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Clinical Cost-Effectiveness Analysis of NAAT Diagnostics for Active TB Diagnosis and Rifampicin Resistance Testing in Public Primary Healthcare in India

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INTRODUCTION

Tuberculosis (TB), including drug-resistant TB, causes significant mortality and morbidity in India.[1,2] India's National TB Elimination Program (NTEP) aims at improving TB diagnosis in public primary health care (PHC) through the "up-front" use of nucleic acid amplification test (NAAT) diagnostics, reducing reliance on less accurate sputum smear microscopy (SSM) and chest x-rays (CXR), and through universal drug-susceptibility testing.[3,4]

Recent advances in the development and manufacturing of NAAT have led to the possibility of low-cost, near-POC NAATs that could substantially improve access, affordability, and uptake of TB diagnostics in primary healthcare settings in high-burden countries. However, the economic value of introducing such low-cost diagnostics into the Indian PHC landscape remains poorly characterized.[5]

OBJECTIVE

We evaluate the clinical cost-effectiveness of three distinct diagnostic strategies that replace the status quo diagnostic strategy (SSM+CXR) with NAAT diagnostics for active pulmonary TB diagnosis and for rifampicin resistance testing in India. Two of these strategies include the use of a prospective, near-POC $2 TB NAAT, representing the frontier of low-cost, molecular TB diagnostics in PHC.

METHODS

We conducted a clinical cost-effectiveness analysis (CEA) of four diagnostic strategies (rifampicin resistance testing only occurs for TB-positive patients):

1) **Status quo:** SSM+CXR for active TB diagnosis and Truenat for rifampicin resistance testing.
2) **Truenat only:** Truenat for active TB diagnosis and for rifampicin resistance testing.
3) **Blended NAAT:** Prospective near-POC $2 TB NAAT ("novel $2 NAAT") for active TB diagnosis and Truenat for rifampicin resistance testing. We specify the novel $2 NAAT based on WHO guidelines.[6]
4) **Novel $2 NAAT only:** Novel $2 NAAT for active TB diagnosis and for rifampicin resistance testing.

The study population is a nationally representative cohort of 20,000 15-year-olds presenting to PHC with presumptive pulmonary TB in India in 2024.

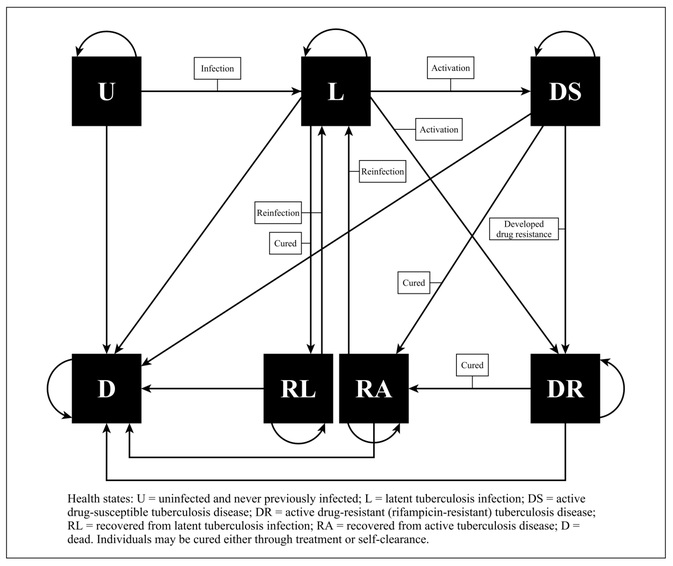
We adopt a national health payer perspective and discount future health and costs at 3% annually.

We use a discrete-time individual-based microsimulation model with a monthly time step to estimate individuals' lifetime health and costs in each diagnostic strategy. In each month, an individual is in one of seven health states: uninfected, latent TB infection, active drug-susceptible TB, active drug-resistant TB, recovered from latent TB, recovered from active TB, or dead (Figure 1).

METHODS (continued)

We use decision trees to model the monthly transition between health states (Figures S1-S5). An individual's path through a decision tree is determined by their health state, their treatment history, and their age.

We use estimated lifetime health and lifetime costs to calculate the incremental cost-effectiveness ratio (ICER) for each diagnostic strategy relative to the status quo. We also calculate net monetary benefits (NMB) relative to the status quo, valuing health gains at 60% of per capita GDP in India in 2024. We perform one-way sensitivity analyses and three scenario analyses to assess our results' robustness.



Health states: U = uninfected and never previously infected; L = latent tuberculosis infection; DS = active drug-susceptible tuberculosis disease; DR = active drug-resistant (rifampicin-resistant) tuberculosis disease; RL = recovered from latent tuberculosis infection; RA = recovered from active tuberculosis disease; D = dead. Individuals may be cured either through treatment or self-clearance.

Figure 1. Model health states and possible transitions.

RESULTS

All three diagnostic intervention strategies economically dominate the status quo, improving health while reducing costs (Table 1, base case). The novel $2 NAAT only diagnostic strategy produces the largest net monetary benefit per cohort member (NMB: $964.63), followed by the blended NAAT diagnostic strategy (NMB: $397.00) and Truenat only diagnostic strategy (NMB: $382.69).

Our finding of positive NMBs for all diagnostic strategies is robust with respect to different model parameterizations (Table 1, scenario analyses). Depending on the scenario, however, the ordering of NMBs can change.

Our finding of positive NMBs for all diagnostic strategies is also robust with respect to changes in individual model parameters (Figure 2).

All three diagnostic intervention strategies increase appropriate treatment and, thus, improve health outcomes across the cohort (Table S1).

Table 1. Base case and scenario analysis results per cohort member. Differences (Δ) in lifetime costs and lifetime DALY losses are taken as the difference from the status quo diagnostic strategy. All DALY losses are due to TB or its sequelae. ED = economically dominant intervention.

Diagnostic Strategy	Expected Lifetime Costs (2024 USD)	Expected Lifetime DALY Losses	Δ Lifetime Costs (2024 USD)	Δ Lifetime DALY Losses	ICER	Net Monetary Benefit (2024 USD)
Base case results						
Status quo	65.76	3.20	NA	NA	NA	NA
Truenat only	55.22	2.98	-10.54	-0.22	ED	382.69
Blended NAAT	49.25	2.98	-16.51	-0.23	ED	397.00
Novel $2 NAAT only	50.23	2.64	-15.53	-0.56	ED	964.63
Scenario analysis: GBD estimates of TB incidence and deaths						
Status quo	64.80	3.27	NA	NA	NA	NA
Truenat only	54.18	3.07	-10.62	-0.20	ED	341.91
Blended NAAT	48.28	3.06	-16.52	-0.20	ED	355.32
Novel $2 NAAT only	49.85	2.71	-14.95	-0.55	ED	948.47
Scenario analysis: Novel $2 NAAT compatible with only sputum samples						
Status quo	65.76	3.20	NA	NA	NA	NA
Truenat only	55.22	2.98	-10.54	-0.22	ED	382.69
Blended NAAT	48.12	3.06	-17.64	-0.14	ED	258.77
Novel $2 NAAT only	48.57	2.78	-17.19	-0.42	ED	729.02
Scenario analysis: Study cohort 39 years old at t=0						
Status quo	72.35	9.47	NA	NA	NA	NA
Truenat only	68.02	8.99	-4.32	-0.48	ED	819.99
Blended NAAT	62.04	9.00	-10.30	-0.47	ED	805.81
Novel $2 NAAT only	66.94	8.06	-5.41	-1.41	ED	2384.55

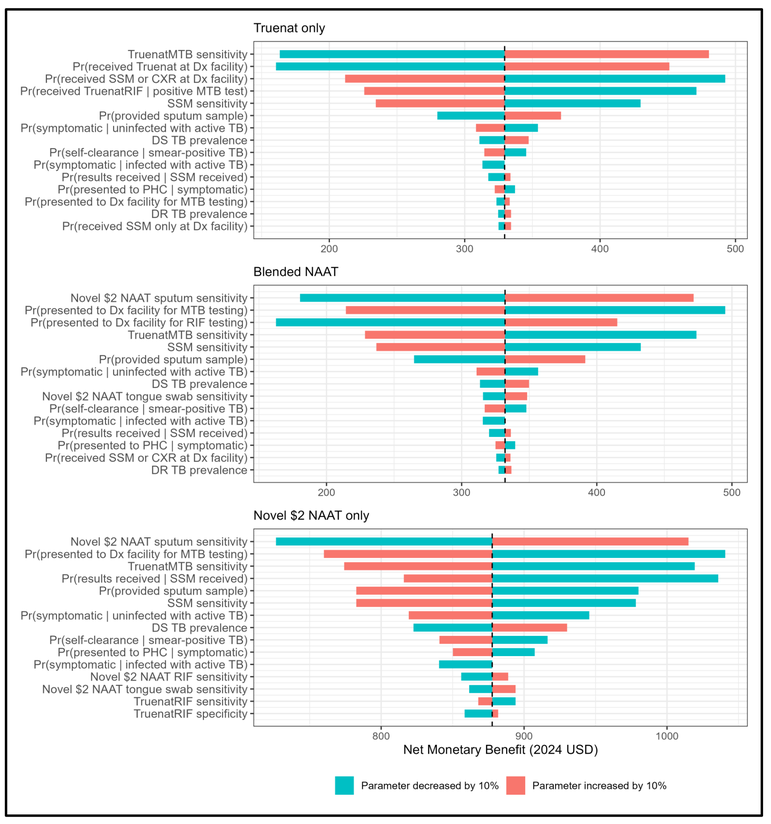


Figure 2. OSA tornado diagrams for the Truenat only, blended NAAT, and novel $2 NAAT only diagnostic strategies. The 15 parameters with the largest effect on NMB in each diagnostic strategy are included.

DISCUSSION

We find that all three of the diagnostic intervention strategies economically dominate the status quo, and that the NMB is largely accounted for by health gains. The NMB of the novel $2 NAAT only strategy is over twice as large as the other two diagnostic strategies. This result suggests that significant economic value is reflect by the novel $2 NAAT's near-POC character, including reduced loss-to-follow-up and increased diagnostic eligibility.

Previous studies have found near-POC NAAT diagnostics to be cost-effective in India,[7] while we find them to be cost-saving over the lifetime horizon due to lower rates of unnecessary treatment and higher rates of appropriate treatment.

Study limitations include: (1) using prospective attributes and specifications of the novel $2 NAAT; (2) excluding transmission effects, HIV coinfection, extrapulmonary TB, other types of drug resistance, health impacts of antibiotic use, and technological or pathogen evolution; (3) adopting a narrow health payer perspective.

CONCLUSIONS

- **Our results suggest that NAAT-based active TB diagnosis and rifampicin resistance testing in public PHC in India produces significant economic value.**
- **This value reflects substantial improvements in patient health and slight reductions in health sector costs.**
- **Our results provide economic evaluation support for India's NTEP goals of wider up-front use of NAAT TB diagnostics.**

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INFORMATION

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