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## Contact screening and chemoprophylaxis in India's Revised Tuberculosis Control Programme: a situational analysis

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### SUMMARY

**BACKGROUND:** India's Revised National Tuberculosis Control Programme (RNTCP) recommends screening of all household contacts of smear-positive pulmonary tuberculosis (PTB) cases for tuberculosis (TB) disease, and 6-month isoniazid preventive therapy (IPT) for asymptomatic children aged <6 years.

**OBJECTIVE:** To assess the implementation of child contact screening and IPT administration under the RNTCP.

**METHODS:** A cross-sectional study conducted in four randomly selected TB units (TUs), two in an urban (Chennai City) and two in a rural (Vellore District) area of Tamil Nadu, South India, from July to September 2008. The study involved the perusal of TB treatment cards of source cases (new or retreatment smear-positive PTB patients started on treatment), interview of source

cases and focus group discussions (FGDs) among health care workers.

**RESULTS:** Interviews of 253 PTB patients revealed that of 220 contacts aged <14 years, only 31 (14%) had been screened for TB, and that of 84 household children aged <6 years, only 16 (19%) had been initiated on IPT. The treatment cards of source cases lacked documentation of contact details. FGDs revealed greater TB awareness among urban health care workers, but a lack of detailed knowledge about procedures.

**CONCLUSION:** Provision for documentation using a separate IPT card and focused training may help improve the implementation of contact screening and IPT.

**KEY WORDS:** contact screening; IPT; RNTCP; chemoprophylaxis; children

EACH YEAR about 1 million cases (11%) of tuberculosis (TB) are estimated to occur in children aged <15 years, with the 22 high-burden TB countries contributing 75% of these cases.<sup>1</sup> The source of infection for most children is an infectious adult in close proximity (usually the household). The concentration of bacilli in the sputum of a person with TB correlates highly with the infectivity of that person.<sup>2</sup> Studies have highlighted high rates of infection and disease among child contacts of adults with sputum positive pulmonary TB (PTB).<sup>3,4</sup>

India's Revised National TB Control Programme (RNTCP) recommends screening of all household contacts of smear-positive PTB cases, especially those aged <6 years, for symptoms of TB.<sup>5</sup> For asymptomatic children and those found not to be suffering from TB disease, daily isoniazid preventive treatment (IPT) at 5 mg/kg is recommended for 6 months.<sup>5</sup> To ensure that proper preventive chemotherapy is given to children, the Medical Officer should ask (or have the health workers ask) all smear-positive PTB patients if they have children aged <6 years and ensure that they

are brought to a health unit for screening. On the reverse side of the RNTCP TB treatment card, the number of household contacts (children aged <6 years) and the number of contacts placed on IPT can be recorded.

A study was conducted to assess the implementation of contact screening and IPT under the RNTCP. The awareness of and barriers to child contact management among health care workers and PTB patients were also studied.

### METHODOLOGY

A cross-sectional study was conducted in four TB units (TU), two in an urban (Chennai City) and two in a rural (Vellore District) area\* of Tamil Nadu, which were selected by simple random sampling technique. A source case was defined as a new or retreatment smear-positive PTB patient who had been started

\*Under the RNTCP, a TU is a subdistrict supervisory unit that covers a population of, on average, 500 000.

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on treatment during the period from April to June 2008.

TB treatment registers and individual TB treatment cards were perused for documentation on contact screening and IPT. Awareness about RNTCP contact screening and IPT policies among source cases was studied by an interview conducted in the local language (Tamil) by trained field investigators using a semi-structured interview schedule. This contained questions on the duration of symptoms, awareness of risk of transmission to family contacts, number of close contacts—especially children aged <6 years, screening for TB among children aged 0–14 years by symptom elucidation and relevant investigations (chest X-ray, sputum examination), initiation of chemoprophylaxis, and treatment adherence and completion. There is currently no provision for documentation of the details of contact screening, IPT administration and follow-up, and these details therefore could not be elicited from the TB treatment card of the source case. The patient interview was thus considered as the most reliable source of information. Four focus group discussions (FGDs), one at each site, were conducted among health care workers (HCWs) in Tamil by a facilitator. These included Medical Officers (MOs), senior TB treatment supervisors (STS), TB health visitors and village health nurses (VHNs) involved in administering treatment. There were about 10 participants in each focus group. Discussions focused on issues related to RNTCP policy on contact management and IPT, and the difficulties encountered in implementation. The responses were recorded and later transcribed.

The study was approved by the Institutional Ethics Committee of the Indian Council of Medical Research, and informed consent was obtained from patients and HCWs before interviews/discussions. Data were double entered and analysed using SPSS V13.0 (Statistical Package for the Social Sciences, Chicago, IL, USA). FGD analysis identified issues around the key discussion topics.

## RESULTS

Among the 370 registered source cases, 32 (9%) defaulted, 7 (2%) died, 7 (2%) transferred out and 5 (1%) migrated. Of the remaining 319 patients, 253 were interviewed. Their profile is shown in Table 1. There were 118 (47%) patients from the rural and 135 (53%) patients from the urban study sites. There were 191 (75%) males, 202 (80%) new smear-positive PTB patients on Category 1 treatment, and 110 (43%) patients were aged between 26–45 years. The duration of symptoms before diagnosis was <4 weeks in 134 (53%) patients; this was significantly higher among urban than rural patients (88/135, 65% vs. 46/118, 39%,  $P < 0.01$ ). Overall awareness that the mode of transmission is by the airborne route and

**Table 1** Profile of 253 interviewed smear-positive PTB patients and awareness of TB transmission

Characteristics	Rural (n = 118) n (%)	Urban (n = 135) n (%)	Total (N = 253) n (%)
Male sex	88 (75)	103 (76)	191 (75)
Age, years			
≥15–25	16 (14)	32 (24)	48 (19)
26–35	23 (19)	20 (15)	43 (17)
36–45	27 (23)	40 (30)	67 (26)
46–65	23 (19)	25 (19)	48 (19)
>65	29 (25)	18 (13)	47 (19)
Categorisation			
Category 1*	95 (81)	107 (79)	202 (80)
Smear grading			
1+	62 (53)	69 (51)	131 (52)
2+	29 (25)	29 (21)	58 (23)
3+	27 (23)	37 (27)	64 (25)
Duration of symptoms prior to TB diagnosis			
≤4 weeks	46 (39)	88 (65)	134 (53) <sup>†</sup>
>4–8 weeks	37 (31)	25 (19)	62 (25)
≥9 weeks	35 (30)	22 (16)	57 (23)
Patients aware of airborne route of TB infection transmission	92 (78)	95 (70)	187 (73)
Patients aware that TB is transmissible to other family members	25 (21)	113 (84)	138 (55) <sup>‡</sup>
Patients aware that the mouth should be covered when coughing	104 (88)	128 (95)	232 (92)

\*New smear-positive PTB.

<sup>†</sup>Rural vs. urban,  $P < 0.01$ .

<sup>‡</sup>Rural vs. urban,  $P < 0.001$ .

PTB = pulmonary tuberculosis.

that the mouth should be covered while coughing was respectively 73% and 92%. The knowledge that TB is transmissible to other family members was significantly lower among rural than urban patients (25/118, 21% vs. 113/135, 84%,  $P < 0.001$ ).

The information obtained on contact screening and IPT initiation is shown in Table 2. Among the 220 contacts aged 0–14 years, only 31 (14%) had been screened for TB disease. None of the child contacts screened was diagnosed with active TB disease. Of the 55 patients who had children aged <6 years, only 15 (27%) stated that they had been informed about the provision of IPT for their children. Among children aged <6 years, only 16 (19%) had been initiated on IPT, with no difference between rural and urban groups. In these cases, isoniazid (INH) was given to the source case as a monthly supply to be given to the child contact, and there was no follow-up of the child initiated on IPT. According to the patients, these children did not experience side effects with INH.

The treatment cards of 253 source cases contained no documentation of the number of children aged <6 years residing in the household, nor of those screened for TB. IPT initiation was recorded for all 16 children initiated on IPT. There was, however, no documentation of screening, follow-up, drug supply or treatment completion for these children.

**Table 2** Information on contact screening and IPT initiation from 253 interviewed smear-positive PTB patients

Characteristics	Rural n (%)	Urban n (%)	Total n (%)
Contacts in the same house			
Adults	299	308	607
Children aged ≥6–14 years	73	63	136
Children aged <6 years	51	33	84
Patients who were informed by			
HCWs to screen all close contacts for TB (n = 253)*	24 (20)	36 (27)	60 (24)
Children aged (0–14 years) screened for TB (n = 220) <sup>†</sup>	21 (17)	10 (10)	31 (14)
Patients who said that they were informed about the provision of IPT for children aged <6 years in their house (n = 55) <sup>‡</sup>	6 (18)	9 (41)	15 (27)
Children aged <6 years initiated on IPT (n = 84) <sup>§</sup>	7 (14)	9 (27)	16 (19)

\*Rural (n = 118) and urban (n = 135).

<sup>†</sup>Rural (n = 124) and urban (n = 99).<sup>‡</sup>Rural (n = 33) and urban (n = 22).<sup>§</sup>Rural (n = 51) and urban (n = 33).*Excerpts from focus group discussions among health care workers**Awareness of IPT and RNTCP guidelines for contact management*

Urban: HCWs were aware of both contact screening for TB and the recommendation to offer IPT to children aged <6 years:

We refer the child contacts of smear-positive patients who are less than 6 years of age to the Government Children's hospital for investigations before starting them on chemoprophylaxis. (HCWs)

Rural: there was general awareness that all contacts with respiratory complaints have to be screened for TB. However, most HCWs were unaware of the need for IPT for child contacts aged <6 years.

If a child of a smear-positive patient is symptomatic, we ask them to take a chest X-ray in a private laboratory, and in case of doubt, refer them to a higher speciality centre for opinion, based on which we give treatment. We have not started any child on chemoprophylaxis so far. (The MO of one TU)

In the other TU, the MO said that the children were given IPT at the TU level.

*Awareness of IPT administration*

Urban: the HCWs were aware that INH was to be given at a dosage of 5 mg/kg for chemoprophylaxis.

*Documentation and isoniazid administration*

HCWs said that they entered the child's name on the reverse side of the treatment card of the index case under the 'Prophylaxis' column. INH was issued to the index case on a monthly basis, with instructions to give the drug daily to the child.

We ask the patient to report after the drug container becomes empty and give him the next monthly supply. (HCWs)

No record was made of the drug supply:

There is no provision for recording the supply of INH anywhere except what we do while accounting for the drug. (HCWs)

However, one HCW said: 'I record the date of drug supply in a pocket diary and ask the patient to bring it along when he comes for drug collection.'

*Ensuring drug intake*

The HCWs said that when they supplied the INH to index cases they instructed them to give the drugs regularly to the child. They said, 'There is no existing procedure to be followed to ensure drug intake or default retrieval.' In addition, 'Even if the index case defaulted, the family member came for collection of the drug for the child after the medicines were over.'

*Periodic evaluation of the child on IPT*

Children initiated on IPT are not periodically reviewed.

We enquire about the child when the parent attends for drug collection and ask them to bring the child for check-up in case of complaints. (HCWs)

*Report of side effects to isoniazid*

According to the HCWs, there were no reports of adverse effects.

*Ensuring treatment completion*

The date of starting IPT is entered on the index card by the HCWs. IPT administration ends with the completion of treatment in the index case. The completion date is also entered in the remarks column of the index case's treatment card.

Rural: the MO from one rural study site was aware of the need for IPT administration. He said that children aged <6 years who are contacts of smear-positive patients are given a monthly supply of INH for 6 months after screening for TB at his primary health centre (PHC). However, he admitted that there was no periodic follow-up or mechanism for monitoring drug intake for these children. The other HCWs, including the MOs, were ignorant about IPT for child contacts aged <6 years.

*Suggestions from HCWs*

Urban: the HCWs felt that IPT implementation would be much easier if a separate card was provided for documentation. They said: 'We have no provision for recording the drug supply and a separate card would be useful.' They expressed their willingness to implement IPT if a detailed procedure and a separate card were provided.

Rural: the MOs were willing to implement IPT in the future. However, the VHNs, who are the directly observed treatment (DOT) providers in rural areas, were reluctant to take the responsibility of providing IPT for the children.

TB patients experience a lot of side effects and patients have also died due to jaundice. In case the child develops side effects with the drugs, it is difficult to manage at the field level and we will be blamed. (VHNs)

They felt that IPT for children should be administered at the PHC or TU level, under the supervision of the MO or STS.

## DISCUSSION

The study findings suggest that RNTCP policies on child contact screening and IPT are not being effectively implemented. Among those patients with young child contacts, only a quarter had been informed of the availability of IPT for these children; this is similar to findings of a survey conducted in Malawi.<sup>6</sup> This implies a lack of awareness among both HCWs and patients of the need to screen all close contacts and provide IPT for young children. Screening of young children living in the households of smear-positive PTB cases has identified active TB disease in 22–34% (higher rates have been seen in high human immunodeficiency virus [HIV] prevalent settings), and can contribute a significant proportion of the total number of registered childhood cases of TB.<sup>3,4,7–10</sup> A study from Morocco observed that the proportion of TB cases identified in household contacts of registered TB cases was significantly higher in children aged <10 years.<sup>11</sup> Among child contacts (aged <5 years) of sputum-positive PTB patients, the proportion infected ranged from 27.9% to 62.6% in various studies.<sup>4,8,9,12</sup> The progression to disease is highest among infants, followed by children aged 1–5 years, subsequently decreasing in the age 5–10-year group and increasing again in adolescence.<sup>13</sup> In addition, children aged <5 years are at higher risk of developing disseminated forms of TB, including miliary disease and meningitis, which are frequently associated with greater morbidity and mortality. Moreover, studies have shown that young age and HIV infection are risk factors for more severe disseminated disease, with HIV infection increasing the risk of TB disease twenty fold.<sup>14</sup> A comprehensive review of the natural history of childhood TB showed that primary infection before 2 years of age frequently progressed to serious disease within the first 12 months, without significant prior symptoms.<sup>15</sup> However, for infants, the time span may be as short as 6–8 weeks.<sup>16</sup> It is therefore important that all child contacts of smear-positive PTB patients be screened for active TB.

The 19% rate of IPT initiation in child contacts in

the present study is higher than the findings of a Malawi survey, in which only 23 of 365 children aged <5 years received IPT.<sup>6</sup> We found no documentary evidence of IPT completion rates, which further highlights the inadequate implementation of IPT services. Even where policies are being implemented, documentation of the activities is weak. The FGDs revealed greater awareness of the policy on contact screening and IPT among HCWs at urban sites, highlighting the need for training of rural HCWs. The FGDs also suggested that contact screening and IPT could be implemented easily if detailed procedures and a separate ‘patient’ card for the individual child were to be made available. The card would be a reminder for IPT and would help ensure accountability.

Active screening and chemoprophylaxis of children exposed to adult index cases are often neglected due to resource constraints and the high burden of adult TB. It is documented that a substantial proportion of transmission in highly endemic areas, such as the study community, occurs outside the household, especially once children become mobile within the community.<sup>17</sup> Nonetheless, the fact that the majority of transmission in children aged <3 years occurs in the household, and that this is the group at highest risk of progressing to disease following primary infection, emphasises the importance of active contact tracing and the provision of IPT in high-risk children.<sup>18</sup> With a prevalence of INH resistance and of multidrug resistance among previously untreated PTB patients of respectively 15.4% and 3.4% in Tamil Nadu, the protective efficacy of IPT among contacts of drug-resistant TB patients needs further evaluation.<sup>19</sup> However, active tracing and screening of high-risk household contacts will also allow diseased children to be diagnosed earlier, lessening complications.

In the present study, the duration of symptoms (diagnostic delay) was shorter and the knowledge that TB is transmissible was more frequent among urban patients. This reinforces the need to educate patients in rural area about the risk of transmission to family members and the symptoms of TB.

The situation observed in this study is likely to occur in other parts of India, as contact screening and IPT have not been prioritised by the RNTCP. IPT for young children is essential to limit the risk of progression to disease, especially its severe forms. Furthermore, treating latent infection in childhood would reduce the pool from which infectious TB cases may later arise. It is now planned to pilot the implementation of the World Health Organization (WHO) guidelines for contact management in children in two sites in Tamil Nadu, in order to develop detailed procedural and documentation mechanisms.<sup>20</sup> If found to be feasible and successful, these could be adopted by the RNTCP and scaled up across the country.

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### RÉSUMÉ

**CONTEXTE :** Le Programme National Révisé de Lutte contre la Tuberculose (RNTCP) en Inde recommande de dépister pour une maladie tuberculeuse (TB) l'ensemble des contacts au sein du ménage des cas de tuberculose pulmonaire (TBP) à frottis positif et de soumettre les enfants asymptomatiques âgés de moins de 6 ans à un traitement préventif à l'isoniazide (IPT) pendant 6 mois. **OBJECTIF :** Evaluer la mise en œuvre du dépistage des enfants-contact et de l'administration de l'IPT dans le cadre du RNTCP.

**MÉTHODOLOGIE :** Etude transversale entre juillet et septembre 2008, menée dans quatre unités TB (TU) sélectionnées au hasard, deux dans un site urbain (Chennai City) et deux dans un site rural (district de Vellore) à Tamil Nadu, Inde du Sud. L'étude a comporté la lecture des cartes de traitement TB des cas-source (patients TBP à frottis positif mis sous traitement) nouveaux ou en re-

traitement, l'interview des cas-source et des discussions focalisées de groupe (FGD) chez les travailleurs de soins de santé.

**RÉSULTATS :** Les interviews de 253 patients TB ont révélé que sur 220 contacts âgés de <14 ans, 31 seulement (14%) avaient été dépistés pour la TB ; sur les 84 enfants du ménage âgés de <6 ans, 16 seulement (19%) avaient été placés sous IPT. La documentation sur les détails des contacts faisait défaut dans les cartes de traitement des cas-source. Les FGD ont révélé une prise de conscience plus élevée chez les travailleurs de soins de santé urbains, mais un manque de procédures détaillées.

**CONCLUSION :** La fourniture d'informations utilisant une carte d'IPT séparée et une formation focalisée peuvent aider à améliorer la mise en œuvre des activités de dépistage et d'IPT.

**MARCO DE REFERENCIA :** En el Programa Nacional Revisado de lucha contra la Tuberculosis (RNTCP) en India, se recomienda la detección sistemática de la tuberculosis (TB) en todos los contactos domiciliarios de los casos con tuberculosis pulmonar (TBP) y baciloscopia positiva y la administración de tratamiento preventivo con isoniazida (IPT) durante 6 meses a los niños asintomáticos <6 años de edad.

**OBJETIVO :** Evaluar la ejecución de la detección sistemática y la IPT a los niños, dentro del RNTCP.

**MÉTODOS :** Se llevó a cabo un estudio transversal en cuatro unidades de control de TB, dos en zona urbana (la ciudad de Chennai) y dos en zona rural (el distrito de Vellore) en Tamil Nadu, escogidas en forma aleatoria en el sur de la India entre julio y septiembre del 2008. El estudio comprendió una revisión de las tarjetas de tratamiento de los casos iniciales (pacientes con baciloscopia positiva nuevos o en retratamiento que habían comen-

zado una pauta terapéutica), entrevistas a estos pacientes y reuniones en grupos de discusión (FGD) con los profesionales de la salud.

**RESULTADOS :** Las entrevistas a 253 pacientes con TBP pusieron evidencia que de los 220 contactos <14 años, solo en 31 (14%) se practicó la detección sistemática de la TB ; de los 84 niños <6 años en los hogares, solo 16 (19%) comenzaron la IPT. Las tarjetas de tratamiento de los casos iniciales carecían de información sobre los contactos. Los FGD con los profesionales de salud revelaron una mayor sensibilización en los centros urbanos, pero la falta de procedimientos detallados.

**CONCLUSIÓN :** Es posible fomentar la ejecución de las actividades de la detección sistemática y la IPT mediante la provisión de documentación sobre el manejo de los contactos, el uso de una tarjeta exclusiva para el IPT y la capacitación específica.

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