

Rapid Health Technology Assessment for incorporating TrueNat as a diagnostic tool for tuberculosis under RNTCP in India

SUMMARY

India has world's highest tuberculosis (TB) and multi-drug resistant tuberculosis (MDR-TB) burden with the incidence rate of approximately 2.8 million annually[i]. Due to the poor diagnostics tool at the health care facilities with low sensitivity and low linkage-to-care rates, over 25% of patients who prefer public sector are neither diagnosed nor started on treatment[ii]. Hence there is an urgent need for an affordable and high-sensitivity screening or diagnostic test which could be installed in peripheral health facilities with minimal infrastructure and training.

Based on preliminary search of literature and available evidences, this study aims to compare clinical effectiveness of smear microscopy, GeneXpert and TrueNat with reference to culture as gold standard. We also analysed the cost-effectiveness study conducted by Lee et. al., 2019. The study also looked in to operational feasibility and challenges of implementing TrueNat under RNTCP.

If used as a point-of-care (POC) test within primary healthcare facilities, Truenat could increase treatment initiation by reducing turnaround time for test results and decreasing the need for laboratory referrals.

In India, CB NAAT has been used for diagnosis of TB under RNTCP program. Recently, the Andhra Pradesh State Government adopted TrueNat for TB diagnosis at various health levels like CHCs, PHCs and DMCs. A total of 225 TrueNat Duo modules have been installed so far in the state. Out of these, 200 have been installed at CHC level and 25 at PHC level.

POLICY BRIEF

POLICY RECOMMENDATIONS

- TrueNat is more cost-effective and feasible option for peripheral healthcare facilities (due to portability and requirement of less sophisticated infrastructure).
- GeneXpert is almost equally good (in terms of sensitivity as well as cost) and cost-effective as compared to other diagnostic tools like Smear Microscopy and can be used at District level and above due to its ease of use and less chances of error (due to automation) results.



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Apart from published literature on these devices interviews with program experts were also conducted. These experts had been working with TrueNat and had experience of working with CB NAAT as well. This exercise was done in order to understand operational feasibility of the TrueNat system.

Table 1: Summary table of studies conducted on TrueNat

Study Title	Author/year	Place of study	Sample size	Type of study	Data reported (Sensitivity/ specificity)
ICMR Study: Operational feasibility and performance of TrueNat MTB RIF assays in field settings under the Revised National Tuberculosis Control Program	Tripathi et al, 2019	India	10878	Sensitivity/ Specificity analysis	TrueNat: 84.1% (Sensitivity) GeneXpert: 81.0% (Sensitivity)
Rapid, point-of-care diagnosis of tuberculosis with novel TrueNat assay: Cost-effectiveness analysis for India's public sector	Lee et al, 2019	Indian setting	-	Cost-effectiveness analysis	-
Evaluation of the Indian TrueNat micro RT-PCR device with GeneXpert for case detection of pulmonary tuberculosis	Nikam et al,2014	Mumbai	247	Observational	TrueNat: 99% (Sensitivity) GeneXpert: 100% (Sensitivity)
Rapid Diagnosis of Mycobacterium tuberculosis with TrueNat MTB: A Near-Care Approach	Nikam et al,2013	Mumbai	266	Validation	TrueNat: 91.1% & 100% GeneXpert: 90.58% & 91.43%

CONCLUSION

- Truenat as compared to GeneXpert is very cost-effective in Indian settings with ICER: INR 8400 per Life Year saved (against threshold of per capita GDP 1,20,000). Sensitivity and Specificity of both equipment are comparable but TrueNat is more sensitive (Difference=3.1%).
- As per Lee et al., 2019 deploying Truenat POC instead of GeneXpert increased 5-year expenditures by \$270 million, due mostly to treatment costs. Cost per test for both is also comparable but GeneXpert is cheaper. (Difference = Rs. 86 per test).
- [Budgetary Impact of TrueNat for RNTCP](#)

1. Capex Model (To Install machine in 1 TU): ANNUAL

COST FOR 1 TU = 10,45,738

ANNUAL COST FOR 2698 TUs = 282 Crores

2. Opex Model

(To Install machine in 1 TU): ANNUAL COST FOR 1 TU = 17,72,833

ANNUAL COST FOR 2698 TUs = 478 Crores

Acknowledgement:

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References:

- 1) World Health Organization. Global tuberculosis report 2017 [Internet]: World Health Organization, Geneva, Switzerland; 2017.
- 2) Subbaraman R, Nathavitharana RR, et al. The tuberculosis cascade of care in India's public sector: a systematic review and meta-analysis. PLoS Med. 2016; 13: e1002149.