



Assessment of Barriers in Initiation and Completion of Isoniazid Preventive Therapy among Household Child Contacts of Pulmonary TB Patients in Delhi: A Mixed Method Study

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ABSTRACT

Background: Young children (aged < 6 years) in contact with Sputum positive TB adults are often infected with *Mycobacterium tuberculosis* and once infected are at higher risk of progression to TB disease than adults.

Objectives: The study was conducted To find out the proportion of < 6 years of age children having household contact of a pulmonary TB patient, screened, initiated, and completed IPT in the year 2019 and to find out the barriers for not completing/taking IPT.

Methodology: A mixed-method study was conducted during July-September 2019 among household contacts of < 6 years of age of sputum positive pulmonary TB patients attending a DOT centre in South – East Delhi.

Results: A total of 52 household contacts of less than 6 years of age were identified. Whereas 65% of the study population was aware of IPT, only 26.9% of individuals were on IPT out of the total study population and only 4 % had completed the IPT. On qualitative analysis, most of them informed that the DOTS provider didn't emphasize them about IPT. Some of them felt that it isn't required since the child does not have the disease.

Conclusion: Adherence to IPT is low. The dearth of IEC activities in the study area adds to this burden. Hence prompt IEC activities and adequate training of DOT providers for initiation and adherence of IPT is the need of the time.

Keywords: Household contact, isoniazid preventive therapy, pulmonary tuberculosis

INTRODUCTION

Tuberculosis (TB) is a communicable disease that is a major cause of ill health, said to be one of the top ten causes of death worldwide and the leading cause of death from a single infectious agent (ranking above HIV/AIDS). About a quarter of the world's population is infected with *Mycobacterium tuberculosis* and thus at risk of developing TB disease. The global burden of the disease is estimated to be 10 million. Geographically, most TB cases in 2018 were in the WHO region of South East Asia (44%). India accounts for about one-fourth of the global burden of tuberculosis ¹.

Though the treatment of tuberculosis has undergone a number of changes with new drugs being added to the regimens, TB continues to be a public health threat especially in individuals who are immune-compromised and those at the extremes of age. The WHO guidelines on TB treatment issued in 2018 recommended TB preventive treatment for persons living with HIV (PLHIV), household contacts of bacteriologically confirmed TB cases and clinical risk groups (those receiving dialysis, etc.).

Young children (aged < 6 years) in contact with

Sputum positive TB adults are often infected with *Mycobacterium tuberculosis* and once infected are at higher risk of progression to TB disease than adults.^{2,3} The source of infection for most children is an infectious adult living nearby, usually inside the household itself. The World Health Organization (WHO) and the Government of India's Revised National Tuberculosis Control Programme (RNTCP) recommend screening of household contacts of an infectious source case to identify children with TB disease, and enable their prompt treatment, and to provide children who do not have TB disease with Isoniazid Preventive Treatment (IPT). Daily Isoniazid (INH) for at least 6 months given as preventive therapy to young children has been shown to greatly reduce the likelihood of the child developing TB disease during childhood.^{4,5}

Despite these recommendations, the implementation of IPT in children is suboptimal in India, thus resulting in an increased risk of acquiring the disease in children after being exposed to a contact.^{5,6} There is a need for research in this area to find the reasons for non-initiation or non-completion of the IPT. The objectives for the present study were a) To find out the proportion of < 6 years of age children having household contact of a pulmonary TB patient, screened, initiated, and completed IPT in the year 2019 and b) To find out the barriers for not completing/taking IPT.

METHODOLOGY

The study was conducted using a mixed-method design, with the quantitative phase first, followed by the qualitative phase. The quantitative phase included a house to house survey while the qualitative phase consisted of interviewing the caregiver/key informant. The study was conducted for a period of 3 months, from July -September 2019, among the household contacts of all the pulmonary TB cases registered during that period at the DOTS Centre at the study site.

For the quantitative phase of the study, all the children contacts (aged < 6 years) of sputum positive TB patients in the study setting registered between July and September 2019 were included. For the qualitative phase, we conducted in-depth interviews of TB-related healthcare providers and the parents/caregivers of selected children. Subjects, willing to participate were included.

The outcome was studied in terms of the Proportion of children in the household contact of sputum positive tuberculosis patients who were screened for TB, Proportion of initiation of IPT among child contacts of smear-positive TB patients, Proportion of completion of IPT among child contacts of

smear-positive TB patients, and the barriers for initiation of IPT among child contacts as perceived by caregivers.

The data related to Sputum positive TB patients registered between July-September 2019 was extracted out of TB treatment cards and registers. These patients were visited at their homes and the information regarding child contacts was verified. Patients with child contacts were interviewed in Hindi (local language) using a structured, pretested questionnaire. Those who could not be contacted even after two attempts were not interviewed and hence their child contacts if any could not be included in the study.

The definitions used while conducting the study includes: a) **Smear positive TB**: A patient with at least one positive sputum specimen for AFB of the two sputum specimens subjected for smear examination by direct microscopy. b) **IPT**: A short course of Isoniazid monotherapy with 10 mg/kg body weight given as prophylaxis for all the household pediatric contacts (aged <6 years) of a sputum positive TB case. IPT is given daily for 6 months on a self - administered basis. c) **Household contact**: A person who shared the same enclosed living space for one or more nights or for frequent or extended periods during the day with the index case during the 3 months before the commencement of the current treatment episode d) **Child Contact**: All the children < 6 years who are in contact with smear-positive pulmonary TB case who live or have lived (irrespective of the duration) within the household of the smear-positive PTB patient during the course of his/her disease (after the onset of symptoms). e) **Index TB Patient**: Smear - positive TB patient, perceived to be the source of infection in the household contact. f) **Index IPT**: For the study purpose, the child contacts started on IPT within 1 month after the diagnosis of index TB case is considered IPT initiated, otherwise not. g) **Completion of IPT**: Completion of the full course of IPT within 7 months from the date of initiation.

ETHICAL CONSIDERATION

Approval of the institutional ethics committee was sought before conducting the study. Parents or caregivers of child contacts were interviewed after explaining the objectives of the study and obtaining informed consent in the local language. For the qualitative part, verbal consent was taken from all the study participants for the interview and audio recording.

RESULTS

The number of study participants was 52. Out of these, only 25 % of subjects (13 people) were cur-

rently on IPT, and rest 75 % were not on IPT. The sociodemographic details are presented here in table 1.

Around 77% of subjects were residing within 3 kilometers from the nearest health facility. About 42% of the subjects had their parents as the contact case of pulmonary TB while about 58% had other persons as contacts. In 69.2 % of cases, initial home visits were not done by paramedical workers. More than 65% of the parents/caregivers were not aware of IPT while for others the source of information was the Health Worker concerned. About half of the participants did not start IPT due to lack of any initial home visits by the DOIS provider, 15.4% had no information about IPT despite home visits. Around 2% of the subjects could not start IPT as the drugs were not provided while a similar number of the subjects did not take it due to pill burden. This is summarized in Table 2.

Only 5.7% of subjects could not complete IPT. 3.8% gave the reason as INH tablets were not provided and 1.9% said it was discontinued due to side effects.

Some of the factors being studied were also found to be associated with the proportion of childhood contacts being initiated on treatment and those having completed treatment. It was found that the level of education of the mother did affect whether the child was initiated on IPT. However, it was not found to be statistically significant.

It was also seen that there is a significant association between the levels of awareness of IPT among parents/caregivers, whether any initial home visit was conducted but the healthcare worker and the relationship of the child contact with the PTB case (parent or any other relative) and the initiation and completion of IPT in the children. The statistical values have been detailed in Table 4.

Table 1: Sociodemographic variables

Variable	Number (%)
Gender	
Males	34 (65.4)
Females	18 (34.6)
Age	
0 - 1 yrs	6 (11.5)
1 - 2 yrs	8 (15.4)
2 - 3 yrs	11 (21.2)
3 - 4 yrs	7 (13.5)
4 - 5 yrs	5 (9.6)
5 - 6 yrs	15 (28.8)
Religion	
Hindu	43 (82.7)
Muslim	9 (17.3)
Mother's education	
Illiterate	15 (28.8)
Up to High School	23 (44.2)
10 +2 and above	14 (26.9)

Table 2: Reasons for non-initiation of IPT

Reasons for non-initiation of IPT	Numbers (%)
Patients on IPT	16 (30.8)
Home visits done but no Information	8 (15.4)
No initial home visits by the field staff	26 (50.0)
Informed about IPT but drugs not provided	1 (1.9)
Drugs provided but not initiated due to pill burden	1 (1.9)

Table 3: Association of Maternal Education with the IPT initiation

Maternal Education	IPT initiation	
	Yes (n=16)(%)	No (n=36)(%)
Illiterate	4 (25%)	10 (27.8%)
Up to High School	6 (37.5%)	14 (38.8%)
12 th and above	6 (37.5%)	12 (33.3%)

Table 4: Chi-square and P values of IPT initiation and completion for various variables

Variable	IPT initiation		χ ² value	P value	IPT completion		χ ² value	P value
	Yes (%)	No (%)			Ongoing (%)	No (%)		
Home visit by the healthcare worker								
Visit done	8 (50)	8 (22.2)	4.012	0.0451	7 (58.3)	9 (22.5)	5.564	0.0183
No visit	8 (50)	28 (77.7)			5 (41.6)	31 (77.5)		
Awareness of IPT among parents/caregivers								
Present	9 (56.2)	9 (25)	9.0278	0.0026	8 (66.6)	10 (25)	7.080	0.0077
Absent	7 (43.7)	27 (75)			4 (33.3)	30 (75)		
Relationship of child contact with the PTB case								
Parent	12 (75)	10 (27.7)	10.119	0.0014	9 (75)	13 (32.5)	6.831	0.0089
Other relative	4 (25)	26 (72.2)			3 (25)	27 (67.5)		

#-All 'p' values are at 95% confidence levels; ##-Fishers' exact test used for χ², wherever applicable

DISCUSSION

The study shows that 34.6% of parents were aware of initiating IPT among household contact aged <6

years residing with sputum smear-positive TB patients registered for treatment under RNTCP in PulPrahadpur, New Delhi, India. 98.1% of 52 subjects were living with sputum smear-positive PTB.

None of the household contacts were screened for TB.

Of those aware, were informed by health care workers regarding IPT. 77% of 52 household contacts aged < 6 years were residing within 3 kilometers of the health facility. 30.8% of the 52 subjects were visited by paramedical workers. Our study also revealed several important concerns of the caregivers of household contacts. The study included the majority of children of age group 5 to 6 (28.8%) of the total 52 household contacts aged < 6 years.

Furthermore, among those starting IPT, the majority of the subjects were currently on IPT treatment and 7.7% had not completed the full course of IPT. Similar to our study, **Shivaramkrishna et al** conducted a study in Tamil Nadu which showed that 28% contacts did not complete IPT course, while a study conducted by **Osman M. et al** in Cape Town, South Africa found that less than 14% of children initiated on IPT completed the 6 months of treatment.^{7,8} Overall, of the 52 household contacts aged <6 years, only 25% received all the benefits of the present policy on IPT. After the diagnosis of index TB case, 26.9% of child contacts were started on IPT within 1 month. In our study, 69.2% of 52 subjects did not initiate IPT and 50% gave the reason for the non-initiation of IPT that initial home visits were not done by the field staff. 15.4% of the subjects stated that home visits were done but they were not well informed about IPT whereas, in the study conducted by **Pothukuchiet al** in the Vijayvada district, 16% of contacts were not initiated on IPT due to shortage of INH tablets at peripheral health centres⁹. Also, in the study conducted by **Singh AR, et al**, 78% of children were not initiated on IPT. On comparing it with our study, it is found to be similar. The reasons for the non-initiation of IPT were lack of home visits by health care providers, lack of information on IPT, and lack of drugs.¹⁰ In our study, the scenario is quite comparable as only 1.9% of subjects were informed about IPT but drugs were not provided and for about 1.9% the drugs were provided but not taken due to pill burden. Our study also suggests that when the index TB patient is the parent of the child contact, compliance to IPT is better. Similar findings were reported by **Hall C. et al** in the study conducted in Timor-Leste.¹¹

These shortcomings might be explained, in part, by the programme staff themselves not fully understanding the benefits of IPT in preventing disease among children, and thus a lack of urgency, and also to some degree by the challenges of procuring and delivering IPT drugs to patients on a monthly basis. This difficulty might also be due to the absence of systems to monitor implementation. Our

findings thus highlight an urgent need to develop and implement monitoring and evaluation tools to assess IPT initiation and completion in India.

Finally, this study also provides information about the status of household contacts after the index case was diagnosed and initiated on treatment. One contact was found dead. 69.2% of the total contacts were not visited by paramedical health care workers despite being registered for treatment under RNTCP. 65.4% were not made aware of prophylactic IPT resulting in non-initiation of IPT among 75% of TB registered for treatment under the RNTCP having household contacts <6 years.

This represents a missed opportunity for TB control and prevention; regular visits, screening (if required), creating awareness about IPT could prevent further spread of the disease. A major limitation of this study is that information on screening for TB disease, IPT initiation, and completion was ascertained through a questionnaire administered to caregivers of household contacts. If there were any deficiencies in information recall or in understanding the questions, then the results may be biased. To address this possibility, we also reviewed the information recorded in the programme records to cross-verify the consistency of information. The magnitude of errors as a result of deficiencies in the recall is therefore likely to be minimal.

CONCLUSION

This study finds that in the study area i.e. South East Delhi, the awareness of IPT is not up to the desired level. The cause of unawareness is a mixture of inadequate training of the staff and non-compliance on the part of the patients. The dearth of IEC activities in the study area adds to this burden. If we are able to provide IPT for childhood contacts, it would help in reducing the burden of TB.

RECOMMENDATIONS

The barriers in non-initiation may be removed by training health care personnel, improvement in logistics, and enhanced supervision and monitoring. It was also found that daily pill intake for 6 months was itself a barrier to completion; hence, shorter regimens may improve both initiation and completion of preventive treatment. It is suggested to use alternative preventive regimens as a means to improve adherence. These must be weighed against the probable high cost of delivering these regimens under direct observation as recommended. There is a need to strengthen the programme by routinely providing IPT for childhood contacts.

CONFLICT OF INTEREST: There is no conflict of interest.

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