

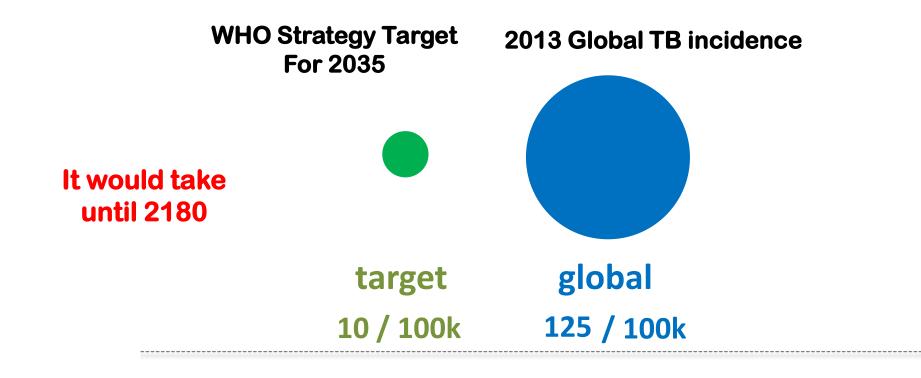
CHALLENGE)TB

Accelerating access to quality TB care for presumptive paediatric TB patients through improved diagnostic strategies





Current progress = Too Slow to reach 2035 target?



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2020

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Credit: WHO

Background

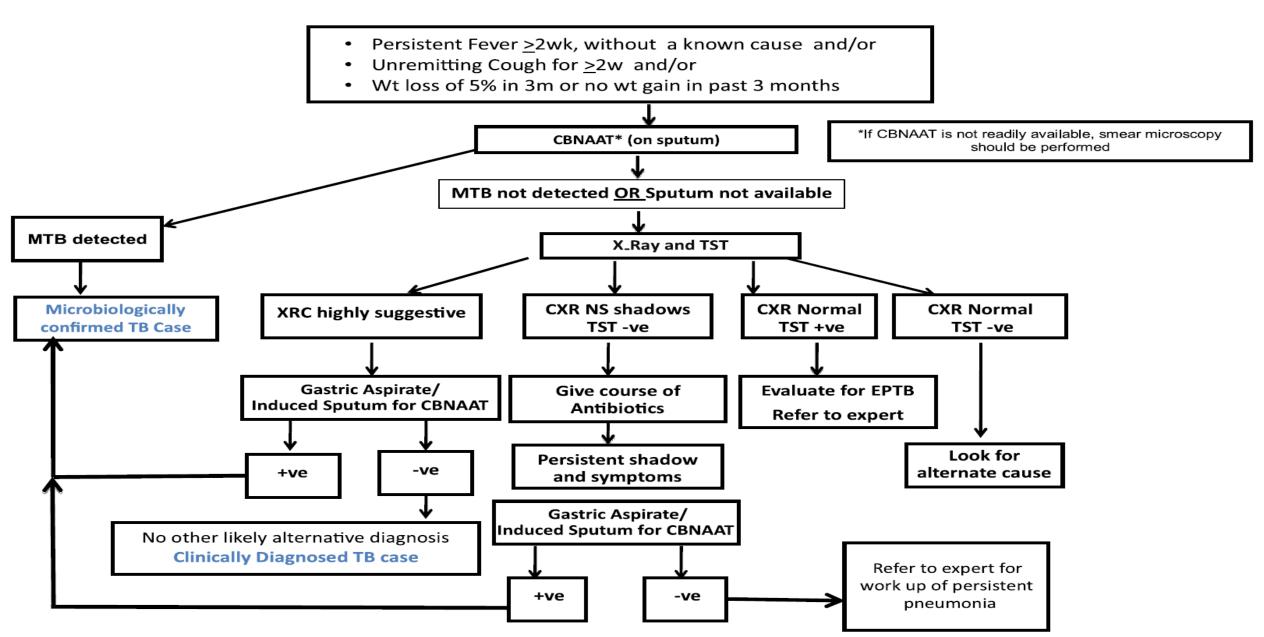
- Burden of childhood TB is not well understood
 - TB in children not upfront suspected
- Challenges in diagnosis of TB in children
 - Difficulty in obtaining quality specimen
 - Low sensitivity of widely available low costs tools (smear microscopy)
 - Affordability challenges wrt. high sensitivity tools in the private sector
- Diagnosis based on clinical criteria &/or triad of:
 - History of contact with TB case
 - CXR
 - TST
- >80% of Pediatric TB cases- Clinically diagnosed
- No scope of diagnosing Rif resistant TB, which is laboratory diagnosis



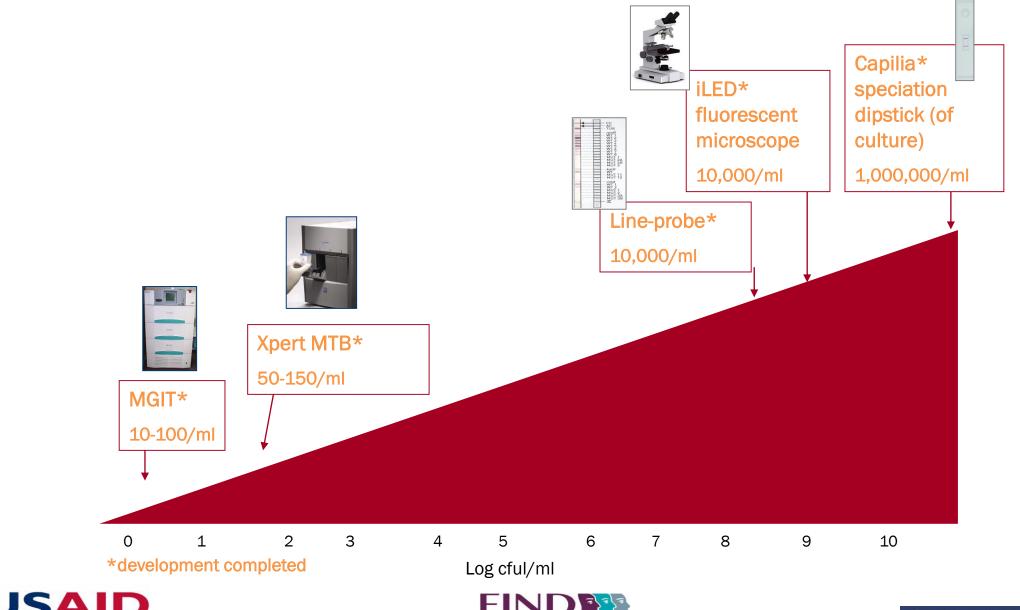




Diagnostic algorithm for Pediatric Pulmonary TB



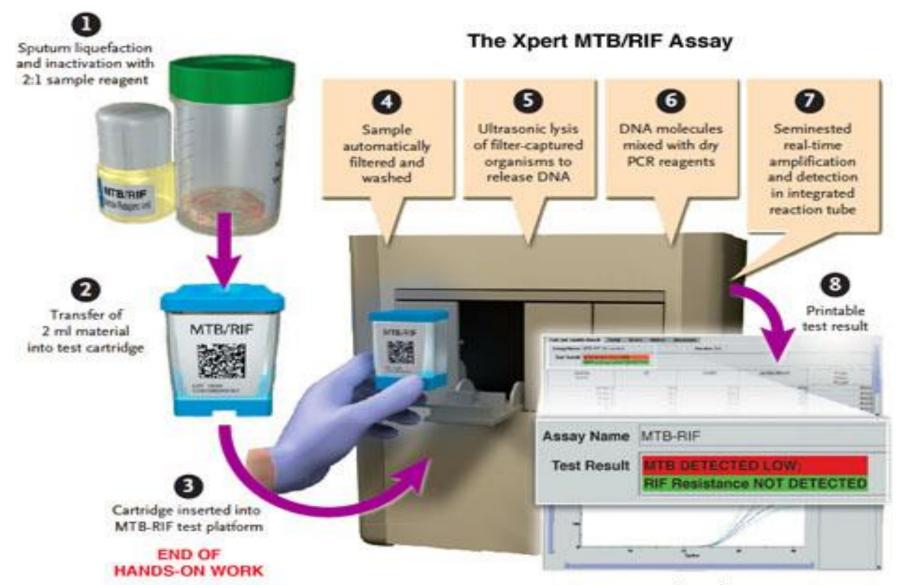
Analytical sensitivity of diagnostic tests



















WHO recommendations - 2013

- 16 studies, 12 published and 4 unpublished, all studies were performed at higher levels of care, and the children included were mainly inpatients.
- Pulmonary TB was evaluated in 13 studies including 2603 participants. The overall pooled sensitivity
 - Xpert MTB/RIF against culture (10 studies) in children presumed to have TB was 66% in 10 studies where expectorated sputum (ES) or induced sputum (IS) was used (pooled 95% CrI 52% 77%),
 - 66% in seven studies where gastric lavage aspirates (GLA) were used (pooled 95% CrI 51% 81%).
- Pooled specificity of Xpert MTB/RIF against culture as the reference standard was ≥98% with narrow confidence intervals.
- The sensitivity of Xpert MTB/RIF to detect rifampicin resistance in pediatric specimens was 86% (95%CI 53% - 98%).







WHO recommendations - 2013

Specimen type	Comparison (No. of studies, No. of samples)	Median (%) pooled sensitivity (pooled 95% Crl)	Median (%) pooled specificity (pooled 95% Crl)
	Xpert MTB/RIF compared against	84.9	92.5
Lymph node tissue and aspirate	culture	(72–92)	(80–97)
	(14 studies, 849 samples)		
	Xpert MTB/RIF compared against	83.7	99.2
	a composite reference standard	(74–90)	(88–100)
	(5 studies, 1 unpublished)		
Cerebrospinal fluid	Xpert MTB/RIF compared against	79.5	98.6
	culture	(62–90)	(96–100)
	(16 studies, 709 samples)		
	Xpert MTB/RIF compared against	55.5	98.8
	a composite reference standard	(51–81)	(95–100)
	(6 studies, 512 samples)		
Pleural fluid	Xpert MTB/RIF compared against	43.7	98.1
	culture	(25–65)	(95–99)
	(17 studies, 1385 samples)		
	Xpert MTB/RIF compared against	17	99.9
	a composite reference standard	(8-34)	(94–100)
	(7 studies, 698 samples)		
Gastric lavage and aspirate	Xpert MTB/RIF compared against	83.8	98.1
	culture	(66–93)	(92-100)
	(12 studies, 1258 samples)		
Other tissue samples	Xpert MTB/RIF compared against	81.2	98.1
	culture	(68–90)	(87–100)
	(12 studies, 699 samples)		





Recommendations Continue

- For CSF specimens, Xpert MTB/RIF should be preferentially used over culture if the sample volume is low or additional specimens cannot be obtained, in order to reach quick diagnosis.
 - If sufficient volume of material is available, concentration methods should be used to increase yield
- Pleural fluid is a suboptimal sample for the bacterial confirmation of pleural TB, using any method.
 - A pleural biopsy is the preferred sample.
 - Sensitivity of Xpert MTB/RIF in pleural fluid is very low.
 - Nevertheless, any positive Xpert MTB/RIF result on pleural fluid should be treated for pleural TB, while those with a negative Xpert MTB/RIF result should be followed by other tests;
- Children presumed to have pulmonary TB but with a single Xpert MTB/RIF -negative result should undergo further diagnostic testing, and a child with high clinical suspicion for TB should be treated even if an Xpert MTB/RIF result is negative or if the test is not available
- These recommendations do not apply to stool, urine or blood, given the lack of data on the utility of Xpert MTB/RIF on these specimens.









Geographic Area

- Initially launched in the 4 cities of Delhi, Chennai, Hyderabad and Kolkata
- Subsequently, 5 more cities were added – Vizag, Surat, Bangalore, Nagpur and Guwahati
- Intervention was added in one more city in 2017- Indore
- The initial 4 sites were transitioned to the RNTCP by 31st March 2017
- Currently, the project is operational in six cities covering a total population of >53 million (Census 2011)

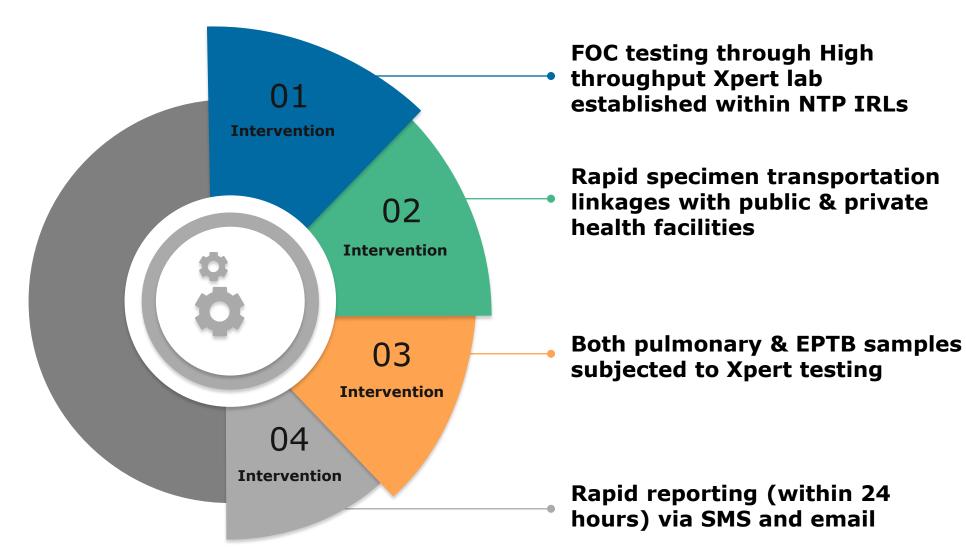




Project overview

Additional -

- Rif detection
- Prompt linkage to treatment
- Providing collection tubes to providers
- Culture/DST for Rif cases





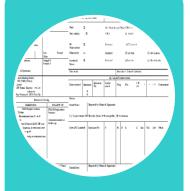




How to Engage in the Project?



Specimen of paediatric TB suspect can be sent to the project lab by any provider from public / private sector



Fill the form-Annex-1 and send the sample for FOC testing



Samples are tested and results transmitted electronically within 24 working hours



Specimen transportation costs are covered by the project



Diagnosed TB cases can opt for free of cost Rx under RNTCP or seek treatment in the private sector

Simplified Engagement

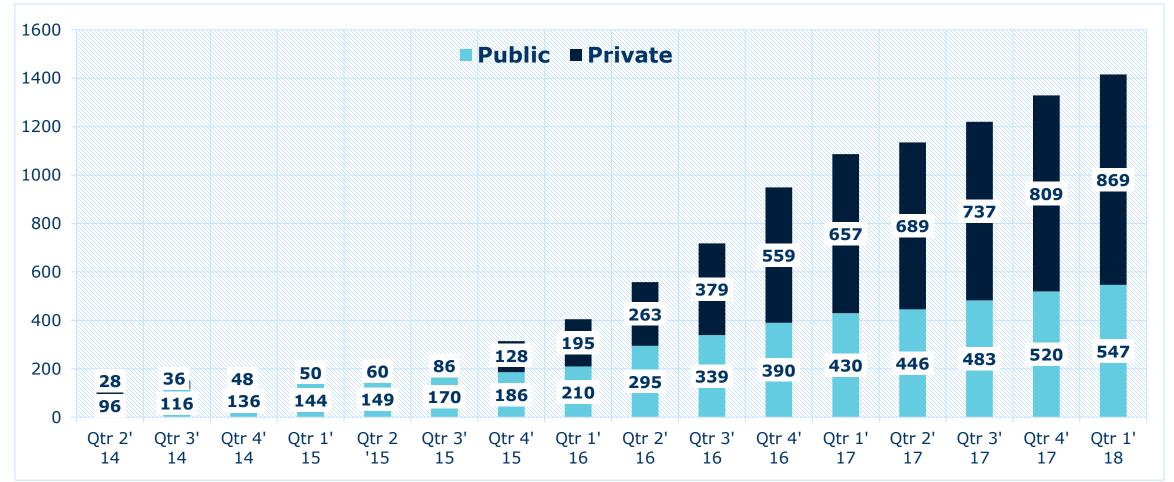






Provider engagement: Providers/facilities engaged

Overall 94,415 presumptive cases have been tested of which 6270 (6.6%) TB cases detected with 545 (8.7%) Rif resistant

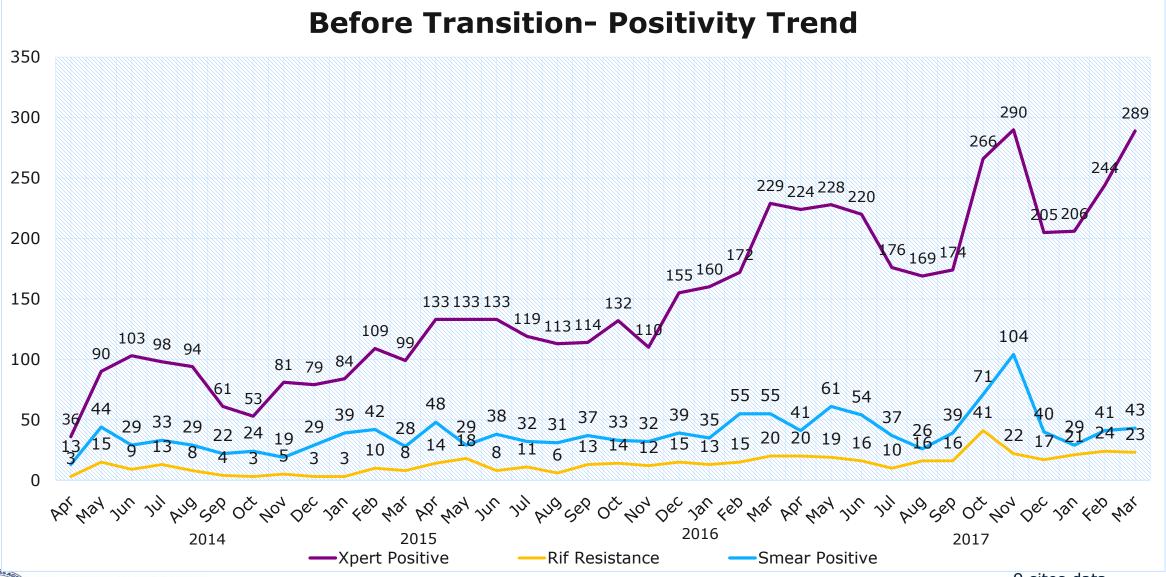








Positivity trend









3 Pillars of Performance

96.2% of specimens transported on the day of collection

95% of specimens tested on the same day

98.9% of the tested specimens reported the same day

Transportation

Diagnosis

Reporting



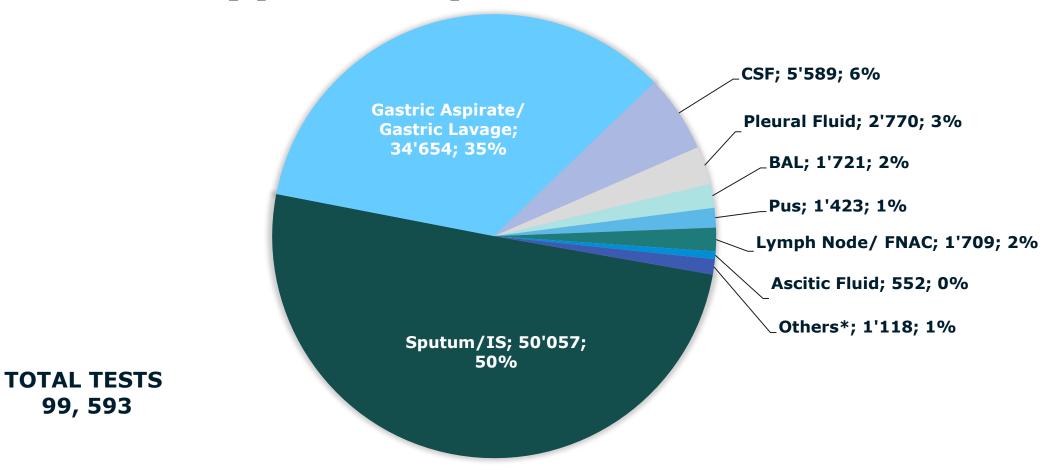
Overall 89.5% of the result reported within 24 hours of collection







Type Of Specimen Tested



*Others: Tissue, Pericardial Fluid, Urine, Cervical Aspirate, Peritoneal Fluid, Tracheal aspirate, Abscess, Synovial Fluid, Serum Bone, Chyle fluid, Nasal Aspirate, Pleural Biopsy, Thoracic swab, etc







Xpert MTB/RIF & Smear Microscopy Performance

Specimen Type	Specimen Tested	Xpert Positive (%)	Smear Positive (%)	Rif Resistance (%)	
Sputum/IS	50,057	3176 (6.3%)	1285 (2.6%)	371 (11.7%)	
Gastric Aspirate/ Gastric Lavage	34,654	1767 (5.1%)	355 (1.1%)	167 (9.5%)	
CSF	5,589	353 (6.3%)	7 (0.2%)	34 (9.6%)	
Pleural Fluid	2,770	112 (4.0%)	12 (0.6%%)	17 (15.2%)	
BAL	1,721	227 (13.2%)	36 (2.8%)	17 (7.5%)	
Pus	1,423	535 (37.6%)	107 (9.0%)	72 (13.5%)	
Lymph Node/ FNAC	1,709	494 (28.9%)	55 (5.4%)	63 (12.8%)	
Ascitic Fluid	552	24 (4.3%)	1 (0.2%%)	2 (8.3%)	
Others*	1,118	121 (10.7%)	21 (2.9%)	17 (14.0%)	
Total	99,593	6808 (6.8%)	1879 (2.0%)	760 (11.2%)	

- Detection rate >3x
 higher over Xpert vs
 smear microscopy
- >50% RIF resist. detected from nonsputum samples
- High detection rates on Pus, FNAC, Lymph node specimens

Others= Tissue, Pericardial Fluid, Cervical Aspirate, Peritoneal Fluid, Tracheal aspirate, Abscess, Synovial Fluid, Serum Bone, Chyle fluid, Nasal Aspirate, Pleural Biopsy, Thoracic swab, etc







Treatment Information

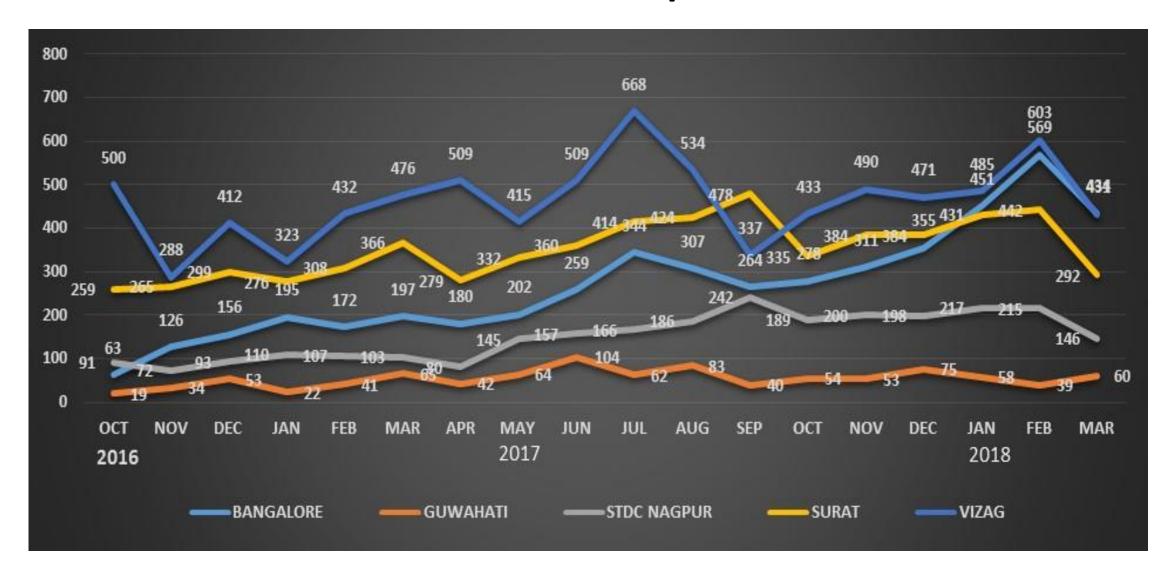
	Total Xpert Positives		Total Rif Resistant	%	Total	%
Patients diagnosed under the project	5725		545		6270	
Number initiated on treatment	5096	89.0%	467	85.7%	5563	88.7%
Died before treatment initiation	113	2.0%	28	5.1%	141	2.2%
Initial Default/Not traceable/Treatment refusal	492	8.6%	49	9.0%	541	8.6%
Referred Out	24	0.4%	1	0.2%	25	0.4%







Site wise- uptake









Summary

First routine initiative with upfront access to CBNAAT /GeneXpert for TB detection exclusively for pediatric population;

For the first time large volumes of non-sputa specimen tested under RNTCP

3X increase in detection rates vs. Smear microscopy

Significant levels of MDR cases in pediatric population documented

Enhanced involvement of private providers & medical colleges catering to pediatric population







The diagnostic challenge-

Accurate timely diagnosis of active pediatric TB is challenging for many reasons:

Innovative technology



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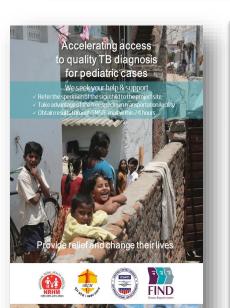
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HESE DELAYS IN THE DIAGNOSIS COULD HAVE BEEN AVERTED









Pandiatric cases in A major sities in India' for TB Diagnosis, at laboratory of New Delhi TB Centre Intermediate Reference Liberatory), STDL-Mare Daible under RNTCP (Remised National Tuberrulein Control Programme) Govt. of Delhi Supported by 1990 IRDA from April 2014. Since the project initiation, we have tested more than 7000 paediatric samples, both pulmonary and extra pulmonary. Till now see have detected 909 Rifampic in Sensitive and 98 Rifampic in Resistance patients. CRNART has proved to be better option in establishing YB diagnosis and Rifemplein Resistance in paediatric group with speed.

In the last one and half years me have got a very good output in this Project in line with the WMD ecommended diagnostic strategy for pendiatric population. Under the Project, we have extended this free of cost corrice to medical enlarges and other public health facilities. We would now like to extend these sendors so prediatric 19 supercts coming to your facilities.

urine, stool and blood to New Dolhi Till Centre, Adjusent to Lok Nayak Hesaltal Dolhi Gato, Novy Dolhi 110002. This text will be done free of cost for all postingers cases in the age group between 0-14 years. The report will be cent within 24 foors through eroall in PDF formation 5MS.

Please refer to the attached project fiver for the project details.

This is kind request to all possibilitidans to give us support in improving the detection of TB in psediatric

7859907266 9891970391

Dr. L.K. Chapre

New Orth TE Centre







FIND

పిల్లలకు ఉచిత TB పరీక A new program to promote rapid & accurate diagnosis using GeneXpert - an innovative molecular test



GeneXpert - முஷுய



Ask your provider or contact us for more details!

Covt Hospital for Chest & Communicable Diseases (CHCCD), Mr. A. Simhachalam - 9000855498 First Floor ,C&DST Lab, Opp Mental Hospital,

బంద్రిపించిపలిసిన ఫోస్ నంబర్స్

Mr. P.L.M. Brahma Redde - 8977065207



Bring the benefits of accurate rapid TB tests to your patients — free of charge!

- Tost results will be communicated through SMItter ernal within 12 working hours of specimen re-ceipt.

Project Site Details



Progress Options: Description of the April 16 (April 16 under this project, A total 16 (April 16 under this project, April 16 under this project, April 16 (April 16 under this project, April 16 under this project, April 16 (April 16 under this project, April 16 under this project, April 16 (April 16 under this project, April 16 under this project, April 16 (April 16 under this project, April 16 under this project, April 16 (April 16 under this project, April 16 under this project, April 16 (April 16 under this project, April 16 under this project, April 16 (April 16 under this project, April 16 under this project, April 16 (April 16 under this project, April 16 under this project, April 16 (April 16 under this project, April 16 bacteriologically confirmed. TB detection rates were three fold higher on apert as compared to smear microscopy. Further, a total of 265 rifampicin resistant TB cases were detected. The project has morrescopy, retrained, a tension years (unappear research 19 cases were obtained. The project case demonstrated for identifiary of interface) given tensing its mana spetture speciment from distinction with a very high properties of interpretable results with some than a threshold increase in TB case detection over means retrievely and distribute of spellinger trainings for infragrant restaurant. The results with some than a threshold increase in TB case of the project has a less shown the utility of offering jurison Myert increase paragraph as pediatric pressure prior TB and DR-TB. patients under programmatic conditions.

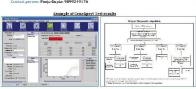
we now seek your support to further expand the project coverage and thereby maximize the

- How to engage in the project.

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- If TE is diagnosed the case can opt for free of cost treatment under RNTCP or opt for private.
- Project site contact details

New Delh: Tubercalosis Centre, Jawaharial Nehru Marg. Delhi Gate, New Delhi - 120002



his preliatric TB project represents concerted efforts of RNTCP, FIND, USAID, CDC and MRT putting in

place within a short period, a possible solution to the diagnostic gap. FIND in consultation with RNTUP is

Implementing this project in Delhi, Hyderabad, Chennai and Kolkata, Nagpur, Street, Vizag, Agra, Lucknow

Other this inflation; 1130 her edge [14] throughput movember her at a four after outering enthancely to the TD diagnostic root of polisities propulation. These to be gooded accurate reducers haved same doublingwords in like with interestinantly accepted standards of TD save with no cost to potient or provider both a province and public except. That diagnostic option has been attradeded at the centuring NTTO label province and public except. That diagnostic option has been attradeded at the centuring NTTO label. On the century of the century

Any pediatrician both in public and private sector is those 9 cities ran richor refer their podiatric suspects to these labs or regentee transfer of speciones for free of too besting. The spectrum would be treated on the same day and the results commissioned to referring provider electronically (e-med and SMS) and at the same time notified to RNTCP under Michay.

When 'I' is replaced by 'We'.

- Diagnosis of TUBERCULOSIS in children is challenging, with most TB cases being treated based on clinical symptoms.
- We addressed this challenge by introducing Xpert MTB/RIF testing across
- Xpert has demonstrated excellent performance in detecting TB and Rif-
- Results are available within 24 hours, at no cost for the patient and
- Any doctor can refer the specimen from pediatric TB suspects and provide them this benefit.











Accelerating access to quality TB diagnosis for pediatric cases in 9 major cities in India

Accurate diagnosis of TB remains an impediment in the management of pediatric TB cases. The diagnosis is complicated because children are unable to expectorate sputum and TB can minds many other rommon childhood disesses, including premiumin, generalized buckerial and viral infections, are localizing and more including and successful with the sensibility and are continuously for the diagnosis of childhood 13 remains low, in the attention of hasteriological confirmation, the diagnosis of childhood TII in countries where TB is not endernic is based on a triad of close contact with an infectious patient, a positive informalia skin test (TST) result, and abnormalities on a chest radiograph. This criteria, however, has limited application in countries where TS is endentic as most individuals acquire infaction and become TST positive during childhood and adolescence. Although growth of Alterecolouis on Lowenstein-Jensen medium is considered to be the gold standard and liquid culture offers the possibility of more sensitive diagnosis of active TB and drug susceptibility, the turnament time for results no culture trais remains high. These limitation pass challenges in establishing accurate diagnosis of TB in children and odd to the potential for both under

The WIIO codorsed Xport MTB/RIP® (Cepheid, Sunnyvale, CA, DSA), is a cutrider-based fully utomated nucleic acid amplification test (CBNAAT) for the diagnosis of TB and rifampion resistant -TB, auttable for use in disease-endentic countries







It extracts DNA, concentrates, amplifies, and identifies targeted nucleic acid sequences in the TB genome Rpert MYB/RE, is a highly sensitive and specific tool with a quick turn-around time, ofters an easy and prumising solution in addressing the challenges in the diagnosis of pecifatric TB. Recently in the global guidance document released by WHO, it has been recommended that Xpert MTR/RTF may be used rather than conventional microscopy and culture as the initial diagnostic test in all children presumed to







Thankyou





