INT J TUBERC LUNG DIS 10(10):1091–1097

OFFICIAL STATEMENT

Guidance for National Tuberculosis Programmes on the management of tuberculosis in children
CHAPTER 1 IN THE SERIES

Chapter 1: Introduction and diagnosis of tuberculosis in children

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SUMMARY

About one million children develop tuberculosis (TB) annually worldwide, accounting for about 11% of all TB cases. Children with TB differ from adults in their immunological and pathophysiological response in ways that may have important implications for the prevention, diagnosis and treatment of TB in children. There is an urgent need to improve the diagnosis and management of children with TB, and the prevention of TB in children, by ensuring their inclusion under the implementation of the Stop TB strategy by National TB Programmes. Critical areas for further research include a better understanding of the epidemiology of childhood TB, vaccine development, the development of better diagnostic techniques, new drug development, and the optimal formulations and dosing of first- and second-line TB drugs in children.

Specifically regarding the diagnosis of TB in children, this relies on a careful and thorough assessment of all the evidence derived from a careful history, clinical examination and relevant investigations, e.g., tuberculin skin test, chest radiograph and sputum smear microscopy. Although bacteriological confirmation of TB is not always possible, it should be sought whenever possible, e.g., by sputum microscopy in children with suspected pulmonary TB who are old enough to produce a sputum sample. A trial of treatment with TB medications is not generally recommended as a method to diagnose TB in children. New, improved diagnostic tests are urgently needed.

KEY WORDS: tuberculosis; children; diagnosis

IT IS ESTIMATED that one third of the world's population is infected with *Mycobacterium tuberculosis* (the bacterium that causes tuberculosis, or TB), and that each year, about 9 million people develop TB, of whom about 2 million die. Of the 9 million cases of TB worldwide that occur annually, about 1 million cases (11%) occur in children <15 years of age. Seventy-five per cent of these childhood cases occur annually in 22 high-burden countries that together account for 80% of the world's estimated incident cases. The reported percentage of all TB cases occurring in children varies from 3% to more than 25% in different countries.

Infection with *M. tuberculosis* usually results from inhalation into the lungs of infected droplets produced by someone who is coughing and who has pulmonary TB disease. The source of infection of most children is an infectious adult in their close environment (usually the household). This exposure leads to the development of a primary parenchymal lesion (Ghon focus) in the lung with spread to the regional lymph node(s). In the majority of cases, the resultant cell-mediated immunity contains the disease process at this stage. Risk of disease progression is increased in the very young (<3 years old) and in immune compromised children. Progression of disease occurs by 1) extension of the primary focus with or without cavitation; 2) the effects of pathological processes caused by the enlarging lymph nodes or by 3) lymphatic and/or haematogenous spread.

Implementation of the Stop TB Strategy[1] (see Table 1), which builds on the DOTS strategy[2] developed by the World Health Organization (WHO) and the International Union Against Tuberculosis and Lung Disease (The Union), has a critical role to play in reducing the worldwide burden of disease and thus in protecting children from infection and disease. The management of children with TB should be in line with the Stop TB Strategy, taking into consideration the particular epidemiology and clinical presentation of TB in children.

The International Standards for TB Care,[3] WHO's TB treatment guidelines[4] and WHO's TB/HIV clinical manual[5] provide useful guidance for patients of all

Adapted from: World Health Organization. Guidance for national tuberculosis programmes on the management of tuberculosis in children. WHO/HTM/TB/2006.371. Geneva, Switzerland: WHO, 2006.

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[A version in French of this article is available from the Editorial Office in Paris and from the Union website www.iuatld.org]

Table 1 Components of the Stop TB Strategy and implementation approaches

1 Pursue high-quality DOTS expansion and enhancement
• Political commitment with increased and sustained financing
• Case detection through quality-assured bacteriology
• Standardised treatment with supervision and patient support
• An effective drug supply and management system
• Monitoring and evaluation system, and impact measurement
2 Address TB-HIV, MDR-TB and other challenges
• Implement collaborative TB-HIV activities
• Prevent and control multidrug-resistant TB
• Addressing prisoners, refugees and other high-risk groups and special situations
3 Contribute to health system strengthening
• Actively participate in efforts to improve system-wide policy, human resources, financing, management, service delivery and information systems
• Share innovations that strengthen systems, including the Practical Approach to Lung Health
• Adapting innovations from other fields
4 Engage all care providers
• Public-public and public-private mix (PPM) approaches
• International Standards for TB Care (ISTC)
5 Empower people with TB and communities
• Advocacy, communication and social mobilisation
• Community participation in TB care
• Patients' Charter for Tuberculosis Care
6 Enable and promote research
• Programme-based operational research
• Research to develop new diagnostics, drugs and vaccines

TB = tuberculosis; HIV = human immunodeficiency virus; MDR-TB = multidrug-resistant tuberculosis.

ages. The guidelines developed by the childhood TB subgroup are designed to complement current national and international guidelines on the implementation of the Stop TB Strategy and existing guidelines, but also to fill existing gaps to ensure that children with *M. tuberculosis* infection and TB disease are identified early and managed effectively.

The human immunodeficiency virus (HIV) epidemic threatens TB control efforts, particularly in Africa. Children are at risk of HIV, and HIV-infected children are at risk of TB. These guidelines thus also include recommendations for HIV-infected children.

For National TB Programmes (NTPs) to successfully manage TB in children, standardised approaches based on the best available evidence are required. The engagement of all who provide care to children (including paediatricians and other clinicians) is crucial. These standardised approaches need to be incorporated into existing guidelines and strategies that have been developed by NTPs. Reducing the burden of TB in children will require changing and improving many existing practices, such as those that relate to contact investigations.

These guidelines are based on the best available evidence. However, epidemiological data on TB in children in high-burden countries are scarce. Children with TB differ from adults in their immunological and pathophysiological response in ways that may have important implications for the prevention, diagnosis and treatment of TB in children. Critical areas for further research include a better understanding of the epidemiology of childhood TB, vaccine development, the development of better diagnostic techniques, new drug development and the optimal formulations and dosing of first- and second-line TB drugs in children.

Table 2 Recommended approach to diagnose TB in children

1 Careful history (including history of TB contact and symptoms consistent with TB)
2 Clinical examination (including growth assessment)
3 Tuberculin skin testing (TST)
4 Bacteriological confirmation whenever possible
5 Investigations relevant for suspected 1) pulmonary TB, and 2) extra-pulmonary TB
6 HIV testing (in high HIV prevalence areas)

TB = tuberculosis; HIV = human immunodeficiency virus.

DIAGNOSIS OF TUBERCULOSIS IN CHILDREN

The diagnosis of TB in children relies on careful and thorough assessment of all the evidence derived from a careful history, clinical examination and relevant investigations, e.g., the tuberculin skin test (TST), chest radiograph (CXR) and sputum smear microscopy. Although bacteriological confirmation of TB is not always possible, it should be sought whenever possible, e.g., by sputum microscopy in children with suspected pulmonary TB who are old enough to produce a sputum sample. A trial of treatment with TB medications is not recommended as a method of diagnosing TB in children. The decision to treat a child should be carefully considered, and once such a decision is made, the child should be treated with a full course of therapy.

Most children with TB have pulmonary TB. The proposed approach to the diagnosis of TB in children (see Table 2) is based on limited published evidence and rests heavily on expert opinion.

In most immunocompetent children, TB presents with symptoms of a chronic disease after they have been in contact with an infectious source case. Infection with *M. tuberculosis* can be demonstrated by a TST, and CXR changes typical of TB are usually present. The presentation in infants may be more acute, resembling acute severe pneumonia, and should be suspected when there is poor response to antibiotics. There is often an identifiable contact, usually the infant's mother, in this situation. Table 3 shows key features suggestive of TB, and Table 4 key risk factors.

Existing diagnostic tests for TB in children have shortcomings, and the full range of tests (including bacteriology and TST) may not be readily accessible in settings where the vast majority of TB cases are diagnosed. The development of affordable diagnostic tests for TB in children in low-resource settings should be a priority for researchers and policy makers.

Some countries and NTPs use score charts for the diagnosis of TB in children, although these have rarely been evaluated and validated against a 'gold standard'. They should therefore be used as screening

Table 3 Key features suggestive of TB

The presence of three or more of the following should strongly suggest the diagnosis of TB
- Chronic symptoms suggestive of TB
- Physical signs highly of suggestive of TB
- A positive tuberculin skin test
- Chest radiograph suggestive of TB

TB = tuberculosis.

Table 4 Key risk factors for TB

- Household contact with a newly diagnosed smear-positive case
- Age <5 years
- HIV infection
- Severe malnutrition

TB = tuberculosis; HIV = human immunodeficiency virus.

tools and not as a means of making a firm diagnosis. Score charts perform particularly poorly in children suspected of pulmonary TB (the most common form) and in children who are also HIV-infected.

Recommended approach to diagnose TB in children

Careful history (including history of TB contact and symptoms consistent with TB)

1 *Contact*: A close contact is defined as living in the same household or in frequent contact with a source case (e.g., care giver) with sputum smear-positive TB. Source cases who are sputum smear-negative but culture-positive are also infectious, but to a much lesser degree.

The following points concerning contact are of importance for children:

- Children (especially those <5 years of age) who have been in close contact with a case of smear-positive TB must be screened for TB (see Chapter 4 of this series: Childhood contact screening and management—to appear January 2007).
- After TB is diagnosed in a child or adolescent, an effort should be made to detect the adult source cases, and especially other undiagnosed household cases.
- If a child presents with infectious TB, then childhood contacts must be sought and screened as for any smear-positive source case. Children should be regarded as infectious if they are sputum smear-positive or have a cavity visible on CXR.

2 *Symptoms*: Children with symptomatic disease develop chronic symptoms in most cases. The commonest symptoms are chronic, unremitting cough, fever and weight loss. The specificity of symptoms for the diagnosis of TB depends on how strict the definitions of the symptoms are.

- Chronic cough: an unremitting cough that is not improving and has been present for >21 days (3 weeks).
- Fever: of >38°C for 14 days after common causes such as malaria or pneumonia have been excluded.
- Weight loss or failure to thrive: always ask about weight loss or failure to thrive and look at the child's growth chart.

Clinical examination (including growth assessment)

There are no specific features on clinical examination that can confirm that the presenting illness is due to pulmonary TB. Some signs, although uncommon, are highly suggestive of extra-pulmonary TB and the threshold to initiate treatment should be lower. Other signs are common and should initiate investigation as to the possibility of childhood TB.

1 *Physical signs highly suggestive of extra-pulmonary TB*:

- Gibbus, especially of recent onset (vertebral TB)
- Non-painful enlarged cervical lymphadenopathy with fistula formation.

2 *Physical signs requiring investigation to exclude extra-pulmonary TB*:

- Meningitis not responding to antibiotic treatment, with a sub-acute onset or raised intracranial pressure
- Pleural effusion
- Pericardial effusion
- Distended abdomen with ascites
- Non-painful enlarged lymph nodes without fistula formation
- Non-painful enlarged joint
- Signs of tuberculin hypersensitivity: phlyctenular conjunctivitis, erythema nodosum.

Documented weight loss or failure to gain weight, especially after being treated in a nutritional rehabilitation programme, is a good indicator of chronic disease in children, and TB may be the cause.

Tuberculin skin test

A positive TST occurs when a child is infected with *M. tuberculosis*. However, in children, TST can also be used as an adjunct in diagnosing TB disease, when it is used in conjunction with signs and symptoms of TB and other diagnostic tests. There are a number of TSTs available, but the Mantoux skin test is the recommended test.

1 *Using the test*: The TST should be standardised for each country using either 5TU (tuberculin units) of tuberculin purified protein derivative (PPD) S or 2 TU of tuberculin PPD RT23, as these give similar reactions in infected children. Health care workers must be trained in performing and reading a TST

(see Appendix A*). A TST should be regarded as positive as follows:

- High-risk children: TST ⩾5 mm induration (high risk includes HIV-infected children and severely malnourished children, i.e., those with clinical evidence of marasmus or kwashiorkor)
- All other children: TST ⩾10 mm induration is regarded as positive (whether or not they have been BCG vaccinated).

2 *Value of the test*: A positive TST indicates that the child has been infected with TB but does not necessarily indicate disease. However, when used in a child with symptoms and other evidence of TB disease (such as an abnormal CXR), it is a useful tool in making the diagnosis of TB in a child. TST can be used to screen children exposed to TB (such as from a household contact with TB), although children can still receive chemoprophylaxis even if TST testing is not available (see Chapter 4: Childhood contact screening and management).

The TST is useful in HIV-infected children to identify those with dual TB-HIV infection and as an aid in the diagnosis of TB, although fewer HIV-infected children will have a positive test, as a normal immune response is required to produce a positive TST, and many HIV-infected children have immune suppression.

There can be false-positive as well as false-negative TST tests (see Appendix A*). It is sometimes useful to repeat the TST in children once their malnutrition has improved or their severe illness (including TB) has resolved, as they may be initially TST negative, but positive after 2–3 months on treatment. A negative TST never rules out a diagnosis of TB in a child.

Bacteriological confirmation whenever possible

It is always preferable to make a bacteriological diagnosis of TB in a child using whatever specimens and laboratory methods are available. Samples include sputum, gastric aspirate and other material (e.g., lymph node biopsy or any other material that is biopsied). Fine needle aspiration of enlarged lymph glands for both histology and staining for acid-fast bacilli (AFB) has been shown to be a useful test with a high bacteriological yield. All specimens that are obtained should be sent for mycobacterial culture whenever possible. This will improve the yield of the test (i.e., it is more sensitive), but it is also the only way to differentiate *M. tuberculosis* from other non-tuberculous mycobacteria. A bacteriological diagnosis is especially important for children who have one or more of the following:

- Suspected drug resistance
- HIV infection
- Complicated or severe cases of disease
- An uncertain diagnosis.

The more common ways of obtaining sputum for microscopy include:

1 *Expectoration*: Sputum for smear microscopy is a useful test and should always be obtained in adults and older children (>10 years of age) who are pulmonary TB suspects. Among younger children, especially children < 5 years of age, sputum is difficult to obtain and most children are 'sputum smear-negative'. However, in children who are able to produce a specimen, it is worth sending for smear microscopy (and culture if available). Yields are higher in older children (>5 years of age) and adolescents, and in children of all ages with severe disease. As with adult TB suspects, three sputum specimens should be obtained: spot specimen (at first evaluation), early morning, and spot specimen (at the follow-up visit).

2 *Gastric aspirates*: Gastric aspiration using a nasogastric feeding tube can be performed in young children who are unable or unwilling to expectorate sputum. If performed, gastric aspirates should be sent for smear microscopy and mycobacterial culture.

3 *Sputum induction*: Several recent studies have found that sputum induction can be performed safely and effectively in children of all ages, and the bacteriological yield is as good as or better than for gastric aspirates. However, training and specialised equipment are required to perform this test properly.

In developing and improving laboratory services for TB diagnosis, the priority is to ensure a network of quality-controlled microscopy for AFB in clinical samples, most often sputum. Appendix B† includes more specific guidance on the above procedures.

Investigations relevant for suspected 1) pulmonary TB and 2) extra-pulmonary TB

1 *Relevant for suspected pulmonary TB, i.e., CXR*: In the majority of cases, children with pulmonary TB have CXR changes suggestive of TB. The commonest picture is that of persistent opacification in the lung together with enlarged hilar or subcarinal lymph glands. A miliary pattern of opacification in non-HIV-infected children is highly suggestive of TB. Patients with persistent opacification that does not improve after a course of antibiotics should be investigated for TB.

* Appendix A (Placement and interpretation of tuberculin skin test) is available on request from the corresponding author.

† Appendix B (Procedures for obtaining sputum specimens) can be obtained on request from the corresponding author.

Table 5 Common forms of extra-pulmonary TB in children

Site	Practical approach to diagnosis
Peripheral lymph nodes (especially cervical)	Lymph node biopsy or fine needle aspiration (FNA)
Miliary TB (e.g., disseminated)	CXR
TB meningitis	Lumbar puncture (and CT where available)
Pleural effusion (older children and adolescents)	Chest radiograph, pleural tap for chemistry and culture
Abdominal TB (e.g., peritoneal)	Abdominal ultrasound and ascitic tap
Osteoarticular	Radiograph, joint tap or synovial biopsy
Pericardial TB	Ultrasound and pericardial tap

TB = tuberculosis; CXR = chest X-ray; CT = computed tomography.

Adolescent patients with TB have CXR changes similar to adult patients, with large pleural effusions and apical infiltrates with cavity formation being the most common forms of presentation. Adolescents may also develop primary disease, with hilar adenopathy and collapse lesions visible on CXR.

Chest radiography is useful in the diagnosis of TB in children, and CXRs should preferably be read by a radiologist or a health care worker trained in their reading. Good quality CXRs are essential for proper evaluation. A practical guide for interpreting CXRs has been developed (available at www.iuatld.org).[6]

2 *Relevant for suspected extra-pulmonary TB*: Table 5 shows the usual investigations used to diagnose the common forms of extra-pulmonary TB. In most of these cases, TB will be suspected from the clinical picture and confirmed by histology or other special investigations.

3 *Other tests*: Serological and nucleic acid amplification (e.g., polymerase chain reaction [PCR]) tests are not currently recommended for the routine diagnosis of childhood TB, as they have been inadequately studied in children and they have performed poorly in the few studies that have been done. However, this is an area that requires further research, as they may prove to be useful in the future.

Other specialised tests, such as computerised chest tomography and bronchoscopy, are not recommended for the routine diagnosis of TB in children.

HIV testing

In areas with a high prevalence of HIV infection in the general population where TB and HIV infection are likely to co-exist, HIV counselling and testing is indicated for all TB patients as part of their routine management. In areas with lower prevalence rates of HIV, HIV counselling and testing is indicated for TB patients with symptoms and/or signs of HIV-related conditions, and in TB patients with a history suggestive of high risk of HIV exposure.

Standardised case definitions of TB in children

The diagnosis of TB refers to the recognition of an active case, i.e., a patient with symptomatic disease due to *M. tuberculosis*. Beyond the diagnosis of TB disease, the type of TB case should also be defined to enable appropriate treatment to be given and the outcome of treatment evaluated. The case definition is determined by: 1) site of disease, 2) result of any bacteriology, 3) severity of TB disease, and 4) history of previous TB treatment. All children with TB should be registered with the NTP as smear-positive pulmonary, smear-negative pulmonary TB, or extra-pulmonary TB, and as a new case or a previously treated case. The standard case definitions are the following:

1 *Pulmonary tuberculosis, sputum smear-positive*:

- Two or more initial sputum smear examinations positive for AFB, **or**
- One sputum smear examination positive for AFB plus radiographic abnormalities consistent with active pulmonary tuberculosis as determined by a clinician, **or**
- One sputum smear positive for AFB plus sputum culture positive for *M. tuberculosis*.

Children with smear-positive disease are more likely to be adolescent patients or children of any age with severe intrathoracic disease.

2 *Pulmonary tuberculosis, sputum smear-negative*: A case of pulmonary TB that does not meet the above definition for smear-positive TB. This group includes cases without smear result, which should be exceptional in adults but are relatively more frequent in children.

In keeping with good clinical and public health practice, diagnostic criteria for pulmonary TB should include:

- At least three sputum specimens negative for AFB, **and**
- Radiographic abnormalities consistent with active pulmonary TB, **and**
- No response to a course of broad spectrum antibiotics, **and**
- Decision by a clinician to treat with a full course of tuberculosis chemotherapy.

3 *Extra-pulmonary TB*: Children with only extra-pulmonary TB (i.e., TB of organs other than the lungs) should be classified under this case definition. Children who have both pulmonary and extra-pulmonary TB should be classified under the case definition of pulmonary TB.

Drug-resistant TB

Children are as susceptible to drug-resistant as to drug-susceptible TB. Drug-resistant TB is a laboratory diagnosis. However, drug-resistant TB should be suspected if any of the features below are present.

1 Features in the source case suggestive of drug-resistant TB:

- Contact with a known case of drug resistance
- A source case who remains smear-positive after 3 months of treatment
- History of previously treated TB
- History of treatment interruption.

2 Features of a child suspected of having drug-resistant TB:

- Contact with known case of drug-resistant TB
- Child not responding to the TB treatment regimen
- Child with recurrence of TB after adherent treatment.

The diagnosis and treatment of drug-resistant TB in children is complex and should be done at referral centres.

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Introduction

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RÉSUMÉ

Environ un million d'enfants développent une tuberculose (TB) chaque année dans le monde, ce qui représente environ près de 11% de tous les cas de TB. Les enfants atteints de TB diffèrent des adultes dans leurs réponses immunologique et pathophysiologique de manière telle qu'elle puisse avoir d'importantes implications pour la prévention, le diagnostic et le traitement de la TB chez les enfants. Il est nécessaire d'urgence d'améliorer le diagnostic et la prise en charge des enfants atteints de TB ainsi que la prévention de la TB infantile en s'assurant de leur inclusion dans la mise en œuvre de la stratégie Stop TB par les programmes nationaux TB. Les zones critiques pour les recherches ultérieures comportent une meilleure compréhension de l'épidémiologie de la TB infantile, le développement de vaccins, le développement de meilleures techniques de diagnostic, celui de nouveaux médicaments, et de formulations et dosages optimaux des médicaments TB de première et de seconde ligne pour les enfants.

En ce qui concerne spécifiquement le diagnostic de la TB chez les enfants, celui-ci repose sur une évaluation soigneuse et approfondie de toutes les données provenant d'une anamnèse soigneuse, d'un examen clinique et d'investigations utiles, par exemple le test cutané tuberculinique, le cliché thoracique et l'examen microscopique des frottis d'expectoration. Quoique la confirmation bactériologique de la TB ne soit pas toujours possible, elle devrait être cherchée lorsque c'est possible par exemple par l'examen microscopique des expectorations chez les enfants suspects de TB pulmonaire et qui sont suffisamment âgés pour produire un échantillon d'expectoration. On ne recommande pas en général un traitement d'essai antituberculeux comme moyen de diagnostic de la TB chez les enfants. Il existe un besoin urgent de nouveaux tests diagnostiques améliorés.

RESUMEN

Cerca de un millón de niños contraen tuberculosis (TB) cada año en el mundo y representan el 11% de todos los casos de TB. Los niños con TB difieren de los adultos en su respuesta inmunitaria y fisiopatológica, en aspectos que pueden tener implicaciones importantes para la prevención, el diagnóstico y el tratamiento de la enfermedad. Existe una necesidad urgente de mejorar el diagnóstico y el tratamiento de los niños con TB y la prevención de la TB en la infancia, mediante su inclusión en la ejecución de la estrategia Alto a la TB por parte de los Programas Nacionales de Tuberculosis. Entre los aspectos primordiales que requieren mayor investigación se encuentran una mejor comprensión de las características epidemiológicas de la TB en la infancia, el desarrollo de vacunas, el diseño de mejores técnicas diagnósticas, la formulación de nuevos medicamentos y la definición de óptimas formas farmacéuticas y pautas de administración de los medicamentos antituberculosos de primera y segunda línea en los niños.

En relación con el diagnóstico de la TB en niños, este se basa en una evaluación exhaustiva y metódica de toda la información obtenida a través de la historia clínica, el examen físico y los exámenes pertinentes como la prueba cutánea de la tuberculina, la radiografía de tórax y la baciloscopia del esputo. Si bien no siempre se obtiene la confirmación bacteriológica, esta debe buscarse cuando sea posible mediante la baciloscopia del esputo, en niños con presunción diagnóstica de TB pulmonar y que tienen edad suficiente para suministrar una muestra de esputo. En general, no se recomienda un tratamiento de ensayo con medicamentos antituberculosos como método diagnóstico de la TB en los niños. Necesita pruebas diagnósticas nuevas y mejoradas.