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Editorial

India's contribution to global TB control: Innovative & integrated implementation research

TB control

In 1993, the World Health Organization (WHO) declared TB a global emergency and catalyzed a co-ordinated global response that came to be known as DOTS, the Stop TB Strategy[1]. This package of interventions was based on a large body of evidence and designed to have maximal deliverability and impact. Its subsequent scale-up was enabled in no small part by a rigorous attention to monitoring data.

This scale-up of basic TB control is arguably one of the greatest public health accomplishments of our generation[2]. Thanks to the Stop TB Strategy, in 2009, 87 per cent of TB patients treated were cured, with 46 million people successfully treated and 7 million lives saved since 1995[3,4]. The Revised National Tuberculosis Control Programme (RNTCP) of the Government of India, based on DOTS strategy was launched in 1993 on a pilot scale. It was scaled up in 1997 and by 2006 covered the entire country. RNTCP is the world's largest TB control programme and every month more than 1,00,000 patients are put on treatment under this programme. And yet, in India - which has the world's highest TB burden, approximately 3,00,000 people will die of TB this year - an estimated 960 deaths a day. There exist multiple reasons for these deaths, but all imply that early and effective TB treatment and control is difficult in India with its current tools and systems. An overall 12-15 per cent multi-drug resistance (MDR) in category II pulmonary cases and around 3 per cent (1-5 %) in fresh pulmonary cases has been estimated[5] and indicates the need for urgency and new thinking.

TB control in the future: Implementation research

A key aspect of addressing this challenge, not just in India but also elsewhere, is experimentation, innovation and implementation research to improve and simplify TB control[4]. In contrast to the era of DOTS scale-up, where the interventions were relatively well established from the outset, the coming decade will be characterized by evaluation and course correction - moving from waypoint to waypoint through the fog of new opportunities.

The coming decade will see huge shifts in the battle's armamentarium as well as the context in which it is fought (such as demography, economics, and health systems). In India, evaluating and implementing new interventions will need to be a much more dynamic process. For a multitude of interventions, the question will be how to implement for a million people, rapidly evaluate that effort, and stop what is not working while scaling-up what works to 10 million, then repeating this cycle with a hundred million, and finally a billion.

Implementation research must play a pivotal role in assessing interventions and taking them to scale[6-8]. "Implementation research aims to develop strategies for available or new health interventions in order to improve access to, and the use of, these interventions by the populations in need. Implementation research is intervention-specific, but in contrast to operational research, it is often designed with the intention of creating outputs that can be applicable beyond the local environment in which the research is done"[9]. It is an inherently multidisciplinary field including the principles and practices of conventional and molecular epidemiology, biostatistics, analytical modelling, health economics, health management, behavioural sciences, information technology, modelling and impact evaluation and implementation science.

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The role of implementation research

By bringing together relevant principles and practices from diverse fields, implementation research can provide India quick and reliable assessment of how efficacious and replicable interventions are in a real world setting. Findings from implementation research can be integrated into the design and implementation of programmes ensuring evidence based interventions. This is particularly true for national programmes where enormous investments are necessary for maximizing public benefit.

However, to be successful, implementation research initiatives will not only require better integration among those already involved in TB research globally, but also include those not involved in it. For instance, implementation research will need to integrate two historically distinct domains - technology and health systems. And finally, the implementation researcher must understand advocacy and communications to ensure that lessons learned reach the appropriate audience that can apply these lessons to save lives.

Evaluating critical interventions and implementing them based on evidence is not new to India. India, has witnessed several successful scale-up of interventions such as routine immunization, contraception, HIV testing and counselling. From the private sector is the incredible expansion of mobile telephone services in India - a great example of how useful technologies can be taken to scale very quickly, especially if there is a market for them.

TB diagnostics is an excellent example of the potential for integrated implementation research to address the fact that undiagnosed TB is driving the TB epidemic[10,11]. Diagnostics technology is particularly well suited to this work because the cycle time between product conceptualization, development and evaluation is relatively short for diagnostics[12]. On a similar time scale, components of health systems can be adapted to take advantage of new technology and promptly evaluated. Taken together, implementation researchers can rapidly iterate cycles of integrated product and system development, deployment, evaluation and modification. Such a process can be conducted in parallel, for example, establishing the phased implementation of a decentralized technology in a system that moves patients to laboratories and a centralized technology that moves specimens to laboratories in both the public and private sectors. The relative merits, costs and impacts of each approach can be evaluated and used to decide if or where each should be taken to scale. Considering the fact that Indian researchers have been in forefront of development of new methods of TB diagnosis which have yet to reach the masses, a focused analysis of the environment for evaluation and implementation is necessary. As the genetic profile of bacterial populations (*e.g.* differences in drug resistance or even strains) can make an accumulative impact on the success of current regimen tracking the population genetics of bacteria could help the country to make adaptive changes in the face of bacterial evolution. The lessons learned can be fed back to programme as well as regulatory authorities such as the Drug Controller General of India, to help define specific performance characteristics that are needed for each system and inform the programme and all stake holders to make right choices. Finally, the data derived from these implementation exercises will help to shape models and quantitative parameters that can be used to anticipate the health impact of theoretical products with a spectrum of performance characteristics and thus help guide product developers to robust and impactful markets. It is through such a process that India can best bring the full range of its innovation engine to address the challenge of promptly diagnosing and treating TB early and effectively. This will prevent deaths, reduce the emergence of drug resistance but most importantly reduce transmission to reach the goal of elimination.

Why India can be a leader in TB control?

As one of the world's largest emerging economies, India is uniquely situated to be a global leader in TB control[13]. It is an emerging technology innovator with an increased focus on health[14]. India has rich history of mycobacterial research and has made contributions in basic biology, genetics, epidemiology, clinical, diagnostic and therapeutic aspects[15,,16]. It is important that this innovation is integrated in all aspect of health care systems - particularly to the complex interactions of new technologies and the systems needed to deliver them to those in need[14].

India's RNTCP comes to these challenges with incredible momentum, having initiated over 12.8 million patients on treatment, thus saving more than 2.3 million additional lives in comparison to the earlier programme[17]. It will have increasing resources, given the Prime Minister's commitment to increase spending on health by nearly 3-fold to 2.5 per cent of GDP. Most importantly, it has requisite ambition, including for example, the goal of universal access to

quality diagnosis and treatment for all TB patients in the country, and addressing the need for provision of consistently high quality of TB care through the private sector[17,18]. Finally, India has a powerful entrepreneurial spirit, for example, one can find a private laboratory providing digital chest X-rays in a district level town in Bihar that are read within 4 h by a teleradiologist in Bengaluru - all for ₹ 150! Implementation research will be critical for determining if such a technology is found to have value and if so, how it can be best incorporated in TB control protocols.

These attributes pave the way for India to execute the phased implementation of innovative TB control that will be critical in order to reach the ambitions of India's National Strategic Plan (2012-2017).

In conclusion, TB is a gold mine for Indian scientists who want to do research with direct impact on saving lives. The country is uniquely situated to solve its TB problem and in so doing, that of the world. Implementation research that integrates technology and systems will be critical to bringing innovation into this process. Advocacy and communication efforts can accelerate turning these lessons into action. In so doing it is our belief that India can establish itself as a global leader, not in TB burden, but TB control.

Peter M. Small & V.M. Katoch*
Senior Program Officer
TB, Global Health Program,
Capital Court Building, 3rd Floor
Left Wing Olof Palme Marg
Munirka, New Delhi 110 067 &
*Secretary, Department of Health Research
Ministry of Health & Family Welfare
Government of India & Director-General
Indian Council of Medical Research
V. Ramalingaswami Bhawan, Ansari Nagar
New Delhi 110 029, India
For correspondence:
peter.small@gatesfoundation.org

References

1. Raviglione MC, Uplekar MW. WHO's new stop TB strategy. *Lancet* 2006; *367* : 952-5.
2. Lonnroth K, Castro KG, Chakaya JM, Chauhan LS, Floyd K, Glaziou P, *et al*. Tuberculosis control and elimination 2010-50: cure, care, and social development. *Lancet* 2010; *375* : 1814-29.
3. World Health Organization. *Global tuberculosis control 2011*. Geneva: World Health Organization; 2011.
4. Frieden TR. Lessons from tuberculosis control for public health. *Int J Tuberc Lung Dis* 2009; *13* : 421-8.
5. Chauhan LS. Challenge towards upscaling MDR TB under RNTCP. NDCP_LSC4 Available from: *http://www.google.co.in/#hl=en&sclient=psy-ab&q=Chauhan+LS.+Challenge+towards+upscaling+MDR+TB+under+RNTCP&oq=Chauhan+LS.+Challenge+towards+upscaling+MDR+TB+under+RNTCP&aq=f&aqi=&aql=&gs_sm=3&gs_upl=2142l2773l2l3109l3l3l0l0l0l2l454l8811l4-2l2l0&gs_l=hp.3...2142l2773l2l3109l3l3l0l0l0l2l454l8811l4-2l2l0.&pbx=1&bav=on.2,or.r_gc.r_pw.r_qf.,cf.osb&fp=a10589eb44223114&biw=1280&bih=522*, accessed on January 17, 2012.
6. Squire SB, Ramsay AR, van den Hof S, Millington KA, Langley I, Bello G, *et al*. Making innovations accessible to the poor through implementation research. *Int J Tuberc Lung Dis* 2011; *15* : 862-70.
7. Wilson N, Chadha S, Beyers N, Claassens M, Naidoo P. Helping the poor access innovation in tuberculosis control: using evidence from implementation research. *Int J Tuberc Lung Dis* 2011; *15* : 853.
8. Lienhardt C, Espinal M, Pai M, Maher D, Raviglione MC. What research is needed to stop TB? Introducing the TB Research Movement. *PLoS Med* 2011; *8* : e1001135.
9. Remme JH, Adam T, Becerra-Posada F, D'Arcangues C, Devlin M, Gardner C, *et al*. Defining research to improve health systems. *PLoS Med* 2010; *7* : e1001000.
10. Small PM, Pai M. Tuberculosis diagnosis - time for a game change. *N Engl J Med* 2010; *363* : 1070-1.
11. Engel N, Kenneth J, Pai M. TB diagnostics in India: creating an ecosystem for innovation. *Expert Rev Mol Diagn* 2012; *12* : 21-4.
12. Perkins MD, Small PM. Partnering for better microbial diagnostics. *Nat Biotechnol* 2006; *24* : 919-21.
13. India must lead the way in developing new diagnostic tools for TB. Available from: *http://www.thehindu.com/news/states/tamil-nadu/article963222.ece*, accessed on December 19, 2010.
14. Economist Intelligence Unit. Healthcare in Asia: The innovation imperative. Available from: *http://download.economistconferences.asia/HIA_White%20Paper_2011.pdf*, accessed on Deember 18, 2011.
15. Katoch VM. Mycobacterial research in India: Successes and challenges. *Indian J Microbiol* 2002; *20* : 171-3.
16. *Grand challenges explorations grants*, *create low-cost cell phone-based solutions for improved uptake and coverage of childhood vaccinations.* Available from: *http://www.grandchallenges.org/Explorations/Pages/GrantsAwarded.aspx>*, accessed on January 25, 2012.
17. Central TB Division. TB India 2011. *Revised National Tuberculosis Control Programme. Annual Status Report*. New Delhi, India: Directorate General of Health Services, Ministry of Health and Family Welfare; 2011.
18. Pai M. Tuberculosis control in India: time to get dangerously ambitious? *Natl Med J India* 2011; *24* : 65-8.