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Ethical aspects of the Revised National Tuberculosis Control Programme

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Abstract

This paper identifies some ethical concerns regarding the Revised National Tuberculosis Control Programme (RNTCP).

Only 10% of those with chest symptoms visiting public health facilities get specific treatment as they are diagnosed with TB. The remaining 90% who suffer from non-TB diseases are not given scientific treatment. This compartmental approach denies treatment to millions of people with chest symptoms. It has also eroded the popularity of public health facilities.

Second, though 87% of those diagnosed on the basis of x-ray alone are unlikely to have TB, such unethical wrong diagnoses continue to be carried out under the TB programme. Still worse, the RNTCP's expectation that only half of TB cases should be smear positive effectively permits up to 50% of diagnoses to be wrong. The actual extent of wrong diagnosis is even higher as the majority of people with chest symptoms first visit private health facilities which base their diagnosis almost exclusively on radiological examination.

Third, though 25% to 33% of TB cases get cured spontaneously, and at least two-thirds were cured even with incomplete treatment, the RNTCP insists on full treatment for all TB cases. This over-treatment is unethical, wasteful and also tantamount to scientific dishonesty. Studies to identify different categories of cases (those needing full treatment, short treatment or no treatment) have not been attempted. The introduction (under the RNTCP) of the "success rate" in preference to the well recognised "cure rate" was unethical and unwarranted. "Crying wolf" over Multiple Drug Resistant (MDR) TB to justify DOTS when there is no apparent alarming increase in the incidence of initial MDR tuberculosis cases is also questionable.

Other ethical concerns about the RNTCP include the irrational choice of districts leading to exclusion of those that need the services most; exclusion of diagnosed patients from the DOTS scheme, and exclusion from treatment on non-medical grounds. Such exclusions can be up to 58% of TB cases.

Introduction

The Revised National Tuberculosis Control Programme (RNTCP) (1) was initiated in the early 1990s. This paper identifies some ethical aspects of the programme for discussion.

A compartmental approach

Case finding under the RNTCP is based on the diagnostic examination of outpatients with complaints of chest problems visiting health facilities, mainly in the public sector. Even if case finding (as designed under the RNTCP) is totally successful, not more than 10% of these chest symptomatics (CS) seeking relief, who alone are likely to be suffering from pulmonary tuberculosis (TB), can be diagnosed and treated. The programme has nothing specific to offer to the remaining 90% of sufferers who are knocking at the doors of health facilities with chest problems. Is it ethical to continue, year after year, to deny proper treatment to millions of such persons seeking help, on the ground that the RNTCP is expected to give relief only to those suffering from TB? This compartmental thinking and approach have led to large-scale denial of specific treatment to millions of people who suffer from chest symptoms but who do not have TB. What makes it even more unethical is that no serious attempts have been, or are being, made to overcome this gap in services. This has eroded the popularity

of government health facilities. And the vast majority of people with chest symptoms first visit private health facilities (2-4), though the government offers free services. As a result, the scope for diagnosis of TB cases under the RNTCP has been badly limited, resulting in non-treatment of large numbers of infectious TB cases who spread the disease. To overcome these ethical and programmatic lacunae and failures, it is essential to give serious attention to research for providing proper diagnosis and care to persons with other chest diseases who present themselves with symptoms.

Wrong diagnoses

Diagnosis on the basis of x-ray examination has been in practice for a long time. One study (5) showed that 87% of those diagnosed on the basis of x-ray alone are unlikely to have TB. An in-depth evaluation of the National Tuberculosis Programme (NTP) by the Institute of Communication, Operations Research and Community Involvement (ICORCI) (6) found that during 1983 to 1987 (the last five years before the ICORCI evaluation), on an average, 6.9 lakh cases were diagnosed by x-ray every year, of whom about 6 lakh (87%) were unlikely to be suffering from TB. This practice also results in huge wastage of drugs and x-ray facilities every year. The money spent on these could be put to better use. Even more important, this causes mental agony and permanent social problems to lakhs of people wrongly diagnosed as having TB, and their families. This human aspect is often overlooked. Yet, serious discussions about this aspect are lacking.

ICORCI (6) recommended that repeated sputum examination should be the main criterion for diagnosis of TB. It is heartening that the RNTCP emphasises the importance of repeated sputum examination and spells out the limited use of x-ray. However, about 3 lakh wrong diagnoses continue to take place every year under the RNTCP alone. Further, the expectation set by the RNTCP that at least half of the cases should be smear positive leaves room for acceptance of wrong diagnoses of up to 50%. The actual situation is even worse. New smear-positive cases formed only about 40% among total new cases registered for treatment (7). For example, the reported figures for RNTCP case detection during the first quarter of 2003 shows that only 72,797 (39%) were smear positive among 185,875 treated (7). The corresponding figures were 129,083 (39%) out of 333,315 for the first quarter of 2006 (7), 152,426 (41%) out of 372,837 for the 1st quarter of 2008 (7) and 153,888 (41%) out of 373,655 for the first quarter of 2010 (7). Thus, every year about 60% of the treated cases were not likely to be true cases of TB and were unnecessarily treated and this had resulted in a colossal wastage of costly TB drugs, besides being grossly unethical.

It is pertinent that all the above mentioned reports for 2006, 2008 and 2009 showed that only 13% were smear positive among suspects (diagnosed on x-ray alone) and repeatedly confirmed that about 87% of those diagnosed on x-ray alone were not likely to be true cases of TB.

In this situation, it is of utmost urgency to conduct research to improve diagnosis by x-ray or identify simple methods to diagnose cases which cannot be detected by direct smear examination. Gene scans / mapping for diagnosing and treatment of TB should also receive attention. Meanwhile, the vast majority of smear-negative cases diagnosed on x-ray are unlikely to suffer from TB. Classifying them as "TB cases" without exception (causing worry to them and their families), and treating them, is much more unethical than waiting for some time and treating only those among them who develop TB as demonstrated in subsequent sputum examinations.

As the government realises the seriousness of the problem created by a large majority of CS visiting private clinics before they approach government facilities (2-4), it is making efforts to involve private clinics in the RNTCP. But as private clinics need to make profits, there are limits to involving them in a free service programme. Moreover, these clinics depend exclusively on x-rays for diagnosing lung TB (2) which has serious consequences for the programme (8). Private practitioners are also known to have irrational prescribing practices when treating TB, and this too is unethical. Unfortunately, providing knowledge alone does not help (9). It is a pity that this over-dependence on x-ray persists despite the caution (5), as far back as 1974, that the vast majority of those diagnosed on the basis of x-ray alone are not likely to have TB. ICORCI warned in 1988 that this was not only unethical but could also be considered a crime against society (6).

The RNTCP has restrictions on treatment of cases diagnosed on x-ray but these may not be adequate. Further, even these restrictions are yet to be achieved even under the RNTCP, since only 44% under directly observed treatment short course (DOTS) and 26% under non-DOTS are new smear positive cases (10). Thus, the majority of cases on treatment are doubtful cases.

Moreover, we do not know how well private clinics follow these restrictions in practice. The claim by many private practitioners that x-ray diagnosis is superior may be nourished by financial incentives. Further, if people have access to, and trust in, general health services for speedy diagnosis and treatment of good quality, they are less likely to approach private clinics for treatment. After all, many patients spend money and go to private clinics only because they don't get what they need from government services (11). Patients are likely to cooperate better if government institutions ensure convenient services that are quick in providing relief (12). Improvements in the quality of services have always been associated with greater utilisation of these services (13). Nevertheless, efforts at education and building private-public partnerships will have to be pursued.

Unethical treatment

Tuberculosis disease is not a uniform entity but embraces cases of several types, differing considerably (14). One possible reason for this is the fact that tubercle bacilli isolated from individuals vary in several biologically distinct factors (15). It is incorrect to assume that all TB cases require the same drugs and same duration of treatment. Some important concerns that need to be addressed are given below.

Cure rate without completing the standard course of chemotherapy: Many countries achieved a steep reduction in the prevalence of TB before the advent of chemotherapy for treatment of TB. Repeated surveys by the National Tuberculosis Institute (NTI) (16) have shown that during the 1960s one-third of sputum-positive TB cases in rural areas without proper treatment facilities were cured. Baily (17) found that in a subsidiary group of 62 patients, who were excreting drug-resistant organisms and treated with the drugs to which they were resistant (i.e., virtually not effectively treated), nearly 30% were negative on sputum culture after one year. Another study (18) showed that about 22% of sputum-positive cases detected by a house-to-house survey had shown sputum conversion after three months without proper treatment, which further increased to 25% at second follow-up after an additional 2-12 weeks. These findings show that as much as 25% to 33% of TB cases get spontaneous cure and may not need any specific treatment for TB. Moreover, studies by the NTI (16, 19) in the Bangalore rural area found that during a five-year period, the prevalence rate of infection steadily declined in the age group 0-24 years and the prevalence rate of disease showed a continuous decrease during the study period for the younger age group of 5-34 years. Further, during a period of 23 years, there was a decline of 41% in the observed annual incidence of infection from the first to the sixth survey, with the annual risk of infection (ARI) declining at 2.3% per year. With an ineffective programme which diagnoses much less than the inflow of new cases, it is likely that the observed decline in infection and disease was due to an increase in the spontaneous cure rate beyond the 33% level that has been stabilising the prevalence of the disease (16).The spontaneous cure rate might have increased slowly but steadily due to socio-economic development and improvements in living conditions. For the same reason, this increase might gather momentum and pave the way for a steady natural decline in TB in areas with socio-economic development. All these imply that at least one-fourth of people diagnosed as having TB and given supervised (i.e., compulsory) treatment are likely to have spontaneous cure, and the treatment was unnecessary and unethical for them.

Cure rate from incomplete treatment: Various studies have information on the cure rate for patients with incomplete treatment (defaulters under the programme) and those treated under the National Tuberculosis Programme (NTP) (a mixed group of defaulters and those "satisfactorily treated"). Some of these findings are revealing. Among the first group, defaulters, the cure rates varied from 66% to 74% (20-24). Cure rates among the second group varied from 72% to 90% (25-29). Out of 34,245 cases on self-administered short course chemotherapy (SCC) in different states, results of sputum examination at the end of treatment were available for 14,541 cases (30). It was estimated that 96% became smear negative (better than under DOTS?).

To summarise the findings of several studies: 25% to 33% of bacillary cases were cured without any specific treatment for TB. Second, at least two-thirds of people with TB were cured with incomplete treatment. Third, among the mixed group of NTP cases, the cure rate was even better (72% to 90%).

The extent to which the results from these three groups overlap is not known. Buet it is clear that a minimum of 66% TB cases (i.e., a large majority) did not need the complete treatment which the programme forced on them. This large-scale unethical over-treatment has been continuing for years only because we have not made any attempts to identify the characteristics of patients who got cured even with incomplete (or no) treatment.

Unfortunately, the reports on almost all the studies on treated patients, mentioned in this paper, highlight the cure rate from complete treatment but sideline the important findings on the cure rate for defaulters, even though the programme considers default a serious problem and the data were available. Research workers and planners can dig out such data from many more published reports and/or use the primary data from these studies to carry out detailed analysis according to the duration of treatment. However, these important findings are not even mentioned in publications reviewing this subject, despite availability of the data. Is this an unintentional lapse or is this a deliberate omission, and therefore scientific dishonesty?

Need for further studies: The above analysis clearly shows that studies to identify at least three different categories of cases (those needing short treatment, full treatment or no treatment) should be given the highest priority. To start with, we ought to study socio-economic and cultural status as well as physical, dietary, hygienic and other health practices and deficiencies (anaemia, vitamin deficiency etc.) as well as the mindset of all TB cases put on self-administered SCC; and follow them up irrespective of the duration or regularity of their treatment, to ascertain whether their cure rate is influenced by any of these factors. The part played by genetic factors can also be studied. Such a series of studies, using discriminant analysis as well, would help to substantially reduce or even eliminate the present unethical treatment practices. This would also lead to large savings in the cost of drugs. It is relevant here that even with very little information about patients, a discriminant analysis (31) had indicated the possibility of identifying patients under treatment who require special attention. On the other hand, it is essential to spread the net wide and choose an elaborate questionnaire for such studies to identify the three groups to the extent possible. An inadequate or limited choice of questionnaire could lead to wasted efforts or premature stoppage of the much-needed investigations. Purists might question the accuracy in identification of such groups, ignoring that (1) large scale inaccuracies in diagnosing cases have already been tolerated for far too long and even now lakhs of wrongly diagnosed cases are put on treatment, causing agony to many and (2) about two-thirds of defaulters are being given unnecessary treatment. In other words, it seems that the purists may be comfortable with about 50% wrong diagnosis and 66% to 74% unnecessary treatment. The emphasis ought to be on going ahead urgently, with scientific studies to improve accuracy in diagnosis of cases, as well as in identification of cases needing no treatment, short treatment or full treatment.

Epidemiological, sociological, bacteriological and genetic studies to ascertain the factors contributing to spontaneous cure also deserve high priority.

Other ethical issues

Ethical issues directly relevant to RNTCP: Four ethical issues have been discussed in the earlier paragraphs viz., (1) inadequate care of 90% of CS who are suffering from diseases other than TB, because of a compartmental approach; (2) the RNTCP's expectation that at least half of the cases should be smear positive when it is likely that about 87% of those diagnosed on x-ray (sputum negatives), are not TB cases; (3) grossly unethical treatment of at least 66% to 74% of the cases; and (4) serious lapses in analysis of data and/or reporting findings.

A public health ethics perspective identifies a number of other concerns in the TB programme (32). For instance, better-off districts are chosen for short course therapy and DOTS with the result that they get even better services and poorly serviced districts become further disadvantaged, even though the TB problem is likely to be more acute in the latter. Second, several criteria lead to exclusion of diagnosed patients from the DOTS scheme. The use of non-medical exclusion criteria for DOTS is certainly unethical. It is outright condemnable when the exclusion rate is as high as 58% (33). One of the key findings of the WHO's 2003 Joint Tuberculosis Programme Review of India (34) is that a significant number of patients diagnosed at government health facilities are not registered or offered RNTCP regimens (the actual proportion not reported, though this is important). It seems that the exclusions from DOTS include high-risk groups. When DOTS is claimed to be more effective, medical and social justice demands that it should be applied to the more serious cases. But, under the RNTCP, it is the other way around. Could it be that exclusions are guided by the desire to report high cure rates, even at the cost of neglecting acutely suffering patients? Moreover, a paper on ethical aspects of the tuberculosis programme (32) also pointed out that the structure of the programme does not allow inculcation of an ethics of caring and that the sole emphasis is on fulfilling the evaluation criteria rather than on well-being of patients, showing lack of ethics of care.

Even reviews of RNTCP tend to be "selectively objective", suggesting a degree of scientific dishonesty. For instance, the WHO's 2000 Joint Tuberculosis Programme Review of India (35) gives a rosy picture under the executive summary while reporting a number of negative findings under the full text (these details need more space than can be devoted here but can be expanded upon in another paper) and the WHO's 2003 Joint Tuberculosis Programme Review (34) reported that a significant number of patients diagnosed at government health facilities are not registered or offered RNTCP regimens. But the report did not mention the actual proportion, though this is important. It is also wrong to raise an alarm about Multiple Drug Resistant (MDR) TB in order to justify the use of DOTS when the increase does not warrant such panic (36). It is also overlooked that the same study did not find any increase in drug resistance over the years even though, for several years, many cases in the country did not receive "complete treatment". Further, since those under DOTS form only a small proportion of TB cases treated in the country, reduction in emergence of resistance by use of DOTS could have only a small overall impact.

Further, the extensive and dynamic Information Education and Communication (IEC) activities under the RNTCP are responsible for generating fear and stigma, something that the national TB programme had actually reduced (32). This stigma discourages the public from seeking treatment, thus delaying diagnosis and affecting completion of treatment. Declaring that non-DOTS regimens are second rate, when most of the TB cases in the country are not put under DOTS, can be a setback to the entire programme. This declaration is also unethical and unjustified because the majority of patients under the preferred DOTS are being given unnecessary treatment.

It has also been pointed out that while DOTS claims an 82% "success rate" among registered patients, SCC has a cure rate of 72% in non-DOTS as long as the drugs are available (32). This is despite the fact that non-DOTS programmes almost never exclude patients. This raises two other important questions. First, the term "success rate" includes both cured and "completed treatment" patients (among whom some might not have been cured) and has to be used with caution. Only the cure rate shows the success of the treatment. Cure and relapse rates have been well recognised as the best indicators of a treatment's effectiveness. More specifically, the first objective of RNTCP is to achieve and maintain a cure rate of at least 85%. Hence, the introduction (under the RNTCP) of the heterogeneous "success rate" in preference to the well recognised "cure rate" was unwarranted, unnecessary, misleading and therefore unethical. Second, would an increase from a 72% "cure rate" to a possibly inflated "success rate" of 82% justify the use of DOTS with all the ethical concerns that it raises?

Ethical issues indirectly relevant to RNTCP - Doctoring of political will, globally and nationally: The ethical problems are not only indigenous. For instance, how ethical is it for international organisations to influence national governments regarding health programmes? (32) How far is it ethical to motivate countries through foreign funding, without investigating ethical aspects of programmes and even indirectly encouraging unethical practices in them?

Concluding remarks

To sum up, the RNTCP is riddled with many unethical practices. Its structure is deficient in an ethics of care (32) and its main functions of diagnosis and treatment are unscientific and unethical in many ways. Some of these may be due to operational and technical problems, which are, admittedly, not easy to solve. However, we should be worried by the complacency and scientific dishonesty characterising the programme. Further, it ignores the facts and need for research. Finally, there is a lack of will to tackle problems with an open mind, by systematically adopting both scientific and human approaches.

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