

Management of Pediatric TB under the Revised National Tuberculosis Control Programme (RNTCP)

A joint statement of the Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, and experts from Indian Academy of Pediatrics

The joint statement came as a result of the workshop on the “Formulation of guidelines for diagnosis and treatment of Pediatric TB cases under RNTCP” held at LRS Institute of TB and Respiratory Diseases, New Delhi, 6–7 August 2003.

Background

The actual global disease burden of childhood TB is not known, but it has been assumed that 10% of the actual total TB caseload is found amongst children. Global estimates of 1.5 million new cases and 130,000 deaths due to TB per year amongst children is reported ^{1,2}. *However these figures appear to be an underestimate of the size of the problem.* Childhood TB prevalence indicates:

- community prevalence of sputum smear-positive pulmonary tuberculosis (PTB)
- age-related prevalence of sputum smear-positive PTB
- prevalence of childhood risk factors for disease
- stage of epidemic

Proper identification and treatment of infectious cases will prevent childhood TB. However often childhood TB is accorded low priority by National TB Control programmes. Probable reasons include:

- Diagnostic difficulties
- Rarely infectious
- Limited resources
- Misplaced faith in BCG
- Lack of data on treatment

But this disregards the impact of tuberculosis on childhood morbidity and mortality. Children can present with TB at any age, but the majority of cases present between 1 and 4 years. Disease usually develops within one year of infection – the younger, the earlier and the more disseminated. PTB is usually smear-negative. PTB to extra-pulmonary TB (EPTB) ratio is usually around 3:1. The PTB prevalence is normally low between the ages of 5 and 12 years, and then increases in adolescence when PTB manifests like adult PTB (post primary tuberculosis). ³

Revised National TB Control Programme

India has had a National Tuberculosis Programme (NTP) in operation since 1962. In 1992, a joint Government of India / World Health Organisation review found that despite the existence of the NTP, TB patients were not being accurately diagnosed and that the majority of diagnosed patients did not complete treatment. Based on the recommendations of the review, the Revised National Tuberculosis Control Programme (RNTCP), incorporating the internationally recommended DOTS strategy, was developed. In 1993, RNTCP was started in pilot areas covering a population of 18 million. Large-scale implementation of the RNTCP began in 1998, with a World Bank credit of Rs 604 crore.

Since 1998, the RNTCP has been rapidly expanding and to date covers over 740 million of the population. RNTCP is the fastest expanding TB control programme in the history of DOTS, and nationwide coverage is planned by 2005. In 2002, over 6.2 lakh patients were initiated on treatment under RNTCP. Of these, almost 2.5 lakh were infectious new sputum smear positive pulmonary TB. ⁴ Over 70,000 patients are now being placed on treatment each month. ⁵

Good data on the burden of all forms of TB amongst children in India are not available. Most surveys conducted have focused on pulmonary TB and no significant population based studies on extra-pulmonary TB are available. Pulmonary TB is primarily an adult disease and it has been estimated that the 0-19 year old population contains only 7% of the total prevalent cases. ⁶

In 2002, of the 2,45,051 new smear positive PTB cases initiated on treatment under RNTCP, 4,159 (1.7%) were aged 0-14 years. From a survey of RNTCP implementing districts, Paediatric cases were seen to make up 3% of the total load of new cases registered under RNTCP. Lymph node (LN) TB cases predominated (>75%) amongst the paediatric EPTB cases registered under RNTCP. Many EPTB cases (>40% of LN cases) were diagnosed on clinical grounds with no confirmatory examinations performed. An almost equivalent number of Pediatric TB cases were being diagnosed in the same health facilities, but were not being registered under RNTCP. Of those Pediatric cases treated under RNTCP, cure and completion rates were both above 90%. Comparative figures for those cases not treated under RNTCP were 80% and 70%, with default rates between 27-33%. (Central TB Division. Unpublished data)

Hence for RNTCP, there are the issues of under diagnosis and under registration of Pediatric TB cases in the programme. To seek consensus on improved case detection and improved treatment outcomes for all diagnosed pediatric TB cases, a workshop on the “Formulation of guidelines for diagnosis and treatment of Pediatric TB cases under RNTCP” was held in New Delhi on 6th and 7th August 2003. In attendance were National and International Pediatricians, TB experts and TB Control Programme Managers.

1. Diagnosis

Suspect cases of PTB will include children presenting with: fever and / or cough for more than 3 weeks, with or without weight loss or no weight gain; and history of contact with a suspected or diagnosed case of active TB disease within the last 2 years. * Diagnosis to be based on a combination of clinical presentation, sputum examination wherever possible, Chest X ray (PA view), Mantoux test (1 TU PPD RT23 with Tween 80, positive if induration >10mm after 48-72 hours) and history of contact. Diagnosis of TB in children should be made by a Medical Officer. Where diagnostic difficulties are faced, referral of the child should be made to a Pediatrician for further management. The existing RNTCP case definitions will be used for all cases diagnosed. The use of currently available scoring systems is not recommended for diagnosis of pediatric TB patients.

2. Treatment of Pediatric TB

DOTS is the recommended strategy for treatment of TB and all Pediatric TB patients should be registered under RNTCP. Recommended treatment regimens are given in table below. Intermittent short course chemotherapy given under direct observation, as advocated in the RNTCP, should be used in children. To assist in calculating required dosages and administration of anti-TB drugs for children, the medication may be made available in the form of combipacks in patient wise-boxes, linked to the child's weight.

Category of treatment	Type of patients	TB treatment regimens	
		Intensive phase	Continuation phase
Category I	<ul style="list-style-type: none"> New sputum smear-positive PTB Seriously ill sputum smear-negative PTB Seriously ill extra-pulmonary TB 	2 H ₃ R ₃ Z ₃ E ₃	4 H ₃ R ₃
Category II	<ul style="list-style-type: none"> Sputum smear-positive relapse Sputum smear-positive treatment failure Sputum smear-positive treatment after default 	2 S ₃ H ₃ R ₃ Z ₃ E ₃ / 1H ₃ R ₃ Z ₃ E ₃	5 H ₃ R ₃ E ₃
Category III	<ul style="list-style-type: none"> Sputum smear-negative and Extra-pulmonary TB, not seriously ill 	2 H ₃ R ₃ Z ₃	4 H ₃ R ₃

Seriously ill sputum smear-negative PTB includes all forms of PTB other than primary complex. Seriously ill EPTB includes TB meningitis (TBM), disseminated/miliary TB, TB pericarditis, TB peritonitis and intestinal TB, bilateral or extensive pleurisy, spinal TB with or without neurological complications, genito-urinary tract TB, bone and joint TB. Not-seriously ill EPTB includes lymph node TB and unilateral pleural effusion.

In patients with TBM on Category I treatment, the four drugs used during the intensive phase should be HRZS (instead of HRZE). Continuation phase of treatment in TBM and spinal TB with neurological

complications should be given for 6 - 7 months, extending the total duration of treatment to 8 - 9 months. Steroids should be used initially in hospitalised cases of TBM and TB pericarditis and reduced gradually over 6-8 weeks. In all instances before starting a child on Category II treatment, s/he should be examined by a Pediatrician or TB expert, wherever available. As recommended by WHO and in view of the growing evidence that the use of Ethambutol in young children is safe, Ethambutol is to be used as per RNTCP regimen for all age groups.^{3,7}

3. Chemoprophylaxis

Asymptomatic children under 6 years of age, exposed to an adult with infectious (smear-positive) tuberculosis from the same household, will be given 6 months of isoniazid (5 mg per kg daily) chemoprophylaxis.

4. Monitoring and evaluation

Pediatric-focused monitoring may preferably be an integral part of the programme. Wherever possible, follow-up sputum examination is to be performed with the same frequency as in adults. Clinical or symptomatic improvement is to be assessed at the end of the intensive phase of treatment and at the end of treatment. Improvement should be judged by absence of fever or cough, a decrease in the size of lymph node(s), weight gain. Radiological improvement is to be assessed by Chest X-ray examination in all smear-negative pulmonary TB cases at the end of treatment.

A review of the RNTCP existing treatment card will be undertaken as the collecting of additional information in relation to Pediatric TB patients, such as the basis for starting treatment along with categorization, documentation of clinical and radiological monitoring is required. Until this review is completed, the remarks section in the current card should be used to document diagnostic and clinical data as needed. Also there will be an evaluation of the need for modification in other RNTCP formats and registers to facilitate drug ordering of pediatric formulations and potential analyses of data by age groups.

5. General issues

A revision of the RNTCP training modules will be undertaken to include Pediatric TB issues. District TB Control Societies should include representatives from the local bodies of Pediatricians. In coordination with the Indian Academy of Pediatrics (IAP), RNTCP should organise sensitization of Pediatricians regarding the programme.

6. Operational research issues

Identified operational research should be prioritised and conducted. Topics include: development of, and implementation of a multicentric field evaluation of a Pediatric TB diagnostic scoring system; feasibility of using mothers as DOT providers for children with TB; examination of the Pediatric TB case yield if the children who have a history of contact with smear negative patients are additionally screened.

A committee, including representatives of the Indian Academy of Pediatrics, will be set up to monitor the implementation of these recommendations.

References

1. Kochi A. The global tuberculosis situation and the new control strategy of the World Health Organisation. *Tubercle* 1991; 72: 1
2. World Health Organisation (WHO). WHO report on the Tuberculosis epidemic. Geneva: WHO; 1996.
3. WHO. Treatment of tuberculosis. Guidelines for National Programmes. Geneva; WHO; 2003 (WHO/CDS/TB 2003.313).
4. Central TB Division (CTD), DGHS, MoHFW, Government of India. TB India 2003: RNTCP Status Report. Delhi: CTD; 2003.
5. www.tbindia.org Accessed 7th October 2003.
6. Chakraborty AK. Prevalence and incidence of tuberculosis infection and disease in India. Geneva: WHO; 1997 (WHO/TB/97.231).
7. Graham SM et al, *Arch Dis Child* 1998; 79: 274-278

Participants of the workshop on the Management of Pediatric TB under the RNTCP (in alphabetical order by institution)

Kalra V (All India Institute of Medical Sciences, New Delhi)

Seth V (Formerly Head of Dept of Pediatrics, All India Institute of Medical Sciences, New Delhi)

Chauhan LS, Salhotra VS, Tonsing J, Roy D (Central TB Division, New Delhi)

Gupta VK, (Dr. Ram Manohar Lohia Hospital, New Delhi)

Shah RC, (IAP, Ahmedabad)

Lahiri K, (IAP, Mumbai)

Sachdev HPS, (IAP, New Delhi)

Chopra K, (IAP, New Delhi)

Caminero JA (IUATLD, Paris, France)

Srinivasan S, (JIPMER, Pondicherry)

Dutta AK, Singh V (Lady Hardinge Medical College & Kalawati Saran Children Hospital, New Delhi)

Arora VK, Gupta S, Sarin R, Sharma S, Singla N, Khalid S, (LRS Institute of TB & Allied Diseases, New Delhi)

Mittal SK, Sethi GR, (Maulana Azad Medical College & LNJP Hospital, New Delhi)

Mahadev B, (National Tuberculosis Institute, Bangalore)

Singh M, (PGIMER, Chandigarh)

Salhan RN (VMMC & Safdarjung Hospital, New Delhi)

Graham SM, (Welcome Trust Research Laboratories, Malawi)

Granich R, Sahu S, (WHO-India)

Wares F (WHO-SEARO)