The utilitarian logic of maximum good for the maximum number, and the deontological logic of doing the maximum possible for each individual, appear in contradiction to each other. However what experience shows, for example with HIV/AIDS or tuberculosis, is that one cannot be effective without the other. Curative care cannot be effective if it is inaccessible and a mass programme cannot succeed if it does not provide a caring attitude towards each patient.

Good management of a health programme cannot focus only on the supply side issues. A rigorous service delivery structure can become exclusionary and coercive if it is not flexible to adapt to local context and individual needs.

Finally, it needs to be acknowledged that good ‘management’ alone is inadequate for a democratic system. Priority setting is a political task as it mediates between different sections of society and their interests.

I. INTRODUCTION

Health activities can be broadly grouped into three for consideration of ethical issues - public health, clinical medicine, and research. Public health as the over-arching discipline, which develops policy for the health sector as a whole, considers all three spheres together. Therefore, it has to take into consideration the issues relevant to each. However, the perspectives of the three may often be contrary to each other, sometimes making it very difficult to reach decisions about interventions. Clinical practitioners diagnosing and treating TB cases too, often face difficult decisions amidst the multiplicity of diagnostic tests and drug regimens, their differential costs and the social constraints of patients. Often there are diverse perspectives and opinions on the best option. Therefore it would be useful to have a general, commonly shared framework to guide the process of decision-making by policy makers, programme administrators and service providers. Bio-medical ethics and social ethics can provide such a framework. The ethical guidelines could provide a benchmark against which to test the available options, develop and implement the programme.

This paper first sets out an ethical framework for public health and then uses it to examine issues for the national programme against tuberculosis and the delivery of medical services to persons suffering from tuberculosis.

II. AN ETHICAL FRAMEWORK FOR PUBLIC HEALTH

There is an on-going discussion around ethics in public health policy-making in general(1) and tuberculosis control in particular(2,3). However ethical issues have been formulated more for biomedical research than for provision of medical care or the practice of public health(4). Four principles for ethics of biomedical research on human subjects currently provide the basis for much of the discussion on ethical guidelines for all health interventions (Box - 1).

BOX -1 : General Principles for Bio-ethics

i) Autonomy - of individuals to decide about biomedical interventions for themselves. Consent of individuals for participating in any research becomes important here. Similarly, in clinical practice it requires participation of the patient in decisions about management of their problem. For a mass programme, responding to the expressed needs of the affected persons/community and allowing for initiation of action by them would allow for their autonomy.

ii) Non-maleficence - the intervention must not have negative impact, or have only minimal negative impact that is outweighed by the benefits to the participating persons.

iii) Beneficence - the intervention must give benefit to those participating.

iv) Justice - the benefits must be equitably distributed, to each according to his/her need. [Based on Beauchamp & Childress, (5)]

These general principles can be taken as universally applicable. However, they are open to

*     *     *

Good management of a health programme cannot focus only on the supply side issues. A rigorous service delivery structure can become exclusionary and coercive if it is not flexible to adapt to local context and individual needs.

*     *     *

Finally, it needs to be acknowledged that good ‘management’ alone is inadequate for a democratic system. Priority setting is a political task as it mediates between different sections of society and their interests.
very different interpretations when translating them into concrete action. A common source of disagreement and controversy in the translation of such ethical principles is the dichotomy existing between the operational spheres of public health as intervention at population level and clinical medicine as intervention at individual patient level. This applies very centrally to debates on the tuberculosis programme.

There is an inherent professional logic of each of the three operational spheres, depending upon their respective primary objectives. Sources for interpretation of the general ethical principles into concrete plans and practice can be the internal logic of the operational sphere and external influences. While it is generally the internal logic by which decisions are taken within each sphere, it is being proposed here that the final translation of the principles into implementable decisions requires a mix of the internal and external logic. External influences on decisions within each sphere include the overlap with other spheres as well as social values that influence all spheres. It is also being proposed that, as ethics have to be practiced in very diverse real life settings, decisions must be made with due consideration to the given situation so that the spirit of the ethical principle is brought into effective practice (Table-1). When applying the principles in a specific context, ethical decisions will have to take into consideration the local epidemiological condition, the existing health services, and the economic, social and cultural context. For actual decision taking, it will have a mix of the various kinds of logic, maximising the points of convergence and resolving points of conflict between them, in the real life situation.

Among the differing social value positions relevant to bioethics, two of which are considered central to public health, are the utilitarian and the deontological perspectives. These can help understand the implications of various options better. The utilitarian conception is one that provides public health its inherent logic of maximum good for the maximum number. The utilitarian evaluation of an intervention is based purely upon its consequences for the larger number in the physical sense, without emphasis on the process and moral implications of the means employed. In contrast the deontological conception of ‘moral imperative’ places a focus on each individual as an end in himself/herself, not to be viewed as the means to an end. This conception gives importance to the motivation for an intervention, not only its consequences, demands adherence to universal and absolute moral imperatives such as ‘do not kill’, ‘do not lie’(6). The former taken to its logical extreme can even justify coercion in the name of ‘larger good’, for example as was seen in the family planning programme of the 1975-77 Emergency period in India. The latter can, similarly, lead to victim blaming at individual level, while allowing for non-action at the mass level. Yet both are of value for health service decisions if all of the four general principles are to be adhered to. Table 2 outlines the dominant principles for the public health and clinical sphere that are directly relevant to the discussion on tuberculosis.

While the utilitarian and deontological conceptions seem diametrically opposed to each other, it is being argued here that neither of them can effectively retain their basic ethical spirit when applied in practice without the other. There appears to be the need for public health to somehow bring them together in practical terms. The former reflects the basic tenet of public health from a population perspective, while the latter does so for clinical practice where the duty to treat the individual patient to the best of one’s ability is the basic tenet. If the processual dimension is ignored, the utilitarian ends up excluding one or more sections of the population through bureaucratic categories, thereby minimising the spread of benefits. On the other hand the deontological perspective remains limited in practice as it ends up giving maximal service to a few and denying any service to many. It is being proposed here that the two can be brought together in a common framework by incorporating two other kinds of ethic that have been proposed in the context of health services - the ethics of caring and cooperation (Table 2). The utilitarian emphasis is on the role of experts in making rational choices to be applied for maximum good of the maximum number. Deontological conceptions rely upon the performance of ‘duty’ to individuals by detached rational professionals. Both are thus based on technocratic abstractions. When these become the basis for planning the health services, notions of a human relationship between service provider and patient, of ‘responsibility’ and ‘caring’ slide downwards. The ethic of caring, as developed by women scholars and feminists since the 1980s(7,8) is a response to this bureaucratisation of dealing with human suffering in the liberal welfare state and its services. It is also responding to the abstract discourse of rights and justice which allows this bureaucratisation to occur. It is not for women alone but as an input into conceptualising ethics beyond that of ‘rights’ and ‘justice’(9). The ethics of caring includes the practice of equity, non-discrimination, a sympathetic and responsible attitude towards the suffering of patients, and a relationship of trust. This implies a transparency in decision-making and implementation. Its practice beyond bureaucratic services structured
Table - 1: Sources for Interpretation of General Ethical Principles

<table>
<thead>
<tr>
<th>Internal to Operational Sphere</th>
<th>External to Operational Sphere</th>
<th>Mixed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dominant Professional Logic</td>
<td>Inter-sphere logic (i.e. public health logic for clinical issues and clinical logic for public health issues).</td>
<td>An attempt to practically integrate both internal and external logic for achieving desired outcome in the real life situation.</td>
</tr>
<tr>
<td>Social Values.</td>
<td>Ground reality in specific context.</td>
<td></td>
</tr>
</tbody>
</table>

Table - 2: Conceptual Basis of Interpretation of General Ethical Principles in the Operational Spheres of Public Health and Clinical Services

Basis for Operational Principles

<table>
<thead>
<tr>
<th>Technical Tenets</th>
<th>Public Health</th>
<th>Clinical</th>
<th>Common</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal Disciplinary</td>
<td>Maximum good to maximum number in a society</td>
<td>Healing and prevention at individual level</td>
<td>Non-maleficence Beneficence</td>
</tr>
<tr>
<td>Areas of Decision-Making</td>
<td>Prioritising Interventions and Delivery Systems</td>
<td>Determining Relative Effectiveness of Various Options</td>
<td>Autonomy Justice</td>
</tr>
<tr>
<td>Measure of Effectiveness</td>
<td>% Coverage x Treatment Completion Rate x Regimen Efficacy</td>
<td>Treatment Efficacy in ideal situation</td>
<td>Decrease in Morbidity and Mortality</td>
</tr>
</tbody>
</table>

Social Perspectives in Ethical Considerations

<table>
<thead>
<tr>
<th>Conceptual Basis of Social Values</th>
<th>Public Health</th>
<th>Clinical</th>
<th>Common</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dominant Internal Logic Utilitarian</td>
<td>Deontological</td>
<td>Positivist, Reductionist, Science</td>
<td></td>
</tr>
<tr>
<td>Supplementary External Logic Deontological</td>
<td>Utilitarian</td>
<td>Social Science Determined Context</td>
<td></td>
</tr>
<tr>
<td>Basis for a Holistic Praxis Caring and Cooperation</td>
<td>Caring and Cooperation</td>
<td>Lay people’s Perspective and Action</td>
<td></td>
</tr>
</tbody>
</table>

158
by the ‘larger good’ requires cooperation between public action and civil society, with public services not being rolled back or absolved of their responsibility. Caring health care providers could act as the bridge between the public service programme with a utilitarian basis for mass programmes and civil society initiatives that could supplement it with resources for the fewer number requiring additional inputs.

Finally there is the issue of work culture and the ethics of cooperation becomes significant here. “Cooperation throughout a health care system can produce better outcomes and much greater value for individuals and for society. Such cooperation requires agreement across disciplinary, professional, and organizational lines about the fundamental ethical principles that should guide all decisions in a truly integrated system of health care delivery”(10). It has been well documented even for health systems of several European countries that shifting from public services to market mechanisms as part of the present health sector reforms led to disenchantment with competition. There was a sense of conflict between the culture of public service and the culture of the market, the greater demands for ‘efficiency’ making health care providers cut corners that went against their professional ethics, and finally leading to a shift back from competition to cooperation”(11). The deontological perspective of individual doctors would benefit by a utilitarian understanding e.g. in making them more conscious of the issue of access for all, and in their cooperating with the public health programme, in appreciating the logic of its regimen for their own patients. Thus the ‘caring and cooperation’ discourse is not mutually exclusive or conceptually opposed to ‘rights and justice’, but their complementarity in practice is the ideal public health needs to strive for. Accountability to the wider community has to be a corner-stone of any programme espousing these ethics.

III. ETHICS OF THE TUBERCULOSIS PROGRAMME

The ethical framework for public health outlined above, can be applied to several debated issues within the national programme for tuberculosis, where it can help evaluate interventions and improve the programme. It needs to be recognised that in India the providers of tuberculosis treatment include the public services and the private sector in equal measure. The public health programme must therefore address both. Secondly, the public services have two different management structures, the Revised National Tuberculosis Control Programme (RNTCP) and the National Tuberculosis Programme (NTP), and at least three different regimens in use - Directly Observed Therapy (DOT i.e. patients come to the TB center and take the short course chemotherapy under observation of the TB health worker), (non-DOT i.e. patients take away drugs for a fortnight to a month) with short course chemotherapy (SCO and non-DOT with the longer standard regimen (SR).

The districts under RNTCP with DOT-SCC and non-DOT-SR, and the districts with NTP with non-DOT-SCC and non-DOT SR are as given in Table 3. The private practitioners use an even greater plethora of combinations of drugs, some rational by pharmacological principles and others which are irrational(12). Currently, the dominant understanding being propagated among service providers and to the general public is that SCC with DOT is “the best’. It is being implemented with wide international and national support, additional funding coming as loans to the government of India. It is in this whole context that the ethical principles are being applied to the tuberculosis programme.

IV. ISSUES

A. Criteria for Inclusion and Exclusion

Ideally, all persons needing treatment should be able to get it. However, that being an unreachable goal, the principle of justice demands equitable distribution, i.e. the resources be evenly distributed so that each one has an equal chance of getting treatment, without any structural exclusion. But exclusion often occurs due to resource constraints, operational feasibility and epidemiological or technological rationale. The basis of exclusion in any programme is therefore a primary ethical concern. The criteria used for analysing cost and benefit in order to maximize the impact of resources used are crucial arbiters here. If cost and benefit take only the supply side considerations then the differential impact of social context on access and utilisation of programme services is ignored. This excludes the most vulnerable in society in the name of cost-effectiveness. The tuberculosis programme current demonstrates such exclusion at different levels.

The tuberculosis programme, working through the District Tuberculosis Programmes (DTP), still does not cover all parts of the country. The rationale earlier (i.e. in the 1960s when the NTP was initiated) was primarily ‘operational problems’ (lack of roads etc.) that now no longer holds. Decades ago the understanding was also that hill regions have little tuberculosis relative to other regions. Now this too does not hold. The first ethical task in strengthening the programme should be to remove this exclusion by expanding the
programme to all districts. But this exclusion by geographical area still forms a primary basis of exclusion of over 1/5th of the country’s population as there is no District Tuberculosis Programme (DTP) in 119 districts (Table 3).

Table 3 - Coverage of Districts by the National Programme against Tuberculosis

| Districts with RNTCP (DOT-SCC+ non-DOT-SR) | 149 |
| Districts with NTP (non-DOT-SR + non-DOT-SCC) | 320 |
| Total DTP districts | 469* |
| Districts with No DTP | 119** |
| Total districts | 588* |

* Total more than total districts (457 DTP districts and 576 total districts) due to overlap of NTP and RNTCP in some.
** Districts not implementing a TB programme largely in J&K, Uttaranchal, 5 N-E States, Chhattisgarh, Goa.

Sources: NTI,(13)
Ministry of H&FW, Annual Report 2001 (14)

Among the districts where DTPs are operational, the Directly Observed Treatment Shortcourse Strategy (DOTS) programme covers less than one-third of total population of the country because of 'operational feasibility'(15). The criteria used for choosing districts to implement SCC and DOTS are those that lead to selection of the better ones(16). So the already endowed get even better services and the deprived remain with what are considered poorer service structures. The ethics of justice requires just the reverse.

Further, in areas with DOTS implementation, several criteria lead to exclusion of diagnosed patients from the DOTS scheme(3):

a) inability to produce proof of stable residence (most difficult to obtain by the migrant poor)
b) lack of acquiescence or ability to come to the DOTS center every alternate day (which is difficult for daily wagers and the severely ill)
c) the health care provider's (TB Health Visitor, Treatment Organisers, Supervisors and Medical Officers) assessment of the patients' incapacity to complete treatment. Many, therefore, are then sent to what is considered 'second rate' regimen and services, the non-DOT, and often end up going to the private sector. This leads to an increased time lag in starting treatment and to a higher default by those outside the DOTS programme.

And thus the DOTS centers provide services to only 9% of total estimated cases in the country (calculated as given in Table 4).

The basis for discouraging registration in DOTS are customarily justified on the grounds that any patient who does not complete treatment is likely to acquire multi-drug resistant tuberculosis (MDR-TB) i.e. the ethical ground of 'non-maleficence'. So to ensure good completion rates, those who are most likely to default are excluded. However, this is a distorted utilitarian perspective, as leaving out the most vulnerable (through a system such as that of DOT that does not allow for continuation of treatment by migrants and the poorest) is likely to create conditions of greater number of cases with incomplete treatment in the community and an increase in MDR. The outcome would thus be contrary to the very reason for developing such a ‘rigorous’ discipline into the programme. This is a violation of the principle of justice and of non-maleficence from the public health logic (see measure of effectiveness given in Table 2). The low level of primary resistance even after 40 years of the earlier strategy of giving home-based treatment to all 17,18,19,20 demonstrates the low risk of MDR developing with an open strategy based on convenience and initiative of the patient.

There is in effect also an exclusion of the multi-drug resistant (MDR) cases on economic grounds, as there is no provision for specific treatment of MDR cases. The treatment is extremely expensive and not feasible in the mass programmes based on utilitarian principles. This denies treatment to the individuals with MDR-TB and increases the risk of spread of MDR-TB in the population. One possibility of providing treatment to such cases comes from the 'ethics of caring' of the TB programme personnel, leading them to utilise community mobilisation to obtain treatment for such cases. The onus would then be on the programme to inculcate an ethics of caring in its personnel. We examine this aspect in the next section. The other could be a more efficient programme i.e. one which gives similar returns for less input. The financial resources thus conserved could then be used for treatment of MDR-TB cases. We will examine the possibility of this in the section on technological options.
Table 4: Calculation of Percentage of Total Estimated Cases Treated Through DOTS Expected Break-up of cases@:

New smear positive cases: New smear negative cases :: 1:1
New smear positive cases: Re-treatment smear positive cases :: 1:0.5
New smear positive cases: Extra Pulmonary :: 1:0.2
Total cases = 230/100,000 population annually

60% of community load is expected to come into RNTCP = 135/100,000 annually

1% Annual Risk of Infection (ARI): 50 New Smear Positive Pulmonary Cases/100,000 annually

In India, Average ARI = 1.75%.
Therefore New Smear Positive Pulmonary Cases = 85 / 100,000 annually (Chakraborty 1997, page 16)(23).

<table>
<thead>
<tr>
<th>Expected ratios@</th>
<th>Estimated Cases in the Community /100,000</th>
<th>Expected Cases under RNTCP@ /100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>New smear positive cases: New smear negative cases</td>
<td>1:1 = 85:85</td>
<td>(b) = 60%of (a)</td>
</tr>
<tr>
<td>New smear positive cases: Re-treatment smear positive cases</td>
<td>1:0.5 = 85:43</td>
<td>43</td>
</tr>
<tr>
<td>New smear positive cases: Extra Pulmonary</td>
<td>1.0.2 = 85:17</td>
<td>17 (Retreatment smear positive cases)</td>
</tr>
<tr>
<td>Total</td>
<td>230</td>
<td>135 (Extrapulmonary cases)</td>
</tr>
<tr>
<td>Estimation for the whole country (10^9 population)</td>
<td>Cases=23,00,000</td>
<td>Cases =13,50,000</td>
</tr>
<tr>
<td>Performance of RNTCP</td>
<td>Total cases treated 2,11,751$</td>
<td>211751/23,00,000x100 =9.2%</td>
</tr>
<tr>
<td></td>
<td>211751/13,50,000x 100 =15.69%</td>
<td></td>
</tr>
</tbody>
</table>

Source: @ DGHS, Central TB Division, ‘RNTCP at a Glance’, (21)
$ World TB report 2002 (calculation based on data provided for year 2000)(22)
ChakrabortyAK, 1997.(23)
Thus one of the first ethical imperatives is to limit the processes of exclusion that are operating at each level, as they deny justice to the individual and lead to negative consequences for disease in the population.

B. Providers’ Attitudes

Some processes of exclusion arise out of the health care provider’s attitudes and practices, which are shaped by the structure of the programme, their training and the wider social attitudes. The training of workers emphasizes the seriousness of the disease and the problem of MDR-TB in order to enthuse them for their tasks. The Information, Education and Communication component, undertaken to make patients adhere to the alternate day DOTS regimen, does the same. This is bringing back the fear and stigma of the disease, which the stable, low key, NTP had helped to decrease, even when inadequately implemented. The doctors have now started insisting on patients covering their mouth and, as observed in DOTS centers and T.B. Hospitals, often maintain a physical distance from them as far as possible, despite the scientific irrationality of such behaviours. This fear conveys itself down the line and stigmatisation increases(24). This hinders early diagnosis, accessing and continuation of treatment.

Non-DOTS regimens have been declared ‘second rate’; in training manuals, popular IEC and technical papers(16,25). Focus is shifted to ‘the best’. The pre-existing services under NTP get discredited as a second grade service in the minds of providers and patients. Morale of workers in it plummets and the patients catered to by it become only those unable to go elsewhere and most vulnerable to default. The performance thereby further declines. Those filtered out of DOTS now have an even poorer option left for them in the public system. Turning to the private sector, many drop out soon due to the inability to continue payments. Strengthening the drug supply to the NTP as well in recent years has been an extremely positive outcome of the RNTCP, but the perception of this as ‘second rate’ colors its implementation and prevents it from achieving its potential.

Autonomy of the patient is decreased with DOTS as the patient is now not trusted and needs ‘policing’ in the name of ‘observed therapy’. However it is also true that for complete treatment of a disease like tuberculosis, support is often necessary for the patient to keep up morale and persist with treatment. A caring attitude, rather than policing for ensuring compliance, would provide this without violation of the ethical principles and limit the stigmatising attitude.

However the structure of the programme does not allow inculcation of an ethics of caring. The programme literature, guidelines, regimen and structure all communicate a very straitjacketed technocratic approach to the programme personnel. There is little sense of ‘dealing with suffering’. When they are expected to turn the most vulnerable over to what has been communicated as ‘second rate services’, the sputum negative T.B. cases are shunted back and forth between microscopy centers and T.B. clinics, when they leave the MDR cases with no real option, it does not cultivate a sense of dealing empathetically with patients. Ensuring implementation according to the technocratic logic becomes the sole purpose. Further, inability of the T.B. treatment providers in the T.B. centers to cater to any of the patient’s other health problems, whether co-morbidities or side-effects of the anti-TB drugs, tells them that the programme is ‘non-caring’ of suffering and only concerned about decreasing the ‘pool of infectious cases’. A number of problems in this regard arise out of non-integration of the TB services with the general health services. If integrated, many of the ethical problems, e.g. non-treatment of co-morbidities and side-effects or stigmatizing behaviour, could be automatically dealt with.

When they themselves are insecure (as contract workers which is an integral part of the programme’s management structure) or feel compelled to ensure fulfilling of quantified targets, they become more concerned with the programme evaluation criteria rather than well-being of the patients. They adopt even more rigorous criteria for registration of cases under DOTS than demanded of them by the programme guidelines, and add to the exclusion of the more vulnerable that are likely to default.

With all this they themselves see no ‘caring’ in the system and so do not trust its intentions. Then, instead of being able to convince the skeptics among other medical treatment providers of the public health logic of the programme, they imbibe their skepticism, e.g. about efficacy of an alternate day regimen relative to a daily regimen, which they still have to continue to propagate. Thus the system generates a work environment of ‘on-caring’. The management sciences too emphasise that work ethics arise out of what the management structures communicate. It is important to acknowledge the significance of this deontological dimension for implementation of public health programmes and incorporate considerations of the ethic of caring in the tuberculosis programme as well.
C. Technological Options

At population level, the benefit of any tuberculosis programme, with current technological capacity for diagnosis, can at best be ‘containment’ of the problem, not even expecting a decline in prevalence, leave alone elimination or eradication(26,27). Any claim of ‘control’ is therefore epidemiologically unjustifiable. It must be remembered that the declines in prevalence in the industrialized countries had occurred as a consequence of socio-economic development and the natural cycles of the disease in any population, not any medical technological intervention(28). So the programme is more to deal with the suffering being caused by the disease than decreasing the number of persons getting infected. In this context ‘caring’ becomes important again.

The options for treatment regimens lie in the drugs to be used and the strategy for their administration. Relative to DOTS with 82% success rates among the registered patients, the use of SCC in unsupervised programme (non-DOTS) has shown a rate of 72% with assured drug availability (29). In the situation of erratic drug availability, as prevailing in the old non-DOTS situation, completion rates were found in a TRC study to be 54% with unsupervised SCC treatment and 49% with fully supervised regimen(SO).

A 7-year feasibility study by the Tuberculosis Research Centre (TRC), providing 3 different regimens in 3 different groups covering 18 districts found that the completion rate of unsupervised treatment is similar, and in fact better, than the supervised one (table 5; comparing regimens 1,2 and 3). Also that the inclusion of Rifampicin for only two months of the intensive phase gives either same or better rate of sputum conversion (comparing regimens 1 and 2). The third regimen’s mechanism of delivery, i.e. self-administered for the first two months and then observed therapy for the next four, takes patient behaviour pattern into account (as maximum stoppage of treatment by patients occurs after 2 months when they start feeling relief from symptoms) and minimizes patients coming to the center for treatment on that basis, so treatment is higher than for the other two regimens. However, sputum negativity by the end of treatment is similar in groups 2 and 3. The point is that programme managers should examine these options for their suitability to extend the benefit to a maximum through rational options of regimen and flexibility in treatment choices.

Technological reasons for exclusion from ‘full treatment’ have been three -

(i) Sputum positive cases getting greater importance because they are infectious to others, and therefore sputum negative and non-pulmonary cases being put in category 3-DOTS, to get INH + Eth/Th without Streptomycin or Rifampicin, i.e. getting one drug less in the combination therapy than sputum positive new cases and two drugs less than retreatment cases and the non-DOTS regimen.

(ii) Another reason for this approach to sputum-negative pulmonary cases has been that they are more likely to be false positive cases. It has been argued by many that radiologically active cases should be given the same treatment as sputum positive ones, now that X-ray facilities are available. As only 35% of all new pulmonary cases are estimated to be sputum positive, not doing so is a form of exclusion. Diagnosis of the other 55% i.e. radiologically active cases needs to be simultaneously strengthened so that the over-diagnosis occurring on radiological grounds can be minimised and so greater reliance can be placed on radiological diagnosis even in the programmed 1. (10% of TB cases have non-pulmonary disease).

(iii) Focus of DOTS being preventing default rather than increasing diagnosis, because Rifampicin regimens are expensive and because if resistance develops to these drugs there is little to offer, leading to exclusion of the most vulnerable. This we have already discussed.

It can be argued that the additional ‘cost per patient cured’ due to the shift from NTP to the DOTS within the programme structure itself(23,32) could be more profitably utilised for support to radiologically active cases and to MDR cases.

There is no treatment for MDR cases in the public programme as the only available regimens are exorbitantly expensive. The denial of treatment because of economic cost justified on grounds of maximum good for maximum number violates the deontological logic and the ethics of caring, besides increasing the maleficence of MDR. While upholding the validity of the utilitarian principle for a mass public programme, the ethic of caring can be applied here. The technical guidelines state that MDR cases should be sent to ‘specialised institutions’(21). The same document then argues that TB Hospitals are not cost effective and implicitly discourages a policy for their use. The widely reported closure of a TB Hospital in
Table 5: Results of A Seven Year Feasibility Study Introducing SCC under Existing NTP Conditions and Comparing Three Optional Regimens

<table>
<thead>
<tr>
<th>No. Drugs</th>
<th>Delivery Regimen</th>
<th>Total patients</th>
<th>Completed treatment (&gt;80% of total days)</th>
<th>Patients available for Sputum examination</th>
<th>End of treatment Sputum examined</th>
<th>Sputum negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 2RHZ/4RH₂</td>
<td>Drugs being given twice a week under supervision for 2+4 months</td>
<td>12929</td>
<td>6349 49</td>
<td>5334</td>
<td>3441 64</td>
<td>3276 95</td>
</tr>
<tr>
<td>2. 2RHZ/6 TH</td>
<td>Drugs being self-administered for 2+6 months</td>
<td>44383</td>
<td>23944 54</td>
<td>22609</td>
<td>18065 80</td>
<td>17842 99</td>
</tr>
<tr>
<td>3. 2RH/ 4 RH₂</td>
<td>Self-administered daily for the first 2 month and under supervision for the next 4 month twice a week</td>
<td>7417</td>
<td>4541 61</td>
<td>4374</td>
<td>3665 84</td>
<td>3643 99</td>
</tr>
</tbody>
</table>

Source: Tuberculosis Research Centre (ICMR), Madras 1996 (30)

Table 6: Additional Cost Of Cure in Sputum Positive Cases Under DOTS System

i. Total likely smear positive cases in 5 years in project area = 1.9 million*

ii. Total cured in 5 years of project =1.08 million$

iii. Total project cost in RNTCP Area phase II= 5459.6 million
    Cost of Dots strategy = 4094.0 million
    Cost of NTP in the phase II = 1365.6 million

iv. Additional cost of cure per smear positive case under DOTS system +0.38#
    X 4094.0 /ii = 1307.00 (the cost of curing each patient under DOTS including those for drugs, special supervisory staff at TUs, training, etc., for category one cases. This cost is in addition to that already spent for basic DTP operation and services, including maintenance at services in a given area.)

Source: Chakraborty 1997 app. 16 (23)

* (Incidence of smear positive cases 50/100,000 p.a., corresponding to ARI of 1%, i.e 437.5/100,000 say 450, in 5 years at 1.75% ARI) x project population, 271.21 million = 1.9 million

$ Cure rate 85% in Smear positive cases under DOTS X 1.9 million

# Proportional expenditure under RNTCP on smear positive new cases
Bhopal and another in Chennai, in the recent past, throwing out the indoor patients in a most callous manner, then becomes a natural consequence.

D. Community Involvement

Social and economic support to patients is an important input to prevent default by the most vulnerable but is not part of any official programme strategy. Some programme implementers have attempted to provide such support and find it very useful (personal communications). Community resources can be mobilised for this by a caring system.

The WHO estimates 2-6% cases of failure to cure even with complete treatment through DOTS in the Indian context (22). The caring health system should also be able to mobilise civil society for the more expensive treatment for these cases.

Community mobilization for both these tasks requires a shared understanding of ethical principles between the programme and the community. The onus on the programme formulators would therefore be to consciously make efforts to know the community’s perception of ethics of a health service and to relate to it, even while communicating its own ethical logic. A process of organic linkages and dialogue between the providers and the community would make this possible.

Often there is a conflict of views on the management of TB cases between public and private providers as well as between providers and patients. Shared ethical considerations could help resolve the conflicts. The programme itself would have to be more flexible to incorporate local innovations developed to improve access and utilisation in specific contexts. This can be witnessed in the DOTS adaptation of adopting members of the community as the ‘observers’ for DOTS rather than health workers only.

Besides giving information to the community about TB treatment and how it can be accessed, the collective family process of decision-making about treatment will have to be considered. With ‘passive case finding’ i.e. the patient coming to the TB centers upon suffering the symptoms, the extent of trust in the public programme will determine utilisation to a large extent. Generating this relationship of trust is important for community involvement and giving access to the most vulnerable.

E. Transparency and Accountability

Trust can come only with transparency. Complete and correct information to the patients and their relatives is one ethical requirement. Providing complete and clear data on the programme, showing both its achievements and limitations is just as important an ethical public health requirement. The published reports do not provide data on the number or proportion of cases put on non-DOTS regimen in RNTCP areas, which is essential for any evaluation of impact of RNTCP. On the other hand there is discrepancy in report of different agencies (i.e. between DGHS, NTI & WHO 33,34,13,22) creating doubts about the mechanisms for monitoring and transparency of the programme (Table 7).

V. CONCLUSION

Ethical principles are very general and universally applicable but their translation into concrete practice requires a consideration of specific context and a holistic rather than a technocratic perspective. Here we have dealt with the case of a public health programme dealing with a serious communicable disease in a resource poor social setting. The current context is also of a resource intensive internationally backed strategy being introduced along with new management structures replacing the old ones of an indigenously developed programme.

For any health service, exclusion from treatment on non-medical grounds is undebatably unethical. Some exclusion is justified in mass programmes on grounds of resource constraints. But the basis of exclusion on the medical or economic grounds must be transparent so that others can assess them and ideas can be pooled to minimise the exclusion.

The utilitarian logic of maximum good for the maximum number, and the deontological logic of doing the maximum possible for each individual, appear in contradiction to each other. However what experience shows, for example with HIV/AIDS or tuberculosis, is that one cannot be effective without the other. Curative care cannot be effective if it is inaccessible and a mass programme cannot succeed if it does not provide a caring attitude towards each patient.

Good management of a health programme cannot focus only on the supply side issues. A rigorous service delivery structure can become exclusionary and coercive if it is not flexible to adapt to local context and individual needs, or sensitive to the ethical principles of autonomy, justice, and non-maleficence simultaneously. Complete transparency on financial and technical assessments with the professional peers and lay public alike, is necessary for sustaining ethical action.
Finally, it needs to be acknowledged that good ‘management’ alone is inadequate for a democratic system. Priority setting is a political task as it mediates between different sections of society and their interests. What are the ethical considerations of international programme managers in ‘generating political will’ at the top of the administrative and political leadership in individual countries for specific programmes? Doing so through enticement of foreign currency loans for adjusting the country’s balance of payments and not as a way of dealing with suffering of their people cannot generate a ‘caring’ programme.

‘Education funds’ for such generation of ‘will’ led to the Enron phenomenon. It can be viewed as interference in the local social and political dynamics for determining priorities and thereby antidemocratic and unethical. Each health administrator and health care provider therefore needs to understand and weigh the technological options and possible delivery systems against a comprehensive, shared ethical framework. It is hoped that this paper will contribute to developing such a framework.

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