cavitatory TB, positive sputum AFB smears, laryngeal involvement, extensive pulmonary infection, congenital TB undergoing procedures that involve the airway.¹⁴
1 Basic Principles of Treating Tuberculosis in Children

Children usually have paucibacillary disease with cavitatory disease being uncommon in those < 10 years, but children develop extrapulmonary disease more often than adults including miliary and meningeal disease with infants < 3 years particularly at risk. For paucibacillary childhood TB, a three drug intensive phase is sufficient, if resistance is not suspected. If no isolate is available from source case or for complicated disease, including miliary and meningeal disease four drugs should be started.

Basic principles of drug treatment in children are same as for adults. However:

- due to different patient pharmacokinetics, children’s dosage are based on mg/kg
- medication dose needs to be adjusted for weight increases with growth to prevent under dosing
- in younger children it is better to dose at the higher end of recommended ranges
- children have lower risk of adverse effects
- limited paediatric drug formulations can result in difficulties with administration
- children are dependent on caregivers for adherence.

2.1 Management of tuberculosis in children

Early discussion with a paediatric TB expert should be undertaken in cases:

- of disseminated TB
- poor or slow resolution of TB despite adequate treatment
- presence of comorbidities, especially HIV co-infection
- cases of suspected or proven drug resistance
- neonatal TB.

Optimal treatment regimens and dosages are not known for children, but most children using current regimens have good outcomes. Treatment regimens are available from a number of different international organisations (see chapter treatment). Many studies have confirmed that the regimen of 6/12 of isoniazid rifampicin, with pyrazinamide in the first two months cures over 99% cases of drug susceptible pulmonary TB.

In cases where pyrazinamide is not tolerated, isoniazid and rifampicin for 9/12 is adequate, but this should be reserved for only mild cases.

- As most cases of TB in children do not have an isolate available, the treatment regimen is based on sensitivities from source case. Usually three drugs alone are started, but if a fourth drug is required ethambutol is most common, but penetrates poorly into CSF except in the presence of inflamed meninges.
• A fourth drug would be recommended in all cases of disseminated and meningeal TB, severe disease, co-infection with HIV, and smear positive pulmonary TB if no source case identified. A fourth drug should also be considered if there is a high risk of drug resistance based on epidemiologic characteristics of the child or source case.2

• In cases of meningitis an alternative is prothionamide which has good penetration into the CNS, both normal and inflamed meninges, and is generally well tolerated. Rifampicin also penetrates poorly into CSF and longer continuation phase (10 months, ie, 12 months total) is recommended for miliary and meningeal TB by some experts.7,18

• Intermittent treatment regimens have been used in children but these studies have enrolled children with less severe disease.19 In both intensive and continuation phase treatment can be given daily or intermittently three times weekly. Although twice weekly regimens have been used in children they are not recommended by the WHO and are not used in New Zealand.1

• Children with severe forms of TB should be hospitalised, including cases of miliary and meningeal TB, often for most of the intensive phase, as well as children with airway obstruction, some bone and joint disease and severe adverse reactions. Occasionally hospitalization will be required for difficulties with medications, eg, palatability.

• In most case of extrapulmonary disease excluding lymphadenopathy, 9–12 months treatment will be required.

• For treatment of HIV infected children with TB – see HIV chapter.

• Adherence issues are the same as for adults – see chapter on DOT.
Table 2.1: Dosage recommendations for anti-tuberculosis agents for children

<table>
<thead>
<tr>
<th>Medication</th>
<th>Daily dose mg/kg (range)</th>
<th>Thrice-weekly dose mg/kg (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First-line agents</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Isoniazid</td>
<td>5* (5–15)</td>
<td>10# (8–12)</td>
</tr>
<tr>
<td>Maximum dose/day</td>
<td>300 mg</td>
<td>900 mg</td>
</tr>
<tr>
<td>Rifampicin</td>
<td>10 (8–12)</td>
<td>10# (8–12)</td>
</tr>
<tr>
<td>Maximum dose/kg</td>
<td>600 mg</td>
<td>600 mg</td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td>25</td>
<td>35</td>
</tr>
<tr>
<td>Maximum dose/kg/day</td>
<td>2 g</td>
<td>3 g</td>
</tr>
<tr>
<td>Maximum dose/kg/day</td>
<td>2.5 g</td>
<td></td>
</tr>
<tr>
<td><strong>Second-line agents</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prothionamide and ethionamide</td>
<td>15–20</td>
<td></td>
</tr>
<tr>
<td>Maximum dose</td>
<td>1 g</td>
<td></td>
</tr>
<tr>
<td>Rifabutin</td>
<td>10–20</td>
<td>10–20</td>
</tr>
<tr>
<td>Maximum dose/kg/day</td>
<td>300 mg</td>
<td>300 mg</td>
</tr>
<tr>
<td>Moxifloxacin</td>
<td>7.5–10</td>
<td></td>
</tr>
<tr>
<td>Maximum dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Streptomycin</td>
<td>15 (12–18)</td>
<td>15 (12–18)</td>
</tr>
<tr>
<td>Maximum dose, intramuscular, intravenous</td>
<td>1 g</td>
<td></td>
</tr>
<tr>
<td>Amikacin</td>
<td>15–22.5</td>
<td></td>
</tr>
<tr>
<td>Maximum dose, intramuscular, intravenous</td>
<td>1 g</td>
<td></td>
</tr>
<tr>
<td>Kanamycin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Amount/kg</td>
<td>15–30</td>
<td></td>
</tr>
<tr>
<td>Maximum dose, intramuscular, intravenous</td>
<td>1 g</td>
<td></td>
</tr>
<tr>
<td>Capreomycin</td>
<td>15–30</td>
<td></td>
</tr>
<tr>
<td>Maximum dose intramuscular</td>
<td>1 g</td>
<td></td>
</tr>
<tr>
<td>Cycloserine</td>
<td>10–20</td>
<td></td>
</tr>
<tr>
<td>Maximum dose</td>
<td>1 g</td>
<td></td>
</tr>
<tr>
<td>P-aminosalicylic acid (4 g sachets)</td>
<td>150 mg</td>
<td></td>
</tr>
<tr>
<td>Maximum dose</td>
<td>12 g</td>
<td></td>
</tr>
</tbody>
</table>

* Younger children less than five years INH dose of 10 mg/kg.

# Dose range of isoniazid 20–30 mg/kg (maximum 900 mg) and rifampicin 10–20 mg/kg (maximum 600 mg) for 3x weekly regimen is recommended in some guidelines.14

2.2 Formulations/administration

- For ease of administration tablets may be crushed and mixed with water immediately prior to administration. Choice of agent used as the mixing agent needs to be approved as some agents can reduce bioavailability of drugs.1
- The addition of vitamin C containing products to antituberculous drug suspensions should be avoided. When vitamin C is added to a suspension, it may reduce the concentration of the anti-TB drug.21 Reduced serum levels have also been found when isoniazid is given with apple sauce.
- Non-proprietary suspensions are prepared extemporaneously by pharmacists for multi-dose use. They are based on non-validated formulae, often use non-funded excipients and have a limited period before expiry. These suspensions should rarely be needed.
• Rifampicin, isoniazid and pyrazinamide should never be put in a suspension together, because the rifampicin becomes unstable.

• Families may have problems administering medications to young children, due to swallowing difficulty, number of medications, taste and limited formulations. People with experience helping families in this circumstance should work with families early to resolve any problems. If problems are not resolved early, significant delays and interruptions in therapy can result, which may negatively affect the adequacy of treatment.

2.3 Pyridoxine

Isoniazid peripheral neuritis is rare in children, so most do not require pyridoxine supplementation. Pyridoxine (5–10 mg/day) should be given to:

• breastfeeding infants
• adolescents (because of their rapid growth)
• malnourished children or children with inadequate diets (eg, meat- or milk-deficient diets)
• breastfeeding infants whose mothers are taking isoniazid
• HIV-infected children
• children who develop paraesthesiae.

2.4 Corticosteroids

Corticosteroids may be used for some cases of TB, although limited evidence is available. These include cases of TB meningitis, airway obstruction secondary to enlarged lymph nodes, severe miliary disease and pericardial TB.

• Prednisone dose of 2 mg/kg per day (maximum 60 mg/day) for four weeks and then reduce over 1–2 weeks.
• Corticosteroids should only be given with appropriate antituberculosis therapy.

2.5 Monitoring

Clinical and radiological follow-up are used to evaluate a child’s response to treatment.

• Clinical follow-up should include assessment of growth, symptomatology, adherence and adverse events, as well as dose adjustments for weight gains. As a guide this should occur two weeks after initiation of treatment, at the end of the eight-week intensive phase and two-monthly after that. This will vary according to a number of factors including age of child, severity of disease and tolerance of medication.
• Chest X-ray – radiological changes usually require longer than six months for complete resolution, but improvement would be expected in the healthy host after three months. A normal CXR is not necessary for discontinuing anti-TB medication.
• Long-term complications such as development of bronchiectasis are uncommon but awareness of this risk is needed.
- Adverse events are less common than in adults.

- Most common is development of hepatotoxicity which can be caused by isoniazid, rifampicin and pyrazinamide. If liver function tests are normal at initiation, serum liver enzymes do not need to be monitored routinely in most children as an asymptomatic elevation (< 5 x normal) is not an indication to stop treatment.\textsuperscript{18,23} If symptoms suggestive of liver toxicity occur, all potentially hepatotoxic medication should be stopped. Liver function tests should be done and if significantly elevated, other tests to evaluate causes of hepatitis should be undertaken (see chapter treatment).

- There has been longstanding concern over the effect of acetylator status on isoniazid metabolism. Recent work has found that younger children eliminate isoniazid faster than older children.\textsuperscript{24} It is now recommended that young children < 5 years should receive an isoniazid dose of at least 10mg/kg to ensure that faster acetylators of INH are exposed to adequate serum concentrations of isoniazid.

- Recent reviews suggest ethambutol is safe at recommended doses. The WHO guidelines recommend higher doses of ethambutol in children at 20 mg/kg/day (15–25 mg/kg/day) because pharmacokinetics are different, with peak serum concentrations lower in children than in adults receiving the same dose.\textsuperscript{18} Renal function should be monitored if child has, or is at risk of renal impairment, as ethambutol is renally excreted.\textsuperscript{1}

- Prothionamide causes gastrointestinal discomfort and vomiting in 50%. This can be modified by starting with a twice daily dose.
3 Management of Neonates

- Congenital TB is rare.\textsuperscript{25,26} Congenital TB is defined by tuberculous lesion in the infant and one or more of following revised criteria of Cantwell and colleagues:
  - tuberculous lesions evident in first week of life
  - primary hepatic complex or caseating hepatic granulomas
  - evidence of tuberculous infection of the maternal genital tract
  - exclusion of the possibility of postnatal transmission of disease.

Primary TB rather than reactivation of TB in mother is more likely to lead to congenital TB. A neonate may acquire TB in-utero through direct spread through the umbilical cord, haematogenous spread or aspiration of infected amniotic fluid or vaginal secretions.

- Transmission is most likely to occur in women with miliary TB, untreated smear positive disease or diagnosis in late pregnancy or post delivery.\textsuperscript{25} Greater than four months of treatment of the mother will protect foetus.

- Breastfeeding does not transmit TB.

- Symptoms of TB in the neonate are non-specific; lethargy, poor feeding, low birth weight, unresolving or recurrent pneumonia and may mimic other congenital viral infections or bacterial sepsis. The commonest reported symptoms are hepatosplenomegaly and respiratory distress, less commonly fever and lymphadenopathy. The diagnosis can be difficult but should be considered in the child not responding to broad-spectrum antibiotics, negative tests for other congenital infections and in whom TB is suspected in the mother. Overt expression of disease often does not occur until the second to third week of life.

- A high index of suspicion should be kept when evaluating an unwell infant with symptoms not able to be explained by other causes and born to a mother at high risk for TB.

- If the diagnosis is suspected a Mantoux test, chest X-ray, lumbar puncture and appropriate cultures should be performed. The tuberculin skin test is unhelpful if negative as it can take up to three months to become positive. Most infants will have an abnormal chest X-ray, although it can be normal immediately after birth. Diagnosis is usually made on clinical suspicion and microscopy and culture from gastric aspirates, biopsy tissue (lymph nodes, bone marrow, liver) or placental tissue. CSF is also recommended.

- Newborns with pulmonary TB requiring ventilation can transmit TB to contacts.

- Perinatal TB from airborne spread from an adult case including health care worker has been well documented over the years.\textsuperscript{27}

3.1 Management of neonate exposed to maternal TB

Management will depend on stage of maternal disease.\textsuperscript{25,28} Case management can be complex and should be discussed with an expert in paediatric TB.
3.1.1 Mother with active disease
If the newborn presents with symptoms the infant should be assessed for congenital TB. For the asymptomatic infant (when congenital TB has been excluded):

- isoniazid (10 mg/kg) for three months (if maternal isolate is known to be sensitive)
- at 3/12 Mantoux – if negative Mantoux with normal chest X-ray and asymptomatic infant, stop isoniazid and consider BCG vaccination
- if Mantoux positive assess for TB disease, if negative treat for six months isoniazid
- breastfeeding is recommended irrespective of mothers TB status. First-line antituberculous drugs cross into breast milk in variable amounts, although at an inadequate level to treat the infant and is considered safe
- the decision to separate mother and infant is difficult. The American Academy of Paediatrics recommends separation until the mother has been fully evaluated or until both mother and child are on treatment. However some experts permit contact if the mother wears a mask and follows infection control measures. Once the infant is receiving isoniazid separation is not necessary.
- separation is suggested if the mother has MDRTB, or has poor adherence.

3.1.2 Mother with latent TB infection, but no disease
The neonate of a mother with latent TB infection but no disease is not at risk and requires no special evaluation or treatment.

Household contacts should be evaluated for an infectious source case.
References