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Time to create enabling environment for TB innovators

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Globally, Tuberculosis (TB) is the leading cause of death from a single infectious disease agent. In 2018, an estimated 10 million people fell ill with TB globally and a total of 1.5 million people died from TB, including 251,000 people with HIV. Unfortunately, India accounted for the largest share of the worldwide burden – 27 per cent. According to the World Health Organization's global TB report 2019, 2.69 million cases of TB and 4,40,000 deaths were estimated to have occurred in India that year.

In 2018, 2.15 million cases were notified to Revised National Tuberculosis Control Programme. Almost one quarter of all deaths among people living with human immunodeficiency virus (HIV) are estimated to be due to TB (RNTCP TB Report 2019). Nearly 40% of Indian population has latent TB infection; 5–10% of those who are infected will develop active TB disease during their lifetime (Madhukar Pai, 2015). These are not just numbers but human lives.

As per the 2019 G-FINDER report, TB, HIV/AIDS, and Malaria as a group received about 70% ($2,799m) of all global funding for research and development in neglected disease; this was the lowest share ever recorded in the history of the G-FINDER survey. According to the Treatment Action Group's 2019 report, global TB research funding was over US$ 900 million in fiscal year 2018, which still falls considerably short of the US$ 2 Billion annual target set at the United Nations High-Level Meeting of 2018.

But the good news is that, India is at the fore-front, among the BRICS (Brazil, Russia, India, China and South Africa) countries, with over US$ 30 million in funding for TB. The Indian Council of Medical Research is in the top-ten funding organizations for research and development at the global level.

According to the National Tuberculosis Programs (NTPs), across the globe, case notifications for TB are on the rise while mortality is decreasing. Therefore, the need of the hour is to reduce TB incidence by improving surveillance, diagnosis, treatment, and follow-up amongst other issues. This is where innovative tools and approaches can bridge the gaps faster and ultimately, facilitate TB elimination in the coming years.

While there is constant and much-needed debate on the need to increase funding for research and development, the potential of innovations to make a key difference does not find adequate mention. India is well positioned to respond to the TB crisis dynamically by developing and infusing innovations into health system.

During the process of creating product or process innovations, innovators face overwhelming issues and challenges. Some of these include the lack of relevant socio-economic, epidemiological, genomic, and demographic data; the requirement for conducting detailed comparative analyses between proposed innovations and the existing gold standard methods; the lack of implementation in real-world settings; the need for staff who possess unique scientific and business skills; access to resources required to upgrade and scale-up the device; tax rules; and cumbersome in-house repair and maintenance processes.

Besides this, sparse legal knowledge may prevent innovators from filing patents concerning their product and process innovations. Due to a lack of human resources and financial constraints, innovators are often unable to publish their findings in national and international peer-reviewed journals. This lack of publications and patents may be factors that deter reputable national institutions from supporting many innovators. Continuous social media presence and documenting their findings in newspapers and business magazines, to raise awareness about the product/process innovation, is necessary to reach potential angel investors.

Another bottleneck is the availability of relevant data which are critical for the success of the product or process innovation in question; for example, access to chest radiographs may be essential to train an algorithm. The lack of real-world data may hinder validation. Furthermore, due to absence of facilities such as bio-bank, specimens remain unavailable to innovators. Occasionally, local or national innovators have to compete with global pharmaceutical companies and reputed international institutions that are heavily funded and may have received WHO-prequalification for their product. Each of the above-mentioned factors create incredible pressure on innovators in India today.

Creating a consortium of public (E-Cell of Indian Institute of Technologies and Indian Institute of Management) and private entities (pharmaceutical companies, diagnostic labs) that enables usage of real-time data for testing products and process innovations would immensely benefit these innovators. These consortiums should also possess the capacity to accommodate real-time changes that arise; for example, development of a multi-disease platform is the need of the hour.

Prototype improvement and lab-to-last mile transition of the product/process innovation can be facilitated by immersing the innovators in real-life settings for a period of 3-6 months that a) enables interaction with healthcare workers from remote areas/program managers of relevant non-profits/ state- and central- government officials and b) allows innovators to be in constant touch with these parties to receive pertinent feedback. The importance of study design, detailed methodology, statistical analysis, data interpretation, and providing substantial scientific evidence, via publications in peer-reviewed journals, should be communicated clearly to innovators.

Moreover, considering the timelines set for TB elimination by the Government of India and in view of the Sustainable Development Goals (SDGs), validated and approved innovations TB should be implementable in 2-3 years. Importantly, innovators should be trained on legal and regulatory affairs from national institutions, including Indian Patent Advance Search Systems, Biotechnology Industry Research Assistance Council, Department of Science & Technology; such trainings would enable them to acquire knowledge regarding patent filing, safety parameters, and validation studies.

An example of potential ground-breaking innovations can be found in an innovative kit that uses a combination of native and recombinant antigens to detect bovine TB. Developed by CisGen Biotech Discoveries Pvt Ltd, this is important today when zoonotic infections continue to be transmitted to humans. Another innovation, aimed at enabling screening of TB in remote areas with low human resources and skill level, was developed by Qure.Ai Technologies Private Limited to develop algorithms using artificial intelligence that can be used to accurately screen TB prior to diagnosis.

Such novel products can create a disruptive impact in mitigating disease burdens. For many such appropriate innovations to be developed, there could not be a more appropriate time to create an enabling environment for innovators to be quick and agile in building pipeline of novel technologies and programs to eliminate tuberculosis.

To this end, India Health Fund (IHF), an initiative seeded by Tata Trusts with strategic inputs from The Global Fund, is issuing a Quest for Innovations toward Eliminating Tuberculosis (TB Quest). This is an open challenge to innovators, bio-incubators, e-cell and other technology hubs to showcase their ideas for sustainable and effective change in infection control, anti-microbial resistance and diverse other challenges to tuberculosis elimination in India. The quest will be launch on 7 April 2020 and selected innovations will stand a chance to receive funding and other support to pilot and scale up their technologies and services. Together, we can support the government’s commitment to eliminating tuberculosis and making India TB Free by

2025.

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