Editorial:
CBNAAT versus conventional sputum microscopy: Are we really prepared for this diagnostic strategy shift?
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It is no secret that India is in the midst of a real public health emergency, as far as Tuberculosis is concerned. We are world number one in Incidence of TB cases (28 lakhs/ annum, 27% of global), TB related deaths (4.8 lakhs/ annum, 37% of global), Drug-resistant TB (5.6 lakhs/ annum, 25% of global) and gap in identification of new cases (10 lakhs/ annum, 26% of global and 36% of estimated cases within India. We also come a close second in terms of HIV associated TB and to top it all, the high levels of malnutrition, diabetes, smoking, alcohol use, and high latent TB infection (23%) increases our life-time risk of TB to 15%.1

That the developed world is not oblivious of this situation is evidenced by the fact that countries like US, UK, Canada and Australia insist on ‘not suffering from TB’ certificate from Indians before accepting our visa application2. In the backdrop of this gloomy scenario it is encouraging to note that our political leadership has aligned itself with RNTCP the national programme for TB control and vowed to eliminate TB from India by 2025, five years ahead of the SDG target and ten years earlier than the global end TB target3,4. The nation proposes to win this war against TB through the “detect-treat-prevent-build” strategy espoused in RNTCP’s National Strategic Plan (NSP) 2017-2025.5

A prominent objective of NSP’s strategy is to ‘reduce TB incidence by 80% from 211 to 43 per lakh population’ and the greatest challenge before us is to detect the 28 lakhs new TB cases occurring annually in this country including the ten lakh who are presently being missed out. NSP proposes the cartridge based nucleic acid amplification test (CBNAAT) as the high efficiency diagnostic tool for early and accurate diagnosis and simultaneous detection of Rifampicin resistance.6,7 With all districts now having been provided with CBNAAT machines it is apparent that our case detection strategy is transitioning from ‘sputum microscopy for all’ to a ‘CBNAAT for All’ approach.

While this change in diagnostic strategy appears to have scientific as well as WHO’s backing, but whether we are ready for this mass transition, and whether it would help in achieving TB elimination needs to be scrutinized. Some authors/researchers have already expressed their concerns/reservations regarding some specific aspects of the strategy. Prasad et al, for example, note that eliminating TB from India by 2025 may not just be a herculean task, but rather a distant dream in the absence of effective surveillance measures and substantial increase in budget.8 Similarly, Qin et al opines that TB can’t probably be eliminated from India even by 2050 since case finding has plateaued and incidence is declining very slowly.9 Sharath et al note that India’s new TB diagnostic algorithm is far from reality.10 Desai et al caution that RNTCP must adhere to sputum microscopy even if we have access to newer diagnostics.11
A search of the literature shows that there is hardly any study documenting the practical feasibility of transition from conventional microscopy to CBNAAT in Indian settings nor its cost-effectiveness. Till the time that such studies become available, we academicians feel duty bound to exhort our budding public health managers and co-professionals to scrutinize, at least theoretically, whether such a transition is feasible and cost-effective given our ground realities. This critical scrutiny becomes even more important because of the hype created by CBNAAT in the media and the resultant impression among health professionals and the lay public about it being the panacea for TB detection.

The feasibility of employing the sophisticated CBNAAT machines (currently placed at district headquarters only) as the primary diagnostic tool of TB has first of all, to be weighed against the ground level realities that exist in most of our districts. In this context it is worth mentioning that these machines require a continuous and stable electric supply, ambient temperatures below 30°C, and a lap-top/PC with internet connection. Needless to say, they require gentle, careful and expert handling and mandatory annual recalibration. The cartridges also demand large air-conditioned space for storage, critical inventory control to minimize stock-outs/wastage and theft-proofing in view of their cost.

Further, in order to operationalize the CBNAAT for all approach, districts should have the capacity to conduct at least 42,000 CBNAAT tests in a year (assuming 20 lakh populations, TB incidence of 210/lakh and screening efficiency for case detection being 1:10). But the 4-module CBNAAT machines currently available at our districts can handle approximately just 10% of the expected load, because each machine can handle just 16-20 samples per day. It means that many more CBNAAT machines would be required in each district if we are seriously desirous of a change in the diagnostic strategy.

The second aspect of scrutiny is the cost. The subsidized cost of each CBNAAT machine is about Rs. 5 lakh though the real cost is approximately Rs. 17 lakhs and the subsidized cost of each test cartridge is about US$ 10/- (actually US$ 17/). Even if we take into consideration just the discounted costs, the unit cost per CBNAAT test is very high being about Rs. 5000/-. If RNTCP were to perform just 20% of its ‘presumptive screening’ (~ 80 lakh) through CBNAAT, that alone would entail Rs. 632 crores annually (Rs. 560 crore would be for cartridges alone) which is against our average annual allocation of Rs. 640 crores per year (three year average of 2014-15, 15-16 and 16-17) for the entire gamut of functions of RNTCP.

A third aspect of scrutiny is also warranted - the spin-effect that CBNAAT may have on our sputum microscopy capability. The hype created in media as CBNAAT being the panacea for TB detection and the impression it has already created on the minds of young health professionals and laity, is likely to promote widespread (and possibly injudicious) use of CBNAAT within and outside of RNTCP. Widespread use of CBNAAT has the potential to throw our existing case detection mechanisms built up within the ambit of primary health care, using locally available resources and cost effective technology, into disarray. Remote tribal, rural, and difficult to reach areas would be the worst affected and sometimes an entire district may go off the case detection map especially whenever the machines are out-of-order.
Through this editorial, we call upon the scientific community, within and outside of RNTCP, to take up operational research on feasibility and cost-effectiveness of transitioning from conventional microscopy to CBNAAT, and implore upon our programme managers and co-professionals to weigh carefully the pros and cons. We also simultaneously wish to impress upon our think-tanks that TB case finding is undoubtedly a human resource-intensive job and that there aren’t really any shortcuts other than having a vibrant and functioning universal health care and this has been stated unequivocally in the 2015 Joint Monitoring Mission Report for TB and also in the 2017 Annual Status Report of RNTCP.7,18

Till such time that a clear cut verdict emerges, it might be prudent to side with a former technical head of RNTCP according to whom “CBNAAT cannot be used as a technique for routine testing and that sputum testing and solid culture remains the golden standard for Indian conditions”.19 Such a programmatic decision is also in line with WHO’s earlier recommendation to use CBNAAT as the ‘initial diagnostic test’ for Drug-resistant TB, HIV associated TB, Extra-pulmonary TB and TB in children and the current WHO rider to use it as the initial diagnostic test “subject to resource implications”.20, 21

Whether India becomes TB-free and whether an aspiring super-power is able to retain the confidence of the global community in her health stewardship depends greatly on the future course that RNTCP and the nation takes in this respect at this critical juncture before TB elimination.

References


