Public health, ethics, and tuberculosis

Is DOTs a breakthrough or inappropriate strategy in the Indian context?

J Porter and **J Ogden** call for a debate

Since 1993, directly observed therapy short course (DOTS) has been adapted and tested in India on more than 200 lakh population in various parts of the country, with excellent results (7). This comprehensive strategy has been incorporated into India's Revised National Tuberculosis Control Programme (RNTP) and will be implemented in a phased manner in a population of nearly 300 million over the next three years.

There is an emerging debate around DOTS in India. Some claim that the strategy is a 'breakthrough' in the treatment of tuberculosis. Others disagree, having strong feelings, for example, about the importance of daily (versus intermittent) therapy or about the implications of direct observation. Some of these critics suggest that DOTS as it currently stands is simply inappropriate in the Indian context. All of these groups have data to support their positions. This paper suggests that the needs of Indians with TB can best be met through uniting these groups and engaging in a creative process of development and change. Applying the perspectives of public health and ethics can assist this process and can support the creation of a strong and effective response to the management of tuberculosis in India. It is hoped that by its publication here, this essay may help to instigate a debate within India, amongst Indian scholars, practitioners and policy makers about the usefulness of these concepts within the specific social, cultural, economic and political context of the sub-continent.

The production of health

Public health is often defined as 'providing the conditions in which people can be healthy' (13). In practice this means that public health policies, programmes and practitioners are called upon to support both the health of the individual and the health of the wider community. Yet the needs of the individual are not always - or even usually - consonant with the needs of the community. This basic dichotomy can create tension and conflict within public health and between public health, clinical medicine, patients and communities.

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In recent years a number of definitions of health have emerged which challenge us to look beyond the narrow view of health as being the mere absence of disease and towards a concept of the production of health and 'healthy communities' (14, 22). According to the World Health Organisation (WHO), for example, health is a state of total physical, social and mental well-being (31). Baer et al (2) suggest that health may be usefully thought of as "access to and control over the basic material and non-material resources that sustain and promote life at a high level of satisfaction". By situating health within the broader contours of people's lives, these definitions enable us to think about how health is created - effectively de-emphasising the view that the key to health is merely the treatment of disease.

Ethics, morality and relationship

Ethics is 'the science of morals in human conduct' (21), wherein 'moral' is 'concerned with goodness or badness of character or disposition, or with the distinction between right and wrong'. More simply, ethics can be understood as 'learning to live together' (5): at its root it is about relationship and how we use relationships to develop 'community'. Ethical principles can be used to manage conflict and to find a way forward that is appropriate both for individuals and the communities in which they live. At the core of ethics are human questions about right and wrong ('values'), criteria for guiding human action and codes of conduct that communities develop to assist the process of living together.

Ironically, perhaps, there are also disagreements and dichotomies within ethics. Currently the discipline of ethics is polarised between those who assert that there exists a 'core morality' possessed by the inhabitants of most, if not all, human communities and those who emphasise local narratives, the heterogeneity of cultures, incommensurable moral worlds, and a diversity of moral tongues (27). These opposing perspectives are important when considering the universality of ethical principles.

For those who argue the importance of local narratives, the forces acting on the creation of ethical principles are highly variable by time and place, by politics and economics, by religion and science. Although taking ethical principles from one country to another and from one culture to another is difficult, there do appear to be some common features between frameworks. How relevant are the ethical principles constructed internationally to India? Could they be useful? In this essay we argue that these principles can assist in providing a perspective for supporting and improving the current RNTP and for bringing together the disparate views currently being voiced in the debate on DOTS.

Ethics principles and tasks

Beaufort and Dupuis (4) have suggested that the ethical process might be used to clarify concepts, analyse and structure arguments, weigh alternatives, and provide advice on an "appropriate" course of action. Another way of looking at ethical argument is that it can assist us to identify the obstacles to acting “morally”. Once these obstacles have been identified, it is easier to find ways of overcoming them.

The four principles currently used by bioethicists are 1) respect for autonomy, 2) beneficence, 3) non-maleficence and 4) justice (3). Attempts have been made to bring people from different cultures together to develop these principles and use them for decision making (26).

These principles - plus attention to their scope (i.e. how and to whom they apply) - can provide the basis for a rigorous consideration and resolution of ethical dilemmas. Although they do not provide “rules”, these principles can help public health workers make decisions when moral issues arise. In effect they make a common set of moral commitments, a common moral language, and a common set of moral issues more visible and more accessible (9). These principles are considered to be *prima facie*: they are binding unless they conflict with other moral principles. They are outlined briefly below:

Autonomy

Autonomy, “self rule”, although perceived differently in different cultures, is an attribute of all moral agents. Autonomy gives one the ability to make decisions on the basis of deliberation. Autonomy is also reciprocal: we have a moral obligation to respect the autonomy of others as long as it is compatible with equal respect for the autonomy of all those potentially affected. According to the Western philosopher Immanuel Kant, respect for autonomy means ‘treating others as ends in themselves and never merely as means’ to some (externally defined) end (9).

Beneficence and non-maleficence

There is always a need to balance the effort to help and the risk of causing harm. The traditional Hippocratic moral obligation of medicine is to provide beneficence with non-maleficence: net medical benefit to patients with minimal harm.

‘Empowerment’ in health care - enabling people to be more in control of their health - is a concept which has gained much popularity in recent years. Empowerment means combining beneficence and respect for autonomy, whereby autonomy is both respected and enhanced (9).

Justice

Justice refers to the moral obligation to act on the basis of fair adjudication between competing claims. Equality is at the heart of justice, but as Aristotle argued, justice is more than mere equality - people can be treated unjustly even if they are treated equally (1). Justice and equity can be seen as synonymous, meaning in formal terms ‘to each his or her due’ (29). Both equity and justice imply that everyone should have an opportunity to attain his or her full potential for health.

These principles can be applied to tuberculosis control and the DOTS strategy. When combined with the concept of public health, they provide a perspective which allows us to weigh up the roles of the different actors involved, and to focus on concepts of interdependence, respect and relationship between these actors, persons with TB and the communities in which they live.

Tuberculosis control :DOTS

The main elements of WHO’s DOTS strategy are: government commitment to a national programme; case detection through ‘passive’ case finding (sputum smear microscopy for pulmonary tuberculosis suspects); short course chemotherapy for all smear positive pulmonary TB cases (under direct observation for at least the initial phase of treatment); regular, uninterrupted supply of all essential anti-TB drugs; and a monitoring system for programme supervision and evaluation (32, 11). The strategy has been created from a biomedical perspective and therefore concentrates on treating disease rather than on ‘providing the conditions in which people can be healthy’. Both perspectives are important and valid, both can be incorporated into a more ethical approach to TB control.

In addition to addressing technical requirements, tuberculosis control strategies for the future will look at community health needs and how and where TB fits into local health priorities. If also involved in the creation of ‘healthy communities’, TB control programmes will increasingly encompass issues which are wider than the biomedical perspective and will include interdisciplinary involvement in decision making as well as inter-sectoral collaboration.

Ethics of DOTS strategy

Each element of the DOTS strategy presents ethical and public health dilemmas which, whether consciously in the minds of the protagonists or not, feature in the DOTS debate in India. It is hoped that elucidation of these issues can instigate a process of discussion by which they can be resolved to the ultimate benefit of those affected by TB in India.

1) ***Government commitment to a national TB programme***

History has shown that disease control programmes lacking in governmental support are not sustainable. Indeed this has been the fate of a number of tuberculosis programmes where they have had to compete with higher priority vertical programmes (such as Family Planning in Asia). The converse also appears to be true: those programmes receiving full government support and sanction have met with impressive successes (e.g. smallpox and Family Planning). Yet the fact remains that tuberculosis is only one contributor to ill health amongst Indians. Although the national figures are daunting, with some analysts suggesting that as many as 4 million Indians are affected, many believe that before TB can be tackled there needs to be a stronger commitment to health itself both within national governments and within the international arena. Although there has been increasing attention to the links between poverty and health, and despite information on health inequalities world-wide, preservation of health is slipping down the priority lists of government expenditure. For example, a Save the Children report shows that each year Tanzania spends $105.3 per person on defence but only $0.7 on health; in Zaire it is $9.7 and $0.4 respectively (16).

And thus we return to the New Public Health imperatives of ‘the production of health’ and the ‘creation of healthy communities’. A single-stranded government commitment to a national tuberculosis programme may, if that programme is structured vertically (thus being independent from the consequently under-resourced health service), make some in-roads in tackling the prevalence of tuberculosis in India. Yet if it does so at the expense of the felt needs of the community and at the expense of a stronger, safer and more humane public health service, then it will have failed as a public health measure.

2) ***Case detection through ‘passive’ case finding (sputum smear microscopy for pulmonary tuberculosis suspects presenting at a health facility).***

The term ‘case finding’ takes cognisance of the fact that there are unknown cases in a community who may not present to the health sector, or who may not be identified when they do present (6).

Active v/s passive : Differences between active and passive case finding approaches, and problems with the effectiveness of passive case-finding, have been evident throughout the history of the NTP in India. In the 1960s the strongly held belief was that “...the extension in the work and aim of a clinic must not take place until and unless the clinic or the service is able to deal adequately with patients that report to it with symptoms ...” (24). This belief is reflected in WHO’s DOTS strategy. From this perspective more damage than good can be done by actively bringing patients into a programme which cannot adequately meet their needs - either for correct diagnosis or for drugs. There is also the belief that active case finding leads to over-diagnosis, over-treatment, and therefore wastage and unnecessary burdens being placed on an already over-burdened system.

In essence passive case detection relies on people presenting to health facilities for TB treatment. It pre-supposes a community where people with TB will be educated sufficiently to understand the symptoms of TB and will be able to present for treatment. It also pre-supposes the accessibility and availability of a health care facility providing TB treatment and that people with tuberculosis symptoms are autonomous agents.

Access : Over the past decade AIDS research has made important contributions to our understanding of the relationship between illness, infectious disease and social structures (20). This research has demonstrated that not all people have equal access to health care structures, and that the social meanings ascribed to certain diseases also affect people unequally. In terms of ethics, this means looking at the relative autonomy of people with TB within their community, the balance between beneficence and non-maleficence, the net gain for being enrolled in the DOTS strategy, and finally whether they are treated justly. In short, the opposition to passive case-finding revolves around 1) the belief that all people have the right to appropriate treatment and 2) the fear that many of society’s most vulnerable members will not receive treatment unless actively supported by the system.

Social and cultural burden : In addition to the effect cultural meanings have on treatment-seeking and, therefore, passive case-finding, there is also evidence that broader social structural factors may also have a role to play. While the burden of tuberculosis has been well defined from the epidemiological perspective, there have been surprisingly few attempts to define the social and economic burden of TB (25). Similarly, there are only a limited number of studies on the actual costs or economic consequences of TB borne by families, communities, and economies in the developing world (28). Nevertheless it is apparent that not all people are equally able to access health care structures (8).

Stigma : Stigma is one aspect that needs to be taken into account when considering the ethics of the passive case-finding approach. Tuberculosis carries a social stigma. It is also a disease which often affects the most marginalised, most poor and most vulnerable groups in communities, the very groups who tend to have the least autonomy. Although it is clear that the effects of stigma on passive case-finding need to be better understood, there is evidence which indicates that it will have an effect on delaying treatment-seeking and that it may substantially constrain the ability of young people and women in particular to seek and obtain care (28).

Passive case-finding may well be sound in public health terms, and even in macro-economic terms, but the ethical implications need to be taken into consideration as well. Considered and well-informed debate should enable the development of solutions which meet the needs of the system as well as the needs of the patients and the communities in which they live.

3) ***Short course chemotherapy for all smear positive pulmonary TB cases (under direct observation for, at least, the initial phase of treatment (DOT).***

The development of short course chemotherapy (SCC) has been an important breakthrough in tuberculosis treatment. The drugs involved enable patients to obtain cure for their disease in less than half the time of standard regimens. As with many technological breakthroughs, however, there are dangers involved. Unless carefully monitored these drugs can lead to the development of resistant strains of micobacteria and eventually to untreatable disease in individuals. The fear of multi-drug resistant tuberculosis (MDR-TB), together with the economic imperative to reduce hospital admissions for TB, has led practitioners and policy makers to require those receiving SCC to do so under the direct observation of a trained health care worker.

Despite the seemingly sound reasoning on which it is based, this element of the DOTS strategy has caused the most controversy. Within and outside India those who express reservations about or oppose the requirement of direct observation argue that there is insufficient evidence to support it. Detractors insist that the assumptions behind the imperative - that patients are essentially untrustworthy and that they cannot be relied upon to complete their course of treatment - have not been validated in populations where the majority of patients are poor, but none-the-less 'ordinary' members of their communities.

In a related theme it has been argued that the discourse of direct observation is one of domination and control - of the health care worker over the patient (19). In ethical terms, it can be argued that the approach fails to respect the autonomy of the person with TB. The 'care relationship' between patients and providers should, in ethical terms, be characterised by a balance between the autonomy of the TB patients and the beneficence/non-maleficence of the health care worker and should lead to net benefit with minimal harm. If the health worker attempts to force the patient into a type of treatment which they do not understand or agree with, then the relationship becomes coercive.

A person goes to a medical practitioner because he is sick and wants to get well. The practitioner has access to technology and knowledge that the patient needs. It is an inherently unequal relationship. Yet this relationship is also the key relationship in health care. In tuberculosis control, the discipline of ethics helps to frame this relationship in order to ensure that this inequality is not abused. Indeed codes of conduct are an important part of ethics in medicine. The stronger this relationship the more appropriate the care provided. This relationship is destroyed if power is abused.

Those opposing direct observation may feel that it threatens this very important relationship. It is not that DOT is wrong. In fact, the direct observation of treatment is a rational approach to the delivery of TB drugs. The problem comes, however, with the abuse of power that is potentially inherent in a relationship between a powerful medical worker and a sick vulnerable patient.

4) ***Regular, uninterrupted supply of all essential anti-TB drugs***

For this to be achieved, questions need to be asked about the type of health care system established in a country. Relating back to point number one, it asks governments to be committed to dealing with tuberculosis and to ensuring an appropriate management and distribution system for TB drugs. It is not simply the uninterrupted supply of drugs that is important, however, it is also the access to those drugs by the people who need them. This statement therefore raises questions about access to services and equity.

In the era of health sector reform, control programmes like tuberculosis, need to be flexible in order to be able to shift with the changes occurring in the overall health structure in countries. Three inter-related sets of reforms have dominated the last ten to twenty years of health policy debates internationally: financing reforms (e.g. user fees), provision reforms, and prioritising public sector resource allocations using cost effectiveness analysis (10).

Ethical processes are critical in promoting equity. 'Equity-promoting action in the health sector must put the needs and interests of the poorest and most vulnerable at their heart, as the relatively worse health outcomes of this group in comparison with other groups are most often a function of circumstances beyond their control' (10)

5) ***Monitoring system for programme supervision and evaluation.*** (32, 11).

As with the other elements of the DOTS strategy, monitoring and evaluation can either promote equity and efficiency or seriously detract from it. It is important, for example, that health care workers are able to perform the tasks they are being evaluated on: the criteria for evaluation need to be realistic and appropriate for particular contexts and given the real constraints faced on the ground. Recent operations research in India, for example, indicate that targets set at the national and international level may be placing stresses on health workers that do not promote the care of patients (15).

Questions that need to be asked in relation to monitoring and evaluation include: Is the system just and equitable? Does the system respect both the TB patients and the health care workers that care for them? Does the system encourage health care workers to identify problems or does it penalise them for 'not doing it right?' Problems need to be identified and dealt with positively. This is the art of making difficult problems soluble, a process which Medawar called the 'art of the soluble' (18). After all it is through tackling problems that we find a process of engagement and integration between people with TB, their communities, districts, states, government and the international community (23)

DOTS makes sense scientifically, but if the emphasis is on targets rather than the process developed to achieve these targets, then health care workers and patients may be used as 'means' to achieving a particular 'end': they may be abused. A system needs to be established in which both patients and providers are respected. The health service is, after all, there to provide a service for patients. A danger of having inappropriate targets for the health care worker is that they will focus on attaining these targets rather than on caring for the patient. This may lead to coercion by the health worker of the patient, or to the exclusion of the patient from the system. Targets need to be adapted to the local community situation and made appropriate to them.

As noted above, ethics requires people to treat each other as ends and not merely as means (9). Concentrating on the moral and social aspects of a monitoring system will help to ensure that this is achieved, that people are respected and TB patients are not abused in the process. 'The provision of social services has a strong person element: the quality of service depends heavily on the attitudes of the people undertaking it, and it is hard to monitor. Service provisioning, furthermore, often involves a position of power over users. Hence the importance of professional ethics' (17).

Monitoring systems obviously require indicators and targets to be set. However, a shift is required away from defining goals and targets in terms of populations (people), towards goals based on changes in organisations and systems (12).

Conclusion

Ethics is at the core of public health. Values are at the core of community life. Looking at values, dilemmas and the conflicts that ensue provides a way for communities to tackle health problems like tuberculosis. This work helps to expand perspectives and leads to interaction with people working in other disciplines as well as sectors outside health. It encourages public health professionals to ask whether disease control strategies like DOTS should encourage rights and empowerment of communities rather than control or exclusion. Should they be about the eradication of disease or about the production of health?

Globalization and health sector reform are moving those of us working on tuberculosis control to an increased understanding of the importance of a more flexible approach to TB control which encourages the active participation and creativity of communities. In infectious disease control, there is a debate which centres around conflicting notions that frame the design of programmes: one informed by bio-medical values and the other by socio-political values. The former tends to reflect programmes in terms of outcomes, numbers of cases treated and cures, following standardised procedures and assuming generalisability; and the latter tends to see TB as a disease of poverty, but which cannot wait for economic development to change that situation, and so reflects programmes which take account of patients' living and working conditions, which are flexible, accessible and try to deal with treatment regimes as well as the stigmatising effects of the disease (30). A bridge needs to be created to bring these two dichotomous positions together and the process to do this rests on the interaction between the TB control structures and the communities with TB patients. From the ethical perspective, the bridge will be constructed in the process of developing relationships between these different groups.

Through the discipline of ethics, it is possible to change perception, to shift awareness and to find different, new, and creative ways of tackling large public health problems. Engaging in the ethical debate, however, is difficult because ethics forces us to look at the other side of the dilemma and to find ways forward which incorporate all sides of the argument. A core part of ethics is 'learning to live together'; it is to do with finding new relationships and ways of interacting with people and with communities.

Ethics needs to be put into action. Mere philosophical discussion is not enough . The ethical framework provides a perspective to help us to change and we take from ethics what is needed to make these changes: flexibility, utility, equity, creativity of community, respect, and relationship.

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Tuberculosis and prisons

Contracting tuberculosis, and not getting treatment, in prison can be considered cruel and unusual punishment

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Throughout the world societies deprive individuals of their liberty in response to real or perceived misdemeanors. Such persons are held in a number of institutions, their names varying from country to country, and according to what stage of the judicial system these persons are passing through. For clarity, I will refer to the sites of incarceration as prisons, and persons in custody as prisoners.

There are no accurate data on the number of persons in the world's prisons - current estimates vary from eight to ten million. The number of persons passing through prisons in a given year is at least four to six times, and the number held in police detention over ten times that number. (i.e. up to 100 million persons annually).

Prisoners are not representative of the general community. Many selective processes operate to transfer a citizen into a prisoner - many of these factors influence the epidemiology of tuberculosis in prisons. Prisoners are predominantly male, young (15-44 years old), and belong to minority groups (with resultant poorer socio-economic status, poorer education and work prospects). It is these community sub-groups who have a high risk of exposure to infection to Mycobacterium tuberculosis.

Human rights derive from the dignity of the individual. They are by definition, universal and indivisible. Minimum levels of healthcare, accommodation and diet for every prisoner are goals that should be pursued by every state. These principles are clearly laid out in the Convention against Torture and other Cruel, Inhuman and Degrading Treatment or Punishment (1984). **Contracting tuberculosis, and not getting treatment because of poor prison conditions can be considered "cruel and unusual punishment".**

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Public health and prison health officials face many dilemmas in delivering services that may challenge, or even impinge on, prisoner rights and human rights issues. These dilemmas are more extreme, the poorer the country and the fewer the resources allocated to prison health.

Resource-poor countries with high tuberculosis burdens face many problems which work against the provision of a comprehensive anti-tuberculosis program including, low-level training of health-care workers, provision of poor salaries (or non-payment of salaries), chronic shortages on medications, and high levels of corruption. Prisons accentuate all these circumstances.

In resource-poor countries, where the custodial bureaucracy is often closely aligned to the military-police apparatus and their funds, an independent prison health service may not be achievable. Certainly prisons in resource rich countries would benefit from added independence.

Given that the health of prisoners impacts on that of the general community, the disposition of a health ministry would conceivably be more favourable toward the prison population. Also, prison health finds a place within the national health priorities, on every health indicator where prisoners are certain to be more needy.

What is important is that the prison health service, and particularly its medical staff, has adequate resources and enjoy professional independence. Where resources are limited, those that are available should be distributed to those in greatest need, in a transparent manner.

Prisons and tuberculosis

Prisons present both risks and