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Ethical implications of the National Tuberculosis Elimination Programme in India: A framework-based analysis

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Abstract:

Tuberculosis (TB), an infectious disease, is transmitted by inhalation of droplet nuclei discharged in the air. Revised National Tuberculosis Control Programme (RNTCP), now National Tuberculosis Elimination Program (NTEP) of India, has made significant gains in strengthening the support structures, program architecture, and implementation environment for TB control in India. Kass's framework for public health includes an analytic tool that consists of a step-by-step list of six questions for deciding how the burdens and benefits of an intervention can be fairly balanced. We have tried to apply each of the elements addressed in the framework with context to RNTCP/NTEP measures, reviewing relevant literature evidence and attempt to view from the " receiver's" perspective instead of looking at from " provider's" perspective. We feel the NTEP provides a sound delivery of ethical principles in the program. Involvement of private sectors into the program for TB control, which is a challenging task, is a requirement for a fair provision of uniform TB care across the nation.

Keywords:

Ethical implications, Kass's framework, National Tuberculosis Elimination Program

Introduction

Tuberculosis (TB), an infectious disease caused by *Mycobacterium tuberculosis*, is transmitted by inhalation of droplet nuclei, which is discharged in the air when a patient with TB coughs or sneezes. India has the highest burden of both TB and MDR-TB and the second highest in HIV associated with TB.[1] The National Tuberculosis Programme of India was initiated (NTP) in 1962, and later, in 1993, the Revised National Tuberculosis Control Programme (RNTCP) was phased in. Strengthening of diagnosis and treatment and several activities were initiated. There had been a paradigm shift in TB control[2] by the newer technical and operative guidelines, 2016.[3] Emboldened by its achievements, the program in 12th 5-year plan (2012-2017) has articulated the National Strategic Plan with a vision of TB-free India.[4]

With a strong necessity to strengthen the TB control in India, the RNTCP/National Tuberculosis Elimination Program (NTEP) has been involved in implementing several important measures for the same. However, from another perspective, it is important to review the program activities as visualized on ethical grounds from the public point of view. This review is attempted to do an ethical analysis of this RNTCP using the Kass's framework[5] of ethical analysis.

Tuberculosis Program in India

The RNTCP was phased in from 1993, succeeding the National Tuberculosis Program (NTP). The important goals of this program initially were to achieve at least 85% cure rate among smear-positive TB patients and thereafter a case detection of at least 70% of such cases. The Phase II (2006-2012) of the RNTCP has been successful in achieving its objectives.[6] The goal of the national strategic plan is to achieve universal access of quality of TB diagnosis and treatment

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of all TB patients in the community. There has been a recent announcement of renaming "Revised National Tuberculosis Control Program (RNTCP)" as "National Tuberculosis Elimination Program (NTEP),"[6] however we feel that the activities of the program will be as per National Strategic plan for TB Elimination 2017-2025, the latest available documented plan of the Indian TB program, hence we have focussed this analysis of the program activities over a period of time, as appropriate.

What is Kass Frame Work?

Kass framework for public health aims to raise awareness of the ethical issues of proposed programs and to help consider means of responding to them. It includes an analytic tool that consists of a step-by-step list of six questions for deciding how the burdens and benefits of an intervention can be fairly balanced. The six questions are:

(1) What are the public health goals of the proposed program? (2) How effective is the program in achieving its stated goals? (3) What are the known or potential burdens of the program? (4) Can burdens be minimized? Are there alternative approaches? (5) Is the program implemented fairly? (6) How can the benefits and burdens of a program be fairly balanced? Kass further distinguishes three categories of ethical burdens, namely: Risks to privacy and confidentiality, risks to liberty and self-determination, and risks to justice. We have tried to apply each of the elements addressed in the framework with context to RNTCP measures, reviewing relevant literature evidence related and expressed what we feel. This is an attempt to view from the "receiver's" perspective instead of looking at from "provider's" perspective.

What are the Public Health Goals of the Proposed Program? And How Effective is the Program in Achieving Its Stated Goals?

The main objectives of the Revised National Tuberculosis Control Programme/National Tuberculosis Elimination Program

As said above, RNTCP/NTEP has framed the new objectives.

(1) To achieve 90% notification rate for all cases, (2) to achieve 90% success rate for all new and 85% for retreatment cases, (3) to significantly improve the successful outcome of treatment for drug-resistant TB (DRTB) cases, (4) to achieve decreased morbidity and mortality for HIV-associated TB cases, and (5) to improve the outcome of TB care in the private sector.

The TB notification is mandatory, is being done using the "NIKSHAY" system, and the notification from the public health sectors is being well updated, while there is slow gaining of momentum from the private sector. With the introduction of higher technology inputs brought into the NIKSHAY system, it is expected that it brings a better documentation system and more quantification of data collection. With respect to the effectiveness of the treatment regimens, NTEP recommendations are in par with the WHO-recommended treatment regimens for both new TB patients and treated patients. Furthermore, NTEP adopts the recommendations of the WHO guidelines for the management of DRTB patients. The WHO recommendations have been provided from time to time based on literature evidence. Hence, the NTEP-recommended treatment regimens are likely to be effective and are very likely to meet the objective of successful treatment outcomes. With respect to diagnosis and case detection, the NTEP has updated the guidelines in par with the WHO recommendations. The WHO recommended new molecular diagnostic tests including Gene Expert and Line Probe Assay has been scaled up across the country. Hence, the diagnosis and treatment part are both expected to be at an appreciable level. Furthermore, NTEP had been able to achieve the previous objectives laid down before,[7] and there is a scope for achievements of the new objectives as well. Importantly, the NTEP health-care workers are being imparted regular training, which is a requirement for effective program implementation. Case notification from the private sector and improving the treatment care in private sectors are challenging tasks.

What are the Known or Potential Burdens of the Program?

Although a variety of burdens or harms might exist in any public health programs, as per the framework, the majority of 3 broad categories, namely, risks to privacy and confidentiality, especially in data collection activities; risks to liberty and self-determination; and risks to justice if targeting public health interventions is only to certain groups, are to be assessed.

In process of the diagnosis of pulmonary TB, the recommended test is sputum testing and patients are supposed to collect the sputum for testing, which is a less invasive test and hence it is less likely to be a burden for the patients. In the case of extrapulmonary TB, invasive tests such as biopsy are required, but it is warranted for the diagnosis and hence the benefit overweighs its risk.

During treatment for TB, the anti-TB medications are supposed to be given supervised throughout the 6 months of treatment duration for a new TB patient, to ensure direct observation of the intake of the drugs, as per the Directly Observed Treatment Short-course (DOTS) strategy. Visiting the hospitals daily, could be a burden, but again having shown that

the supervised consumption of anti-TB drugs having a better TB treatment outcome[8] it is certain that the benefit overweighs its risk. Furthermore, utilization of DOTS provider and the provision of evening DOTS and family DOTS provider, that has proven benefits in the research studies when extended could furthermore ease the patients. India has about 40 per cent of the population infected with M. TB (latent TB infection), treating them is neither rational nor practicable and hence the program recommends Isoniazid Preventive Therapy (Tablet INH given daily for 6 months) for high-risk patients such as those receiving long term corticosteroids, immunosuppressant's, HIV-infected and juvenile contacts (less than 6 years) of sputum-positive index cases as laid down by WHO and that again benefit overweighs its risk.

When the patients do not turn up for treatment, there is a requirement for the TB health-care workers of the program to go to the patient's home for retrieval of the patients. This could trigger a burden to the patients, owing to the social stigma associated with TB. The visits might make an embarrassing situation for the patients when neighbors or relatives happen to know about the patient's TB status. However, avoiding home visits may end up in lesser compliance of TB treatment medications and is likely lead to treatment failure, development of drug resistance, and also a chance of leading to further spread of the disease into the community. Furthermore, the implementation of '99 DOTS' scheme rolled out in 5 states,[9] which is based on higher technological monitoring of consumption of the anti-TB medications, when extended to other states as well, could reduce the burden of physical visits in addition to improving the treatment compliance. The program has a provision of active case finding, where the health-care workers have to actively screen persons for TB, instead of passively waiting for them to come during seeking care with symptoms of TB; however, this may not be labeled as a burden as active case finding is restricted to high-risk individuals listed as vulnerable groups[4] and detecting the disease could some way benefit them by early diagnosis.

It is to be noted that the TB health-care workers including the doctor, nurses, lab technicians, paramedical personnel, and others have a risk of getting the TB disease while handling the patients during TB management. There could be a plan for screening for TB for the RNTCP staff members at regular intervals of time.

Can Burdens be Minimized? Are there Alternative Approaches?

When we envisaged whether the program could be modified in ways that minimize the burdens spelt above, while not greatly reducing the program's efficacy, we arrived at the following suggestions.

Instructions to TB health-care workers to be more cautious to maintain privacy and confidentiality of the patients may be given. Furthermore, with mobile phones being used much commonly by most of people, communication and motivation could be stepped up using m-health and other technologies. With Aadhar card identification procedures being streamlined, initial home visits could be avoided after verifying the Aadhar cards. Intensifying the counseling at every visit of the patient to the TB treatment center may minimize the chance of making home visits.

Screening of the staff working at the NTEP centers for TB may be done at regular intervals. It must be ensured that every TB treating units of the NTEP have adequate ventilation.

Is the Program Implemented Fairly?

Fair implementation means here whether the benefits and risks of the program are distributed fairly to all. The program aims for the same, but it is to be noted that about more than 50% of the people in India seek health care in private hospitals for TB[10] and the NTEP has limited control on these hospitals on TB management. Delay in diagnosis, overdependence on X-rays, use of multiple nonstandard regimens for inappropriate durations, lack of a mechanism to ensure full course of treatment, and to record treatment outcomes are some of the issues in private sectors.[3]

Although the new policies brought in by NTEP to strengthen the public–private partnership, their role is limited owing the prevailing health system in India. The NTEP has brought out some guidelines[11] on the public–private partnership, providing options to the private institutions and NGOs in rendering their services in Advocacy Communication Social Mobilization, Diagnosis and Treatment, TB comorbidities management, contact screening, and capacity building in operation research-by providing funding, accreditation of the laboratories and provision of the necessary materials and support. The frame work of the guideline is theoretically meritorious, but there could be some practical issues when implemented due to the current nature of the country in general. There is a need for a change in the system in general to have transparency and accountability on the TB treatment given in private hospitals. Only then NTEP will be able to provide a fair TB care management to those taking treatment from private sectors similar to their public sector care. Hence, while we do not find any evidence of discrimination between the different populations from the program perspective, we could identify a different maneuver of

care between people taking TB treatment from public and private sectors.

How Can the Benefits and Burdens of a Program be Fairly Balanced?

A system of bringing the private hospitals into the TB control program is to be developed. Operational research that could identify the difficulties on implementing the stated partnership guidelines could be studied. A strenuous effort in improving and strengthening of the public–private partnership has to be done. A method of making TB treatment in private to be accountable and transparent has to be done without affecting the vibes of the physician treating the patients has to be thought of. More frequent Continual Medical Education programs on TB management is to be conducted across the country. Involvement of professional bodies such as the Indian Medical Association and the Indian Paediatric Associations could improve the dissemination of the knowledge on the management of TB. Universal diagnostic algorithm for the diagnosis of TB that could be applicable to both public and private health-care settings could be thought off.

Incentives if giving cash of Rs. 500/-per month per patient during TB treatment recently implemented by RNTCP is a welcome move, and the NTEP personnel involved may be instructed to help and support the beneficiaries in opening bank accounts and other logistics in the process of availing the amount.

To conclude, while applying the Kass's ethical framework and analysis, we feel the NTEP provides a sound delivery of ethical principles in the program. Involvement of private sectors into the program for TB control, which is a challenging task, is a requirement for a fair provision of uniform TB care across the nation.

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Conflicts of interest

There are no conflicts of interest.

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