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Innovation to combat tuberculosis in India

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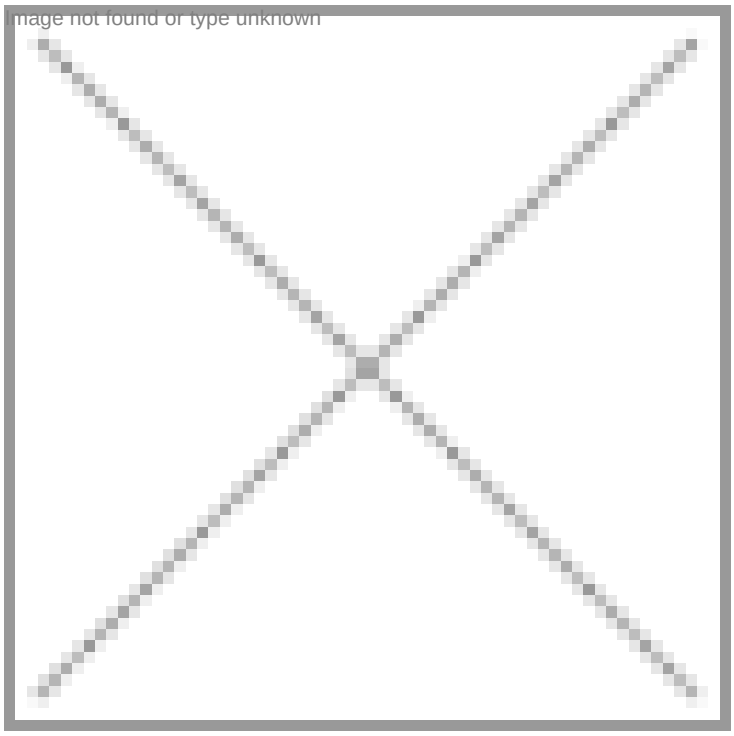

India has the highest number of Tuberculosis (TB) patients with over one-fifth of the world's cases being reported in the country. India has the potential to solve its TB problem with â€œhome-grownâ€? solutions and lead the world in developing innovative TB diagnostics

Image not found or type unknown Shutterstock33406625bacteri The first line of intervention in any disorder is its diagnosis. But what if there is no exact method for diagnozing the condition? Tuberculosis (TB) falls under the category of such diseases.

India adds around two million new cases of TB every year and there is an urgent need for better, cheaper and more efficient methods of diagnosis of the condition. The government has set an ambitious goal of providing universal access to quality diagnosis and treatment to all TB patients and innovative tools and delivery systems are critical for reaching this goal.

A conference on TB diagnostics in India: From importation and imitation to innovation, held at the St John's Research Institute in Bangalore on August 25 and 26, 2011, focused on these concerns and discussed at length, ways to tackle TB and improve its diagnosis. The participants at the event comprised entrepreneurs, scientists and government officials, involved in TB research. Briefing about the objective of the conference, Dr Lucica Ditiu, executive secretary of Stop TB Partnership based in Geneva, Switzerland, said, â€œDiscussion between academicians and the industry will further foster development in TB diagnostics.â€?

Dr K S Sachdeva, chief medical ofiicer, Revised National Tuberculosis Control Programme (RNTCP), Ministry of Health, Government of india, highlighted the achievement of the Directly Observed Treatment, Short Course (DOTS) program in the country. The program has achieved 100 percent accessibility in India with over 1.5 million patients being treated in 2010.

â€œCurrently, the method of detection of TB in the public sector is through smear microscopy using sputum samples, which

in addition to being a 125-year-old method, is both tedious and inaccurate. With over half of the TB cases being sputum negative, there is a need for a more sensitive diagnosic tool. People in the private sector, on the other hand, make use of highly unreliable serological tests,â€? he said.

Alternatives in diagnosis needed

During September 2010, in an unprecedented move, the World Health Organization (WHO) advised against the use of serodiagnostic tests for diagnosis of TB because of its poor performance and adverse impact in case of a misdiagnosis. Despite this, a burgeoning market still exists in India due to lack of regulation and public awareness.

Line Probe assays and liquid culture systems are other methods used in diagnosis of TB, but have problems such as inadequate sensitivity and high costs associated with them.

Sharing his thoughts on the adverse effect of misdiagnosis through serological tests, Mr Christopher Dye, director, office of health information, WHO, said, â€œCurrently, in 17 out of 22 countries, where the enzyme-linked immunosorbent assays (ELISA) tests are available, are inaccurate. Each extra doctor seen in an effort to diagnose the illness adds 12 days to worsen the condition.â€?

He said that the Gene-Xpert system, a new diagnostic tool, was a nucleic acid amplilfication test with a high degree of accuracy and specificty. â€œIt can even detect the multi-drug resistant TB (MDR-TB), which is on the rise due to rampant and unregulated use of TB medication. The rising number of cases of co-infection (HIV-TB) also demand a sophisticated tool, such as Gene-Xpert, for diagnosis.â€?

The Gene-Xpert system has been validated by trials carried out around the world, including India, with the RNTCP acquiring the system at a few centers such as Hinduja Hospital, Mumbai; CMC Vellore and Apollo Hospital on a trial basis. However, it remains to be seen if it can be successfully integrated in the RNTCP programme because of the high costs involved. Currently, the cost of a test using the system can range from 1,197 to 1,474 ($26-$32), which makes scaling up of the test very difficult, thus keeping the field open for any cheap and accurate rapid diagnostic test for detection of TB.

Mr Ajay Bakshi, associate principal, McKinsey, India, estimated the market potential for TB diagnostics to be around $60-70 million in India. However, these figures do not fully account for the private sector and, hence, the potential is thought to be much bigger. Pointing towards the correlation between the GDP of a country and the amount it spends on healthcare, he said the potential for TB diagnostics was only going to grow upwards.

Presenting a perspective from the diagnostic industry, Mr Chandrashekhar Nair, director, Bigtec Labs, Bangalore, said, â€œMoney remains the primary roadblock in the development of new diagnostics. Public grants for pilot manufacturing plants are difficult to get. Also a standard sample panel for testing the diagnostics that can help manufacturers validate the product is not available.â€?

Innovation is key

Dr Virendra Chauhan, director, International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi, said, â€œIn the diagnostic market, developing ways to enhance existing technologies so that they produce cheaper and more accurate products, is innovation. It can also be described as good quality imitation, providing scientists ample scope for development.â€?

In light of the social and economic impact that TB has on the general population, many industry representatives called for more public-private partnerships to fuel research in this area. The industry also sought the government's assurance on product procurement after they develop and if they met the necessary criteria.

Dr Camilla Rodrigues, consultant microbiologist, PD Hinduja National Hospital and Medical Research Center, Mumbai, said that there was an absence of guidelines which can be followed to develop and market innovation. Dr BV Kumar, founder of XCyton Diagnostics, Bangalore, was of the opinion that both the industry and the academia should have a symbiotic relationship and a proper structure was necessary for the collaboration to proceed smoothly.

Call for a regulatory body

The need for a stronger, more accessible regulatory body, such as the National AIDS Control Organization (NACO) for HIV-AIDS, which will evaluate and recommend diagnostic tools for the Indian population was also felt by the entrepreneurs who described the lack of clear regulatory standards as a major stumbling block in getting products validated and manufactured.

Addressing the need for adequate funding for start-ups in developing diagnostics for TB, Dr Peter Small, deputy director, TB, Global Health Program, Bill and Melinda Gates Foundation, who will now be based out of New Delhi, spoke of the various sources through which entrepreneurs can access funds for the same. Representatives from the Wellcome Trust, National

Institute of Health, BIO Ventures for Global Health and United States Agency for International Development were also present who informed the audience about loans and grants available for research in TB diagnostics.

Lack of awareness

One of the key reasons for the apparent apathy towards tuberculosis has been the lack of information about the seriousness of the condition and alarming statistics associated with TB. The role of the media in disseminating this information in an interesting manner was highlighted in the last session of the conference, where eminent media personalities spoke about the challenges in getting the decision makers and the public to understand the gravity of the situation. The importance of using local media to reach the affected people in remote locations was emphasized. Mr Narayanan Suresh, group editor, BioSpectrum, spoke about the disconnect between the policy makers, diagnostic industry and the public and how media can play an important role in bridging that gap.

Dr Madhukar Pai, associate pofessor at McGill University in Montreal and consultant with the Bill & Melinda Gates Foundaton, pointed out that â€œTB remains one of the most neglected diseases and there is a need for it to enter the public consciousness. Diagnostics is only one of the many areas requiring attention and, with the tremendous potential that India has, the hope for a low-cost, accurate and sensitive diagnostic tool for TB lives on,â€? concluded Dr Pai, also co-chair of Stop TB Partnership's new diagnostic wing.

Manasi Vaidya in Bangalore