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Original Research Article

Time to Diagnosis of Tuberculosis (TB) and Associated Factors in Children below 15 Years of Age Registered as New TB Cases under Revised National Tuberculosis Control Program (RNTCP) in Pune City

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ABSTRACT

Background: Tuberculosis (TB) is among the top 10 causes of death in children. Childhood TB remains a major health burden because of diagnostic and treatment delays.
Objective: To determine time to diagnosis and factors associated with it in children less than 15 years of age registered as new cases under RNTCP.
Materials and Methods: Cross-sectional study was conducted among newly diagnosed TB patients below 15 years of age registered under RNTCP in 6 Tuberculosis Units in Pune city between October 2012 and October 2013. Total 138 such patients were registered in RNTCP in the same period of which contact details of 90 were obtained. Finally, 61 patients consented to take part in the study.
Results: Median time to TB diagnosis as well as treatment initiation from onset of first symptom was 35 days (range 8-198 days). Patients who first visited government health facility were diagnosed early as compared to those who visited private health facility, this difference being statistically significant, OR 4.2(95% C.I 1.2-15.2). Patients who visited less than 3 health facilities were diagnosed within 35 days whereas patients who visited more than 3 health facilities were diagnosed in more than 35 days and this difference was statistically significant (P<0.001). It was also found that 21(65.6%) of pulmonary patients were diagnosed within 35 days as compared to 11 (34.4%) extra-pulmonary patients.
Conclusion: Time taken to start TB treatment is a cause of concern for the RNTCP. Minimization of time to diagnosis and treatment is important for successful tuberculosis control program.

Keywords: Time to diagnosis, risk factors of tuberculosis in children.

INTRODUCTION

Tuberculosis is a leading cause of death worldwide and is among the top 10 causes of death in children. Infants and young children are at particular risk of developing severe, disseminated, and often-lethal extra pulmonary disease, which may present as TB meningitis or military TB. About 81,482 pediatric cases were notified accounting for 7% of all cases registered under Revised National tuberculosis Control Program (RNTCP) for 2012. [(1)] Diagnosis of childhood tuberculosis is largely based on clinical and radiological features supplemented by a positive history of contact and tuberculin test result. Difficulty in diagnosis begins with the fact that unlike the disease in

adults, childhood tuberculosis is largely asymptomatic or may present with symptoms, which are not easily attributable to tuberculosis. A significant proportion of this difficulty is thought to be attributed to delay in diagnosis and effective treatment and can result in increase in TB morbidity and mortality in children. This delay can be due to the result of patient delay in presentation with symptoms to health facility or health facility delay in diagnosis and treatment of tuberculosis. [(2)] Time to diagnosis depends on the behavior of both the patient and health care services, together with the quality and coverage of health care services. [(3)]

Some of the factors responsible for delay in children include lack of suspicion on the part of clinicians, failure to enquire about history of contact from family members, non- specific symptoms, lack of a simple, definitive diagnostic test to diagnose TB in children and lack of coordination between the pediatric medical fraternity (both public and private) and the program. However there are limited studies on time to diagnosis of tuberculosis disease and factor associated with it in children less than 15 years of age. Information about the extent of different kinds of delays as well as risk factors associated with those delays is often helpful for successful treatment of pediatric TB as well as program success. This study tries to determine factors which are associated with development of tuberculosis and time to diagnosis of childhood tuberculosis.

The objective of the study was to estimate the median time to diagnosis of tuberculosis and factors associated with it in children below 15 years of age registered as new cases under RNTCP.

MATERIALS AND METHODS

Study design & study population:

We conducted a cross-sectional study among new pediatric TB patients registered under RNTCP in Pune district from Oct 2012 to Nov 2013. A new TB case is defined as a person who has never taken anti TB drugs or has taken them for less than a month in past. TB patients aged less than 15 years registered under RNTCP were considered for the study.

Study Settings:

The City tuberculosis units (TU) in the defined limits were the points of contact for enrolling patients. Registered pediatrics tuberculosis patients in the past one year from all six TU were contacted with the help of contact details, which was maintained in pediatrics registers. Caretakers of patient were called to tuberculosis unit along with patient after taking permission from parents and appointments were fixed during phone calls.

Sampling and sample size:

Ideally, we would prefer to use random sampling techniques among the six TUs in Pune and calculate sample size for proportions. However, since the total number of children below 15 years of age was low we decided to undertake universal sampling. Thus, all newly diagnosed pediatric patients registered in the last one-year period were studied. 138 such patients were registered in said period, of which contact details of 90 were could be verified. Finally, 61 patients consented to take part in the study.

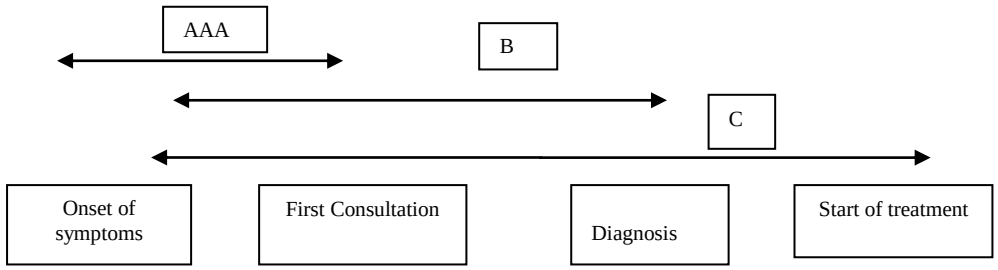
Operational definitions:

1) Patient time: - The time interval from the onset of first symptoms of the disease until the first visit to a medical facility for those symptoms

2) Diagnostic time: - Time to diagnosis defined as the time interval from onset of first symptoms until date first diagnosis

3) Treatment time:-Time to treatment defined as the time interval between onset of first symptoms and initiation of anti-tuberculosis drugs

4) Total Time:-Time interval between onset of first symptoms and initiation of treatment



A= Patient's time, B = diagnostic time, C treatment time, total time =A+B+C

Statistical analysis:

We analyzed data using SPSS software version 20. We calculated the mean and median delays along with their ranges. We conducted univariate analysis to identify risk factors associated with patient, health system and time to diagnosis. For the outcome variable, we used the median delay as a cut-off to dichotomize the TB patients into two groups (> median *versus* < median). Bivariate analysis was used to measure the association between time to diagnosis and factors related to it.

Limitations of the study:

- HIV status of patients was not considered in the analysis
- There may be chance of recall bias in recollecting information related to time to diagnosis and symptoms.
- Due to time constraints we could not include a control group for comparison which would result in greater validity of the associations between different variables studied.

Ethical issues:

After explaining our objectives of research we obtained signed informed consent from all patient caregivers and assured them to keep all information collected from them confidential.

RESULTS

Table 1: Distribution of population according to TB categories

Type	Percent (%)	Frequency(N)
Pulmonary TB	50.8	31
Extra pulmonary TB	44.3	27
Both	4.9	3
Total	100.0	61

Table 1 explains the percentage of those who were affected with pulmonary tuberculosis (50.8 %) and extra pulmonary tuberculosis (44.3 %). Study suggests that most of the children had Pulmonary TB than Extra-Pulmonary TB, also those children who were affected with both type of TB were (4.9 %).

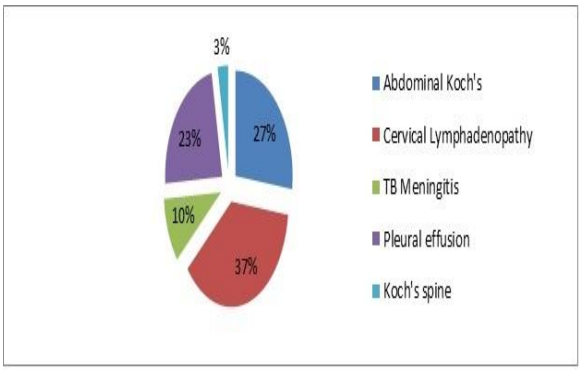


Figure 1: Proportions of types of extra-pulmonary TB cases

Figure 1 shows that among the extra pulmonary tuberculosis patients, 37% (11) patients had cervical lymphadenopathy, 27% (8) cases had abdominal TB, 23% (7) of cases had pleural TB while 10% (6) and 3% (1) had tubercular meningitis's and TB of spine respectively. Among extra-pulmonary TB, the risks of cervical lymphadenopathy were (34 %) more than Koch's spine.

Table 2: Median time for presentation to first health facility, diagnosis, and treatment

Time from onset of first symptom	Days
Median patient time	8
Median diagnosis time	35
Median treatment time	35
Median total time	35

Table 2 shows time to diagnosis for pediatric tuberculosis in our study; median patient time was 8 days, median diagnosis time was 35 days, median treatment time was 35 days, and median total time was 35 days.

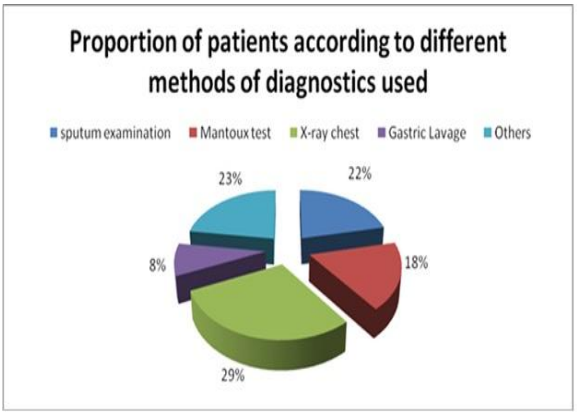


Figure 2: Proportion of patients according to different methods of diagnostic methods used

Figure 2 explains percentage of patients who were diagnosed TB by using various methods, out of total patients (29 %) used chest X-ray, (22 %) sputum microscopy test, (18 %) Manteux test, (8%) gastric lavage and (23%) used other as one of the diagnostic method. In most of the patient's chest X-ray test is used.

Table 3 describes the association between individual symptoms and time to diagnosis. (60.9%) patients with cough were diagnosed within 35 days and (39.1%) after 35 days. (54.3%) participants with fever were diagnosed within 35 days and (45.7%) after 35 days while (55.9%) children with loss of appetite were diagnosed within 35 days and (44.1%) after 35 days. However these associations were statistically not significant.

Table 3: Association between individual symptoms and time to diagnosis

Symptoms	within 35 days	More than 35 days	Total
Cough	14(60.9)	9(39.1)	23(100)
Fever	25(54.3)	21(45.7)	46(100)
Swelling	7(77.8)	2(22.2)	9(100)
Loss of appetite	19(55.9)	15(44.1)	34(100)
Lethargy	1(100)	0(0)	1(100)
Others	7(46.7)	8(53.3)	15(100)

Table 4: Association between TB categories and Total delay

	Total Delay	
TB Categories	**Less than 35**	**More than 35**
Pulmonary TB	21(65.6%)	10 (34.5 %)
Extra-Pulmonary TB	11 (34.4%)	16 (55.2 %)
Both	0	3 (10.3 %)
Total	32	29

Table 4explains the association between total delay and TB categories; 21(65.6%) out of 32 pulmonary TB patients were diagnosed in less than 35 days as compared to 11(34.4%) extra-Pulmonary patients, though the association was not statistically significant.

Table 5: Association between Socio-demographic factors and time to diagnosis

Socio-demographic factors	MEDIAN DIAGNOSIS TIME				
	0-35 days	more than 35 days	Total	P value	Odd ratio(95% CI)
AGE OF THE PATIENT					
1-11 Yrs	13(65)	7(35)	20(100)		
12-14 Yrs	19(46.3)	22(53.7)	41(100)		
Total	32(52.5)	29(47.5)	61(100)	0.136	2(0.7-6.4)
SEX					
Male	11(52.4)	10(47.6)	21(100)	0.6	0.9(0.34-2.8)
Female	21(52.5)	19(47.5)	40(100)		
MONTHLY FAMILY INCOME IN INR					
Less than 7000	14(41.2)	20(58.8)	34(100)		
More than 7000	18(66.7)	9(33.3)	27(100)		
Total	32(52.5)	29(47.5)	61(100)	0.042	0.35(0.12-1)
LEVEL OF EDUCATION OF HEAD OF HOUSEHOLD					
Up to 8th Std	18(48.6)	19(51.4)	37(100)	0.317	0.67 (0.24-1.9)
More than 8th Std	14(58.3)	10(41.7)	7(100)		
Total	32(54.2)	29(47.5)	61(100)		

Table 5 shows the association between time to diagnosis and monthly family income, level of education of head of household and age of patients. 20 (58.8%) patients out of 34 belonging to households with monthly family income

less than INR 7000/- were diagnosed in more than 35 days while 9 (33.3%) patients out of 27 with household monthly family income more than INR 7000/-were diagnosed in more than 35 days. This difference was found to be statistically significant O.R. 0.35(95% C.I. 0.12-1). 13(65%) patient diagnosed within 35 days were in the age group 1-11 years as compared to 19(46.3) patients who were in age group 12-14 years. The difference in time to diagnosis according to age group, sex and level of education of parents was not found statistically significant.

Table 6: Association between time to diagnosis and history of contact with adult TB patient, Malnutrition, Hospital first visited and knowledge about tuberculosis

	Time to diagnosis				
History of contact with adult TB patient	0-35 days	more than 35 days	Total	P value	Odd ratio(95% CI)
Yes	17(65.4)	7(34.6)	26(100)	0.069	2.5(0.8-7.1)
No	15(43)	20(57)	35(100)		
Total	32(52.5)	29(47.5)	61(100)		
Malnutrition					
Yes	28(58)	20(42)	48(100)	0.07	3(0.85-11.6)
No	4(31)	9(69)	13(100)		
Hospital first visited					
Government Hospital	13(81.2)	4(23.5)	16(100)	0.002	4.2(1.2-15.2)
Private Hospital	6(85.7)	1(14.3)	7(100)		
Private doctors	13(32)	24(64.9)	36(100)		
Total	32(54.2)	29(47.5)	61(100)		
Knowledge about tuberculosis					
Yes	15(60)	10(40)	25(100)	0.235	1.6(0.6-4.7)
No	17(47.2)	19(52.8)	36(100)		
Total	32(52.5)	29(47.5)	61(100)		

17(65.4%) patients out of 26 diagnosed within 35 days, had history of contact with adult tuberculosis patient while among patients with no history of contact with adult tuberculosis, only 15(43%) of them out of 35 were diagnosed within 35 days. However, this difference was not statistically significant. Differences in time to diagnosis were found to be statistically significant when analyzed for type of health facility first visited by caretakers to seek health care services for their children. Time to diagnosis was within 35 days in those patients whose caretakers first visited government health facility (81.2%) as compared to those who first visited private doctors (32%) and private hospitals (85.7%). Knowledge about TB among caretakers had no significant association with time to diagnosis.

Table 7: Association between number of health facilities visited and time to diagnosis

No. of health facilities visited	0-35 days	more than 35 days	Total	OR(95% CI)
Less than 3	26 (81.2%)	10 (34.5%)	36 (59%)	0.001
More than 3	6 (18.8%)	19 (65.5%)	25 (41%)	
Total	32 (100%)	29 (100%)	61(100.0%)	

26 (81.2%) children with visits to less than 3 health facilities were diagnosed within 35 days while only 6 (18.8%) children who visited more than 3 health facilities were diagnosed after 35 days. This difference was significantly different.

Table 8 represents associations between type of TB and selected risk factors. 15(58%) pulmonary patients and 11(42%) of extra-pulmonary gave history of contact with adult TB patient in past two years. While in case of overcrowding, 27(51%) pulmonary TB patient and 26(49%) extra pulmonary patient were living in overcrowding area. When analyzed for nutritional status, 5(38.5%) and 8 (61.5%) pulmonary and extra pulmonary TB patient respectively, were found to be malnourished. In case of exposure to passive smoking, 8(67%) and

4(33%) pulmonary and extra pulmonary TB patients respectively were found to be exposed to passive smoking. When analyzed association with use of biomass fuel, 13(48%) and 14(52%) pulmonary and extra pulmonary TB patients exposed to households using biomass fuel for cooking. BCG immunization status, 12 (52%) of pulmonary and 11 (48%) extra pulmonary TB patients had not immunization history with BCG. 7 (35%) and 13(65%) pulmonary and extra pulmonary TB patients respectively were in the age group of 1 to 11 years. However only association of pulmonary and extra pulmonary tuberculosis with time to diagnosis was found to be statistically significant 21(66%) of pulmonary tuberculosis patients were diagnosed within 35 days while only 11(34%) of extra pulmonary tuberculosis patients were diagnosed within 35 days [OR-3.6(1.2-10.4)]

Table 8: Association of Tuberculosis category (pulmonary and extra pulmonary tuberculosis) with selected factors (household contact, overcrowding, malnutrition, passive smoking, use of biomass fuel, BCG scar, age group and time to diagnosis)

Factors	**Tuberculosis category**				
	Pulmonary TB	Extra pulmonary TB	Total	P value	OR(95% CI)
Sex					
Male	6(28.6)	15(71.4)	21(100)	0.012	0.24(0.07-0.7)
Female	25(62.5)	15(37.5)	40(100)		
Household contact					
Yes	15(58)	11(42)	26(100)	0.253	1.6(0.5-4.5)
No	16(46)	19(54)	35(100)		
Overcrowding					
Yes	27(51)	26(49)	53(100)	0.628	0.96(0.2-4.2)
No	4(50)	4(50)	8(100)		
Malnutrition					
Yes	5(38.5)	8(61.5)	13(100)	0.245	1.9(0.5-6.6)
No	26(54)	22(45.8)	48(100)		
Passive smoking					
Yes	8(67)	4(33)	12(100)	0.184	2.2(0.6-8.5)
No	23(47)	26(53)	49(100)		
Use of biomass fuel					
Yes	13(48)	14(52)	27(100)	0.45	1.2(0.4-3.3)
No	18(53)	16(47)	34(100)		
BCG Scar					
Yes	19(50)	19(50)	38(100)	0.54	0.9(0.3-2.5)
No	12(52)	11(48)	23(100)		
Age group					
1-11 yrs	7(35)	13(65)	20(100)	0.07	0.36(0.12-1.15)
12-14yrs	24(58.5)	17(41.5)	41(100)		
Time to diagnosis					
within 35 days	21(66)	11(34)	32(100)	0.01	3.6(1.2-10.4)
more than 35 days	10(34.5)	19(65.5)	29(100)		

DISCUSSION

The burden of tuberculosis morbidity and mortality is relatively high among children (age <15 years). This report examines the time to diagnosis of TB and certain associated factors in 61 children aged less than 15 years.

In our study we found that the median total diagnosis time was 35 days from the onset of symptoms to initiation of treatment of tuberculosis for all 61 patients. The median patient time, i.e. time taken from onset of first symptom to visit first visit to health facility, was 8 days and median time to diagnosis was 35 days; the median diagnostic time was longer than median patient time. A study conducted in South Africa found similar results in which patient delay was shorter than delay in diagnosis. The mean period from the onset of the symptoms until presentation was 4.3 weeks, from the presentation until diagnosis was 5 weeks and from diagnosis until treatment 0.9 weeks in children. [(4)] In our study diagnostic delay was longer than patient delay because on average, patients visited many health facilities before being diagnosed with TB. A study conducted in

Kenya experienced a longer delay between admission and the start of anti-tuberculosis chemotherapy and suffered a significantly higher mortality (30% and 8% respectively). [5] A study conducted in Mandi, Himachal Pradesh, India found patient delay of 15 days, health system delay of 13 days and treatment delay of 36 days. [6]

We found that 21(66%) pulmonary patients were diagnosed within 35 days while only 11(34%) extra-pulmonary patients were diagnosed within 35 days. This shows that time to diagnosis of extra pulmonary patients were more as compared to pulmonary patients probably due to greater non-specificity of extra-pulmonary symptoms and lesser degree of suspicion by physicians This difference though was not found to be statistically significant which may be due to the small sample size.

In our study, patients having household family members with history of TB were diagnosed earlier compared to those not having history of contact. This can probably be attributed to greater awareness about TB symptoms in the household with previous TB. Time to diagnosis was also associated with type of first health facility visited; those who first visited government health facility were diagnosed earlier than those who visited private health facilities. Similar result was found in a study conducted in Himachal Pradesh in which patients who first consulted private health facility had a diagnosis delay as compared to government facility. [6] This can be attributed to greater awareness, relatively standardized pediatric TB diagnostic algorithms and experience in managing pediatric TB cases in government health facilities. Time to diagnosis depends on number of health facilities visited by patients; in our study patients visiting more than 3 health facilities required longer time for diagnosis of tuberculosis which was and this delay was statistically significant. Time to diagnosis is also affected by symptoms presented by the children because unlike in adults, the disease may present with symptoms that may be non-specific and difficult to diagnose. Our study that found 18% patients presented with cough, 36% with fever, 7 % with swelling and 26% with loss of appetite, though no significant associations were found. A study conducted in South Africa found that 72% patients presented with cough, 36% with fever, 17% with loss of body mass and 12% with wheezing. [4] In our study the time to diagnosis was also significantly higher in households with monthly income of less than INR 7000, while it was not significantly associated with age, gender or education of head of the household.

Apart from median diagnosis times, we also looked at certain factors related to development and diagnosis of TB.

Diagnostic procedures of tuberculosis in children vary widely, with tuberculosis often suspected but difficult to confirm. In our study 22% patients were diagnosed by sputum examination, 18% by Mantoux test, 29% by chest x-ray, 8% by gastric lavage and 23% by others. A study carried out in Kenya in malnourished children found six of 144 children had bacteriological confirmed tuberculosis while seventy-five children had probable tuberculosis, the diagnosis based on the tuberculin response in 19 and diagnostic chest radiograph in 22 patients and the rest by other methods. [5]

In the present study, 51% of patients had pulmonary tuberculosis while 44 % had extra pulmonary tuberculosis. A similar study done in north India found comparable results of about 41 patients with extra pulmonary and 52 patients with pulmonary tuberculosis. [7] Among the extra pulmonary tuberculosis patients in our study, 37% of patient had cervical lymphadenopathy, 27% of cases had abdominal TB, 23% of cases had pleural effusion while 10% and 3% of cases were

of tubercular meningitis and spine TB respectively. Similar study done in Pune found that 12 of 26 (46%) had extra pulmonary disease, of whom 9 (75%) had TB meningitis. [8]

In our study 20 % participants were exposed to passive smoking and 28% of patients resided in households using wood as a cooking fuel which is comparable with study done in Thailand which found that 18.5% of cases were exposed to passive smoking and these children who were exposed to passive smoking had a 9.31 times increased risk of getting tuberculosis (95%CI=3.14-27.58). Prevalence of exposure of passive smoking and exposure to fire wood smoke was found to be 46.3% and 63.4% respectively, [9] which is lower than a study conducted in Kerala, which found these factors to be significant [6.285 (2.317-17.047) and 6.914 (2.529-18.905)] respectively. [10]

In the present study it was found that about 27(51%) pulmonary tuberculosis patients were living with more than 2 persons per room while 26(49%) extra pulmonary patients were living with more than 2 persons per room. However the difference between time to diagnosis was not found to be statistically significant. 60(98.4%) patients had more than 2 members in their family while only 1(1.6%) patient had two members or less in their family. And 34(54%) patients had single room with attached kitchen in their houses while 27(43%) patients had more than 2 rooms in their houses. A study done in Bangladesh, found that about 62% patients were living with more than 2 person per room and the difference was found to be statistically significant [0.30(0.17-0.56)]. [11] Study done in Kerala in 2013 found that 63.4% of patients were living in overcrowded households which was higher as compared to our study [7.150(3.09 -16.52)]. [10]

In the present study, about 12.7% of patients were severely underweight, 9.55 of patients were moderately underweight while 73% of patients were normal. In case of height for age, 12.7% of patients were severely stunted, 6.3% of patients were moderately stunted while 76.2% of patients had normal height for age. However when analyzed for time to diagnosis, there was no statistical difference between the two groups. A study done in Kerala found that 39% of patient had low weight for age among tuberculosis patients [60(91.85– 11.46)] [10] while a study done in north India found that 60% of patients were malnourished which was higher as compared to present study. [7] Another study done in Pune found that 57% of children with TB were malnourished. [8]

CONCLUSION AND RECOMMENDATION

This study shows that TB diagnosis delays in children may be associated with various factors, most of which are preventable and health system associated. Increased standardization of pediatric TB diagnostic procedures and better coordination between communities, private and public health systems with emphasis on greater awareness among physicians along with better education of caregivers will help in early diagnosis, and this will go a long way in reducing the morbidity and mortality caused by childhood tuberculosis. However larger, multi-centric studies with cohort designs are required before we can determine precise, unbiased factors and determinants of TB diagnostic delays and ultimately inform the healthcare system as well as communities for quicker diagnosis and treatment of pediatric TB.

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