FORMULATION OF GUIDELINES FOR DIAGNOSIS AND TREATMENT OF PEDIATRIC TB CASES UNDER 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*

BACKGROUND

The actual global burden of childhood TB is not known, but it has been assumed that 10% of the total TB cases are found amongst children. Global estimates of 1.5 million new cases and 130,000 deaths due to TB per year amongst children is reported1,2. 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 age of 1 and 4 years. Disease usually develops within one year of infection - the younger, the earlier and the more disseminated. 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). PTB in children is usually smear-negative. Pulmonary to extra-pulmonary TB (EPTB) ratio is around 3:1.

Revised National TB Control Programme

National Tuberculosis Programme (NTP) has been in operation since 1962. In 1992, a joint Government of India and World Health Organisation review committee found that despite the existence of the NTP, TB patients were not being accurately diagnosed and 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 crores.

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 nation-wide 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 cases\textsuperscript{4}. Over 70,000 patients are now being placed on treatment each month\textsuperscript{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\textsuperscript{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 outcome 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 6\textsuperscript{th} and 7\textsuperscript{th} 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. 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 should be made available in the form of combipacks in patient-wise boxes, linked to the child’s weight.

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

*Children showing neurological symptoms like irritability, refusal to feed, headache, vomiting or altered sensorium may be suspected to have TBM.
### Table: Recommended treatment regimens under RNTCP

<table>
<thead>
<tr>
<th>Category of treatment</th>
<th>Type of patients</th>
<th>TB treatment regimens</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Intensive phase</td>
</tr>
<tr>
<td>Category I</td>
<td>New sputum smear-positive PTB</td>
<td>2 H_{3}R_{2}Z_{1}E_{3}</td>
</tr>
<tr>
<td></td>
<td>Seriously ill sputum smear-negative PTB</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Seriously ill extra-pulmonary TB</td>
<td></td>
</tr>
<tr>
<td>Category II</td>
<td>Sputum smear-positive relapse</td>
<td>2 S_{1}H_{3}R_{1}Z_{3}E_{3}</td>
</tr>
<tr>
<td></td>
<td>Sputum smear-positive treatment failure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sputum smear-positive treatment after default</td>
<td>1H_{1}R_{1}Z_{1}E_{3}</td>
</tr>
<tr>
<td>Category III</td>
<td>Sputum smear-negative and</td>
<td>2 H_{3}R_{3}Z_{1}</td>
</tr>
<tr>
<td></td>
<td>Extra-pulmonary TB, not seriously ill</td>
<td></td>
</tr>
</tbody>
</table>

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.

4. Monitoring and evaluation

Pediatric-focused monitoring may preferably should 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 at the collection of additional information in relation to Pediatric TB patients, such as the basis for starting treatment along with categorization, since a 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 chemoprophylaxis.

3. Chemoprophylaxis

Asymptomatic children below 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)
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

HOW TO QUIT SMOKING

The very first step for quitting is to shun ambivalence about quitting. And, making a firm resolve to quit at any cost. No sacrifice is big enough to justify giving up in midstream.

First, list all the perceived reasons why you must continue to smoke. Some of the common reasons listed by smokers are: fear of suffering caused by the withdrawal; frequent abouts of anger; weights gain or loss; less than usual appetite; lower mental concentration while at work.

Then, list all the benefits that accrue from quitting: that irritating whaking cough gone; fresh non-foul smelling breath; lower risk of developing lung cancer or other respiratory disorders; avoiding the considerable damage which tobacco use (smoking, sniffing, chewing) inflicts on heart and blood vessels; the money saved would become available for buying nutritional supplements, education of children, purchase of medicines for minor sickness, etc.

The comparison is so overwhelming in favour of quitting that almost any one could resolve to quit and gather the required motivation and self-confidence to do so.

YOU HAVE TO QUIT

Published by the Tuberculosis Association of India in the interest of public health