

Advancing tuberculosis diagnosis in India: Transitioning from conceptualization to realization

Dear Editor,

We were highly interested in the recent article by Ahmad *et al.*^[1] titled, “Reasons and Extent of Delay in the Diagnosis of Pulmonary Tuberculosis After the Appearance of Symptoms”. India bears the highest global burden of TB and MDR-TB, accounting for 27% of worldwide cases. Despite reductions in TB cases, timely diagnosis remains challenging, with over 25% of patients undiagnosed in the public health system. Routine sputum smear microscopy under the National TB Elimination Programme is insufficient due to its low sensitivity and inability to detect drug resistance. Culture-based testing, the current gold standard, is limited by long turnaround times.^[2] Cartridge-Based Nucleic Acid Amplification Tests (CB-NAAT), like GeneXpert, provide rapid and accurate results, but TrueNat, developed in India, offers a cost-effective and versatile alternative.^[3] TrueNat requires smaller samples, detects rifampicin resistance, and is suitable for various TB cases.^[4] It also facilitates the decentralization of TB testing by operating without the need for constant power and air conditioning, unlike GeneXpert.^[5] However, the practical application of TrueNat in certain contexts may diverge from these promising findings.

During a recent visit to a government tuberculosis (TB) hospital, it became evident that there was a shortage of adequately trained staff to conduct TrueNat testing. The personnel reported difficulties with various aspects of TrueNat operation, including setup, installation, daily startup, handling, portability, patient data entry and editing, and equipment cleaning. The introduction of TrueNat has led to issues of inadequate manpower and increased workload, primarily due to the redistribution of lab technicians from other programmes who lacked sufficient training in handling TrueNat. During the visit, it was observed that some patients initially identified as rifampicin-resistant by TrueNat were subsequently found to be rifampicin-sensitive when tested with CBNAAT, a finding further confirmed by Line Probe Assay. Unlike CBNAAT, TrueNat requires two separate cartridges for detecting Mycobacterium tuberculosis and rifampicin resistance, resulting in a longer

total processing time of approximately 2.5 to 3 hours for result generation. TB hospitals have reported higher rates of invalid/error results with TrueNat compared to CBNAAT, attributed to the precise handling of samples and the extensive training required for TrueNat operation. Additionally, TrueNat can only process one sample at a time, whereas CBNAAT can handle up to 16 samples simultaneously. Moreover, clear biosafety cabins are essential for the proper separation of patients and collected samples, especially since TrueNat systems are deployed at District Microscopy Centres (DMCs).

These challenges underscore the need for comprehensive training programs and robust quality control measures to ensure the accuracy and efficiency of TB diagnostics, ultimately improving patient outcomes.

In conclusion, addressing the operational challenges encountered during the implementation of TrueNat in India is crucial for optimizing its effectiveness in TB diagnosis, especially as India aims to eliminate TB by 2025. Comprehensive training programs for healthcare personnel, along with stringent quality control measures, are essential to ensure accurate and reliable results. By overcoming these obstacles, India can fully harness the potential of TrueNat to strengthen its TB control efforts and improve health outcomes for its population.

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Conflicts of interest

There are no conflicts of interest.

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