

## Improving screening and chemoprophylaxis among child contacts in India's RNTCP: a pilot study

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### SUMMARY

**BACKGROUND:** While contact screening and chemoprophylaxis is recommended by India's Revised National Tuberculosis Control Programme for asymptomatic children aged <6 years who are household contacts of smear-positive pulmonary tuberculosis (PTB) patients, implementation is suboptimal.

**OBJECTIVE:** To evaluate the effectiveness of an isoniazid preventive therapy (IPT) register and card in improving the adherence of health care workers (HCWs) to programmatic guidelines.

**METHODOLOGY:** This prospective study was conducted in two Tuberculosis Units in South India. Child contacts of smear-positive PTB patients initiated on treatment between November 2009 and January 2010 were screened, and IPT was initiated in asymptomatic chil-

dren. HCWs were trained in the use of the IPT register and card. The process was evaluated using patient and HCW interviews.

**RESULTS:** Of 87 children identified aged <6 years, 71 (82%) were traced by HCWs; 53 were screened for TB and initiated on IPT, and 39 completed treatment. HCWs expressed satisfaction with the use of the IPT card and register, saying that it helped them to remember to complete required tasks.

**CONCLUSION:** In a programme setting, with HCW training and introduction of specific documentation (IPT card and register), implementation of contact tracing and chemoprophylaxis for child contacts improved from 19% to 61%.

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

INDIA'S Revised National Tuberculosis Control Programme (RNTCP) recommends that all household contacts of smear-positive pulmonary tuberculosis (PTB) patients, particularly those aged <6 years, should be screened for tuberculosis (TB) symptoms.<sup>1</sup> For asymptomatic children and those without evidence of TB disease, isoniazid preventive therapy (IPT) is recommended for a period of 6 months. Recent studies in southern India have found suboptimal implementation of all aspects of the screening and IPT component of the RNTCP.<sup>2,3</sup> A previous situational analysis revealed that among 84 household child contacts (aged <6 years) of 253 smear-positive PTB index patients, only 16 (19%) had been initiated on IPT.<sup>2</sup> One issue highlighted by health care workers (HCWs) during interviews was the lack of provision for the documentation of screening, follow-up, drug supply or treatment completion of these children.<sup>2</sup>

The World Health Organization (WHO) recommends that contact management could be effectively documented by means of a separate register and prophylaxis card.<sup>4</sup> We evaluated the effectiveness of the introduction of additional documentation (IPT regis-

ter and card) in improving the adherence of HCWs to programmatic guidelines and in increasing the proportion of children screened and initiated on and completing IPT. While there was no concurrent control group, we compared the outcomes post-intervention with previously documented outcomes from the same study area.

### METHODS

This was a prospective study conducted between October 2009 and August 2011 in two TB Units (TU),\* one urban (Chennai City) and the other rural (Vellore District) in Tamil Nadu, South India—the same sites at which the previous situational analysis was conducted.<sup>2</sup> The index patient was defined as a new or retreatment sputum smear-positive PTB patient who had been started on anti-tuberculosis treatment under the RNTCP between November 2009 and January 2010. A household member was defined as a

\*In the RNTCP, a TU is a sub-district supervisory unit that covers a population of on average 500 000.

person living with and sharing food from the same kitchen as the patient. Child contacts eligible for IPT were all children aged <6 years in whom active TB disease had been ruled out and who were living in the household of the index patient during the course of his/her disease.

#### *Implementation of the IPT register and card*

Prior to initiation of the study, permission was obtained from the RNTCP State TB Officer. The HCWs, who included Medical Officers (MO), Senior TB Treatment Supervisors (STS), TB health visitors and DOT (directly observed treatment) providers at the study sites, were provided with training in the use of the IPT register and card for the management of child contacts.

The HCWs asked the index TB patient to bring their household child contacts aged <6 years to the health centre for TB screening. As per RNTCP guidelines, children were screened and IPT was initiated by the MO after ruling out TB disease on the basis of symptom evaluation, chest radiograph and tuberculin skin test results, as needed.<sup>1</sup> Once a child had been initiated on IPT, the HCWs were expected to maintain appropriate documentation in the IPT register and card, and the responsible MOs performed periodic monitoring of the child's progress. Monitoring for respiratory symptoms, weight gain and adverse drug reactions was scheduled at months 1, 2 and 4 and at the end of IPT. Isoniazid (INH) was supplied by the RNTCP and delivered once a month to the index case or the child's care giver at a dosage of 5 mg/kg body weight.

The IPT register was maintained by the STS and contained the following details on child contacts aged <6 years: index case TB number; name of the child contact; age of the child; history of previous anti-tuberculosis treatment; any current TB symptoms; result of screening for TB disease; and, if TB disease found, whether initiated on RNTCP treatment (RNTCP TB case number). If no TB disease was found, the TB chemoprophylaxis registration number, adverse reactions and chemoprophylaxis outcome were entered for those children initiated on IPT.

The IPT card was maintained by the TB health visitors or DOT provider for every child initiated on IPT. The details entered included name of the index case and TB number, name of the child, sex, age, weight in kg, date of start of IPT, INH dosage, drug supply dates, IPT number, details of monitoring assessments, and IPT outcome. The outcomes of IPT in the child were defined as follows: completed: completed the prescribed duration of IPT without developing TB disease; TB disease: developed TB disease during IPT; default: did not receive IPT for 2 consecutive months; and death: death due to any cause while on IPT.

The effectiveness of the intervention (training of

HCWs, introduction of IPT register and card) was assessed in terms of the proportion of child contacts aged <6 years screened for TB, initiated on IPT and completing treatment. The study staff monitored entries in the IPT register and card.

#### *Patient and HCW interviews*

The index patients and household members were interviewed by the research staff to verify if all child contacts aged <6 years had been screened and initiated on IPT. The interview schedule comprised questions on the number of household contacts aged <6 years and those initiated on IPT. If any eligible child aged <6 years had not been initiated on IPT, the reasons were documented. The parents/guardians of the children initiated on IPT were interviewed using a semi-structured interview schedule and the responses were recorded in terms of drug collection, difficulties in drug administration, regularity and adverse drug reactions. The HCWs who initiated child contacts on IPT and the STS were also interviewed using a semi-structured interview schedule for their experience with the acceptability of and difficulties in the use of the IPT register and card.

The study was approved by the Institutional Ethics Committee of the National Institute for Research in Tuberculosis; written informed consent was obtained from the patients, parents and HCWs prior to interviews/training.

#### *Data entry and analysis*

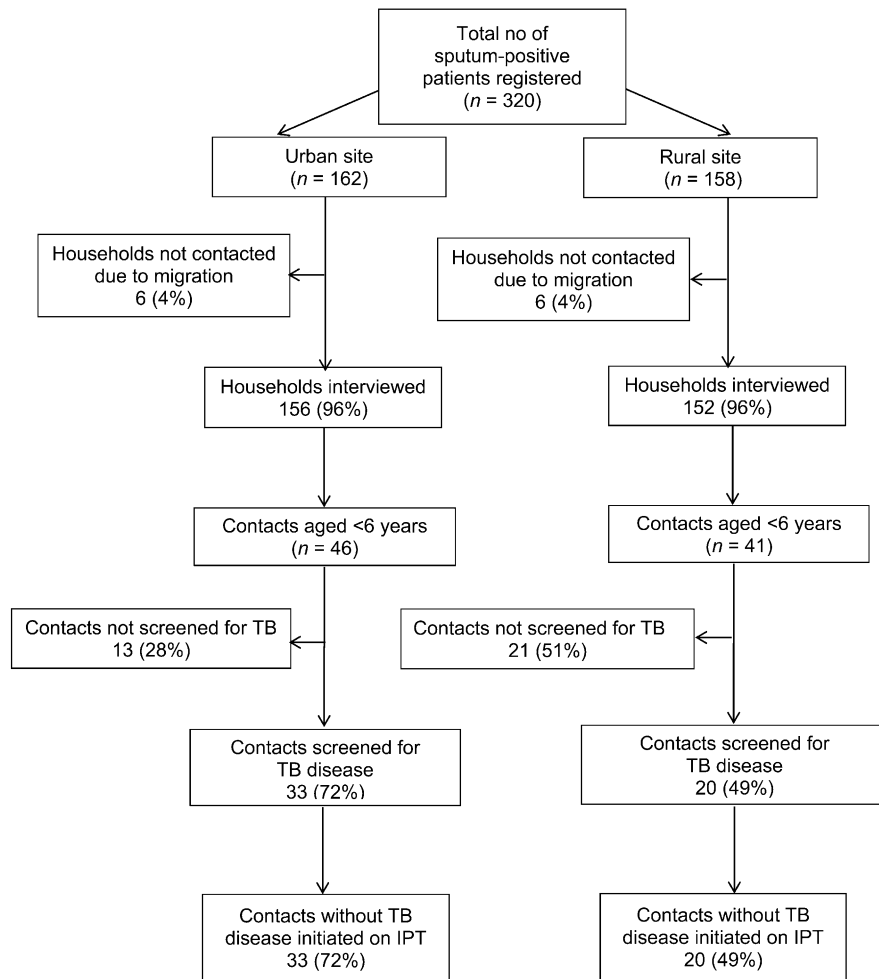
Data were double-verified, entered and analysed using SPSS version 13.0 (Statistical Package for the Social Sciences Inc, Chicago, IL, USA). Variables are expressed in terms of proportions and compared using the  $\chi^2$  test.

## **RESULTS**

Of 320 index TB patients identified, 12 (4%) migrated outside of the study area (Figure 1). The profile of the remaining 308 patients who were interviewed is shown in Table 1.

HCWs identified 71 (82%) of the 87 (46 urban, 41 rural) child contacts aged <6 years, of whom 53 (61%) were screened for TB disease; none were thought to have TB disease (Figure 1). The reasons cited for the 34 children not being screened included not being identified by the HCW (16: 8 urban and 8 rural); parents afraid of having their children screened (7: 2 urban and 5 rural); migrated away from study site (2 rural); parents too busy (6 rural); family problems (2 urban); and IPT had already been given by a private practitioner (1 urban).

All 53 children who had been screened were subsequently initiated on IPT, with a higher proportion screened and initiated on IPT at the urban than at the



**Figure** Contact screening and initiation of IPT in child contacts. TB = tuberculosis; IPT = isoniazid preventive therapy.

rural site (72% vs. 49%,  $P = 0.05$ ), probably due to increased awareness at the urban site. There were 27 (51%) males, with a mean age of 36 months (range 5–66) and a mean weight of 11.3 kg (range 5.3–19).

**Table 1** Profile of interviewed smear-positive pulmonary tuberculosis patients

Characteristic	Urban (n = 156) n (%)	Rural (n = 152) n (%)	Total (N = 308) n (%)
Sex			
Male	120 (77)	119 (78)	239 (78)
Female	36 (23)	33 (22)	69 (22)
Type of patient			
New	117 (75)	128 (84)	245 (80)
Previously treated	39 (25)	24 (16)	63 (20)
Age, years			
15–24	20 (13)	23 (15)	43 (14)
25–34	26 (17)	18 (12)	44 (14)
35–44	27 (17)	32 (21)	59 (19)
45–54	39 (25)	37 (24)	76 (25)
≥55	44 (28)	42 (28)	86 (28)
Patients with child contacts aged <6 years	29 (19)	24 (16)	53 (17)

The index patient was the father of the child for 27 (51%) of the children, and other relatives for the remaining children (Table 2).

Overall, 39 (74%) children completed treatment, with significantly higher completion rates at the rural than the urban site (95% vs. 61%,  $P < 0.01$ ). Reasons cited for the default of the remaining 14 children included migration outside the study area ( $n = 5$ ), death of the index patient ( $n = 3$ ), default of the index patient ( $n = 2$ ), diarrhoea ( $n = 2$ ), family problems ( $n = 1$ ), and parent not interested in continuing with IPT ( $n = 1$ ). Of the 14 children who defaulted, a grandparent was the index patient in nine of the cases. The index patient being other than the parent, migration and work pressures were the main reasons provided for the high default rate at the urban site.

Overall, adverse effects were minimal: three children had diarrhoea, two of whom defaulted. In the third child, the symptoms subsided. No child was observed to develop TB disease during the IPT. During the interviews, the care givers of the children who completed treatment reported no difficulty in collecting INH every month and administering it to the child.

**Table 2** Profile and treatment outcomes of child contacts initiated on IPT

	Urban (n = 33) n	Rural (n = 20) n	Total (N = 53) n (%)
Sex			
Males	15	12	27 (51)
Females	18	8	26 (49)
Age, months			
1–12	6	2	8 (15)
13–24	6	4	10 (19)
25–36	11	4	15 (28)
37–48	3	4	7 (13)
≥49	7	6	13 (25)
Body weight, kg			
5–9	11	3	14 (26)
10–14	16	12	28 (53)
≥15	6	5	11 (21)
Relationship of index patient to child			
Father	13	14	27 (51)
Mother	9	4	13 (25)
Grandfather	7	2	9 (17)
Grandmother	4	0	4 (8)
IPT outcome			
Treatment completed	20	19	39 (74)*
Default	13	1	14 (26)
Death	0	0	0
TB disease	0	0	0
Adverse drug reactions			
Diarrhoea	3	0	3 (6)

\*Urban vs. rural,  $P < 0.01$ .  
IPT = isoniazid preventive therapy.

However, only 22 children (42%) reported for periodic monitoring after IPT initiation. As few children experienced any complaints on IPT, the parents/care givers either did not feel the need to bring the children in, or were too busy to do so.

Fifteen HCWs were interviewed. The STS said that the maintenance of the IPT register was not difficult and ensured accountability. The TB health visitors and DOT providers who had handled the IPT cards reported no difficulty in maintaining the IPT card. Overall, the HCWs expressed satisfaction with the introduction and use of the IPT cards and register, saying that it helped them remember to complete tasks according to programme guidelines.

In summary, chemoprophylaxis initiation improved significantly, from the 19% reported in our previous study to 61%.<sup>2</sup> Significant increases were observed at both the rural and urban study sites (Table 3).

## DISCUSSION

Child contact screening and chemoprophylaxis are not given priority in most national TB control programmes (NTPs) due to resource constraints and the high burden of adult TB. Many studies have documented suboptimal implementation of this programme component, although the importance of active contact tracing and the provision of IPT to

**Table 3** IPT coverage in the study sites during the pre- and post-intervention periods

Site/period	Children aged <6 years n	IPT coverage n (%)	OR (95%CI)	P value
Rural				
Pre-intervention	51	7 (14)	5.99	<0.001
Post-intervention	41	20 (49)	(1.99–18.65)	
Urban				
Pre-intervention	33	9 (27)	6.77	<0.001
Post-intervention	46	33 (72)	(2.25–21.05)	
Overall				
Pre-intervention	84	16 (19)	6.63	<0.001
Post-intervention	87	53 (61)	(3.14–14.14)	

IPT = isoniazid preventive therapy; OR = odds ratio; CI = confidence interval.

high-risk children is well recognised.<sup>2,3,5</sup> Our study found that with minimal training of HCWs and the introduction of specific documentation (IPT register and card), initiation of IPT in child contacts aged <6 years improved from 19% to 61%.<sup>2</sup> However, although much improved, coverage remained suboptimal, emphasising the need for continued training, monitoring and accountability of HCWs.

Lack of awareness among HCWs about child contact screening has been reported previously.<sup>2,3,6</sup> The HCWs at the study site were, however, able to identify 82% of the existing child contacts, as the training and new documents served as a reminder of this component of the programme. However, it is imperative that HCWs identify all child contacts and counsel TB patients effectively on the importance of contact screening and IPT, addressing any misconceptions. Furthermore, greater awareness about child contact screening and IPT is needed among the TB patients themselves and the wider community, through mass information and education campaigns.

Although 2.5–42% of child contacts have been observed to have TB disease in other studies,<sup>7–10</sup> in the current study no child contact screened was found to have TB disease. Again, this is similar to the findings seen in other studies from South India.<sup>2,3</sup> The challenges of diagnosing TB disease in children in routine programme conditions in low-income settings are well recognised, and the lack of cases detected in the study may well be due to this despite the availability of RNTCP guidelines and diagnostic algorithms for the diagnosis and treatment of childhood TB.<sup>5,11,12</sup> The tuberculin required for tuberculin skin testing and facilities for chest radiography are often lacking in peripheral health facilities. How far this contributes to the relatively few cases of TB diagnosed in children is not clear and needs to be investigated.<sup>3</sup>

In our study, which was carried out under routine programme conditions, the IPT completion rate was 74%. Studies elsewhere have documented treatment completion rates ranging from 20% to 99%,

highlighting that NTPs may face many challenges in implementing successful IPT activities.<sup>13–15</sup> Shorter, more acceptable alternative regimens for chemoprophylaxis, such as 4 months of INH and rifampicin (RMP), or 4 months of RMP monotherapy, have been recommended.<sup>14,16</sup> However, their effectiveness, safety and feasibility needs to be studied in children, particularly in resource-limited settings.

The main reasons cited for non-completion of IPT were migration, death or default of the index patient and, less commonly, adverse drug reactions. Patients and care givers need to be counselled appropriately on the importance of treatment completion and the consequences of default. The RNTCP needs to establish a mechanism whereby children can continue with their IPT to completion even if they migrate to another part of the state, similar to the option of transfer which is available for TB patients. Regular, routine follow-up of the child while on IPT, irrespective of the presence or absence of symptoms, is essential given the possibility of adverse reactions and of TB disease. No cases of hepatotoxicity were reported in the study, confirming the safety of IPT in children.

Under the RNTCP, INH is supplied as 100 mg tablets, and the recommended dosage is 5 mg/kg. Parents are instructed to break the tablets to administer the appropriate dosage to the child. As 53% of the child contacts in the study weighed between 10 and 14 kg, these children may not have received the appropriate dosages, as the tablets had to be broken. Tablets of 25 or 50 mg INH that can be used as required according to weight bands (similar to the paediatric boxes available in the RNTCP for the treatment of TB disease), would be a better alternative.<sup>11</sup> It should be noted, however, that based on the recent WHO recommendation of using 10 mg/kg INH for IPT, the RNTCP is currently revising its guidelines to bring them in line with international recommendations.<sup>17</sup>

INH intake was monitored by checking the entries on the IPT cards. This, however, may not reflect the true regularity of drug intake, as monthly supplies of drugs were provided. The feasibility of supervised drug intake or, if supplied monthly, surprise visits by the health staff, or monitoring for INH in the urine under programme conditions, needs to be explored. Although there is an easy colorimetric method for testing for INH and acetyl INH in the urine, implementing the test widely would involve training laboratory technicians and provision of supplies to all primary health care centres, unless a point-of-care test were developed.<sup>18</sup>

#### Limitations

There are inherent limitations to study sites serving as their own controls when interpreting the increase in coverage of contact screening and IPT, due to the gap of 1 year between the two studies and the possible impact of the previous study. Ideally, the study

should have had a concurrent control group. However, we feel our findings are important as the intervention not only had an impact judged by both qualitative and quantitative measures, it is also simple and can be replicated easily in other settings.

#### CONCLUSION

This study has shown that in programme settings, with minimal basic training, motivation of HCWs and provision of specific documentation consisting of a separate IPT card and register, the implementation of screening and provision of IPT for child contacts of sputum-positive PTB patients can be significantly improved. Awareness among patients about the importance of child contact screening and IPT needs, however, to be further increased. Counselling should also be offered to the care givers of children initiated on IPT to stress the importance of treatment completion.

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Conflict of interest: none declared.

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## R É S U M É

**CONTEXTE :** Bien que le dépistage des contacts et la chimioprophylaxie soient recommandés par le Programme National Révisé de Lutte contre la Tuberculose de l'Inde pour les enfants asymptomatiques âgés de <6 ans au contact à domicile avec des patients atteints d'une tuberculose pulmonaire (TBP) à frottis positif, la mise en œuvre de cette directive reste sous-optimale.

**OBJECTIF :** Evaluer l'efficacité d'un registre et d'une carte pour le traitement préventif à l'isoniazide (IPT) pour améliorer le respect des directives du programme par les travailleurs de soins de santé (HCW).

**MÉTHODOLOGIE :** Cette étude prospective a été menée dans deux unités TB d'Inde du Sud. Les enfants au contact de patients atteints d'une TBP à frottis positif et mis sous traitement entre novembre 2009 et janvier 2010 ont fait l'objet d'un dépistage. L'IPT a été mis en route chez les enfants asymptomatiques. Les HCW ont été

formés à l'utilisation du registre et de la carte IPT. Le processus a été évalué par des interviews avec les patients et les HCW.

**RÉSULTATS :** Parmi les 87 enfants âgés de <6 ans qui ont été identifiés, 71 (82%) ont été retrouvés par les HCW. Cinquante-trois ont fait l'objet d'un dépistage pour la TB et ont été mis sous IPT ; 39 ont achevé leur traitement. Les HCW ont exprimé leur satisfaction concernant l'utilisation de la carte et du registre IPT, et ont signalé qu'elle les aidait à se rappeler d'accomplir les tâches requises.

**CONCLUSION :** Dans les contextes du programme, grâce à une formation des HCW et à l'introduction d'une documentation spécifique (carte et registre IPT), la mise en œuvre de la recherche des contacts et de la chimioprophylaxie chez les enfants-contact s'est améliorée de 19% à 61%.

## R E S U M E N

**MARCO DE REFERENCIA** El Programa Nacional de Control de la Tuberculosis de la India recomienda la detección sistemática y el tratamiento profiláctico de los niños menores de 6 años que son contactos domiciliarios de un paciente con tuberculosis pulmonar (TBP) y baciloscopia positiva, pero el grado de aplicación de esta medida es insuficiente.

**OBJETIVO:** Evaluar la eficacia real del registro y la tarjeta del tratamiento preventivo con isoniazida (IPT) en el mejoramiento del cumplimiento de las directrices programáticas por parte de los profesionales de la salud (HCW).

**MÉTODO:** El presente estudio prospectivo se llevó a cabo en dos unidades de atención de la TB en el sur de la India. Se practicó la detección sistemática de la enfermedad en los niños que eran contactos de pacientes con TBP y baciloscopia positiva y que comenzaron tratamiento entre noviembre del 2009 y enero del 2010 y se

inició el IPT de los niños asintomáticos. Se impartió capacitación a los HCW sobre el uso del registro y la tarjeta del tratamiento profiláctico. La intervención se evaluó mediante entrevistas a los pacientes y a los HCW.

**RESULTADOS:** Los profesionales sanitarios localizaron 71 de los 87 contactos de <6 años de edad (82%). Se practicó la investigación diagnóstica en 53 niños y se comenzó su tratamiento preventivo; 39 niños completaron el tratamiento. Los HCW manifestaron satisfacción con el uso de la tarjeta y refirieron que el registro del IPT les ayudaba a recordar la compleción de las tareas exigidas.

**CONCLUSIÓN:** En las condiciones programáticas, con una capacitación de los trabajadores de salud y la introducción de la documentación específica (tarjeta y registro del IPT), se mejoró de 19% a 61% la localización de los niños que eran contactos de casos de TB y el suministro de quimioprofilaxis.