# Cost-Effectiveness of TrueNat as Compared to GeneXpert as a Diagnostic Tool for Diagnosis of Pediatric Tuberculosis/MDR Tuberculosis under the National Tuberculosis Elimination Program of India

## Abstract

**Background:** According to a study on global burden of tuberculosis (TB), India witnessed 60,000 pediatric deaths in the year 2015. In India, most of the children do not get diagnosed with tuberculosis for various reasons. **Aims and Objectives:** This study will evaluate the cost-effectiveness of TrueNat and GeneXpert diagnostic strategies used for tuberculosis detection in children, thus aiding policymakers for taking evidence-based decisions. **Materials and Methods:** For this cost-effectiveness study, a systematic review was done to extract the evidence for estimates of effectiveness of current TB diagnostic tools. Evidence pertinent to cost per test including all direct, indirect costs and health benefits in terms of quality-adjusted life years were researched and documented. Full economic evaluations available in the literature were also explored. **Results:** The results of the study showed that TrueNat is more cost-effective when compared to GeneXpert in the diagnosis of pediatric tuberculosis cases leading to more life years gained and deaths averted. 13,260 additional cases can be detected with TrueNat with an incremental cost of $14.36 per additional case detected. The incremental cost-effectiveness ratio per life year gained was found to be $20.01. **Conclusion:** TrueNat proved to be beneficial and cost-effective as compared to GeneXpert MTB being used in case of children. We recommend the use of TrueNat diagnostic test in India as it is in congruence with Indian health-care settings.

**Keywords:** Children, GeneXpert, screening, TrueNat, tuberculosis

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## Introduction

The COVID-19 impact was a large global drop in the number of people newly diagnosed with tuberculosis (TB). The reporting decreased from 7.1 million in 2019 to 5.8 million in 2020 and India was among the worst affected. Reduced access to TB diagnosis and treatment has resulted in an increase in TB deaths. Best estimates for 2020 show 1.3 million TB deaths among HIV-negative people and India accounted for 38% of global TB deaths among HIV-negative people. In India, of the deaths among HIV-negative people, 53% were men, 32% were women, and 16% were children.[1] Ninety-six percent of pediatric tuberculosis deaths among 60,000 in the year 2015 were reported to have occurred in children who did not receive treatment for the disease.[2] India notified 2.4 million TB patients in the year 2019.[3] Out of the total TB cases notified in India, children (0–14 years) accounted for 5.65% of total TB cases. Although pediatric TB is estimated to be 10% of total incident cases in India, only 5.6% are reported in the National Tuberculosis Elimination Program (NTEP). There is an estimated 56% gap in pediatric TB notification under NTEP, with only 1.5 lakh pediatric cases being notified in 2019.[3] As per global estimates of 2019, 5586 children out of 12 lakh children under the age of 15 have drug-resistant TB.[4] The case fatality ratio due to tuberculosis in India was 6.5% in pediatric cases.[5]

The diagnosis of childhood tuberculosis is based on clinical history, radiological findings, and medical examinations.[6] Young children experience the greatest risk and the most rapid disease progression. Phase 2 of the disease occurs 1–3 months after primary infection and follows occult hematogenous spread. The risk for the development of tuberculous meningitis and disseminated (miliary) TB is highest

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in this stage.[7] Once initiated on treatment, children have a better prognosis relative to adults.[8] There is a lack of high-quality diagnostic tests, sample handling, and point of clinical care. The culture of *Mycobacterium tuberculosis* is considered to be the gold standard in diagnosing the disease but has limitations of 4–8 weeks' time period for detection and need of sophisticated laboratory facilities.[9]

To address the gaps associated with diagnostics in pediatric TB care, the World Health Organization (WHO) recommended the use of a rapid diagnostic test, GeneXpert MTB/RIF (Cepheid Inc., Sunnyvale, CA, USA) as the initial diagnostic test in children suspected of having TB/RR. The GeneXpert MTB/RIF Ultra is a recent advancement in molecular diagnostics of TB with higher sensitivity compared to the Xpert MTB/RIF assay.[10] TrueNat (Molbio Diagnostics/Bigtec Labs, Goa/Bengaluru, India), is a new chip-based, micro real-time polymerase chain reaction.[8] It takes 1 h to detect TB, and if the test is positive, an add-on chip is used to detect RIF resistance which takes an additional 1 h. The system is battery operated with capability of testing four samples at a time. It is portable and can be used as point-of-care (POC) test within primary health-care facilities.[11,12] The results of accuracy studies done by The Foundation for Innovative New Diagnostics (FIND) also indicate that the TrueNat tests have accuracy comparable with Xpert MTB/Ultra and Xpert MTB/RIF, and can be performed in peripheral laboratories and primary health centers, at temperatures up to 40°C and in the absence of reliable electricity.[13] TrueNat can increase disease detection rate without the need for laboratory referrals.[14] As the TrueNat MTB Plus has more sensitivity (29 cfu/ml), it is recommended for TB diagnosis in children [cited from quotation of supplier of TrueNat in India, Appendix 1].

### Objectives

- To assess the effectiveness of GeneXpert and TrueNat diagnostic strategies for TB diagnosis in children
- To evaluate the cost for both these diagnostic modalities
- To assess the feasibility issues for both the technologies.

### Materials and Methods

In this cost-effectiveness study, the existing evidence from literature through the databases of PubMed Central and Web of Science was evaluated including peer review studies and systematic reviews published online, printed material from manufacturers, annual or technical reports from user departments, developmental partners or agencies, and full economic evaluations. Evidence pertaining to the effectiveness of GeneXpert and TrueNat, cost per screening test including all direct and indirect costs, and cost of the treatment was researched and evaluated. Thereafter, a decision tree model was constructed to find the course of events for the two screening modalities in diagnosing

TB in children. TreeAge Pro Healthcare software (updated version) was used for the analysis.

### Intervention

Cost-effectiveness of TrueNat will be compared with GeneXpert for the diagnosis of tuberculosis in children (0–15 years of age) in Indian context.

### Outcomes

#### *Effectiveness*

Literature search was done in databases of PubMed Central and Web of Science to obtain values for sensitivity and specificity of TrueNat and GeneXpert.

Search in PubMed: Following mesh terms were used for search: "((((truenat) OR (truenat mtb)) OR (((GeneXpert) OR (genexpert mtb)) OR (genexpert tuberculosis))) AND ((children) OR (child) OR (infant) OR (pediatrics) OR (preschool children))." Using this strategy, 240 articles were found in PubMed central.

Search in Web of Science: The mesh terms used were "((((truenat) OR (truenat mtb)) OR (((GeneXpert) OR (genexpert mtb)) OR (genexpert tuberculosis))):" 1173 articles were found.

Therefore, out of a total of 1413 articles, 350 articles were found to be duplicates. After reviewing abstracts of 1063 articles, only 43 were studies with children as subjects. After full review of 43 articles by two reviewers, 8 articles were finalized (gave results in terms of sensitivity and specificity, with consent of third reviewer.) as there were limited studies enumerating the results in the form of sensitivity and specificity of TB diagnostic tools for children. Table 1 gives the summary of the included studies as a result of literature search. Since sensitivity for the TrueNat test among pediatric population was not available in literature, a ratio factor of 1.2 was applied. The ratio factor was derived by considering the ratio between the sensitivities of adult and pediatric population for other diagnostic tests such as GeneXpert and Xpert Ultra of tuberculosis. Taking into consideration the systematic reviews, the sensitivity of TrueNat and GeneXpert was taken as 0.69 and 0.65, respectively, in case of children.

### Incremental cost-effectiveness ratio

The aim was to calculate the incremental cost that needs to be spent or gained per additional number of cases detected while using one test over the other in suspected pediatric TB cases. This can be calculated by taking the outcome of interest as incremental cost-effectiveness ratio (ICER).

Outcome of interest = Change in cost/change in effect

Incremental cost-effectiveness ratio $= (C_2-C_1)/(E_2-E_1)$

(*$C_2$ = unit cost per test of TrueNat, $C_1$ = unit cost per test of Xpert, $E_2$ = effectiveness of TrueNat, and $E_1$ = effectiveness of Xpert).

**Table 1: Sensitivity and specificity of TrueNat and GeneXpert for adults and children**

| Study title | Publication (year) | Population | Diagnosis through test | Sensitivity | Specificity | Total number of studies included |
|---|---|---|---|---|---|---|
| Global TB report 2013, WHO | WHO Report 2013[15] | Children (0-14 years) | Xpert MTB/ RIF | 66% (52-77) | 98% | 16 studies (13 studies with 2603 children) |
| Xpert MTB/RIF assay for the diagnosis of pulmonary TB in children: A systematic review and meta-analysis | Detjen *et al.*, 2015[16] | Children | Xpert MTB/ RIF | 62% (51-73) | 98% (97-99) | 15 studies with 3640 children |
| Xpert MTB/RIF and Xpert MTB/ RIF ultra assays for active TB and rifampicin resistance in children | Kay 2020[17] | Children | Xpert MTB/ RIF | 64.6% (55.3-72.9) | 99% (98.1-99.5) | Studies with 68,544 participants |
| Xpert MTB/RIF Ultra improved the diagnosis of pauci-bacillary TB: A prospective cohort study | Wang *et al.*, 2019[18] | Adults | Xpert MTB/ RIF | 65% (61-69) | 99% (98-99) | 11 studies with 3801 patients |
| ICMR study: Operational feasibility and performance of TrueNat MTB RIF assays in field settings under the Revised National TB Control Program | Tripathi *et al.*, 2019[19] | Adults | TrueNat | 84.1% | NA | 10,878 adults |
| | | | Xpert MTB | 81.0% | | |
| Evaluation of the Indian TrueNat micro-RT-PCR device with GeneXpert for case detection of pulmonary TB | Nikam *et al.*, 2014[11] | Adults | TrueNat | 99% | NA | 247 |
| | | | Xpert MTB | 100% | | |
| Rapid diagnosis of mycobacterium TB with TrueNat MTB: A near-care approach | Nikam *et al.*, 2014[11] | Adults | TrueNat | 91.1% | | 266 |
| | | | Xpert MTB | 90.58% | | |

WHO: World Health Organization, TB: Tuberculosis, ICMR: Indian Council of Medical Research, RT-PCR: Real-time polymerase chain reaction, NA: Not available

The evidence for unit costs incurred by the government for different diagnostic tools used in the National Tuberculosis Elimination Program was gathered from studies with Indian context.[20] The values of both cost and effectiveness used in cost-effectiveness analysis were approximated to value of 2021 US dollars, and an analysis threshold of 50% of the 2021 *gross domestic product* (GDP) per capita would be considered for decision-making.

### Quality-adjusted life years

The quality-adjusted life year (QALY) is a measure of the value of health outcomes.[21] The next step was calculating QALYs gained through each additional true-positive case detected. Untreated HIV-negative tuberculosis left to its natural history either gets self-cured or leads to death in 3 years.[22] Hence, assuming 6 months to be the average duration within which a tuberculosis is detected using either TrueNat or GeneXpert, a person with tuberculosis spends 6 months with the disease and, if treated promptly on detection, can save the rest of 2.5 years with disease or life itself. The average utility value in tuberculosis patients is 0.74 in the intensive phase of treatment and 0.87 in the continuous phase of treatment.[23] However, for this study, the utility score of continuous phase was considered as it is of longer duration.

Therefore, QALYs of children on tuberculosis treatment are: 0.805 × 3 = 2.415 years. = 2.61

### Model characteristics

A decision analytical model was utilized to simulate a cohort of 1,00,000 children of 0–14 years of age reporting to public health facilities in India with symptoms and signs indicative of TB and requiring diagnostic testing for TB. They undergo a TB diagnostic protocol per national guidelines. The model in Figure 1 follows two scenarios. As TrueNat has higher sensitivity, fewer cases go undetected (sensitivity = 69%) is observed. The cases detected lead to timely diagnosis and treatment reducing mortality and morbidity due to the disease. The cost-effectiveness is reported in terms of life years gained by the cohort, QALYs gained by the cohort, mortality due to nonadherence or treatment failure, and overall treatment cost of the cohort. As per the second scenario, the cases will be diagnosed by GeneXpert. Sensitivity being less than TrueNat, a smaller number of cases will be diagnosed and thus there will be more delay in treatment. The cost-effectiveness of both the scenarios will be evaluated in the form of ICER. This is the ratio of difference in the cost of both diagnostic tests to the difference in effectiveness of both the diagnostic tests. The input parameters are mentioned in Table 2.

### Unit cost calculation

The costs were enumerated from the Rupert *et al.*, 2017, study which uses bottom-up micro-costing technique to calculate the costs of diagnostic strategies from a health system perspective.[20,24] The costs per test for GeneXpert and TrueNat were calculated to be $12.63 and $13.20, respectively, which included costs of labor, overhead and building space, reagents (e.g., cartridges for Xpert and chips for TrueNat), and equipment. It was
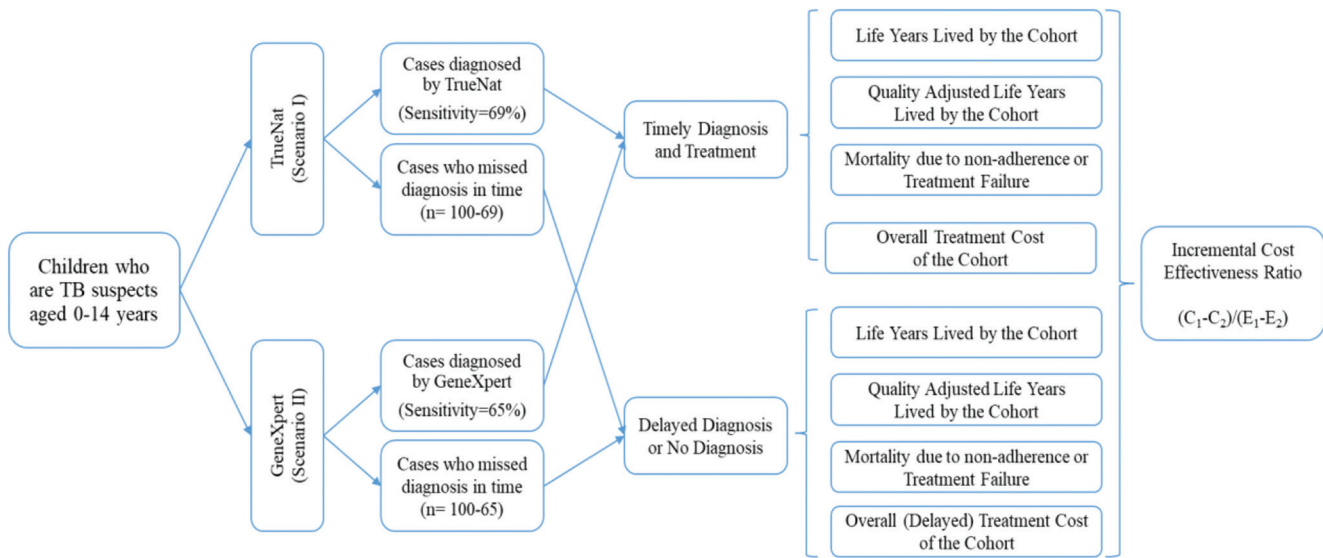
**Figure 1: Conceptual framework of the economic evaluation**

### Table 2: Model parameters

| Input parameter | Value |
|---|---|
| Total estimated pediatric TB cases in India | 340,000 |
| Sensitivity of GeneXpert | 0.646 |
| Sensitivity of TrueNat | 0.685 |
| Cost per GeneXpert test ($) | 12.74 |
| Cost per TrueNat test ($) | 13.3 |
| Cost of TB treatment ($) | 227 |
| Average life expectancy in India | 69 |
| Average age of pediatric TB onset in India | 6.5 |
| Mortality in diagnosed and on treatment TB patients | 0.026 |
| Mortality in undiagnosed TB patients on no/ unspecific/delayed treatment | 0.219 |
| Duration of disease (years) | 3 |
| QoL of TB patients | 0.805 |

TB: Tuberculosis, QoL: Quality of life

assumed that overhead, building space, and labor-related costs for TrueNat strategies would be similar to those of GeneXpert.[20]

According to Vassall *et al*., 2011, cost-effectiveness study, the cost of treatment category 1 was found to be 227 USD and for treatment category 2, 352 USD.[25] Extracted costs/unit costs from different studies were inflated to 2020 USD using GDP deflator. Future costs and effectiveness were discounted by 3% annually, with sensitivity analysis for a range from 0% to 7%.[26] The values of both cost and effectiveness used in cost-effectiveness analysis were approximated to value of 2021 US dollars.[27] The values in 2017 US $ were first converted to Indian rupees (INR) as per the average annual exchange rate, and then, the percent change in inflation was applied to get the value in 2021 INR which was further converted to 2021 US dollars. The costs are enumerated in Table 3.

## Results

As given in Table 4, TrueNat was found to more cost-effective as compared to GeneXpert in the diagnosis of pediatric tuberculosis cases with more life years gained, and around 2559 child deaths averted with a cost of $1250 per death averted. 13,260 additional cases can be detected with TrueNat with an incremental cost of $14.36 per additional case detected. ICER per life year gained will be $20.01. GeneXpert having higher maintenance cost, requires continuous power supply, air-conditioning and connectivity through a computer system, Eventually adding up to maintenance, electricity, and IT manpower costs leading to increased cost and budget eventually.

## Discussion

Every year, millions of children with TB miss out on quality care, usually because their infection remains undiagnosed. The WHO endorsement of TrueNat POC will enable molecular diagnosis in less time and in efficient way.[13] The ICER of TrueNat was found to be $20.01 per QALY gained. One QALY is equal to 1 year of life spent in full health. This is much <50% threshold of per capita GDP of India and can be considered for implementation after budget analysis. Timely diagnosis will ensure more cases being referred for treatment and will eventually lead to higher costs for the health-care system. However, the benefits of tuberculosis treatment are huge in this population segment. There will be more life years saved and more disability-adjusted life years averted. TrueNat MTB is the first TB test with capacity comparable to the 4-module GeneXpert with operational features suited for primary health-care level. If human resource is properly trained and equipped at this level,

**Table 3: Cost of tests and treatment**

| Parameter | GeneXpert | TrueNat |
|---|---|---|
| Sensitivity (%) | 64.6 | 68.5 |
| Cost per test ($) | 12.74 | 13.3 |
| Cost per treatment drug-sensitive TB ($) | 227 | 227 |
| Total unit cost per diagnosis and treatment | 239.74 | 240.3 |
| Total projected cases that can be detected (2019) | 1.5 lakh | 1.62 lakh |
| Additional number of projected cases that can be detected | | 12,000 |
| Total cost due to projected cases that can be detected and treated ($) | 35,961,000 | 38,928,600 |
| Additional cost due to additional projected cases that can be detected and treated ($) | | 2,967,600 |
| Additional deaths that can be averted | | 2305 |
| Total QALYs during duration of disease | 3,62,250 | 3,91,230 |
| Additional QALYs gained due to additional number of cases detected | | 28,980 |
| ICER (cost ($))/QALYs gained | | 102.4 |

QALY: Quality-adjusted life-year, ICER: Incremental cost-effectiveness ratio, TB: Tuberculosis

**Table 4: Results and conclusion**

| Results of TrueNat over GeneXpert | Value |
|---|---|
| Additional number of cases that can be detected | 13,260 |
| Incremental cost ($) | 3,200,420 |
| Incremental cost per additional case detected ($) | 14.36 |
| Deaths averted | 2559 |
| ICER per death averted | 1250.56 |
| Life years gained | 159,949 |
| ICER per life year gained | 20.01 |
| QALYs gained | 166,007 |
| ICER per QALY gained | 19.28 |
| ICER per life year gained | 20.01 |

QALY: Quality-adjusted life-year, ICER: Incremental cost-effectiveness ratio

it can add by decreasing cost of transport of samples as well as the referral of patients to higher facilities. Early diagnosis will lead to better outcomes with improved linkage to care as compared to GeneXpert. TrueNat will definitely help in reducing morbidity and mortality related to TB in children, especially in low- and middle-income countries. We recommend its use as it is in congruence with Indian health-care settings. Budgetary analysis needs to be done to implement this strategy on a wider scale.

## Conclusion

TrueNat MTB is the first TB test with capacity comparable to the 4-module GeneXpert with operational features suited for primary health-care level. Early diagnosis will lead to better outcomes with improved linkage to care as compared to Xpert. TrueNat proved to be beneficial and cost-effective as compared to GeneXpert MTB being used in case of children. We recommend the use of TrueNat diagnostic test in India as it is in congruence with Indian health-care settings.

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### Conflicts of interest

There are no conflicts of interest.

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# Appendix 1

**molbio**

To
Dr.Ragini Bhatia
PGIMER,Chandigarh

Date 14.09.2021

**Subject:Quotation of Truenat MTB,MTB Plus and MTB Rif -Dx**

| Sr.No. | Cat.No. | Product Description | Pack Size (Test ) | Price(Rs) | Cost per Test (Rs) |
|---|---|---|---|---|---|
| 1. | 601030050 | Truenat MTB<br>Limit of Detection -100cfu/ml | 50 | 31250 | 625 |
| 2. | 601130050 | Truenat MTB Plus<br>Limit of Detection -29 cfu/ml | 50 | 37950 | 759 |
| 3. | 601210020 | Truenat MTB Rif-Dx<br>Only for MTB /MTB Plus Positive samples | 20 | 10720 | 536 |

**Term and Conditions :**
1. **Delivery** :2-3 weeks after confirm Order through Our authorized Distributor
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3. **Validity of the Kits** : Two Years from the date of Manufacturing
4. **Payment** :After Delivery .

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