

# **Systematic screening of presumptive paediatric TB patients and gastric aspirate specimen collection in primary and secondary healthcare facilities in Rajnandgaon district, Chhattisgarh.**

## **ABSTRACT**

**Background:** Smear-positive TB in children (<14 years old) – expect up to 3.6% of all reported cases. Paediatric TB - over 10% of all TB in high burden countries. 5% of all new paediatric cases were in age-group 0-14 years (TB India 2014 report). The CBNAAT testing began in April 2016 in Rajnandgaon district of Chhattisgarh.

**Rationale:** Broncho Alveolar Lavage, Gastric aspirate, Induced sputum are limited to tertiary centres. Training below tertiary healthcare facility will improve notification of paediatric TB cases. Study how training would improve diagnosis.

### **Objectives:**

1. To estimate the proportion of presumptive paediatric TB patients out of all out-patients in 0-10 years age group.
2. To know acceptance rate of the parents for the gastric aspirates as a method of specimen collection, if children are unable to produce sputum.
3. To find out the proportion of patients among whom gastric aspirate collected out of those eligible.
4. To find out the proportion of gastric aspirate specimen found to be positive for M tuberculosis.
5. To find out the mean time interval between identification of a presumptive TB patient and receipt of CBNAAT result by the MO PHI and initiation of ATT among those found positive for Tuberculosis.

**Intervention:** The training on Gastric Juice Aspiration started from 7-8 November 2016 in which one doctor and one nurse each from 48 PHC, 10 CHC, and 1 DH were trained.

**Results:** The samples of gastric aspiration among 0 to 10 years children were collected and 18 CBNAAT tests were done during the pre-intervention period (April to October 2016) and 567 tests done during the post-intervention period (November 2016 to December 2017 including Medical College, DH). The samples sent from CHC and PHC are 426. In 2017, 54 paediatric tuberculosis diagnosed out of those 26 were pulmonary including 3 positive from CBNAAT tests whereas 71 cases were diagnosed in 2016, we have information of only 23 TB patients out of those 10 were pulmonary including 2 positives from CBNAAT (1 in project period).

**Policy Implications –**

There is a need for sensitising all doctors at the public and private care centres on the screening of presumptive paediatric patients on gastric aspirates. However, this diagnostic tool can only supplement other diagnostic tools such as Montoux, X-ray and CBNAAT and cannot substitute other tools.

---

## **BACKGROUND –**

India is globally one of the highest tuberculosis (TB) burden countries in the world (3). However, few studies have focused on TB in children, a vulnerable population, where lack of early diagnosis results in poor outcomes (4,5). While the burden of paediatric TB in India is not known, regional data from World Health Organization( WHO) indicates that sputum microscopy smear-positive TB in children (<14 years old) accounts for 0.6%–3.6% of all reported cases (6). However the majority of children are sputum microscopy smear negative, these data underestimate the true burden of childhood TB. Paediatric TB is over 10% of all TB in high burden countries. (7), TB accounts for 8–20% of TB-related deaths (8,4). According to the TB India 2014 report, 5% of all new cases were in age-group (0-14 yrs.). Tuberculosis is widely prevalent among children, especially in those with coexisting severe malnutrition and immunodeficiency (9). Some of the challenges for the surveillance of paediatric TB in the state are following: i) Difficulty in the diagnosis of paediatric TB because of untrained/ill-trained healthcare providers in the health facility ii) Lack of knowledge regarding standard case definition iii) increased extra-pulmonary disease in children and low public health priority of paediatric TB.

**Baseline findings** - In 2016 Rajnandgaon district has reported 71 paediatric TB cases in a total of 752 new Sputum positive cases and 354 extra pulmonary cases. The Presumptive cough detection is only 20000 in Chhattisgarh as per IDSP S records - the expected is 60000 by RNTCP calculations. The CBNAAT testing began in April 2016 in Rajnandgaon district of Chhattisgarh at tertiary care level. A total of 18 children between 0 to 10 years were tested between April and October of whom one was AFB positive.

## **RATIONALE –**

Early diagnosis of paediatric tuberculosis is important because; there is a rapid progression from infection to disease among children. However limited access of paediatric TB diagnostic technique leads to low notification of paediatric TB in Chhattisgarh, India. Gastric aspirates are the procedure of choice for microbiologic confirmation of tuberculosis disease in children

who are unable to produce good quality sputum. RNTCP has recommended gastric aspirate as standardized method for diagnosis to control Paediatric TB (10).

In Chhattisgarh Broncho Alveolar Lavage, Gastric aspirate, Induced sputum to diagnose Paediatric TB cases are still limited to tertiary healthcare facilities.

Imparting training to a healthcare provider about TB diagnostic algorithm and methods of alternate specimen collection (i.e. Gastric aspirate) down the line (i.e. below tertiary healthcare facility) might improve notification of paediatric TB cases.

Hence a study was needed to know how potential capacity building intervention through training would improve diagnosis and care of Paediatric Tuberculosis cases at the lower level of public health facilities.

Department recommendation was to test number of presumptive paediatric pulmonary cases by CBNAAT in order to identify more cases of paediatric tuberculosis.

#### **OBJECTIVES –**

- 1) To estimate proportion of presumptive paediatric TB patients out of all out-patients in 0 - 10 years age group.
- 2) To know acceptance rate of the parents for the gastric aspirates as a method of specimen collection, if children are unable to produce sputum.
- 3) To find out proportion of patients among whom gastric aspirate collected out of those eligible.
- 4) To find out the proportion of gastric aspirate specimen found to be positive for M tuberculosis.
- 5) To find out the mean time interval between identification of a presumptive TB patient and receipt of CBNAAT result by the MO PHI and initiation of ATT among those found positive for Tuberculosis.

#### **METHODS –**

**Study** – Exploratory study design.

**Setting/ Geographic location** – Rajnandgaon district, Chhattisgarh India.

The state is one of the high priority states in terms of high malnutrition among children and pregnant women. The Socio-Economic and Caste Census (SECC) 2011 survey has portrayed a dismal picture of Chhattisgarh, India. According to the survey, about 90.79% of the population

earns less than 5000 per month. It is lowest in India. SECC 2011 indicates widely prevalent malnutrition and immunodeficiency in the state.

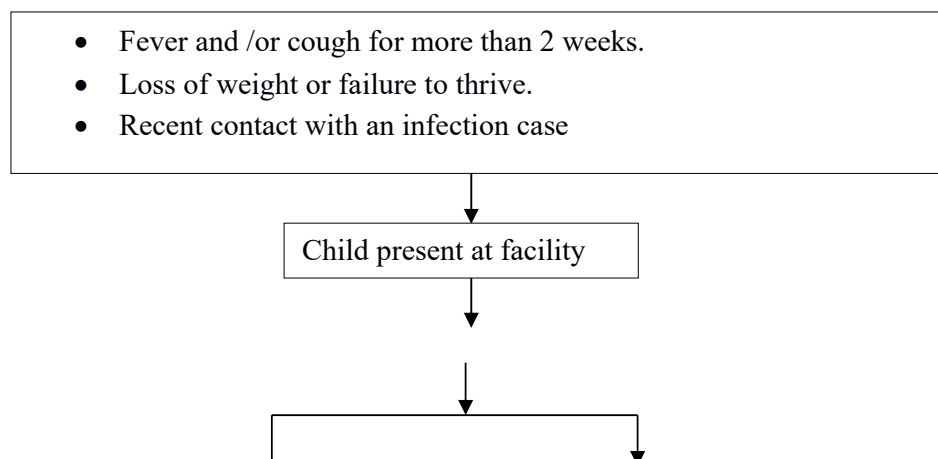
**Stakeholders –**

All diagnosed and registered TB patients from 2016 and 2017, family members, Mitanins who collected lists of presumptive child patients and brought them to the OPD, Community Mobilizers who were recruited in October 2017.

**Responsibility of the different stakeholders –**

Institute	Responsibility
AIIMS	Module development for the training Capacity building of doctors and nurses
JLN Medical college, Raipur (Community Medicine)	Advocacy at state and district level. Hand handling support at facility level to which hesitate to take gastric aspirates
IAP	Advocacy at state and district level. Hand handling support at facility level to which hesitate to take gastric aspirates

**FLOW CHART OF GASTRIC ASPIRATION**



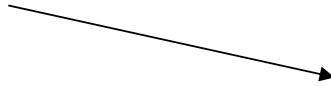
Child screened for TB using national TB screening tool

Record child in presumptive TB register  
Open file (record clinical signs/ symptoms, contact details,  
demographics, TB contacts)  
Book appointments for gastric aspiration (GA) if



Bacteriology positive for  
AFB

Confirmed case



**Inclusion criteria –**

- Children with presumptive TB between age group 0-10 Years.

**Exclusion criteria –**

- Patients will be excluded if they were on anti-TB treatment for >2 days, or recently defaulted on TB treatment.

**Study participants –**

The study participants for the quantitative research were presumptive paediatric TB cases who attended the public health facility to give a gastric aspirate specimen for TB diagnosis.

The study participants for the qualitative research are medical officers, nurses and parents.

#### **Sample size –**

The sample size estimation for this study is not essential; however to demonstrate feasibility of the study following calculation has been made based on the expected presumptive paediatric TB cases attend the OPD.

- Expected average paediatric OPD in 59 facilities in a year= $10*25*50*12=150000$
- Expected presumptive patients= $150000*0.01=1500$
- No eligible for gastric aspirate= $1500*.75=1200$
- No aspirate collected= $1200*.85=1000$
- No found positive= $1000*0.3=300$

These expected numbers were required to demonstrate feasibility.

#### **Qualitative method –**

The study also used qualitative method to find out feasibility, barriers and other factors affecting implementation of the study. It included in-depth interview of parents of presumptive paediatric TB cases who have given specimen and those who refused, MO and nurses. All interviews were to be recorded and transcribed verbatim. The transcription will be coded and analysis will be made according to the emerging theme.

#### **Guideline to identify and test presumptive pulmonary paediatric cases of Tuberculosis –**

- First, the child with a contact history in last six months in his family was assessed for symptoms of tuberculosis by community health workers.
- A line listing of symptomatic cases was done and children were screened by Assistant Medical officers and Medical officers.
- On the basis of clinician's diagnosis, a selected number of pulmonary presumptive cases were identified for gastric aspiration.
- A day in a week was declared in the field for sample collection.
- Presumptive Child was admitted to the hospital a day before the sample collection.
- Next day early morning gastric aspirate was collected in the empty stomach of an admitted child.

- The sample was stored in cold storage conditions and transferred to the CBNAAT centre.
- The sample was run in CBNAAT technique for confirmation of pulmonary tuberculosis.

**Guideline followed- Gastric Aspirate for TB diagnosis –**

<b>Specimen from Non Sterile Body Sites</b>	<b>Recommended Collection Time</b>	<b>Volume Requirements</b>	<b>Collection Frequency</b>	<b>Transport</b>	<b>Recommended for Isolation of MTBC</b>
Gastric Aspirate	Early morning before patient eats and while still in bed. If the child is put on fast for 4 hours before the arrival of the hospital one sample will be collected.	5–10 ml is optimal; maximum volume is 15 ml.	One specimen per day on two consecutive days.	Room temperature; if delayed >1 hour, neutralize with 100 mg sodium carbonate. The specimen will be transported for CBNAAT in the Cool pack next day.	Yes

**Testing of gastric aspirates –**

Immediately after taking gastric aspirates and completing necessary documentation the specimen will be stored into the cool box. Gastric aspirates specimen will be transported to the

nearest district hospital (Rajnandgaon) for CBNAAT test within 2–4 hrs of collection. Detailed clinical evaluation and drug susceptibility testing will be performed at the district laboratory.

#### **IMPLEMENTATION PROCESS –**

- **Training** – Two days training by Department of Paediatrics AIIMS Raipur on Gastric Juice Aspiration were conducted in which one doctor and one nurse each from 48 PHC, 10 CHC, and 1 DH were trained as follows.

Dates of Training	Place of Training
7 <sup>th</sup> – 8 <sup>th</sup> of November 2016	AIIMS Raipur
10 <sup>th</sup> – 11 <sup>th</sup> of November 2016	AIIMS Raipur
15 <sup>th</sup> – 16 <sup>th</sup> of November 2016	AIIMS Raipur
30 <sup>th</sup> – 31 <sup>st</sup> of January 2017	GMC Rajnandgaon
6 <sup>th</sup> – 7 <sup>th</sup> of February 2017	GMC Rajnandgaon
7 <sup>th</sup> – 8 <sup>th</sup> of June 2017	CHC Dongargaon
28 <sup>th</sup> – 29 <sup>th</sup> of June 2017	CHC Dongargaon
5 <sup>th</sup> – 6 <sup>th</sup> of July 2017	CHC Dongargaon

- **Post training** – After the training, they were asked to implement the project by doing the gastric aspiration and send the collected samples to the district for testing.

The registration of the patients into cohort started from the first training in November 2016

**METHODS OF DATA COLLECTION** – from Mitansins, from OPD registers, laboratory registers, Nikshay records, CBNAAT registers, semi structured questionnaire by Community mobilizers

- At health facility level** - format was developed for collecting (OPD, CXR, and Mantoux test & Gastric aspirate) on month wise data i.e. from Nov 2016 - Nov 2017
- At community level** - format was developed for collecting basic socio demographic data as well as the qualitative data with the help of Community mobilizers.
- Data was also collected from laboratory register in health facilities and from records of district tuberculosis office.

Modification (October 1<sup>st</sup> 2017) -Community Mobilizers in 4 blocks

#### **DATA QUALITY –**

Standardized procedures were adopted for preserving data integrity and protocol adherence. Rigorous monitoring and detail attention have been made for data accuracy. The data for each subject were evaluated in the research office for completeness and accuracy.



### **DATA ANALYSIS –**

Data were entered into Microsoft Excel and scrutinized for completeness and consistency. Initial analysis was made using same software to summarize the frequency distribution. Final analysis for treatment outcome was performed using Epi-Info version 7.2 (Centers for Disease Control, Atlanta, GA, 2001).

### **Reasons for choice of software –**

The institution does not own a licensed version of the statistical software. Therefore the researcher made use of available free software which is universally acceptable for any research paper.

### **ORGANISATIONAL BARRIERS –**

**SHRC** – The research implementing agency has adequate staff but the project suffered because of turnover of the project staff. There were two underlying factors for staff turnover: - availability of the multiple options in the state for the trained staff and those unwilling to stay and work in remote areas with low peer support. So the project got affected.

**SYSTEMIC BARRIERS** – Transport of specimens was an important issue. The NHM guideline for transporting sputum specimens was perceived to “not apply “to gastric aspirates. Also giving bus fare to a Group D staff was not accepted as being “transport cost”.

The short supply of ATT drugs and TB nutrition support for the registered TB patients around August to November 2017 (during switchover to daily regime) also affected morale of health care providers.

**DEPARTMENTAL BARRIERS** – Initially district RNTCP staff felt that it was a burden to implement gastric juice aspiration strategy in the district. It was thought to be risky and perceived to be difficult to do below CHC level. It was thought that there would be significant resistance from the community, parents and children.

Medical system in the district-As per the old data of TB that most of the peoples first line of treatment was traditional and non-qualified practitioner therapy, not a government hospital or any health facility especially in those areas who were very far from the sub-centre.

### **ORGANIZATIONAL ADVANTAGES –**

State Health Resource Centre (SHRC) is a civil society organisation which is a Technical support Agency to the Department of Health and Family Welfare, Government of Chhattisgarh, India. The Mitadin initiative, linked to the health system, is facilitated and monitored by SHRC. There are about 70,000 Mitadins in urban and rural setting all over the state. Mitadin is the

village health volunteer placed in every hamlet even those with a population of 300 in Chhattisgarh rural areas which are far less than the average 1000 population per ASHA in other states. The involvement of Mitanins is thought to be an advantage in implementing paediatric case finding as they acted as DOTS providers and were members of the community.

#### **ETHICS CONSIDERATIONS –**

Ethics approval was obtained from the institutional Ethics Committee. Before starting the intervention necessary permissions were obtained from Directorate of Health Services and informed all the district tuberculosis staff and other health care provider about the project. Written informed consents were obtained from parents/ guardians of all study participants. As all were minors- parents/ guardians consent was taken. In cases where respondents were unable to read, the Mitanin/ staff explained the benefits and risk of participation in the study in the local language. If parents refused to participate in the research they were excluded them from the study. Data was not shared with anyone who was not involved in the study to maintain the confidentiality, privacy, and anonymity of patients. If necessary the research team shared data with administrators who were implementing the programme.

#### **RESULTS – DEMOGRAPHIC**

**Table 1- Average age and Gender distribution of the under 10 years presumptive TB- January to September 2017**

	Under 10	Average Age Yrs	Percentage (%)
Male	187	3.13	49.86
Female	188	3.19	50.14
Total	375	3.16	100

The data above was from the laboratory registers present at CBNAAT testing in district Rajnandgaon. The presumptive TB below 10 were 375 between January and September 2017.

## FINDINGS –

The study was conducted during the period of November 2016 and November 2017, among children 18 CBNAAT tests were done during the pre-intervention period (April to October 2016) whereas 557 tests were done on patients equal or below 19 years during the post intervention period (November 2016 to December 2017 including Medical College, DH). The samples sent from CHC and PHC are 426. In 2017, 54 paediatric tuberculosis diagnosed out of those 26 were pulmonary including 3 positive from CBNAAT tests whereas 71 cases were diagnosed in 2016, we have information of only 23 TB patients out of those 10 were pulmonary including 2 positives from CBNAAT (1 in project period).

Overall we have succeeded in the capacity building of the staff from PHC level. Because of that 426 of samples have been sent from secondary and primary institutions.

Case selection - out of 109712 children below ten years who attended OPD =  $85 + 375 = 460$  were called to be tested (out of 700 expected). Total of 567 samples were actually taken in the project period.

2016 data shows 71 Paediatric TB cases in Rajnandgaon of which 2 were by CBNAAT (one of these was among those tested before the project started).

18 tests were done in children in period after CBNAAT started from April to October 2017 (as mentioned above-one of these was positive). Another positive was found in November 2016 after the project began.

In 2017 there were 54 paediatric TB cases reported of which 3 were from gastric aspirate CBNAAT.

Our experience in Rajnandgaon appears to show that positivity rate in pulmonary paediatric TB cases is lower than the expected rate.

**Table 2- Proportion of presumptive paediatric TB patients out of all out-patients in 0-10 years age group in CHC and PHC November 2016 to November 2017 (13 months)**

Month	11/16	12/16	01/17	02/17	03/17	04/17	05/17	06/17	07/17	08/17	09/17	10/17	11/17	TOTAL
CHC OPD Total	2472	2997	3092	2825	3057	3245	3429	3595	4424	4906	4412	3892	3832	46178
PHC OPD	3659	3930	4368	4312	4390	4621	4698	4992	5674	6100	6188	5329	5273	63534
CHC + PHC OPD	6131	6927	7460	7137	7447	7866	8127	8587	10098	11006	10600	9221	9105	109712

0 to 10 year old in whom AFB sample tested = 540

All out-patients in 0-10 years = 109712

Proportion AFB tested out of OPD = 0.49 %

**Table 3- Acceptance rate of the parents for the gastric aspirates as a method of specimen collection**

	<b>CHC Tests</b>	<b>PHC Tests</b>	<b>CHC + PHC Tests</b>	<b>% of OPD</b>
<b>AFB</b>	<b>265</b>	<b>275</b>	<b>540</b>	<b>0.49</b>
<b>CXR</b>	<b>382</b>	<b>0</b>	<b>382</b>	<b>0.35</b>
<b>GJA</b>	<b>298</b>	<b>128</b>	<b>426</b>	<b>0.39</b>
<b>Mantoux</b>	<b>173</b>	<b>3</b>	<b>176</b>	<b>0.16</b>

Gastric Juice acceptors= 426 (0 to 10 year old in whom Gastric Juice Taken)

AFB tested= 540

Proportion accepted= 78.89%

0 to 10 year old in whom Chest X Ray done= 382

Proportion accepted Gastric Juice testing= 298/ 382= 78.01%

Gastric Juice is more common than AFB test in CHCs

Opposite is true in PHCs

0 to 10 year old in whom Mantoux done= 176

Chest X Ray and Mantoux are not usually available at PHC level

**Table 4- Acceptance rate of the parents for the gastric aspirates as a method of specimen collection January to September 2017**

<b>Under 10</b>	<b>Called but did not come from Mitanin Records</b>	<b>January- September 2017 from CBNAAT records</b>
<b>Number</b>	<b>85</b>	<b>375</b>

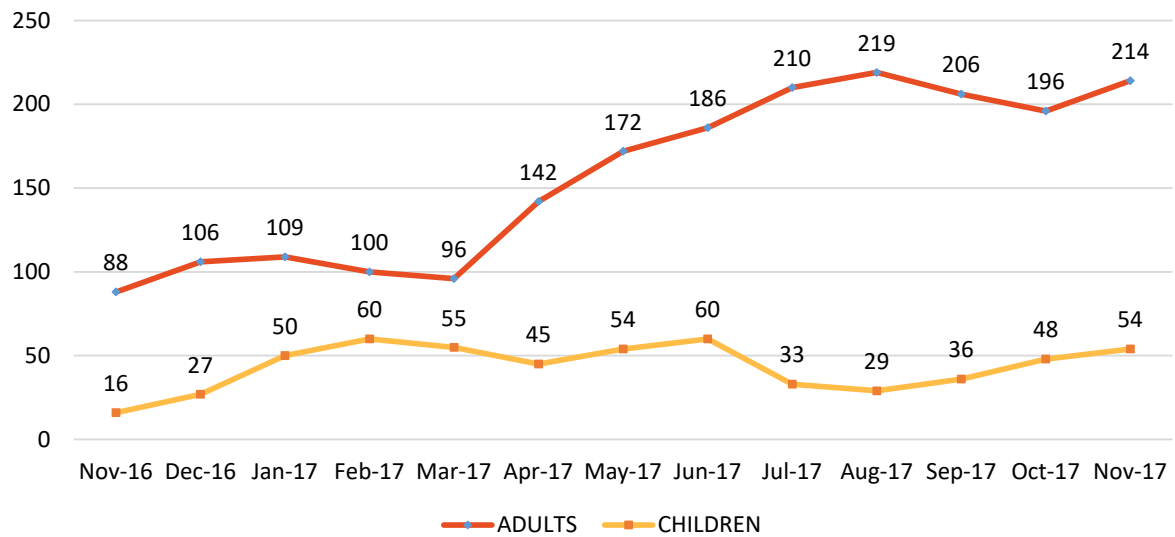
Patient's gastric aspirate collected in 9 months= 375

Patients who were eligible for gastric aspirate collection =460

Proportion= 81.52 per cent

This proportion is done out of reliable name based lists that were available at the CBNAAT centre.

**Figure 1- CBNAAT Tests from November 2016 to November 2017 in Adults and Children in Rajnandgaon District, Chhattisgarh**



**Table 5- Proportion of paediatric gastric aspirate specimen found to be positive for M tuberculosis.**

	2016 April-October	2016 November-December	2017 January-September	2017 October-November	Total April 2016- November 2017
Positive for M tuberculosis	1	1	3	0	5
Paediatric Gastric aspirates	18	43	422	102	585

Positive for M tuberculosis = 1+ 1 +3 = 5

All Paediatric Gastric aspirate patients = 585

Proportion =  $5/585 = 0.85$  per cent

Among known 0 to 10 patients the proportion is similar

3 positive

375 presumptive TB

Proportion =  $3/375 = 0.80$  per cent

**Table 6- Time interval between receipt of CBNAAT result by the MO PHI and initiation of ATT**

Patient	Test result	ATT started	Village	Name of PHI	Block
B Pratip	16/04/2016	16/04/2016	Bijnapur	PHC Mohara	Dongargarh
Anju	28/11/2016	28/11/2016	Katli	PHC Ramatola	Dongargarh
B Sonkar	04/05/2017	No data	Somni	GMC RJN	Ghumka
Aditi	16/05/2017	No data	No record	No record	Manpur
Mukesh	22/05/2017	No data	Gauri Nagar	Private	Ghumka

*\*\*Name of the subjects changed to maintain confidentiality.*

STS Dongargarh said treatment started on the same day as the PHCs are accessible. These cases were diagnosed by the then DTO. Most of the communication happened on WhatsApp with STS. That was the reason for treatment started on the same day

#### **Chhattisgarh context –**

Acceptance of the parents for the gastric aspirates as a method of specimen collection, if children are unable to produce sputum.

*“Earlier guardians of the children were unconvinced about the procedure. They were little worry about the procedure that a tube will be put in child’s nose and collect the stomach content. Also, they were totally unhappy about keeping their children hungry for on morning hours. Apparently the guardians had faced greater inconvenience due to the “each sample on two consecutive days” policy. After counselling by health staff and community workers they were ready to bring child for next day sample collection.”*

*“The children were found more resistant and irritable on the first day. But they were lesser irritable on the day followed.”*

### **Contextual changes which may have affected the desired outcomes –**

Orientation of the different stakeholders & getting necessary approval from department - October 2016. Although, the SHRC conducted proper advocacy meetings with the district concerned government officials. It could be even better if we would involve the district collector for this project. The involvement of the Collector could be resulted in much more positive outcomes as per the administration is concerned.

### **Training of Doctor's & Nurses - November 2016 to July 2017**

The training of the healthcare providers took a lot of time -so it extended up to the first week i.e. 5th & 6th of July 2017. It was very difficult to manage the time slot of the BMO, MO & AMO as per their convenience because all were busy in different health-related activities. So for finalizing the free dates, it took a long time and that was the only reason for being too late. Some of the participants even not attended the training due to their personal issues; as a result, we had to call them again on different dates. This was the other reason.

### **Line listing of presumptive child TB cases - January 2017 to May 2017**

The line listing of the presumptive cases by the Mitaniins took a long time. As a result, their screenings at the health facility delayed which further leads to less number of samples sent for testing.

### **Specimen collection, Testing, Data collection - January 2017- June 2017**

Some of the PHCs have limited infrastructure as well as the limited staff. This was one of the excuses of the AMO's for not doing gastric aspiration. But few of them were performed very well and they send samples for testing. Those PHC's who have sent samples to the district for CBNAAT testing told us the issue of availability of staffs (which act as a human courier) and their travelling allowances. Once the sample has been collected from the children then it was stored in cold chain and they had to wait for the staffs from the facility for sending the samples. But anyhow they managed to send the samples but at the district level, they faced the issue of travelling allowances.

At the district level, there was an issue of not receiving the travelling allowance due to the misconception of the gastric juice as an alternate sample. Due to these issues, some of the facility has stopped sending samples and some facilities managed these issues with the help of

their Jeevan deep funds. With the help of proper advocacy meetings, those issues were resolved.

### **Refresher training -**

There was no refresher training as the training was supposed to finish by January 2017. Some of the staff from the health facilities may not have been competent nor confident enough for doing the gastric aspiration. Lack of refresher training would result in the less performance of the health facilities thereby decreasing the number of the sample sent for testing.

### **Data collection, compilation and analysis - October 2017**

Community mobilizers were introduced in August in a parallel project in Kondagaon district. Based on the success of this concept - Rajnandgaon also selected community mobilizers in October. These community mobilizers had been Mitanins (Community volunteers) for about 12 years in Rajnandgaon and have qualified as ANM recently. They were oriented and then given on the job training for data collection. They interviewed patients with the help of semi-structured questionnaires to obtain information about contacts, weight of children, education of parents, employment.

### **Other administrative issues -**

Some of the BMO's trained for the gastric aspiration were not motivated towards the project and also due to the lack of leadership they did not influence their staff for doing gastric aspiration. There were other issues like procurement of the consumables for gastric aspiration which resulted in a delay of the project. Due to the presence of dual administration, one of the Nutrition Rehabilitation Centre (NRC) present in Government medical college took time in doing gastric aspiration. After some time this issue was solved and they performed very well and most samples were sent for testing.

## **DISCUSSION –**

**Table - Summary of Salient findings**

	Expected (Proposal)	Actual (From facility)
<sup>1</sup> Expected average paediatric OPD in 59 facilities in a year	$10*25*50*12=150000$	109712
<sup>2</sup> Expected presumptive patients	$150000*0.01=1500$	1097
<sup>3</sup> No eligible for gastric aspirate	$1500*0.75=1200$	460
No aspirate collected	$1200*0.85=1000$	375 (in 9 months)
No found positive	$1000*0.3=300$	3 (in 9 months) + 2 earlier



<p><sup>1</sup>. The data has been collected from OPD records of 0-10 year who came for health facilities (PHC+CHC)</p> <p><sup>2</sup>. Expected presumptive cases are 1% of total OPD records of 0-10 year old children</p> <p><sup>3</sup> 75% of presumptive cases are pulmonary tuberculosis and eligible for gastric aspirate</p>
---

Proportion presumptive TB / all out-patients in 0 - 10 years age group

$540 / 109712 = 0.49 \%$

Proportion of patients gastric aspirate collected / those eligible =  $375 / 460 = 81.52$  per cent

Proportion positive for M tuberculosis/ gastric aspirate patients =  $3 / 375 = 0.80$  per cent

Patients and parents were enthusiastic about the test

Increase in samples tested- 426 samples collected at periphery

### **Comparison with other studies –**

Regional data from World Health Organization (WHO) indicates that sputum microscopy smear-positive TB in children (<14 years old) accounts for 0.6%–3.6% of all reported cases (6). Paediatric TB is over 10% of all TB in high burden countries. (7), According to the TB India 2014 report 5% of all new cases were in age-group (0-14 yrs.).

Here 0.59 % presumptive patients were found among the OPD attendees. And only 0.85 per cent of the tested samples were positive which is much lower than even population expected prevalence.

### **Scalability of the intervention strategy –**

This study shows that gastric juice aspiration can be done at PHC level by basic doctors, ANM and GNM. Training, with quality checks, is required. This can be done even at CHC level, with active support from facility paediatricians and trainers from state-level medical colleges. However, this diagnostic tool can only supplement other diagnostic tools such as Mantoux, X-ray and CBNAAT and cannot substitute other tools.

### **Sustainability of the intervention –**

The learning will be permanent. However, there is a need to re-examine the quality of presumptive paediatric case detection, training, specimen selection and transportation. Re-training and quality checks are required.

## **CONCLUSION –**

### **Strengths –**

The acceptability of gastric juice aspiration and the feasibility of training at CHC and implementation at PHC are demonstrated.

### **Limitations –**

- a) There is an extremely low yield in the case detection rate.
- b) There is a need to re-examine the quality of presumptive paediatric case detection, trainings, specimen selection and transportation.

**Bias** – Selection of cough patients who are sputum negative and may not be really infective.  
Selection of contacts who are not infected.

How it was addressed - Guideline for selection

First, the child with a contact history in last six months in his family was assessed for symptoms of tuberculosis by community health workers.

A line listing of symptomatic cases was done and children were screened by Assistant Medical Officers and Medical Officers.

On the basis of clinician's diagnosis, a selected number of pulmonary presumptive cases were identified for gastric aspiration.

A day in a week was declared in the field for sample collection.

Presumptive Child was admitted to the hospital a day before the sample collection

## **POLICY IMPLICATIONS –**

There is a need for sensitising all doctors at the public and private care centres on the screening of presumptive paediatric patients on gastric aspirates. However, this diagnostic tool can only supplement other diagnostic tools such as Mantoux, X-ray and CBNAAT and cannot substitute other tools.

## **FUNDING / ACKNOWLEDGEMENTS –**

This implementation research was supported through The Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund) is an international financing organization and implemented through the Central TB Division, Directorate General of Health Services, Government of India and National Institute of Research in Tuberculosis, Chennai.

We gratefully acknowledge all TB patients and their families, community mobilizers and Rajnandgaon district CMOH, DTO, RNTCP staff, as well as 3 (AIIMS Raipur, JLN MCH,- Raipur and Rajnandgaon) Medical Colleges, Rajnandgaon District Hospital, all CHC and all PHC MOs and staff for their involvement in the study. We would like to thank former DHS R. Prasanna, IAS and STOs Dr Pambhoi and Deshpande for their permission and support to undertake the study. The work and data collection was done by three Programme associates Rakesh, Asmita and Kamlesh and the four Community Mobilizers with the help of other Health system strengthening team members. In particular we thank Kamlesh was involved in collation and preliminary analysis of the final data set.

#### **REFERENCES –**

1. WHO. Global Tuberculosis Report 2014. World Heal Organ. 2014;(ISBN 978 92 4 156480 9).
2. Swaminathan S, Rekha B. Paediatric tuberculosis: global overview and challenges. Clin Infect Dis. 2010;50 Suppl 3(Suppl 3):S184–94.
3. Dodd PJ, Gardiner E, Coghlan R, Seddon JA. Burden of childhood tuberculosis in 22 high-burden countries: a mathematical modelling study. Lancet Glob Heal [Internet]. Dodd et al. Open Access article distributed under the terms of CC BY; 2014;2(8):e453–9. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25103518>
4. Cossio MLT, Giesen LF, Araya G, Pérez-Cotapos MLS, VERGARA RL, Manca M, et al. Global Tuberculosis Report 2015. World Heal Organ [Internet]. 2015;XXXIII(2):81–7. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/15003161>
5. Jain SK, Ordonez A, Kinikar A, Gupte N, Thakar M, Mave V, et al. Paediatric tuberculosis in young children in India: a prospective study. Biomed Res Int [Internet]. 2013;2013:783698. Available from: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3872373&tool=pmcentrez&rendertype=abstract>
6. John TJ, Vashishtha VM, John SM. 50 years of tuberculosis control in India: Progress, pitfalls and the way forward. Indian Pediatr. 2013;50(1):93–8.

7. Marais BJ, Hesselning AC, Gie RP, Schaaf HS, Beyers N. The burden of childhood tuberculosis and the accuracy of community-based surveillance data. 2006;10(April 2005):259–63.
8. Kabra SK, Lodha R, Seth V. Tuberculosis in children--what has changed in last 20 years? Indian J Pediatr. India; 2002 Nov;69 Suppl 1:S5–10.
9. Rajeshwari K, Gupta S, Dubey A, Gera R. Asymptomatic multiple intracardiac tuberculomas in a child. Cardiol J [Internet]. 2012;19(5):518–20. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/23042317>
10. Central TB Division, Directorate General of Health Services M of H and FW. Reach the Unreached: TB India 2014: Annual Status Report. 2014;1–204.

## ANNEXURES

### I: CHECKLIST FOR THE PROCEDURE

Sr. No	PROCEDURE	<i>Rationale</i>
1	1. CHECK chart for prescriber's order.	<i>Obtained a gastric specimen for TB testing requires a prescriber's order.</i>

2	<p>FAST patient overnight (oral/enteral):  3-4 hours for infants  6-8 hours for toddlers and older children  NOTES: The patient should not eat or drink anything overnight to prevent the stomach from emptying.  This test is best performed in the morning before ambulation and best after an undisturbed sleep of at least 6 hours.</p>	<p><i>During sleep, the lung's mucociliary system beats mucous up into the throat. The mucous is swallowed and remains in the stomach until the stomach empties. Therefore, the highest yield specimens are obtained first thing in the morning. Best to collect gastric aspirates before gastric emptying is stimulated by being ambulatory or by eating.</i></p>
3	ASSEMBLE equipment.	<i>Facilitates completion of tasks in a timely manner.</i>
4	DON fit-tested N95 respirator mask and PERFORM hand hygiene.	<i>Routine infection control practices; reduces transmission of microorganisms. N 95 Respirator Mask must be fit-tested to ensure employee protection from airborne organisms</i>
5	IDENTIFY patient and EXPLAIN procedure.	<i>Failure to correctly identify patients prior to procedures may result in errors. Reduces child and family's anxiety. Evaluates and reinforces understanding of previously taught information and confirms consent for the procedure.</i>
6	PERFORM hand hygiene and DON other PPE including gloves, goggles and gown.	<i>Routine infection control practices; reduces transmission of microorganisms. P7PE must be Applied when an exposure to a blood or body substances is anticipated.</i>
7	INSERT nasogastric tube as per Nasogastric Tube Insertion procedure and check placement.	
8	<p>ASPIRATE at least 5 mL of gastric contents/mucous using 20 mL syringe. If less than 5-10 mL of mucous is obtained, re-position the tube and/or the child in order to look for the pool of mucous. While continuing to gently aspirate with the syringe, pass the tube further along several inches and try rolling the child up onto his/her side.</p>	<i>Minimum volume required</i>
9	<p>If unable to aspirate gastric contents, instill 10 ml sterile water followed by air to clear the tube and then reattempt to aspirate. If there is still no significant yield, attempt to advance or withdraw the tube and/or change the child's position in order to find mucous.</p>	<i>The organism is most viable when not exposed to saline or preservatives.</i>

10	Continue to aspirate as you REMOVE the nasogastric tube. NOTE: Best practice is to insert a new tube daily to decrease tube colonization by other mycobacteria from food and water.	<i>Mucous may be present along the oesophagus and can be aspirated while removing the tube.</i>
11	TRANSFER specimen into appropriate container (minimum volume 5 ml). LABEL container and complete requisition. PLACE specimen in transport bag with requisition in outside pocket	<i>Ready for transport to the lab.</i>
12	REMOVE equipment and DISCARD appropriately. REMOVE gloves and other PPE before leaving the room and PERFORM hand hygiene. REMOVE N95 respirator mask after leaving room handling the straps only and PERFORM hand hygiene again.	<i>Routine infection control practices; reduces transmission of microorganisms.</i>
13	ARRANGE for specimen transport to lab immediately.	<i>Requires neutralization of acid within 30 minutes of collection.</i>
	REPEAT collection for a total of 2-3 consecutive	<i>This is the number that maximizes the greatest yield</i>

*Adopted from British Columbia Children's Hospital*

## II: LIST OF EQUIPMENT

- Nasogastric tube 10 French or larger
- 20 ml enteral syringe
- Provincial Health Laboratories gastric aspirate container (available from 2F40) with the appropriate requisition
- 10 ml sterile water
- 10 ml enteral syringe
- appropriately fit-tested N95 respirator mask
- personal protective equipment - PPE (gloves, gown, goggles)
- Pen (to label specimens)
- Laboratory requisition forms
- Litmus paper specimen container

Annexure: Document in nursing record

- Date and time of collection
- Length of time patient fasted (NPO)
- Size of tube used

- Description of aspirate
- Volume of specimen obtained
- Patient's response to procedure
- Any other pertinent actions or observations

### III: GUIDELINE FOR TAKING GASTRIC ASPIRATE

- Use an assistant (counsellor) to help as this procedure requires 2-3 people.
- Prepare all equipment before starting the procedure.
- Disinfect all working surfaces including the bed. Place a drape over the bed. Use one drape to immobilize the child and one to cover the child leaving head exposed.
- Disinfect all working surfaces including the bed. Place a drape over the bed. Use one drape to immobilize the child and one to cover the child leaving head exposed.
- Position the child on his or her back or side. The assistant should help to hold the child.
- Optional: instil 2 drops of oxymetazoline into each nostril to induce vasoconstriction and prevent epistaxis.
- Measure the distance between the nose and stomach, to estimate the distance that will be required to insert the tube into the stomach.
- Attach a syringe (10 if using Levin or 20 ml if using Ryle's tubes) to the nasogastric tube (size 6-10 French, depending on the size of the child).
- Gently insert the nasogastric tube through the nose and advance it into the stomach.
- Withdraw (aspirate) gastric contents (2–5 ml) using the syringe attached to the nasogastric tube.
- To check that the position of the tube is correct, test the gastric contents with litmus paper: blue litmus turns red (in response to the acidic stomach contents). (This can also be checked by pushing some air (e.g. 3–5 ml) from the syringe into the stomach and listening with a stethoscope over the stomach.)
- If no fluid is aspirated, insert 5–10 ml sterile water or normal saline and attempt to aspirate again.
- If still unsuccessful, attempt this again (even if the nasogastric tube is in an incorrect position and water or normal saline is inserted into the airways, the risk of adverse events is still very small).
- Do not repeat more than three times.
- Withdraw the gastric contents (ideally at least 5–10 ml).

- Transfer gastric fluid from the syringe into a sterile container (sputum collection cup).
- Titrate volume of 4% sodium bicarbonate using a pipette or syringe and pH strips, adding to the specimen until pH 6-7 is reached (in order to neutralize the acidic gastric contents and so prevent the destruction of tubercle bacilli).

#### IV: AFTER THE PROCEDURE

- Wipe the specimen container with alcohol/chlorhexidine to prevent cross- infection and label the container.
- Fill out the laboratory requisition forms.
- Transport the specimen (in a cool box) to the laboratory for processing as soon as possible (within 4 hours).
- If it is likely to take more than 4 hours for the specimens to be transported, place them in the refrigerator (4–8 °C) and store until transported.
- Give the child his or her usual food.