External factors affecting tb in India

Dr. Vijay Kumar Yadav

Department of Zoology
B. N. Mandal University

***Abstract*: In spite of far-reaching policy interventions and a national programme that achieved full geographical coverage nearly a year ago, tuberculosis (TB) continues to be one of India's biggest public health challenges. While we continue to evolve newer strategies to ensure more effective TB prevention and control, at the level of care delivery and adherence to treatment regimes, it is important to recognize the need for innovation in TB diagnostics and treatment. Immunization against TB uses a vaccine that belongs to the last century. With the world taking many strides forward on preventive and treatment interventions for a multitude of diseases, it is time that similar innovations for TB prevention and control are ideated on a priority basis.**

***Keywords*: tuberculosis, TB prevention, TB diagnostics, vaccine**

Introduction

Tuberculosis (TB) is caused by bacteria (Mycobacterium tuberculosis) that most often affect the lungs. Tuberculosis is curable and preventable.
TB is spread from person to person through the air. When people with lung TB cough, sneeze or spit, they propel the TB germs into the air. A person needs to inhale only a few of these germs to become infected.
About one-quarter of the world's population has a TB infection, which means people have been infected by TB bacteria but are not (yet) ill with the disease and cannot transmit it.
People infected with TB bacteria have a 5–15% lifetime risk of falling ill with TB. Those with compromised immune systems, such as people living with HIV, malnutrition or diabetes, or people who use tobacco, have a higher risk of falling ill.
When a person develops active TB disease, the symptoms (such as cough, fever, night sweats, or weight loss) may be mild for many months. This can lead to delays in seeking care, and results in transmission of the bacteria to others. People with active TB can infect 5–15 other people through close contact over the course of a year. Without proper treatment, 45% of HIV-negative people with TB on average and nearly all HIV-positive people with TB will die.

TB in India

The scale of the problem TB poses to India is understood by the numbers themselves. With over one-fourth of all new infections worldwide and two deaths occurring every three minutes from TB, [2] the disease poses an alarming threat to India's public health. These numbers persist in spite of the government's Revised National TB Control Programme (RNTCP), which was launched in 1997 and achieved full geographical coverage in 2006. [3] They persist in spite of far-reaching policy interventions in India's TB landscape, namely a nationwide ban on blood serology tests for TB diagnosis in 2012 and the declaration of TB as a notified disease in the same year.

The high incidence of this airborne, infectious disease in India is fuelled by diverse factors, such as undernutrition, lack of awareness and low risk perception. The problem is compounded by the increasing incidence of drug-resistant TB strains, which occur in the first place due to incorrect diagnosis, improper prescriptions and lack of treatment adherence. The regular strain of TB is treated by the RNTCP using the Directly Observed Treatment, Short-course (DOTS) strategy, which involves medication administered to the patient over a minimum duration of six months. Drug-resistant TB strains such as multidrug-resistant TB (MDR-TB) require a minimum duration of 18-24 months to treat, which involves exponentially expensive medication with a lower rate of survival. Untreated MDR-TB patients become carriers of the disease, further complicating an already complex public health challenge.

While the campaign against TB in India has grown considerably in recent years, expanding the reach of critical interventions to a large section of the population, it has been lacking in terms of innovation. There is a clear need to revolutionise TB care in India, not only at the level of delivery of existing interventions and services, but also in terms of research, development and introduction of new anti-TB drugs and diagnostics.

India's Medical Innovation Potential

India has risen to worldwide recognition as a hub of path-breaking, cost-effective innovation. Our space programme is the flag-bearer of Indian innovation throughout the world, most recently sending a spacecraft to Mars on a budget equivalent to a Hollywood science fiction movie. This strength of competitively-priced, cutting-edge technology is by no means restricted to the space programme. India's successes in areas such as information technology and mobile telephony are well documented. The country has also made large contributions in the area of generic drugs and vaccines, being the largest producer of both of these commodities in

the world. We do not, therefore, lack either the resources or the technical expertise to successfully overcome an infectious disease such as TB.

India has the dual advantage of a strong, growing economy and a large talent pool. This provides great potential for India to contribute to what is called as the 'more (value) for less (cost) for more (people)' or MLM innovation, especially in the area of healthcare technologies and delivery innovations.

Possessing the advantages that we do, we have an ideal opportunity to encourage new ways of looking at TB-causing microbes, utilizing the talent we have to develop all-new vaccines and diagnostics that can revolutionise the way we diagnose and treat TB. As the bearer of the world's largest TB burden, it falls on India to participate most actively in research and development. A more supportive environment to conduct trials in India will also be extremely helpful in expediting the development of newer, more effective methods to combat the disease.

Tuberculosis in India – Focus Areas for Innovation

As mentioned before, the RNTCP provides free treatment to notified TB patients through the DOTS strategy, using four first-line drugs over a six month regime. Even though the programme has successfully cured over 85% of the cases detected by it, [4] it is clear that much more needs to be done. The RNTCP has provided the infrastructure through which the latest innovations in TB prevention and control, once developed, can be dispensed to all patients.

In order to successfully implement its vision of providing universal access to quality diagnosis and treatment for all TB suspects in India, the RNTCP has developed an innovative strategy termed the National Strategic Plan (NSP) (2012-2017). The NSP outlines the framework through which the RNTCP can take India closer to the long-term goal of TB eradication over a period of five years. The NSP also takes cognizance of the importance of innovations in the Indian TB control landscape. Some areas for innovation include:

Operations research: This aspect of the NSP focuses on specific, targeted research to evaluate the efficacy of prevalent diagnostic and treatment strategies, and to evaluate the steps necessary for their improvement. This includes the development of diagnostic tests that are faster, more accurate and simultaneously capable of detecting drug resistance. It also includes targeted research to determine the comparative efficacy of daily and intermittent treatment regimes.

Innovative financing: Here, the NSP talks about the need to provide financial assistance to patients and suspects in the form of insurance, pre-paid treatment and diagnostic schemes and other market-based initiatives. It also talks about the need to engage with public-private interface agencies in a results-oriented system of reimbursement.

Information and communication technology: The RNTCP took a step forward in modernising its adherence monitoring and case notification procedure by launching the portal Nikshay in 2012. Further steps to expand the reach of Nikshay can include the development of more user-friendly interfaces through mobile applications, and the encouragement of doctors across the private sector to notify detected cases of TB.

Innovations under Development

An all-round strategy of innovative interventions for TB prevention and control will be incomplete without the development of newer, more effective drugs and vaccines as well as faster, more accurate diagnostic tests. The following is an outline of the anti-TB vaccine landscape in India at present:

TB vaccines: As of today, there is one vaccine, Bacille Calmette-Guérin (BCG), being used to prevent TB in infants. But while BCG is the most widely used vaccine in the world, it has not successfully eliminated the disease due to its limited efficacy. There is also the fact that BCG is a vaccine developed in the early years of the previous century, and given the pace at which our public health challenges continue to evolve, it is high time that a new vaccine is developed. Research and development for new vaccines would have the biggest impact on the TB epidemic, and remains the cornerstone to reaching global elimination within the coming decades. [5]

Diagnostics: Currently, smear microscopy and mycobacterial culture are the most widely used diagnostic tests, but microscopy, though relatively fast, is inaccurate—missing over half of cases. [6, 7] While culture is accurate, it is slow, taking from two to eight weeks to produce a definitive result. These tests are simply not accurate and rapid enough for proper diagnosis of TB, particularly in people living with HIV and in children. These diagnostics tests present the risk of causing critical delays in providing timely treatment to TB patients. Early diagnosis of TB is essential to reducing transmission and mortality, which necessitates the development of diagnostic tools that provide accurate results in a fraction of the current prevalent times taken. We must ensure that newer and more efficacious tests are made affordable and accessible to all suspects and patients, especially those who access the private sector for primary care.[8]

New diagnostic technologies: Several new technologies are available and more are being developed for faster and more accurate TB diagnosis. Many of these are World Health Organization-approved tests and are being used by the government. A test such as Xpert MTB/RIF, for example, is currently being offered by the RNTCP in 18 selected public sector facilities free of charge to all patients accessing these facilities. It is an automated TB detection test that reduces the time of diagnosis from several weeks to just two hours. It can also detect TB in patients co-infected with HIV and detects the presence of MDR-TB. The scaling-up of this test has already been successful in countries like Brazil and South Africa, and has shown to increase the number of TB cases diagnosed and treated. Similarly, another test called the GenoType MTBDRplus version 2 can also diagnose MDR-TB directly from smear-positive sputum samples, providing results in just five hours.[9] This test is also endorsed by the World Health Organizaion and widely used in many high MDR-TB prevalence countries.

However, these tests, developed abroad, remain largely inaccessible to private sector patients because of their high costs both to laboratories and patients. The introduction of innovations for TB prevention and control can only be successful if they are offered at prices affordable not only to patients, but also to private sector diagnostics and treatment providers as well. Again, this points towards the need for indigenous research and development.

Once developed, these indigenous solutions can be demonstrated, adopted and scaled up by the private and public sectors, private organisations, civil society, as well as other donors, all of whom must work together to ensure that these interventions reach and ultimately benefit the end users who need these innovations the most.

Conclusion and future work

At many points during the process of revising the third edition, future research needs were identified. There was often no evidence available to allow the formulation of recommendations for specific issues; sometimes the only available evidence was judged to be of low quality. While seven questions are the focus of this fourth edition, additional questions emerged. Gaps in the evidence and additional questions are summarized below as suggestions for future research. A few may be amenable to systematic reviews, but others will require clinical trials, large cohort studies, epidemiological studies,

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