# India Needs a National Policy to Control Tuberculosis

#### T JACOB JOHN

There is no policy in India for tuberculosis control and the centrally-run Revised National Tuberculosis Control Programme has neither mandate nor agenda for TB control. There are short, medium and long term remedies for the maladies of the revised programme which are detailed in this article. TB is both a biomedical and a social, cultural and economic problem. Citizens must demand a national policy for TB control.

T Jacob John (*tjacobjohn@yahoo.co.in*) retired as professor and head of the department of clinical virology at the Christian Medical College, Vellore. He chaired the India Expert Advisory Group on Polio Eradication and co-chaired the National Technical Advisory Group on Immunisation from 2000 to 2009. India's National Health Policy (NHP of 2002 stipulates that tuberculosis (TB) mortality must be reduced by half by 2015, compared to that in 1990 (NHP 2002). India probably has achieved this goal already (GOI 2012). However, mortality reduction by half does not constitute TB control. There is no policy in India for TB control (ibid).

Disease control is a public health term for the deliberate reduction, to a prestated level of the burden of disease by interventions within an agreed-upon time frame (Park 2009). The decline ought to be monitored and shown to be due to interventions and not merely through a secular trend. In all economically developed countries there was a marked decline in the TB disease burden and mortality, even before anti-TB drugs became available (ibid). Such a decline which is a byproduct of development is referred to as secular trend. India's inevitable secular trend of TB among the well-to-do is not quantified.

TB control needs a baseline burden measurement and periodic monitoring of the downward trend with the secular trend dissected out. None of these requirements are being followed in India. Despite reduction in mortality and despite the secular trend among the well-to-do, India's overall TB burden has increased and the country has the highest population-based TB burden in the world (GoI 2012). Shall we call this "negative control"?

The Ministry of Health and Family Welfare (мон) runs the Revised National Tuberculosis Control Programme (RNTCP) with branches in all states and districts since 2006 (GOI 2012). Despite the word control in its name, the RNTCP has neither mandate nor agenda for TB control. This incongruity does not seem to bother anyone in the MOH probably because our culture tolerates unresolved contradictions!

#### **RNTCP and TB Control**

In 1993 the RNTCP's objective was enunciated as the cure of 85% of persons with pulmonary TB through the directly observed treatment, short course (DOTS) and detection of 70% of such cases through sputum testing for TB bacilli. In all the documents of the RNTCP this sequence is maintained: cure rate first and detection rate next and is confined to lung TB (GOI 2012). There is no mention of TB control as the RNTCP's objective.

This is rather strange. Cure is the aim of healthcare; every patient with TB, pulmonary or extra-pulmonary, can be cured with protocol-based treatment. The aim of public health is preventing disease. The RNTCP is therefore not a public health programme but a public sector (government-funded) TB treatment project. While public health spending in every country is made by the respective government, that criterion alone does not qualify a health-related project to come under public health. Governments also fund healthcare which is not public health.

Universal healthcare through government establishments is grossly deficient in reach; a large proportion of citizens seek healthcare services from the private sector by out-of-pocket spending. In order to ensure that at least a fair proportion receive free treatment thus fulfilling the policy requirement, the RNTCP provides DOTS. Public health interventions are often targeted at a majority with the hope that the remaining minority will benefit from the spillover benefit. This is also known as the "herd effect" (John and Samuel 2000). Applying this principle, the RNTCP considers that only 70% cases of pulmonary тв need to be treated in order to fulfil the policy objective.

Unfortunately this equation is wrong in epidemiology and in ethics. In high prevalence countries like India there is no evidence for the herd effect, particularly for a 60% effective cure rate  $(85\% \times 70\% = 59.5\%)$ . Ethics demand that everyone with TB must be treated and

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obviously that will require a considerably higher budget than the one provided now. If the government is not willing to spend what is required for the purpose it can only mean it lacks the proverbial political will. A clear national policy statement to control TB is the first step to show political will followed by allocation of an adequate budget.

As of now, a scaled-down healthcare outcome masquerades as TB control; the RNTCP is inequitable as healthcare and inadequate as public health. However, within its remit, it provides quality drug treatment through a protocol-based regimen and observer-verified compliance. Although the RNTCP claims to have reached 70% of the pulmonary TB patients, the 100% is unknown in the absence of TB surveillance. The MOH officials seem to accept numbers without validation.

The World Health Organisation (WHO) estimates that only one half of the patients with pulmonary TB reach the RNTCP and receive DOTS (WHO 2013). Even if half are treated well, mortality will be reduced by half. However, extrapulmonary TB is not on the RNTCP radar since sputum examination does not help in its diagnosis. The 50% mortality reduction in RNTCP is probably fulfilled but only for pulmonary TB. Extrapulmonary TB is left to the existing healthcare establishment to be diagnosed.

#### **Default or Design?**

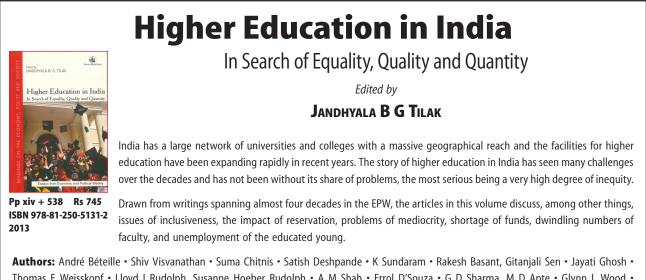
A national health policy was first drafted in 1983 and revised in 2002 (NHP 2002). Decades earlier India had designed a National TB Programme (NTP) for TB control. There is widespread presence of тв bacilli in our environment and infants and children get infected at the frequency of over 1% per year (Park 2009; John and John 2009; Chadha et al 2014). This is called "annual risk of TB infection" (ARTI). In urban communities it is 2.15 and in rural communities 1.3, according to the most recent nationlevel survey (Chadha et al 2014). Infection is chronic and lifelong except in those that develop the disease, receive treatment and thus have their body sterilised of the TB bacilli. In others, the infection remains silent, called "latent тв" and can flare up into active тв any time in the future.

By the age of 14 years the cumulative prevalence of latent TB is about 15% (Park 2009; John and John 2009; Chadha et al 2014). Control was defined under the NTP as its reduction to less than 1%, on par with the western nations. For this ARTI would have to be reduced from over 1% to 0.07% (ibid). At 5% annual reduction of ARTI the control target could have been achieved in 20 years (8). The emphasis was on children and latent TB, not on treatment of TB. That fits with the public health philosophy. However, something seems to have gone completely wrong.

People with TB deserve healthcare; hence a second component of the NTP was district-based TB diagnosis and treatment, free of charge, through existing healthcare institutions under public-private partnership. Government departments in India suffer from institutional amnesia; while revising the NTP into the RNTCP in 1993, not only the second component but also the objective seemed to have got lost suggesting that the lack of a control policy is by default. But there is another interpretation which claims that it is by design.

### **Four Questions**

Whilst teaching public health we ask four questions. One, is there a substantial problem? If there is, we need to proceed.



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Mumbai • Chennai • New Delhi • Kolkata • Bangalore • Bhubaneshwar • Ernakulam • Guwahati • Jaipur • Lucknow • Patna • Chandigarh • Hyderabad Contact: info@orientblackswan.com тв is the number one public health problem in India: we are 17% of global population carrying 26% of global burden of тв, illustrating "negative control" (wHo 2013). Uncontrolled тв in India is a crisis in human health and a block for socioeconomic development; it deserves to be declared as a national emergency. When wHo declared тв as a global emergency in 1993, the мон simply ignored it.

Two, are public health interventions available? If they are, we need to proceed further. Some тв experts believe that no intervention can control TB in India - the problem has grown out of control. They harp on the widespread problems of multi-drug (two first line drugs) resistance, extensive (four to five) drug resistance and even total drug resistance which make TB control extremely difficult. But the problem will only grow if left uncontrolled. Infectious disease epidemiologists like me believe that practical biomedical and sociobehavioural interventions are available to control TB; what is lacking is the necessary political will.

Three, how much will the interventions cost for implementation? There is no cost estimate as there is no policy for TB control. Policymakers, epidemiologists, technical experts and health economists must be asked to create a war room and develop strategy, tactics and logistics for TB control. Only then will we know what the cost will be.

Four, can the nation afford the cost of тв control? If тв control expenses are affordable the мон can bring it into public health. The Planning Commission had estimated that the annual loss to the national economy on account of TB is the equivalent of \$23.7 billion (Citizen News Service 2010). And the annual budget of the RNTCP is only about \$200 million (GOI 2012). The government should budget at least \$1 billion to begin with, redesign TB control and then calculate what it will take for effective control (John et al 2013). As the fourth largest global economy India can afford to spend even more than a billion to plug the leak of 24 billion.

Policymakers have not addressed the four questions; so we live with the "negative control" of TB. Poor people suffer and die while the rich can avail private sector healthcare. The RNTCP website says that every two minutes three persons die of TB (GOI 2012); without the RNTCP six would have died and that surely excludes the rich. Our cultural habit is to save rather than invest for the future. Is money saved from spending on TB control saved for the MOH? This is foolish economics.

I strongly disagree with this negative attitude. Already TB is impoverishing families, communities and the nation; it affects the age group of 20 to 45 years, the most productive years and kills more women in their reproductive age than all other causes of maternal mortality combined (Park 2009). Socioeconomic development requires gains of life, health and productivity by effective control of TB. We cannot afford not to control TB.

### **Losing Hope for TB Control**

The public health intervention under the NTP consisted of mass BCG vaccination which was expected to protect against infection with тв bacilli (primary prevention) and also against latent TB progressing to disease (secondary prevention). Primary prevention should reduce ARTI and the prevalence of latent TB. Since all active TB emerges out of the pool of latent TB, shrinking it from 15% to less that 1% in childhood and reducing the risk of reactivation TB in those with latent TB, would surely have resulted in drastic reduction of the numbers of active TB in adults. As pulmonary тв would be reduced, a virtuous spiral of less transmission and progressively decreasing ARTI and latent TB - in other words true тв control – would have occurred. Thus control depended on the protective efficacy of BCG.

In 1979 the results of the BCG vaccine trial (in Chengalpattu district, Tamil Nadu) were decoded; disappointingly it offered no primary or secondary prevention (wHO 1979). As hope was extinguished the intention to control was also discarded. Believing there was no practical public health interventions to control TB or that the cost of control was unaffordable, TB experts set the objectives of treatment of 70% of easily diagnosed pulmonary TB and easily achieved a 50% mortality reduction. The absence of a policy to control TB is apparently by design.

Should BCG continue to be part of the national infant immunisation? Children below five years are particularly vulnerable to what is called childhood TB (or short incubation period TB) within one to three years after infection. Adult TB, including the infectious form of pulmonary тв has a very long incubation period. BCG protects children against childhood тв, but not against infection per se. The burden of childhood тв has declined drastically in recent decades. thanks to the very high BCG coverage. But there is a caveat: children protected from childhood тв inflate the latent тв pool. Neither the national immunisation programme nor the RNTCP addresses this pool, the reservoir of future TB. This is the partial explanation for the "negative control" of тв in India.

### Is the Pessimism Justified?

If policy pundits believe TB cannot be controlled, it will become a self-fulfilling prophecy. They wait for the avatar of a new and effective vaccine to control TB. They are clearly misguided. Infection by TB bacilli and latent TB do not protect against disease or even reinfection. No vaccine can be expected to do better. These are the given biological principles of TB; we must not let the lack of an effective vaccine deter us from declaring war on TB. The MOH experts lack knowledge of infectious disease epidemiology, health economics and ethics of public health.

The government must first declare a national policy to control TB. An Indian think tank covering all disciplines mentioned above can design a result-oriented programme. After all, India did eliminate wild polio against all odds (John 2014). India's successful AIDS control programme was designed by a small group of Indians way back in 1986 (Dasgupta et al 1994).

On the biomedical front we must shrink the pool of latent TB and reduce the number of active TB emerging out of the pool. Every pulmonary TB prevented will reduce the environmental contamination

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and further help reduce ARTI. Textbooks on TB tell us how to shrink that pool; there are two broad ways. One is to reduce entry, by way of reduction of transmission through the socio-behavioural pathway. The second is the biomedical way, which is to find those with latent TB using the tuberculin skin test (TST) followed by the simplified anti-TB treatment also known as "preventive treatment".

At five years, all children must be screened for latent TB; those who test positive must be given preventive treatment. Those found negative must be screened again at age 10. In addition, every case of TB must be the trigger for screening of all family and household members plus close contacts at workplace. Currently, by the time a person is diagnosed with pulmonary TB and put on treatment, all household members have been infected (Kamat et al 1966). Therefore the RNTCP intervention will never control TB, even if 100% coverage is reached. Such contact screening is practised all over the world, except India. In February 2014, a student in a California school in the us was diagnosed with active TB and 200 students and staff were screened with TST; 111 were found with latent TB and put on preventive treatment (Promed 2014). As the body is sterilised of infection, the risk of future

TB is removed. The RNTCP budget and number of personnel are grossly inadequate for such interventions; they must be expanded and given the mandate to shrink the pool of latent TB.

Under the constructed conspiracy of silence, pessimism is pervasive, but many RNTCP staff members work sincerely and compensate for the pessimism. Remember the Hans Christian Andersen story of the emperor's clothes? Better to pretend that everything is just fine, instead of speaking the truth. We should not expect an internal reform of the RNTCP - its design does not include internal or external evaluation. The earlier version - the NTP - was evaluated in 1990, three decades after launching; the current version which is the RNTCP has not been evaluated since its launch in 1993.

#### **Way Forward**

There are short, medium and long-term remedies for the maladies of the RNTCP. If a disease is targeted for control, the first epidemiological step is to establish what is called "public health surveillance" which is case-based reporting by all healthcare functionaries of all suspected cases. There must be a node for receiving reports within the district or city; and immediate responsive actions must be taken.

Every reported case must be followed up to confirm or exclude diagnosis of тв. Surveillance data will give baseline incidence (annual number of new cases per unit population), prevalence (cumulative number of cases under treatment plus new cases per unit population per year) and the rate of decline over time. Smallpox eradication required the detection of every case; for polio elimination every child with acute flaccid paralysis is detected and tested for polio. This insight dawned on the government only recently, resulting in a circular on 7 May 2012, asking all doctors to report every TB case to the local authorities. This request is in addition to the reporting of тв to the integrated disease surveillance project (IDSP) operating since 2004. The IDSP has no clue as to what to do with the reports. Now local authorities will also get reports but what can they do?

A whole new infrastructure has to be created for ensuring case-based surveillance and for taking actions when cases are reported; without these, surveillance will not be effective. In addition to following up on the progress of treatment of every case, all contacts must be immediately screened. Such intensive activities are only possible if the unit of TB control is small enough for efficiency – that is why the district or the city must be the battleground. The

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war on TB will be won or lost in the districts and cities.

Single disease surveillance is not ideal; all major infectious diseases must be brought under surveillance and effective control interventions applied. Such an infrastructure is what public health is. Failure to create public health is the main reason why we do not have an agenda to control the many infectious diseases including TB that industrialised countries succeeded in controlling in early 20th century. Must TB control wait until public health infrastructure is established or can it be designed now without it? That is for the MOH to decide.

We have one exception to the rule of surveillance first – that of AIDS control. Instead of public health surveillance we designed a unique denominator-based monitoring method for HIV infection prevalence, called sentinel surveillance (Dasgupta et al 1994). Infection-monitoring and concurrent application of all available interventions was India's successful approach for AIDS control (see Table 1). The time-trend of the prevalence of infection is steadily declining over

#### Table 1: Major Differences between AIDS Control Interventions and RNTCP Interventions – The Success Factors of AIDS Control and Failure Factors of RNTCP

	HIV/AIDS	RNTCP
Origin of design	Indian	Foreign
Interventions	Multiple	Single
Monitoring of time trend	Yes	No
Public participation	+++	0
Healthcare: public-private mix	+++	0
Hospital safety interventions	++++	0
The affected as advocates	++++	0
Funding	Adequate	Grossly inadequate
Political will	++++	0

many years. For TB too a way to monitor time-trend of infection, patterned after that of HIV infection can be set up. For example, screening of children at age five years annually will give us the time trend of ARTI; this could be implemented as a school-based programme, wherever enrolment is very high.

#### **Public Participation in TB Control**

One of the factors of success in AIDS control was the early, widespread and sustained campaigns to create awareness, to give correct information regarding personal protection and to solicit people's participation. India has not taken the sociocultural barriers of TB control seriously. Infection is highly contagious since the TB bacilli are inhaled. Reducing contamination of the environment is crucial for reducing the chances of infection; this was named earlier as the sociobehavioural pathway. Coughing without covering the mouth and spitting in open spaces are two habits we have to modify for the sake of public safety. Countries like Britain and Singapore banned open spitting to reduce TB transmission.

All the MOH has to do is declare open coughing and spitting as public nuisances; thereafter the long arm of the law can help habit formation. Just as passive smoking is a risk factor for lung cancer, contaminating the air by coughing and spitting in public is a risk factor for TB. Tamil Nadu has already made such a law; it is not enforced as its importance for TB control has not yet been appreciated by the administrative officers.

Imaginative and sustained campaigns are necessary to teach the public, starting with schools. I believe children aged 10 years, or in middle school, must be taught lessons on TB. We saw that TB is a greater menace than AIDS. There are Red Ribbon Clubs in all schools and colleges as part of the grand strategy to control AIDS. There is a rainbow-coloured ribbon in support of TB control and in solidarity with those affected with TB. All educational institutions can join hands in a grand alliance in India's fight against TB.

There are gross differences in the understanding of disease between Indian and European cultures. There is no better example that illustrates this than the way European culture countries tamed TB and why we continue to tolerate it in India. Their culture is anthropocentric that relentlessly pursues the prevention of infectious diseases in humans through science, technology and their resultoriented application.

Indians are ambivalent about the origins of infectious diseases, many believing it to be fate, karma of past life or punishment by an angry god. We have not imbibed the principles of probability and risk factors; hence TB seems to occur idiosyncratically. If TB is not predictable, how can it be prevented, unless a vaccine was able to protect everyone from it? This mindset has to be overcome. Not being anthropocentric, our culture is weak on social justice ideology also. For the west, taming TB was essential for social equity.

Political parties must declare support for social justice and support for sciencebased solutions for human diseases. Uncontrolled TB illustrates how backward India is in both realms. TB is both a biomedical and a sociocultural-economic problem. Citizens must demand a national policy for TB control.

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