

# A study on coverage of isoniazid chemoprophylaxis among the household contacts of smear positive pulmonary tuberculosis cases aged <6 years under Revised National Tuberculosis Control Programme

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## ABSTRACT

**Background:** According to the Revised National Tuberculosis Control Program guidelines, childhood contacts of a smear positive tuberculosis (TB) cases should be screened for symptoms of TB and if there are any children aged <6 years they should be provided with isoniazid daily for a period of 6 months. Several studies have reported that adherence to isoniazid preventive therapy (IPT) is generally poor, particularly in high-burden and low-resource settings. According to TB India 2014 annual report, 35% of eligible children are not initiated on Isoniazid chemoprophylaxis. **Objectives:** This study was aimed to determine the coverage of isoniazid chemoprophylaxis and factors influencing it. **Materials and Methods:** A cross-sectional study was conducted from January 1, 2016, to December 31, 2016, among the household contacts aged ≤6 years of sputum smear positive pulmonary TB patients (newly diagnosed and previously treated) registered under Davangere TB unit from July 1, 2015, to June 30, 2016, after taking permission from institutional ethical committee. A pre-tested, semi-structured questionnaire was used to collect data and analyzed in SPSS v16. **Results:** Out of 39 child contacts, 24 (61.5%) were screened to rule out active TB disease. None of them were diagnosed to be suffering from TB. Among these screened 24 contacts, IPT was initiated in 21 contacts. Hence, total coverage of isoniazid chemoprophylaxis was 53.84%. The main factor responsible was gender discrimination for female child, lower education status of the mother and suboptimal screening efforts and initial home visit by the health-care staff. **Conclusion:** Uptake of IPT is suboptimal. Capacity building activities and ACSM activities regarding the TB and its prevention as to be strengthened. More studies are required in this regard in other regions.

**KEY WORDS:** Tuberculosis; Chemoprophylaxis; Prevention


## INTRODUCTION

Tuberculosis (TB) is one of the leading causes of morbidity and mortality globally. According to global TB report 2017, 104 lakh people were infected with TB, out of which one forth were from India.<sup>[1]</sup> Children are estimated

to represent 13–15% of TB cases in high burden countries like India.<sup>[2]</sup>

The World Health Organization and Revised National TB Control Program (RNTCP) recommends contact screening of all households of smear positive TB source case (index case) to identify children with TB disease and enable prompt treatment and also to provide Isoniazid chemoprophylaxis for household contacts aged <6 years who do not have disease.<sup>[3,4]</sup>

According to the RNTCP guidelines, childhood contacts of a smear positive TB cases should be visited at their home and all contacts should be screened for symptoms of TB and if there are any children aged <6 years they should be provided

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with isoniazid daily for a period of 6 months. Before initiating the isoniazid preventive therapy (IPT) contact tracing and identification of active cases is done and if no disease detected they are provided with isoniazid, 10 mg/kg for a period of 6 months.<sup>[5]</sup> Isoniazid chemoprophylaxis therapy is safe, as side effects in children are extremely rare and its efficacy in preventing disease is as high as 90% when taken correctly and regularly.

However, several studies have reported that adherence to IPT is generally poor, particularly in high-burden, and low-resource settings. According to TB India 2014 annual report,<sup>[6]</sup> 35% of eligible children are not initiated on Isoniazid chemoprophylaxis during their routine RNTCP program evaluation.

Hence, this study was aimed to determine the coverage of isoniazid chemoprophylaxis and factors influencing it among the household contacts of smear positive pulmonary TB cases aged <6 years in Davangere TB unit.

## MATERIALS AND METHODS

Davangere TB Centre is managed by RNTCP. The RNTCP implemented in the District since 2000. Davangere District has 6 TB unit and 23 designated microscopic centers (DMCs). Davangere TB unit covers the whole Davangere taluk and includes 6 DMCs.

A cross-sectional study was conducted for a period of 1 year from January 1, 2016, to December 31, 2016. This study was conducted among the household contacts aged ≤6 years of sputum smear positive pulmonary TB patients (newly diagnosed and previously treated) registered under Davangere TB unit from July 1, 2015, to June 30, 2016. All household contacts aged ≤6 years of transferred out and lost to follow-up patients and parents/guardian who did not give consent for the study were excluded from the study.

The extract of TB registers of all 6 DMCs from July 1, 2015, to June 30, 2016, was obtained. All smear positive patients registered in TB registers was sorted and listed as per DMC. The TB register contains information on the registered patients, that is, TB number, Date of registration, Name of the patient, Age and sex, Name of the Protected Health Information, and Type of case (New case or previous treated). From the above said variables, name and address of patient (sometimes telephone numbers also) and in which PHI, he/she is receiving DOTS (treatment) were extracted. Among 568 registered sputum smear positive pulmonary cases, 249 were interviewed. Based on inclusion and exclusion criteria, 39 of the household contacts aged <6 years from 25 index cases were considered as study participants.

A pre-tested, semi-structured questionnaire was used to collect data. The questionnaire was pilot tested and necessary

changes were incorporated before the start of the actual study. The subjects interviewed in the pilot study were excluded in the analysis. Parents or guardians of the eligible household contacts were interviewed to get the information regarding initiation of the Isoniazid chemoprophylaxis for the eligible contacts.

Administrative approval for the study was obtained from Davangere District TB Officer as well as Karnataka State TB division. Ethical approval was obtained from the Institutional Ethical Review Board of J. J. M. Medical College, Davangere before the start of the study. The purpose of the study was explained and written consent was obtained from parents/guardians of the study participants.

Data were entered and analyzed in SPSS version 16. Descriptive statistics such as proportions and frequencies were calculated. Categorical variable was analyzed using Chi-square and Fischer's exact test. The level of significance was set at 5%.

## RESULTS

Out of 39 child contacts, 24 (61.5%) were screened by medical staff (medical officer/pediatrician/TB Specialist) and subjected for evaluation to rule out active TB disease. 15 (38.5%) had not been screened as per RNTCP guideline. None of them, were diagnosed to be suffering from TB. Among these screened 24 contacts, IPT was initiated in 21 contacts. Hence, total coverage of isoniazid chemoprophylaxis was 53.84% [Figure 1].

About 75% of the male contacts were screened and only 40% of the females were screened, this difference was statistically significant ( $P < 0.02$ ). Furthermore, the likelihood of screening was significantly higher if contact case being male. Among screened childhood contacts maximum were belonging to the age group of 4–5 years and it was not statistically significant. Maximum (44%) screened childhood contacts had parents as index case followed by grandparents (26%). Association between screening and relationship of childhood contacts with index case was statistically significant. Almost half (54%) of the index cases were visited by the health-care providers and were statistically significant with screening of household contacts. However, there was no association of age of the child and maternal education with IPT screening ( $P > 0.05$ ) [Table 1].

Out of 39 children who were eligible for IPT, only 21 were initiated on IPT. IPT initiation was seen comparatively high among the male children (76%), children with an age 4–6 years (51%). Higher education among the mothers, and in the rural areas. However, this difference was statistically not significant. IPT uptake was more among the children with parents as the index case (62%). This difference was statistically significant ( $P = 0.02$ ) [Table 2].

**DISCUSSION**

The study conducted in Davangere TB Unit from January 1, 2016, to December 31, 2016 under RNTCP. About 10% of Sputum smear positive cases with TB registered under RNTCP for treatment had a child house hold contact aged ≤6 years. Among these contacts almost half of them were not subjected for screening to rule out active TB disease and only few female children were screened for TB. Out of the eligible child contacts half of them (53.84%) were initiated on IPT. The factors identified to be associated with non-screening and non-initiation were when the sputum smear positive case was not parents and when initial home visit not done by healthcare workers. The results showed that the main reason for not screening of the child and non-initiation of IPT is lack of initial home visit by the concerned health care worker. This can be done effectively by constant supervision of the program by the program officers.

Children getting proper IPT services are more if their parents are index cases. Knowledge gap is that, when a parent suffers from TB, they care more about children and indulge in preventive activities like IPT.

The studies done across the world on the status of implementation of IPT shows the proportion of implementation is low. Two studies conducted in Tamil Nadu by Banu Rekha

*et al.*<sup>[7]</sup> and Shivaramakrishna *et al.*<sup>[8]</sup> show the proportion of eligible children who were initiated on IPT was 16% and 33%, respectively. Among them Shivaramakrishna *et al.* study shows that 35.6% of eligible children contacts were initiated on IPT.<sup>[8]</sup> However, study conducted by Pothukuchi *et al.*, in Andhra Pradesh shows that 56% of eligible children were initiated on IPT, which is almost same as our present study.<sup>[9]</sup> The proportion of children who were initiated on IPT shows a range of 7.1–99%. A study conducted by Farebee *et al.* shows that 37% of the eligible contacts were screened, among them 87% initiated on IPT.<sup>[10]</sup> Another study conducted by Adjobimey *et al.* in Benin (West Africa) found that 99% of eligible children were screened and initiated in IPT. This study used an intervention by introducing IPT card for recording and monitoring this might have resulted in maximum coverage.<sup>[11]</sup> Banu Rekha *et al.* also found in their study an increase in coverage of IPT after introducing IPT card.<sup>[7]</sup> If the index case is other than parent there is deficiency and underutilization of the IPT services given for child. Similar finding were also observed by Hall *et al.* in Timor Leste.<sup>[12]</sup>

This study has much strength methodologically. The important one is the investigator visited, observed, and clinically examined all the available Sputum smear positive cases, >80% of child contacts were provided with appropriate consultation. The interviews were conducted meticulously

**Table 1:** Eligible childhood contacts screened for presence of active TB

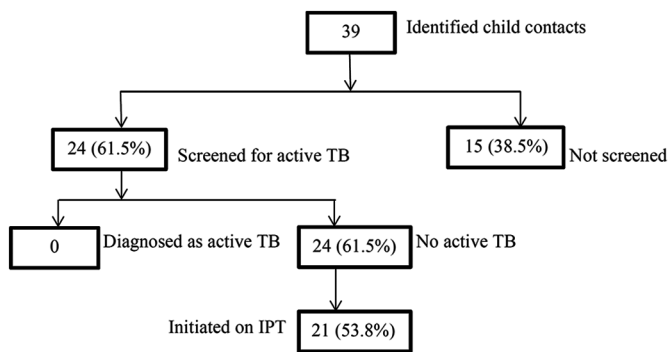
Variables	Sub-Category	Screened (%)			P-value
		Yes (n=24)	No (n=15)	Total (n=39)	
Sex of child	Male	18 (75)	6 (40)	24 (61.5)	0.029
	Female	6 (25)	9 (60)	15 (38.5)	
Age of children (in years)	<1	4 (17)	3 (20)	7 (17.9)	0.89 <sup>#</sup>
	1–2	3 (13)	3 (20)	6 (15.4)	
	2–3	4 (17)	3 (20)	7 (17.9)	
	3–4	2 (8)	2 (13)	4 (10.3)	
	4–5	7 (29)	3 (20)	10 (25.6)	
	5–6	4 (17)	1 (7)	5 (12.8)	
Mother's educational status	Illiterate	5 (21)	2 (13)	7 (17.9)	0.77
	Primary	12 (50)	9 (60)	21 (53.8)	
	Secondary	6 (25)	4 (27)	10 (25.6)	
	Degree and Above	1 (4)	0 (0)	1 (2.6)	
Children relationship with index case	Parents	13 (54)	4 (27)	17 (43.6)	0.01 <sup>#</sup>
	Grand Parents	8 (33)	2 (13)	10 (25.6)	
	Others	3 (13)	9 (60)	12 (30.8)	
Initial home-visit by health staff	Yes	21 (88)	0 (0)	21 (53.8)	<0.001
	No	3 (13)	15 (100)	18 (46.2)	

<sup>#</sup>Fischer's test applied, TB: Tuberculosis

**Table 2:** Initiation of IPT out of those screened and found eligible by sex, age, and area of residence (n=39)

Variables	Sub-Category	IPT initiation (%)		P-value
		Yes (n=21)	No (n=18)	
Sex of child	Male	16 (76)	8 (44)	0.42
	Female	5 (24)	10 (56)	
Age of children (in years)	< 1	3 (14)	4 (22)	0.52
	1–2	2 (10)	4 (22)	
	2–3	3 (14)	4 (22)	
	3–4	2 (10)	2 (11)	
	4–5	7 (33)	3 (17)	
	5–6	4 (19)	1 (6)	
Mother's educational status	Illiterate	2 (10)	5 (28)	0.407
	Primary	12 (57)	9 (50)	
	Secondary	6 (29)	4 (22)	
	Degree and Above	1 (5)	0 (0)	
Children relationship with index case	Parents	13 (62)	4 (22)	0.02
	Grand Parents	5 (24)	5 (28)	
	Others	3 (14)	9 (50)	
Area of residence	Rural	14 (67)	11 (61)	0.71
	Urban	7 (33)	7 (39)	

IPT: Isoniazid preventive therapy



**Figure 1:** Screening and isoniazid preventive therapy initiation

after understanding the prevailing locally practiced customs (Stigma) and cultural beliefs about the TB disease. In the beginning of the study, the investigator was accompanied by a sociologist. Second, the information collected was validated by cross verifying with available treatment cards, PHI documents, drug stock register regarding INH availability, and the presence or absence of children contacts in the Anganwadi centers and in depth enquiry was made to elicit the history of presence of child contacts in the past 3 months before the diagnosis of the sputum smear positive case. The important limitation of the study was information collected through interview method, which is after a substantial gap of 1–2 years, there is a longer duration between the event and the interview which may have resulted in recall bias in the data collection.

## CONCLUSION

In this study, it was found that the proportion of eligible children provides preventive therapy is low. Almost half of the eligible children were denied the benefit of preventive therapy. The main factor responsible was gender discrimination for female child, lower education status of the mother and suboptimal screening efforts and initial home visit by the health-care staff. Hence, capacity building activities and ACSM activities regarding the TB and its prevention as to be strengthened.

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