Decentralised patient-centred TB diagnostics: key considerations for India

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WHO recommendations on near point-of-care nucleic acid amplification tests (NPOC-NAATs) using tongue swabs and sputum pooling and testing represent a transformative shift in Tuberculosis (TB) diagnosis.[1] India has made great progress in expanding molecular diagnostics (NAAT) capacity from 121 sites in 2015 to nearly 6000 sites by 2025. Considering the health-seeking behaviour of the population, where a large proportion of TB patients initially seek care in informal or primary care settings, these strategies could improve diagnosis by ensuring same-day diagnosis and reducing pre-treatment loss to follow-up.[2,3]

Unlike conventional molecular platforms, NPOC-NAATs are designed for use at peripheral health facilities with lesser infrastructure requirements. This decentralisation is critical for reducing diagnostic delays, which often result from specimen transport, test batching, and multiple patient visits.[3] Furthermore, the relatively lower cost and operational simplicity of NPOC-NAATs enhance their scalability within the public health system. Their deployment could be prioritised in primary health care facilities, underserved geographies, and high-risk populations, where access barriers are most pronounced.

In addition to access barriers, there are several limitations in the current symptom-based and sputum-dependent approaches for diagnosing TB. The National TB Prevalence Survey (2019–2021) for India indicates that nearly 40% of TB patients are asymptomatic.[4] Sputum collection has long been a limiting factor in TB diagnosis, particularly among children and individuals with early or asymptomatic disease who are unable to produce an adequate quality sample. The use of tongue swabs as an alternative to sputum and their integration into NPOC-NAATs represent a patient-centred and inclusive diagnostic approach. Tongue swabs are simple to collect, require minimal training, and are generally well accepted by patients. This makes them particularly suitable for use in community settings, mass screening campaigns, and among populations where sputum collection is challenging or stigmatised. Additionally, it carries a lower risk of aerosol generation, which has implications for infection prevention and control in both facility and field settings.

While NPOC tests offer promising avenues, their limitations must also be considered. There are two major requirements for the NPOC to be adopted in microscopy centres and PHCs in India: first, an assay with a minimum number of steps; and second, a wide storage temperature range and a long shelf life. These aspects need to be ascertained. Moreover, current evidence indicates that the yield of TB testing using tongue swabs is equivalent to that of sputum tests in symptomatic individuals attending health facilities[5]; further research is needed to conclusively demonstrate similar effectiveness in community settings, among individuals with low bacillary load, paediatric populations, and those with asymptomatic TB.[6] Furthermore, in Indian settings, the impact of eating, drinking, brushing teeth, and tobacco and betelnut chewing on tongue swab performance may also need to be systematically evaluated to provide optimal operational guidance for sample collection and testing.

Another efficiency-oriented strategy to TB diagnosis is sputum pooling, which is particularly relevant for India, where nearly 25 million people require TB NAAT tests annually. By combining samples from multiple individuals into a single test, laboratories can screen more people while conserving resources such as cartridges, reagents, and technician time. Sputum pooling is most effective in settings with low expected positivity rates, such as community screening campaigns, workplace screenings, and targeted active case finding in lower-prevalence populations, substantially reducing costs and improving turnaround times, thereby allowing laboratories to focus resources on confirmatory testing of positive pools.

The applicability of sputum pooling in India also requires careful contextualisation. In terms of procedure, it may require additional consumables (Falcon tubes and glass beads) at the testing laboratory. Given the country's heterogeneous TB epidemiology, pooling may not be cost-effective or optimal for diagnosis in high-prevalence settings. Additionally, there is a risk of reduced sensitivity, particularly for samples with low bacillary load, which could lead to missed diagnoses.

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Comment

As such, individual testing should continue to be prioritised for high-risk groups, including people living with HIV, children, and those with presumptive drug-resistant TB.

Overall, the successful adoption of these new WHO recommendations for decentralised TB diagnosis in India will depend on thoughtful integration into the existing health system and diagnostic algorithms, as the above tests are better suited for screening and require referral to the relevant laboratory for confirmation and resistance testing. Key considerations include ensuring quality assurance for new testing modalities, training frontline health workers in sample collection and test use and strengthening supply chains to support decentralised deployment. Importantly, these innovations should not be viewed in isolation but as complementary components of a broader diagnostic ecosystem. Combining decentralised testing (NPOC-NAATs), non-sputum-based approaches (tongue swabs), and efficiency-enhancing strategies (pooling) can create a more resilient and responsive system that reaches underserved populations. However, strategic, selective implementation guided by local epidemiology and operational feasibility will be key to addressing the country's long-standing early-detection gap.

Contributors

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Declaration of interests

We declare no competing interests.

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