The Forum for Medical Ethics Society

The Forum for Medical Ethics Society (FMES) was founded in 1994 by a group of health professionals, researchers and activists interested in health care ethics. FMES is a registered body under the Societies Registration Act of 1860.

One of FMES's activities has been the publication of a quarterly journal, *Indian Journal of Medical Ethics* (formerly *Medical Ethics* and then *Issues in Medical Ethics*). Published regularly every quarter since its first issue in August 1993, IJME has promoted discussion on ethical issues in health care in India while raising concerns relevant to developing countries as a whole.

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The Centre for Studies in Ethics and Rights (CSER) is a research and training institution set up by the Anusandhan Trust. CSER was set up in January 2005 to develop research and training programmes in ethics and rights for students, researchers in the social and biomedical sciences, and various professional groups including social workers, medical practitioners, counsellors and lawyers. CSER has organised a number of programmes in collaboration with institutions and individuals interested in the field of bioethics. It has also started publishing collections of papers on ethics, in collaboration with various organisations.

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Technology in healthcare
Current Controversies

Forum for Medical Ethics Society, Mumbai
and
Centre for Studies in Ethics and Rights, Mumbai

Editors
Sandhya Srinivasan
George Thomas

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Introduction

A broad definition of the word "technology" is the application of knowledge. By this definition, the use of fire and the invention of the wheel qualify as technologies, as do the internet and recombinant DNA. Healthcare technology is the application of knowledge towards practices or products that may be used by healthcare practitioners. Such technologies can therefore range from vaccines to vector control, from liver transplants to lethal injections.

The articles contained in the nine sections of this anthology cover important ethical debates on healthcare technologies.

Essentially, discussion on ethics is about tensions: tensions between opposing interests and the principles that could be used to resolve these tensions and decide on a course of right action. Discussions on the ethics of a technology can cover the context in which a technology is developed as well as the way in which it is used in a society.

The articles in each section of this anthology of the *Indian Journal of Medical Ethics* were selected to represent major debates on the ethics of healthcare technology – its development and its application. They cover issues in clinical practice, in research and in public health. The contributors are practising healthcare professionals, heads of institutions, researchers, community workers, activists and patients or their relatives and most of them write on the basis of their experiences rather than within a formal framework of ethics.

Using the debates presented in each chapter as a point of reference, the commentary writers highlight the tensions that emerge in the development or use of various healthcare technologies. In one way or the other, all of them also touch upon four principles that are often presented when analysing the ethical basis of a decision: What is the benefit? What is the harm? Does it ensure the individual's (or organisation's) autonomous decision-making? Does it promote social justice? Finally, all of them take a stand on what an ethical decision would be.

Ruth Macklin thrashes out the nuances of a major controversy in research ethics: the use of a placebo control in clinical trials when an effective treatment exists. The most urgent question in the articles in this section is "(w)hether it is ethically correct for clinician-researchers, with limited resources of manpower and time, to participate in these trials that are clearly being conducted

solely for regulatory bodies overseas, when there are many unanswered questions of clinical relevance to healthcare in the region."

Rammanohar Reddy discusses intellectual property rights and their practical and ethical implications on access to affordable drugs. He states that any discussion on the ethical implications of intellectual property rights must recognise that the basic tension is "between the basic tenets of a humane society and the demands of a market economy driven by profit-maximising behaviour".

Neha Madhiwalla describes the tension between the pressures on healthcare professionals who implement the government family planning programme and the concerns of women who seek contraceptives as a means of some control over their lives. She writes: "Women, at the very outset, are making contraceptive choices in the context of unequal, and often conflict-ridden, relationships."

Bebe Loff and Brad Crammond look at how the principle of justice can be applied in decision-making on access to treatment, using the example of the government's antiretroviral drug programme. They ask: "If the government is the body most able to provide institutional support for distributive justice, utilising fair procedures, what methods will convince it to do so?" and suggest that it is not enough to discuss the process by which decisions should be taken. "Debate should occur around the nature of those social institutions just as it should about their guiding philosophies."

Vikram Patel takes a stand on a heated debate between some psychiatrists and representatives of civil society on the use of electro convulsive therapy without anaesthesia, but emphasises that "the issue of ethics in psychiatric practice needs to go beyond the issue of direct versus indirect ECT…such as the near-complete absence of psychosocial treatments and community care for the vast majority of the mentally ill, and the irrational use of psychotropic drugs."

Sanjay Nagral argues that the pressures of a privatised healthcare system drive the manner in which specific technologies are developed and disseminated, using the example of how a live donor liver transplant programme, with its attendant risks and ethical questions of donor consent, has grown at the expense of a cadaver-based transplant programme. "It is not difficult for anyone familiar with the style of practice of medicine in India to understand that the solidity of two critical components of the ethical basis of living related liver transplant—donation based on true bonding with the recipient and genuine informed consent—will be severely tested."

Ram Rajagopalan suggests that the reluctance that physicians have to withdraw or withhold life-sustaining treatment in certain circumstances is based on misconceptions: of ethical principles, of the law, and of the physician's duty. "…the physician should recognise that he could only serve in an advisory role, with the patient (or his surrogate) given the autonomy to choose the preferred goal...Further, physicians have the ethical obligation to provide only treatments that benefit, and to avoid those that harm the patient."

Mihir Desai looks at the legal and ethical issues that arise when health professionals who are trained to work for the benefit of the patient take on the job of acting in the interests of the government. Using the examples of the narco analysis test for interrogation and lethal injection for the death penalty, he asks: "Do these practices constitute human rights violations? If so, what are the implications for ethics when medical professionals get involved in them?"

Finally, Imrana Qadeer discusses the different ways in which debates in public health ethics are articulated, from "the ethical conundrum of the medical practitioner with faith in his vaccines but reservations about the vaccine programme itself" to "public health practitioners who value technology but are critical of its organisation as well as the scientific basis of that organisation." She notes that "debates with the involvement of the public must become a part of the ethical tenets of public health."

The articles in this anthology represent the beginning of the debate. They must provoke further discussion on the overall context in which healthcare technologies develop, the ways in which they are used, the harms they can cause and the benefits that they can provide.

– Sandhya Srinivasan, George Thomas

Research ethics, placebo controls and standards of care

Ruth Macklin

This series of articles addresses important topics of current concern in research ethics. Three of the articles focus on the ethics of the use of placebos in clinical trials where an available treatment for the condition under study exists. Related to the discussion of placebo are the questions of whether "clinical equipoise" existed in the trial described in the article published in the *British Journal of Psychiatry*; the possibility of a "therapeutic misconception" on the part of trial participants; and the adequacy of informed consent, especially in a population with a psychiatric disorder. The fourth article addresses the topic that has come to be known as "standard of care": whether placebos or other comparators can be justified in clinical trials in developing countries with fewer resources than in industrialised countries where such trials would be deemed unethical. This commentary begins by discussing the topics on which the first three articles focus, including remarks about "standard of care", and ends with a criticism of "double standards".

The literature on the ethics of the use of placebos remains fraught with controversy. At one extreme are those who argue that placebos are never justified in clinical trials when an effective treatment routinely prescribed by practising physicians exists (1, 2). At the other extreme are those who contend that placebos may be used as a comparator in all cases except those in which withholding a medication may result in serious, irreversible harm or death (3). A third position seeks to find a middle ground, and claims that each of the extremes has some merit (4). A rather protracted debate has dealt with the use of placebo in resource-poor countries that cannot afford "the best current method anywhere in the world", questioning whether double standards are acceptable in research involving human beings: one standard for rich countries and a lower one for resource-poor countries (5, 6, 7, 8).

Vikram Patel asks whether there is an ethical basis for a placebo-controlled trial involving participants with severe mania. Not only was an evidence-based treatment withheld from the control group, in addition, participants had to undergo a "washout" period in

which all medications were halted before embarking on the trial using different psychiatric medications. Patel questions whether the most seriously ill patients should have been enrolled in the trial. The ethical principle cited in this critique of the ethics of the trial is: "No trial participant must be harmed in any way." Although well intended, the principle is stated in a form that is too strong and too absolute. It is too strong because it is common in research for participants to be harmed in some ways: such as by being submitted to the known side effects of existing or experimental drugs. Think, for example, of clinical trials of cancer drugs, which are certain to harm the participants. The key, however, is that the risks of harm must be outweighed by the anticipated benefits of the study drug and any comparator used in the trial. Patel's formulation of the ethical principle is also too absolute since some justifiable studies deliberately produce harm. This is true of all dose-finding studies in phase-I clinical trials, the aim of which is to determine the maximum tolerable dose of an experimental treatment. A great many phase-I trials do not proceed to future phases because a safe, non-toxic dose that would also likely be efficacious cannot be found. Moreover, a variety of studies using healthy volunteers may produce some harm even with no possible benefit to the participants (baseline physiological studies involving blood draws, lumbar punctures and treadmill exercise are among the examples).

Nevertheless, Patel's criticism of the placebo-controlled trial can be rescued by a slightly different formulation, still highly critical of the psychiatric trial. That is: "Participants in biomedical research with a disease or other malady should not knowingly be made worse off in a trial than they would be outside the trial." To withhold a medication from individuals who have demonstrated a need for that (or similar) medication, which they could receive outside the trial, is knowingly to make them worse off by enrolling them in the trial. This principle is widely but not universally accepted. Furthermore, it leads directly to the debate about conducting research in developing countries that could not be carried out in industrialised ones. The defence of that situation has generally been that the participants who receive the placebo would not be put in a worse position by being enrolled in the trial, since they would not have access to the medication outside the trial anyway. We shall return to this theme later.

The defence of the use of placebo has a special application in psychiatric trials. As **Prathap Tharyan** correctly points out:

"There is a substantial placebo response rate in people with major depression ranging from 12.5 per cent to 51.8 per cent, supporting the view that the inclusion of a placebo group is scientifically important in trials of new antidepressant medications," adding that: "Spontaneous remission is not unusual in acute mania and would not be detected were a placebo not used." These two circumstances—a substantial placebo response on the part of people with psychiatric (and other) conditions, and a varying course of the disease, including spontaneous remission—are the most cited methodological reasons for the need to include placebos. The question remains, however, from a methodological point of view, since these facts about placebo and spontaneous remission are well known, why can they not be factored into the statistical analysis of the study when both arms of a clinical trial receive a medication? Participants receiving the standard medication and those receiving the experimental product would both be subject to the same placebo effects and the same overall likelihood of spontaneous remission.

When clinicians are seeking a new treatment for their patients, they are not interested in knowing whether a new product is better than placebo. They want to know whether the new medication is more efficacious than the existing ones, or whether it has fewer side effects. Comparing an experimental drug with placebo in a phase-III trial will not provide information comparing side effects or discomforts—unless, of course, there is a "dark side" to the placebo effect that emerges when research subjects are informed about side effects in the consent process (9).

The response by **Sumant Khanna** to Vikram Patel is, therefore, curious: "By including a placebo group in this study, we were able to establish the efficacy and safety of risperidone over and above what can be observed with a placebo." In what specific respects was risperidone observed to be safer than placebo? Critics of the routine use of placebos, especially when clinical trial data is submitted for approval by the US Food and Drug Administration, question whether the data from placebo-controlled trials is useful to physicians who have to determine which of the approved medications is best indicated for their patients.

Prathap Tharyan correctly points out a number of shortcomings in participants' understanding of crucial elements of clinical trials. These include the facts that they are not often

aware that placebos form one arm of treatment, demonstrate inadequate comprehension of the process of chance in treatment allocation, understand and use only a proportion of what is presented in consent forms, do not really understand the issue of equipoise, and participate not for altruistic reasons but because they expect some improvement by participation.

Many empirical studies of informed consent documents and process confirm these flaws, although I am not familiar with studies conducted in India. Given these numerous problems, what is the solution? One glaringly obvious possibility is the need for researchers and sponsors to take considerably more time and effort in the consent process that Tharyan points out is the correct way to view informed consent (that is, not as an event). Is it necessary, however, for research participants to understand "clinical equipoise"? It is surely necessary for them to understand the fact that research is not treatment, and that the researcher is not their personal doctor determining what is best for their clinical care (the therapeutic misconception). If, indeed, it is the case that participants do not understand that they may receive a placebo or an experimental drug, and not a treatment demonstrated to be efficacious, then their consent is not truly informed and a main ethical tenet of research is violated. It could well be that if potential participants knew that their only possibilities were placebo or an experimental drug, some would not choose to participate. That is what informed consent is all about: a right to dissent from participation, as well as to consent.

Tharyan poses what is perhaps the most urgent question of all in this series of articles: Whether it is ethically correct for clinician-researchers, with limited resources of manpower and time, to participate in these trials that are clearly being conducted solely for regulatory bodies overseas, when there are many unanswered questions of clinical relevance to health care in the region.

The question actually divides into two sub-questions: (a) why conduct research in resource-poor countries when the purpose is to get regulatory approval in an industrialised country? and (b) why not focus research in developing countries on the most significant health needs and priorities in those countries? It is abundantly clear why sponsors want to conduct trials in developing countries and why those trials are typically placebo controlled. It is cheaper and faster to do a placebo-controlled trial than a non-inferiority trial because fewer subjects are needed and the results can be analysed more readily. That is obviously of benefit to industrial sponsors. Whether it is easier or more difficult in either case to recruit a sufficient number of participants and to obtain approval from a research ethics committee in developing countries is an empirical question that would have to be studied.

Yet another question of principle arises, that of justice in the conduct of research. If the studies conducted in India yield successful products, and those products will not be accessible or readily available to the population following the trial, is this not a violation of the principle of distributive justice? That principle mandates that the benefits and burdens of research should be distributed equitably among all groups in the population. In this case, the population is the global one: research participants are in India, whereas the majority of potential beneficiaries are in industrialised countries. Just as it violates the principle of distributive justice when research participants are recruited from poorer segments of society in any one country but the benefits accrue to those who can afford to pay for the successful products of research, so too is the principle violated when the scope of research is global rather than national (10).

This brings us to the fourth article in the series, which defends the use of double standards in judging the ethics of research in developing and industrialised countries. **Robyna Irshad Khan** argues that it should be acceptable to hold different researchers to separate standards of care on the basis of their intentions, their financial resources, their ultimate gains from the research, and subsequent utilisation of the results of the research, even when these researchers come from the same country where the research is being conducted.

The problem with judging researchers on the basis of their "intentions" is that these are notoriously difficult to fathom, and anyone can claim to have one intention while in reality having another. Although it is true that financial resources vary considerably among researchers and sponsors throughout the globe, basing the standard of care provided to participants in clinical trials on the wealth of those conducting the research sacrifices ethics at the altar of money. A formal principle of justice mandates treating like cases alike. If participants in a clinical trial in an industrialised country are afforded one standard of care and participants in a similar trial in a resource-

poor country receive a lower standard of care, that principle of justice is violated. The background financial status of the country or community where the research is conducted should have no bearing on what is owed to participants in research.

The two cases Khan provides for discussion are not comparable. In the first, the ethical issue revolves around the comparator (inexpensive, single-dose regimen) for the control group. In the second, the pharmaceutical company agrees to provide the best proven treatment to the control group, but fails to ensure that the resulting product, if successful, will be made available to the community at an affordable price. The unstated assumption is that if Dr K's study proves successful, the resulting drug combination will be accessible and affordable to everyone in the community who may need it. But there is no way of guaranteeing that outcome, as Dr K himself surely lacks the resources to provide the medications, just as he lacks the resources to provide the best proven treatment to the control group. There is, in addition, a methodological problem with the first case. A small randomised, controlled trial would lack the statistical power to demonstrate efficacy. Regulatory agencies do not approve drugs resulting from clinical trials that lack sufficient power. Rigorous scientific standards must be used in the design and conduct of clinical trials in order to ensure that the results are accurate.

Getting sponsors to ensure that successful products of research will be accessible and affordable to populations in developing countries remains an ethical challenge. That responsibility should fall to the Ministry of Health that allows big pharma to conduct trials that can be done more cheaply in resource-poor countries than in the industrialised nation where the company is located. Perhaps if research ethics committees were to begin systematically to reject proposals that did not include a mechanism for distributing successful products, that would induce the rich and powerful companies to fulfil the requirement of distributive justice in the conduct of research.

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Ethics of a placebo-controlled trial in severe mania

Vikram Patel

In October 2005, editors of the IJME *learnt that the* British Journal of Psychiatry *had published a report of a placebo-controlled trial of an atypical anti-psychotic drug. The drug was tested on 290 people experiencing an episode of acute mania. The trial was conducted on in-patients of eight health facilities in India.*

A letter raising questions about this study has been submitted to the British Journal of Psychiatry. *It was also felt that the journal should carry a discussion on this subject. We therefore publish here a comment on the study itself, raising specific questions about the trial. This is followed by a comment on ethical issues in placebo-controlled trials in general. The third article is a response from the corresponding author of the study.*

Bipolar disorder is a severe mental disorder, called manic-depressive disorder in older classifications of mental disorders, characterised by severe mood swings. During the manic phase, the person typically becomes irritable and agitated, is unable to sleep, experiences a rapid flow of thinking, and may become psychotic. The hallmark feature of the phase is the loss of insight: the person is unaware of his / her illness and often needs to be brought to medical facilities by concerned relatives. In severe cases, the person may need a period of hospitalisation to bring symptoms under control. Indeed, acute manic episodes are one of the commonest reasons for hospitalisation in psychiatric care.

Khanna et al have recently published a clinical trial evaluating the safety and efficacy of risperidone, an atypical antipsychotic drug, for acute mania, in the *British Journal of Psychiatry* (1). This article describes a placebo-controlled randomised controlled trial of risperidone for patients with severe manic episodes. The trial was carried out in eight centres in India, and was funded by Johnson & Johnson Research and Development; four of the six authors work for the funding body and are based in the USA and Belgium. In the introduction to their article, they state that "bipolar disorder is a debilitating illness characterised by drastic swings in mood, energy and functional ability". They note that there is abundant evidence of the efficacy of a number of different treatments for acute mania, in particular conventional antipsychotics (such as haloperidol, a cheap drug considered by many as the gold standard for acute mania) and mood stabilisers (such as lithium). In the light of these facts, and the nature of the disorder, this trial raises some important ethical issues.

First, is there an ethical basis for a placebo-controlled trial in severe mania? The authors note in their discussion that the symptoms of their patients were "substantially more severe than those of patients with bipolar disorder participating in trials elsewhere", indicating that these were the most seriously ill patients to be recruited in published trials for acute mania. The ethical principle is that no trial participant must be harmed in any way. This typically translates to ensuring that the control group in a trial must receive what is usual evidence-based care in the circumstances. Haloperidol is cheap, freely available and constitutes usual care even in government facilities in India. Indeed, the majority of patients (>80 per cent) in the placebo group were already receiving psychotropics at the time of enrollment including 41 per cent receiving haloperidol and 42 per cent receiving chlorpromazine (similar to haloperidol); they were "washed out", i.e., these effective treatments were discontinued as a prerequisite for participation in the trial. Thus, not only was this group of extremely sick individuals denied usual care, but they were actually deliberately stopped from receiving such treatment.

Second, how was signed informed consent obtained (as is mentioned in the paper) from such severely ill manic patients, the majority of whom had florid psychotic symptoms when insight and capacity to make informed decisions are typically seriously impaired? What was the independent safeguard to ensure the rights of these patients to freely consent to participate in a trial in which they would be taken off the effective treatment they were already receiving and be possibly subjected for three weeks to a placebo? The authors comment that the rate of "completion" of the trial was high in this trial as compared to developed countries and cite that reasons for this are that patients were more severely ill and that they remained in hospital throughout the trial. This implies that these very sick patients, who were not given (and indeed, who were stopped from continuing) a cheap and effective treatment, were kept in hospital (at least some in the private sector) for longer than they possibly needed to.

Third, was there any financial transaction between the authors and the drug company? In my experience, many private physicians receive

payment for participation in clinical trials. Given that the first author is based in a private facility in New Delhi, a declaration of conflict of interest (not mentioned in the publication) should have been made. As it stands, one must assume that the authors received no remuneration at all; if they did, then they would have contravened the mandatory requirement of declaring a conflict of interest.

Fourth, there is no mention anywhere of any institutional review board (IRB) approval for this trial. Given that patients were recruited from eight centres in India, what were the IRBs which gave approval for this trial?

Fifth, what new information does this trial add that justifies the trial in the first place? In the introduction, the authors provide three citations in support of their statement that atypical antipsychotic monotherapy (for example drugs like risperidone, without any other concomitant medication) is effective and well tolerated for acute manic episodes. Furthermore, risperidone was licensed for use in India in the late 1990s and the indications noted for its use in the *Monthly Index of Medical Specialities (MIMS)* include psychotic syndromes such as those which are seen in acute mania. What does this trial add to the evidence base for patients in India? Surely, a more appropriate question for a low-income setting would have been to compare the atypical drug, which is more expensive, with a conventional drug, which is much cheaper, on clinical, safety and, most importantly perhaps, economic outcomes?

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Placebo-controlled trials in psychiatry on trial

Prathap Tharyan

The well-conducted randomised controlled trial (RCT) is widely regarded as providing the most unbiased estimate of the true efficacy of interventions (1, 2, 3). Ethical concerns have been raised by professionals and lay people since the advent of the RCT. These largely involve the issues of whether true equipoise (a state of uncertainty where a person believes it is equally likely that either of two treatment options is better), which forms (or should form) the basis for conducting an RCT, is possible in clinical research (4); the use of placebo controls, especially where effective treatments exist (5, 6, 7); and the problem of how informed, voluntary and competent the consent obtained for such trials really is, especially in vulnerable populations and when research is conducted in settings of routine clinical care (7). More recent concerns pertain to the ethics of conducting clinical trials in the developing world (8). An additional issue is that of the ethics of conducting clinical trials in resource-poor settings that appear to be purely for the regulatory purposes of foreign agencies.

Do patients lose out by participation in randomised controlled trials?

One of the concerns about RCTs is that by randomisation, patients are exposed to risks they would not face if they had not participated in such trials. Systematic reviews of the evidence indicate that participation in RCTs is not associated with greater risks than receiving the same treatment outside RCTs (9) and that participants given the active intervention as well as controls had better outcomes than those who declined participation, even after adjusting for prognostic confounders (10). This suggests a non-specific "Berksonian" effect of better care accruing from trial participation.

Are placebo-controlled trials justified?

There is general agreement that placebo or untreated controls are not appropriate in trials of therapy for life-threatening conditions if a treatment that prolongs or preserves life is available. The disagreement centres on trials of therapy for non-life-threatening conditions. In

general, the empirical evidence supports the conduct of RCTs if true equipoise exists, that is, if both drugs offer equal benefits, or the known potential side-effects of the treatments are unequal. In Article II.3 of the 1996 version of the Declaration of Helsinki of the World Medical Association (WMA) placebo controls were permitted only in studies where no proven diagnostic or therapeutic method existed (7). Reacting to criticism that this not only limited the use of placebos but ruled out the testing of all new therapies for conditions for which even partially effective "proven" treatments existed, Article II.3 was replaced by the new Article 29 with a clarification in 2001 (7) that clinical trials with a placebo control group would be ethically justified "for compelling and scientifically sound methodological reasons"; or if its use is for "a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm". This then would require a study-specific review of the justifications for placebo use, based on scientific merit and study-specific risk involving careful subject selection and risk-reduction procedures; this has been reported to be applicable to trials of people with schizophrenia (11).

It has been suggested that the need for concurrent placebo control groups in new studies on psychotic patients might be minimised by making comparisons with external placebo; this requires an assumption that the novel medication will perform the same way in a study with only active controls as it would have in a placebo-controlled trial; this assumption is not borne out by the evidence from 32 RCTs involving 7,264 patients randomised to atypical antipsychotics that showed that in atypical antipsychotic medication arms, the degree of improvement was nearly double in active-controlled trials than that seen with the same drugs and dosages in placebo-controlled studies (12).

There is compelling evidence from a systematic review of 75 RCTs that there is a substantial placebo response rate in people with major depression ranging from 12.5 per cent to 51.8 per cent, supporting the view that the inclusion of a placebo group is scientifically important in trials of new antidepressant medications (13). The placebo response rate in acute mania has not been systematically reviewed but in the trial under scrutiny (14) between 35 per cent and 40 per cent of people with acute mania on placebo who were all at least moderately ill at trial commencement were not ill or only mildly ill at the end of the trial (Figure 3, p 232). This appears to justify the use of placebo in this trial from a scientific point of view, since spontaneous remission is not unusual in acute mania and would not be detected were a placebo not used.

Placebo-controlled trials are not uniformly unethical when known effective therapies are available; rather, their acceptability is determined by whether the patient will be harmed by deferring therapy. If patients are not harmed, such trials could ethically be carried out (15). If the trial were conducted in an inpatient setting with careful evaluation of all participants for worsening, non-response in a reasonable period of time, or adverse effects, and the protocol permitted withdrawal of any participant at the discretion of the investigator, then harm could be minimised. All participants in the trial in question (14) were permitted lorazepam for various indications, in addition to the study drug, and 99 per cent of participants received it, including those allocated to placebo; benzodiazepines are of some benefit in the symptomatic treatment of people with acute mania. The report also provides some details of trial completion rates and reasons for discontinuation (Table 2, p 231) that reflect the fact that dropout rates are higher in the placebo control arms of RCTs of conventional and atypical antipsychotics (16).

Would dropouts and non-response alter the overall prognosis of those on placebo? Placebo treatment of manic and psychotic patients involves several potential risks. Among them are the distress and disruption produced by the continuation of manic or psychotic symptoms, the progression of the illness with the potential for poorer recovery from an episode and the risk of suicide. Indications from other sources suggest that rates of suicide and attempted suicide did not differ significantly between the placebo-treated and the drug-treated groups from among 10,118 participating patients in placebo-controlled antipsychotic drug trials (17) nor in 11 placebo-controlled studies of the treatment and prevention of acute manic episodes and bipolar disorder that included 1,511 patients of whom 1,005 were on placebo (18). However, in the absence of systematic information about the other potential and not insubstantial risks apart from suicide, this remains an area of current uncertainty that requires systematic study and follow-up.

How informed, voluntary and competent is consent obtained in randomised controlled trials?

Firstly, should randomised controlled trials be done in people with acute mania or psychosis? The answer is yes, since the efficacy for interventions in acutely ill people with mania or psychosis cannot be

answered by studying another population. The concerns pertain to the validity of informed consent in vulnerable populations. Many participants of undisputed capacity to consent are still unable to differentiate between treatments that increase research validity such as using placebos to mask treatments and those that are therapeutic, and this "therapeutic misconception" is all the more likely when research trials are conducted in treatment centres and by their usual treatment teams. While mania or psychosis does not automatically render a person incompetent to consent, it does raise issues of the validity of the consent obtained and the need for systematic attempts to assess this. One way to ensure this in trials done on vulnerable subjects is to appoint independent qualified professionals to assess the potential subject's capacity to participate in research involving more than minimal risk (19). If, on the other hand, patients with potentially compromised capacity, such as the ones reported in the trial (14), were to be included, then proxy consent from a responsible relative could additionally be obtained, to ensure that those most likely to know the patient's wishes and safeguard the patient's interests are involved in decision-making.

Systematic evaluation has shown that participants in randomised trials recall information poorly, are not often aware that placebos form one arm of treatment, demonstrate inadequate comprehension of the process of chance in treatment allocation, understand and use only a proportion of what is presented in consent forms, do not really understand the issue of equipoise, and participate not for altruistic reasons but because they expect some improvement by participation (10, 20, 21). While creative interventions to improve understanding may improve patients' capacities to consent (22), this requires researchers to be cognisant of the need for ensuring that the consent obtained is valid. This is more likely to be achieved if obtaining informed consent is considered a "process" that requires a continual dialogue between physician and patients with mutual monitoring throughout, rather than an "event" symbolised by the signing of the consent form (23). The pressure of competitive recruitment in industry-sponsored multi-centre trials, the substantial emoluments that trial recruitment confers, and the stringent data monitoring associated with many such trials, makes obtaining valid informed consent, the component of the trial that is supervised and evaluated the least, the most likely to be compromised.

Research into informed consent from India is scant; in a postal survey of 3,622 physicians in India, several constraints in obtaining informing

consent were noted, chief among which was illiteracy of patients, and variations in the amount of information thought necessary to be divulged (24). This then leaves local research ethics committees with a considerable role to play in ensuring the ethical conduct of randomised controlled trials, particularly when placebos and vulnerable subjects are involved. It is uncertain, however, whether local research ethics committees comprise people with uniformly adequate knowledge of the scientific and ethical issues involved in research on human subjects or whether each member is aware of the CONSORT guidelines (24) or the WMA Declaration of Helsinki (7); appointment to such committees is rarely based on competence in these areas. It is also uncertain whether data from systematic reviews are insisted upon before a trial is approved, whether data monitoring is overseen, prospective stopping rules are adhered to and deviations from protocol noted routinely. Audits, whether internal or external, of research ethics committees also appear to be nonexistent. Just as it is required to assess the adequacy of blinding in the CONSORT guidelines, it ought to be an additional requirement that procedures to ensure the validity of informed consent also be reported. The role of regulatory bodies such as the Indian Council of Medical Research in reviewing the conduct of such trials and the functioning of local research ethics committees also needs review.

Research in resource-poor settings conducted primarily for overseas regulatory approval

The epidemic of industry-sponsored trials in the country, many with placebo controls, for psychiatric disorders where effective treatments exist, raises the additional question of whether it is ethically correct for clinician-researchers, with limited resources of manpower and time, to participate in these trials that are clearly being conducted solely for regulatory bodies overseas, when there are many unanswered questions of clinical relevance to health care in the region. Additional concerns pertain to the lack of power the individual researcher has in ensuring that trial results, whether positive or negative, are fully reported; by recruiting between 5 and 20 patients to these trials, the researcher is in effect waiving publication rights, because one cannot independently publish site-specific results with such small numbers. Prospective registration of clinical trials (25) and mandating that industry-sponsored trials (as well as non-industry-sponsored trials) publish all results may reduce these reporting biases as well as the other well-known problem of "salami" or multiple publications from a single

trial; but this does not mitigate the need to evaluate reasons for participating in such trials. While financial and other incentives are often a strong inducement for participation, the lack of any new science should raise questions about participation. Some potential researchers might be encouraged to realise that non-industry-sponsored pragmatic trials addressing questions of relevance to mental health care in India, with clinically relevant outcomes, robust clinical design and relatively low costs, are possible to conduct during routine clinical care (26).

Such concerns highlight the lack of satisfactory regulation in many parts of the world to ensure that patients' interests are adequately protected while scientific knowledge accumulates. This commentary also highlights the genuine uncertainty regarding some of the controversies that surround the science and ethics of RCTs and the need for more systematic and culture-specific quantitative and qualitative research to inform the design of future trials, especially among vulnerable populations in resource-poor countries.

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Response to Dr Vikram Patel

Sumant Khanna

Dr Patel (1) questions the ethics of a placebo-controlled study in patients with acute mania and asks whether institutional review board approval of the trial had been obtained.

Response: The rationale for including a placebo group is that patients with mania generally show a high and variable placebo response, making it difficult to identify their responses to an active medication. By including a placebo group in this study, we were able to establish the efficacy and safety of risperidone over and above what can be observed with a placebo.

Placebo-controlled trials are valuable in that they expose the lowest number of patients to potentially ineffective treatments. In addition, inclusion of a placebo arm allows for a valid evaluation of adverse events attributable to treatment versus those independent of treatment. For these reasons, a placebo control in clinical studies is required or approved by key regulatory authorities.

The design and conduct of this placebo-controlled study were approved by an Independent Ethics Committee or Institutional Review Board at each of the eight study sites. Each patient was fully informed on the trial's procedure, including the information that he or she would be randomly assigned to receive an active drug (risperidone) or a placebo ("a tablet with no active medication"). Each patient or his/her legal representative provided informed consent and signed an informed consent form. As reported in the published article (p 229), "Signed informed consent was obtained for all participants and the study was conducted according to the Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects, in the 1989 version of the Declaration of Helsinki (World Medical Association, 1989)."

Dr Patel asks how signed informed consent can be obtained from severely ill manic patients and suggests that the patients were kept in hospital "for longer than they possibly needed".

Response: It is our experience that severely ill patients are capable of giving their informed consent to participate in a trial. Capacity to consent is not automatically lost because of a symptom score on the YMRS scale. Hospitalisation until the achievement of symptom

remission is part of ordinary clinical practice in India. In fact, Western health care systems may care to emulate this practice.

Dr Patel suggests that a study of this design could potentially harm the patients.

Response: As expected, a high placebo response was shown by these hospitalised patients. Significant improvements versus baseline were seen on each of the efficacy measures in patients receiving placebo, as in the risperidone group: improvements in YMRS total scores at week-3 endpoint: –10.5 ± 1.3 in patients receiving placebo and –22.7 ± 1.1 in patients receiving risperidone ($p < 0.001$ versus baseline in both groups); improvements in MADRS total scores at week-3 endpoint: –2.5 ± 0.3 in placebo patients and –3.2 ± 0.4 in risperidone patients ($p < 0.001$ versus baseline in both groups); improvements in GAS scores at week-3 endpoint: 12.9 ± 1.7 in placebo patients and 27.6 ± 1.6 in risperidone patients ($p < 0.001$ versus baseline in both groups); improvements in PANSS total scores at week-3 endpoint: –5.7 ± 1.2 in placebo patients and –15.4 ± 1.0 in risperidone patients ($p < 0.001$ versus baseline in both groups); clinical response (= 50 per cent reduction in YMRS score) at week-3 endpoint: in 36 per cent of placebo patients and 73 per cent of risperidone patients; and reductions in CGI-severity score at week-3 endpoint: –0.9 ± 0.1 in placebo patients and –2.0 ± 0.1 in risperidone patients ($p < 0.001$ versus baseline in both groups).

Moreover, among the placebo patients, the proportion of patients whose severity of illness (CGI scale) was rated as "not ill," "mild," or "very mild" increased from 1 per cent at baseline to over one third (37 per cent) at endpoint (the increase was from 0 per cent to 72 per cent on the risperidone group)

Dr Patel suggests that haloperidol, a conventional antipsychotic, is "cheap, freely available, and constitutes usual care," and thus it was unnecessary to conduct a study of risperidone in these patients.

Response: As is well known, a primary disadvantage of the conventional antipsychotics is their association with adverse events, particularly extrapyramidal symptoms (EPS). In addition to improved safety, atypical antipsychotics have been shown to be as effective as or even more effective than conventional antipsychotics. Following are some results from three recent studies of an atypical antipsychotic compared with haloperidol:

Vieta et al. *Br J Psychiatry* 2005: 347 patients with bipolar I disorder were randomised to aripiprazole or haloperidol. Prevalence of EPS: in 63 per cent of haloperidol patients versus 24 per cent of aripiprazole patients. Proportion of treatment responders (50 per cent improvement in YMRS scores): 50 per cent of aripiprazole patients versus 28 per cent of haloperidol patients ($P < 0.001$).

McIntyre et al. *Eur Neuropsychopharmacol* 2005: 303 patients with bipolar I disorder were randomised to quetiapine, haloperidol, or placebo. Prevalence of EPS: in 60 per cent of haloperidol patients, 13 per cent of quetiapine patients, and 16 per cent of placebo patients. Improvements in YMRS scores were significantly greater in patients receiving quetiapine or haloperidol than placebo ($P<0.001$).

Smulevich et al. *Eur Neuropsychopharmacol* 2005: 438 patients were randomised to risperidone, haloperidol, or placebo. Prevalence of EPS: in 85 per cent of haloperidol patients, 34 per cent of risperidone patients, and 18 per cent of placebo patients. Improvements in YMRS scores were significantly greater in patients receiving risperidone or haloperidol than placebo ($P<0.001$).

Haloperidol and other older antipsychotics have been known to increase depressive symptoms and the risk for provoking patients into the depressive phase of bipolar illness. Depressive symptoms are debilitating and can increase the risk for mortality. Atypical antipsychotics such as risperidone are not known to worsen depressive symptoms.

Dr Patel writes that "the majority of patients (>80 per cent) were already receiving psychotropics at the time of enrollment (but) these effective treatments were discontinued as a prerequisite for participation in the trial . . . (the patients) were actually deliberately stopped from receiving such treatment."

Dr Patel seems to have overlooked the fact that the patients had been hospitalised for the treatment of acute mania, indicating surely that their current "cheap and effective" treatments were not controlling their symptoms.

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One standard of care for all is not always practical

Robyna Irshad Khan

Multiple research guidelines address the issue of standard of care in international collaborative research. These guidelines fail to appreciate that differing standards may be present within the same country, which makes their application sometimes impracticable. In circumstances where ethics review committees follow one of these guidelines entirely and to the hilt, some relevant and useful research is rejected while the way for "me too" drug trials is paved. It should be acceptable to hold different researchers to separate standards of care on the basis of their intentions, their financial resources, their ultimate gains from the research, and subsequent utilisation of the results of the research, even when these researchers come from the same country where the research is being conducted.

Should a universal standard of care be adhered to in all types of research conducted anywhere in the world? This is an excessively debated question in research ethics (1). Multiple international guidelines try to provide an ethical framework to prevent exploitation when financially robust sponsors from industrialised countries conduct research on vulnerable populations in resource-poor countries (2, 3, 4). Unfortunately, these guidelines do not address the issue from the perspective of local researchers coming from varied backgrounds. Factors associated solely with the researchers like their intentions, their material resources, their ultimate gains from the research, and the subsequent utilisation of the results of the research must be given due consideration while deciding on the standard of care. If all these factors are considered diligently, it seems only reasonable to allow different standards of care within the same country in different settings; it is inappropriate to compel researchers to provide the best care available anywhere in the world, especially where they are not being supported by sponsors.

Case 1

Dr K is a family physician working in a basic health unit of a small rural community in Pakistan. During his clinical practice, he observes that children under the age of five are suffering from a typhoid fever that is resistant to the locally available drugs. He designs a small randomised control trial to determine whether a combination of more than one of these drugs is effective. His study design employs the available single-dose regimen for the control group. The best proven treatment for typhoid fever, intravenous third-generation antibiotics, is not available in his hospital and he has no resources to provide for them. The research ethics board rejects the proposal, as the best proven treatment is not being compared to the studied drug combination.

Case 2

A national pharmaceutical company in Pakistan has developed a newer type of insulin, Insulin-D, to treat Insulin Dependent Diabetes Mellitus (IDDM). This company intends to start a large phase III trial in a local rural community with a high prevalence of IDDM. A renowned researcher from a nearby city is selected to conduct the trial. The study design employs the locally available standard of care for the control group. This is Insulin-B, that has lately been ineffective to manage blood sugar levels. The research ethics board asks the research team to modify the study design and provide the best proven therapy, Insulin-C, to the control group. The primary investigator changes the protocol accordingly and assures the availability of Insulin-C for both the control and study groups for one month after completion of this project. The sponsors declare a hefty budget for the overheads besides the trial expenses. They agree to market the study drug in the community (if it proves effective) but refuse to make it available free of cost for more than a month after the research is finished. In addition, they cannot guarantee that the drug, when marketed, will be available at a cost affordable to the community. However, they offer to compensate the community by building a clinic in the village. The proposal gets approved.

Discussion

On the surface, the decisions of the research ethics boards look genuine. In the first instance, the study protocol was not approved, as the researcher was not offering the best proven therapy for the control group though it is available in the country. The second was approved when the researcher agreed to use the best proven treatment. Let us analyse them in detail.

The intention of Dr K in the first case is to cure a treatable disease when the causative organism has developed resistance to the available

therapy. His goal is to provide the community with a desperately needed drug, without extra cost. He is using the patients as a means to an end, but not merely as means. The pharmaceutical company, on the other hand, is using these patients only as the means. Though the research participants need insulin, they will not have access to it after the conclusion of the trial. The company has no intention of providing the patients or their community with either Insulin-D or the best proven therapy, Insulin-C. This trial should preferably be conducted in a sub-group of private sector patients where the drug will be marketed in view of the fact that justice requires an equitable distribution of harms and benefits (5).

Dr K does not have the financial resources to provide for third-generation antibiotics to the control group. As a result, his choices are limited to either using the best locally available treatment or giving up the idea altogether. If he is forced to give up this study, the best interests of the community are not being served. The pharmaceutical company, on the other hand, has declared a hefty overhead budget. Provision of the best proven treatment is merely a procedural issue for them. Researchers in non-industrialised countries commonly insist on providing the best locally available standard of care, arguing that it is not practicable to sustain the best proven treatment (6). Those conducting trials of "me too" drugs with huge marketing potentials should be held to the highest ethical standards with the proviso that they must sustain this standard for as long as the research participants require it.

There is no possibility of Dr K making personal financial gains from the study he proposes. On the other hand, the pharmaceutical company is conducting this trial only for financial gain. It is willing to provide Insulin-C to trial participants for a month after the study is completed, but do not feel responsible for their remaining life span. Since Insulin Dependent Diabetes Mellitus necessitates lifelong use of insulin, these patients will have to revert to the less effective Insulin-B after a month. The pharmaceutical company is making a clinic for the community. But there are many instances of such infrastructure ending up as a burden to the local community which is unable to meet exorbitant recurring expenses (7, 8). The fate of the building that is being offered is not likely to be different.

The trial by Dr K has potential benefits for the participating community on a long-term basis. In contrast, the trial by the drug company has no long-term benefit for the local community. Researchers conducting non-beneficial research for participating communities tend to provide alternative, one-time compensations. Any dealings with the research subjects should be above and beyond these financial incentives. If a decision is made to accept these arrangements, each research subject should be clearly informed that he or she will be eligible for the new insulin free of cost only for a month after the trial; they will get a clinic for the community instead. These incentives may compensate for the lack of long-term availability of the new drug for the whole community. But they should not be seen as an alternative to a sustainable standard of care for research subjects with chronic diseases.

Conclusion

Conditions of uniform standards of care are emphasised in all international ethical guidelines. Application of this uniform standard is good for accountability but sometimes it is an obstacle to relevant, essential research. It may also facilitate "me too" drug trials. Ethics review committees should take these guidelines for what they are – only guidelines. Medicine is a dynamic, ever changing field. Generalisation and application of universal frameworks to all situations is neither practical nor in the best interest of patients. The two cases cited above may look similar on the surface and may have been conducted in the same community, but their implications for the participants are very different. It is only fair to respond to these differences in different ways.

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The costs of intellectual property rights

Rammanohar Reddy

Among the ethical issues in healthcare, the price of medicines is now perhaps among the most important. High prices reduce access to health care. This is a simple fact. The prices of pharmaceuticals have always been known to depend heavily on the structure of the industry, but over the past two decades yet another factor has come to have a major effect on pricing: notions of intellectual property rights (IPR).

Patents in one form or the other have been around for decades, yet it is the increased (real and perceived) knowledge intensiveness of the late 20th-century economy that made protection of intellectual property so important for firms in the advanced economies. While companies in a number of areas have always taken steps to protect their inventions/discoveries (to name a few, automobiles, precision tools and chemicals in the industrial sector, and software and entertainment in the service sector), nowhere were the stakes so high as in the pharmaceutical industry.

Even as the so-called laws of economics (on competition, withdrawal of the state and free trade) were brought into play to buttress the case for the dominance of market forces across the world, a peculiar aspect of the extending reach of the new paradigm was the insistence on monopoly rights to those who made useful and novel inventions. The contradiction rarely struck those who were pushing for greater IPR (or if it did, it was swept under the carpet) that going by the "laws of economics", the very idea of monopoly rights as contained in IPR, even for an identified period of time, went against the principles of competition.

That, however, did not constrain leading firms from a number of industries and services pushing for greater global IPR rules to deal with what they saw as counterfeiting, piracy and violation of patent protection. As we know, these rules came to be enshrined in the 1994 General Agreement on Tariffs and Trade, specifically in the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In pharmaceuticals, what the world has been eventually saddled with is a uniform set of global rules on IPR that will eventually squeeze the space

created in developing countries by vibrant pharmaceutical industries in Brazil, India, Thailand and a few other countries.

Post-TRIPS, the world has tried to grapple with the implications of the premium placed on IPRs to medicines. In this collection, **Swartz** and **Kamtekar** in particular, and **Sengupta**, in a different way, deal with aspects of this issue. More fundamentally, they dissect the notion that ideas, knowledge or information as embodied in medicines can be made private property.

Swartz makes the interesting argument that "market inalienability" (that is, a good cannot be alienated to [sold in] the market) should characterise the ideas contained in medicines because they deal with something—life—that society considers invaluable.

Both Swartz and Kamtekar argue that considering the functions that medicines perform, these are public goods, and, therefore, should not be converted into private goods ("privatised", as it were).

There are some lines of inquiry that need to be further explored on this issue. A relatively trivial matter is that knowledge does not meet the definition of public goods as in mainstream economics, where public goods are "non-rival" and "non-excludable", in the sense that use by one does not reduce its availability to others, and consumption of the goods cannot be prevented/controlled (classic examples being lighthouses and traffic lights). But granted that whatever mainstream economics may say, from the viewpoint of any human society medicines should be seen as public goods. Two issues that then arise are: (a) we should look at not just medicines but health care in its entirety as public goods; and (b) more important, there are other "goods" that are just as important and should be considered public goods as well—like water, and even basic food, clothing and shelter, all of which are essential for human life.

Once these questions are posed, the tension between the basic tenets of a humane society and the demands of a market economy driven by profit-maximising behaviour become apparent. This does not admit to any easy resolution (Swartz's example of distributed production of medicines is not a solution), but one has to highlight it if the monopoly power of IPRs is to be countered.

The problems posed by the power of the pharmaceutical industry are addressed succinctly by Sengupta, who makes the interesting observation that the push to restrict access to knowledge/information is increasing even as the means to disseminate such information are also increasing. This raises the tantalising possibility of IPR regimes being simply impossible to enforce. (This could also explain in part why TRIPS was made part of a global agreement that had provision for cross-retaliation.)

More than a dozen years on, the full impact of the 1994 TRIPS agreement, which is now administered by the World Trade Organisation, is yet to be felt across the world. For one thing, it applies only to medicines patented after January 1, 1995, and a vast number of medicines now in use—such as the first generation of drugs for AIDS care—were patented before 1995 and their generic variants continue to be sold even after the coming into force of the TRIPS agreement.

However, there is no question that slowly, as post-1995 discoveries enter the market, the TRIPS agreement will begin to threaten domestic pharmaceutical industries in countries such as India. Gradually, domestic companies will find that what earlier gave them an edge—the ability to produce generic variants of patented medicines at low cost and price them correspondingly—will no longer be an option. Correspondingly, the foreign multinational majors will increase their market hold and influence in all segments. This will naturally have implications for the production capabilities of the domestic industry and also for the prices of drugs that are out of patent. Local firms may protect their profitability by allying themselves with the multinational majors (as many Indian companies are already doing), but as far as patients and seekers of healthcare are concerned, the prospect is only of rising prices.

It is often argued that with only around 10 to 15 per cent of medicines on an "essential list" under patent protection at any point of time, the influence of IPR on the costs of treatment of major illnesses is exaggerated. It is also argued that patent protection is not the only factor influencing the cost of medicines. Both are correct to a certain extent, but what such arguments ignore is the multifarious ways in which global IPR rules influence the overall price level and, therefore, access to medicines in individual countries. As pointed out earlier, uniform levels of patent protection will increase the market power of the multinational firms (which hold most patents) and eventually squeeze domestic generic producers, thereby influencing the prices of off-patent drugs on the essential list as well. And while prices of drugs outside patent have also been rising sharply in recent years in India (as drug price

control is gradually lifted), this process will be accelerated once the industry is dominated by fewer and fewer firms.

That IPR is not the only avenue through which the global market is taking healthcare more difficult for the citizen is illustrated by **Ekbal** in his exploration of what a possible General Agreement on Trade Services (GATS) that covers health services may imply. An important point that Ekbal makes, that is linked to the Swartz–Kamtekar argument of public versus private goods, is that an expansion of GATS could mean the privatisation of water supply and sanitation, and the conversion of more public goods into private ones, with the inevitable impact on people's health

Holders of IPRs on medicines have not always had their way. Two instances of weakening of the hold of IPR are the withdrawal of the suit filed by a number of global drug companies against the government of South Africa for patent infringement, and the WTO's 2001 declaration on public health and TRIPS. The latter delineated the extent of a so-called "flexibility" available within the TRIPS agreement to use compulsory licences to increase availability and reduce prices when there is a health crisis. Yet these are both exceptional instances and also very limited in their effectiveness. The fact is that a paradigm that stresses the importance of IPRs over that of the right to inexpensive health care remains dominant.

Access to AIDS medicine: ethical considerations

Omar Swartz

The concept of property is usually understood as a moral and legal right to exercise exclusive influence and control over a material object (1). A person who owns something, such as a patent or medicine, can dispose of (or control access to) it without regard for others. The example of the patent is particularly illustrative because most property in a modern capitalist economy is intangible (2). For example, pharmaceutical companies do not merely own the medicine they produce, but (in many cases) they also "own" the intangible molecular-biological formulation of the medicine. They own the medicine's "blueprint" and thus can prevent others from producing the same or similar medicine.

Despite this conceptualisation of property, ideas easily can be considered a "public good" in the sense that sharing an idea is relatively costless and can be as easy as exchanging a sheet of paper. Ideas do not easily exhaust themselves with use; more is always better. Rather than having one drug company in Switzerland or in the United States producing AIDS medication, as we do under our contemporary property model, we could have factories throughout the world producing medicines that are patented by companies in the wealthy industrialised nations. Such regional manufacturing would be particularly effective in places such as Africa, Asia and India, which are hardest hit by AIDS and where locally produced medicines could be distributed easily to the people who need it, particularly to those who live in tribal or village communities that ordinarily lack access to western-produced goods. If 50 or 100 factories throughout the world were to produce the medicine, as opposed to two, the nature and effectiveness of the medicine would remain unaltered.

What would change, however, is profitability. As private social goods become public, the ability of individuals to gorge themselves on public misfortune (or collective inaction) is lessened. Medicine does not have value outside its use — the existence of medicine implies its utilisation. In other words, medicine is the antithesis of symbolic exchange. To commodify medicine as capital — to exchange it in the open market — is to invalidate its function as medicine at the expense of its human

ends and the good of the community. Society ceases to function ethically when life-saving medicine is withheld from afflicted people to benefit the minority over the majority.

Practically speaking, to suggest public access to AIDS medicine goes against important individual rights that are privileged within the private property regime. Given this tension, the private property regime can reasonably be made to yield, and we may come to consider it a crime against humanity to sacrifice the common good to protect an individual's wealth. Those who possess wealth should be considered obligated to hold that wealth in trust for humanity.

Simply, morality now must be considered part of the cost of doing business. After the collapse of Enron and other major US corporations in 2001-02, this argument is becoming much more culturally salient. But even before recent events returned the issue of corporate responsibility to the forefront of the world's consciousness, commentators supported this idea. As articulated by John J Maresca (3,4):

"[T]oday a business can no longer be seen as a creator of wealth solely for its owners. The role of business as a creator of wealth is broader than that. Business is the principal engine for generating wealth for society as a whole. And business is the producer of new and beneficial products, which increasingly must be safe, environmentally harmless, and give long term benefits."

In other words, the world of business must increasingly be viewed as a world where human creative energy produces the conditions of life in new and creative ways. As such, business has an important public role to play in the development of society — it must serve to the best of its ability; this and not profit *per se* is the reason for its existence.

Related to exclusivity is the notion that owners have the power to alienate their rights and control over a resource on whatever terms they alone consider appropriate. For example, a property owner is free to trade on terms that are most favourable to the owner, without regard to non-market possible implications of the owner's actions, relative to health, peace or world stability. Exclusivity and alienation mean that property must be free to shift from what law and economics theorists consider to be "less productive to more productive use through a voluntary exchange" (5). The assumption is that the person who most highly values a good is willing to pay the most money for it. Yet this assumes, quite erroneously, that the value of money is constant, that a hundred dollars to someone who is poor is the same as to someone who is rich. In reality, the value of money often relates to the amount of wealth one possesses.

Similarly, there are many situations in which people value something highly, such as their health, but cannot pay the "premium" that is expected for it by market logic. More specifically, some objects exist that cannot be reconciled easily with the notion that goods should be sold to the person who is willing to pay the highest price — there are values that society recognises as important that the market does not easily reflect. These things we either take out of the market entirely or make an exception to asserted principles of so called "economic effectiveness". AIDS medicine (and ultimately, other types of medicine) should fall into this category.

The idea that certain objects are unfit for market exchange is known as "market inalienability". As Margaret Jane Radin explains, society values certain things that cannot or should not be sold for a price. People, body parts, sex, and children are typical examples. While many people feel very uncomfortable (or should feel uncomfortable) selling people, body parts, sex, or children, society does not have any issue with giving away these things for free under certain circumstances (6). The point of market inalienability is that, as a society, we value the non-commodification of some items, rendering those things non-saleable. Rather, we perceive the item as a personal human good or resource to which a monetary value cannot be assigned. To identify something as invaluable is to say that it should not be corrupted by market processes. When we talk about market inalienability, then we often justify our departure from market norms by using the term "integrity". Some things, such as those stated above, that otherwise we could commodify and sell in an impersonal market to the highest bidder, have a normative value that supersedes the normal rationales of the market. To place them in the market is considered repulsive and prohibited in civilised society.

In highlighting the term "integrity", we try to affirm ourselves as people with identities and authentic needs. In doing so, we reject our false identities as faceless consumers whose only worth to the producer is the power of our pocketbook. When we consider the concept of integrity, we acknowledge that normal market practice can be dehumanising and oppressive, particularly for lower income people. We also realise that normal market practice is positively unconscionable when the people objectified as consumers are those AIDS victims who cannot pay for a life-extending, suffering-reducing medicine.

Market inalienability recognises that some people do not have deep pocketbooks; thus, they do not have a market personality. Still, poor people remain human beings and we protect them by prohibiting them from selling their bodies, organs, or children. In much of the developing world, however, extreme poverty forces many people to do just this (7). As Ulla Fasting, Jan Christensen, and Susanne Glending note, "It is well known and widely publicised that many poor people living in India have sold one of their kidneys, or one of their eyes, for a sum of money that would enable them to cover the basic needs of their family for a period of time . . . This was going on in an open market, also refereed to as 'India's kidney bazaar' ". (8)

Few people disagree with the paternalistic protection of prohibiting people from selling their body parts. Some things must be given away. To repress knowledge of medicine that can reduce the spread of AIDS (as in the simple and inexpensive procedure that protects children from inheriting AIDS from their mothers during childbirth) or to fail to reduce the suffering of people afflicted with AIDS on the grounds that one person "owns" the medicine and another has no right to it without payment of a premium is so completely reprehensible that it should be beyond acceptance and legal protection in civilised society. The fact that many in the international community tolerate this system is a sign that we have much moral growth to accomplish as a global community.

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Intellectual capital as property

Amit Sengupta

The global HIV/AIDS crisis and issues related to access to drugs for its treatment, on which Omar Swartz's paper (1) focuses, also raise key questions about the notion of property and property rights. It would be useful in this context to discuss how intellectual property rights (IPRs) have developed in modern times, and the contradictions inherent in the system today.

While property rights have long been recognised, "intellectual" property is a modern notion that comprises information, ideas and knowledge. Unlike other property rights, IPRs are essentially state-mandated monopolies. Discoverers and inventors are thought to deserve special reward or privilege because of the benefit of their discoveries or inventions to society. Public good is not considered a reward in itself and certain incentives are needed to encourage invention or innovation.

Contradiction in the philosophy of IPRs

The philosophy behind IPRs is built on the contradiction that to promote the development of ideas, one must reduce the freedom with which people can use them. Liberal philosophy has reflected this contradiction during the genesis of the concept of IPRs — a tension between an individual's claim to the product of his labour and undeserved monopoly privilege granted by the State.

The industrial revolution and capitalist mode of production led to the necessity of redefining "property". Tools acquired a new economic value and it became possible to duplicate and distribute them in quantity. To encourage their invention, copyright and patent laws were developed. The earliest patent laws were an expression of the need to ensure that innovations did not die with the original inventor; they were designed to promote disclosure and dissemination of knowledge (2).

We are entering an era in which major parts of the world economy are based on ideas and knowledge — goods that take no material form. Unlike physical goods, there are no physical obstacles in providing an abundance of ideas. IPRs are, thus, an attempt to create an artificial scarcity to give rewards to a few at the expense of many.

Let us examine what is sought to be protected through IPRs. The central distinction between intellectual property and physical property

is that the former can be transferred without it leaving the possession of the original owner. Information is acquiring intrinsic value, not as a means to acquistion but as the object to be acquired. Laws to protect property rights were developed to protect, in the first instance, land. Later, when manufacturing became the dominant mode of economic activity, laws grew around the centralised institutions that needed protection for their reserves of capital labour, and hardware. Today, to a large extent, information has replaced land, capital and hardware as a commodity that needs to be protected in order to protect control over the means of production.

Alongside this has developed a new contradiction — information or ideas are sought to be commodified at the same time when technology has made it possible to exchange ideas in a radically free environment. Exchange and control cannot coexist — the more tightly we protect one, the less there will be of the other. If ideas are to be exchanged in the marketplace, the basic assumption of a marketplace with regard to physical objects, that value is based on scarcity, should hold good. But this is contrary to the nature of information, which may, in many cases, increase in value with dissemination.

Monopoly as a facilitator of creativity?

Central to the projected utility of IPRs is the notion that creation is facilitated by providing a temporary monopoly which ensures that the author of a work will be the sole beneficiary of any profits. The earliest patent and copyright laws were geared, to an extent, to benefit the individual artisan, or the author of a literary piece or a musical score. But with the institutionalisation of the concept of IPRs, individual creators ceased to be the beneficiaries and were replaced by large corporate interests. In practice, today, most creators do not actually gain much benefit from intellectual property. Independent inventors are frequently ignored or exploited. When employees of corporations and governments have an idea worth protecting, it is usually copyrighted or patented by the organisation, not the employee. Since intellectual property can be sold, it is usually large corporate entities that benefit.

The value of intellectual products is not due to the work of an individual, or any small group. Intellectual products are social products. Even in the US and Japan, an enormous part of research is funded by the State. The line, therefore, is blurred between what constitutes "basic research" by a company and what it draws from public-funded research. In fact, half of the US$ 70 billion invested in drug research each year comes from the public sector, chiefly as funding for basic research, which is the highest risk part of the drug development pipeline. Ten AIDS drugs were fully developed or supported by publicly funded research, and the US government supported the clinical research for 34 of the 37 new cancer drugs marketed in the US since 1955 (3).

Knowledge in the marketplace

Open ideas can be examined, challenged, modified and improved. To turn scientific knowledge into a commodity arguably inhibits the development of science. Innumerable examples show that IPRs have been used to suppress innovation. Companies may take out a patent, or buy someone else's patent to inhibit others from applying the ideas.

The pharmaceutical sector is a classic pointer to the dangers of a strong IPR regime. The huge inequity in the IPR system today is exemplified by the fact that while millions die due to HIV/AIDS and national economies are being devastated, the prices of drugs to treat the disease can be 40 times or more than what is warranted by the actual production and distribution costs. Large pharmaceutical companies have generated super profits through the patenting of top-selling drugs. But drugs which sell in the market may have little to do with the actual health needs of the global population. Often, there is nobody to pay for the drugs required to treat diseases in the poorest countries. Research and patenting in pharmaceuticals are driven not so much by therapeutic needs as by the need of companies to maintain their super profits. Today, transnational corporations (TNCs) with global tentacles, wishing to retain the huge growth rates of the 1970s and 1980s, are trying to pool resources for research and development. As a consequence, we will see 10-12 large TNCs survive as "research-based" companies in the business of drug development and patenting. The bulk of drug manufacturing will be done by smaller companies. Today, in the US, this trend is already discernible. While the volume of sales of large multinational corporations (MNCs) has stagnated in the past decade, sales of small companies producing generic drugs show a double-digit growth. Still, the profitability of large MNCs has actually increased. Clearly, these companies can thrive on "rent incomes" made possible by strong IPR protection without enhancing their manufacturing activities (4).

Given their monopoly over knowledge, these companies will decide which drugs to develop — those that can be sold to people with the money to buy them. Thus, we have the development of "life-style"

drugs such as Viagra, which target illusory ailments of the rich. On the other hand, we have "orphan" drugs that can cure life-threatening diseases in Asia and Africa, but are not produced because the poor cannot afford to pay for them. Today's medical research is highly skewed in favour of heart diseases and cancer rather than diseases such as malaria, cholera, dengue fever and AIDS, which kill many more, especially in developing countries. Less than 10 per cent of the US$ 56 billion spent each year globally on medical research is aimed at the health problems affecting 90 per cent of the world's population (5). On the other hand, some drugs developed in the 1950s and 1960s to treat tropical diseases have begun to disappear from the market because they are seldom or never used in the developed world.

Clearly, the imbalance between the rights and obligations of a patentee has become grossly skewed in the course of the development and expansion of IPRs. It is time to reflect how "ideas" that are clearly "public goods" can be protected — not for monopoly control by TNCs but for their rapid dissemination for the alleviation of human suffering.

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Why life-saving drugs should be public goods

Rachana Kamtekar

Omar Swartz (1) presents a number of good arguments in favour of treating the formulae for making human immunodeficiency virus (HIV) and other life-saving drugs as public goods rather than private property: ideas can be shared without being used up; the most effective use of blueprints for life-saving medicine is to provide drugs to sick people; finally, it is clearly unreasonable if "a person who owns something...can dispose of (or control access to) that [thing]...without regard for others."

But where, in all of these considerations, do we find the claims of those who have devoted their labour, time and resources to the research that goes into developing medicines? Although ideas, once we have them, can be shared without being used up, it can take a lot of money to come up with those ideas in the first place. One estimate (probably on the high end) by the US government is that it takes US$ 500 million to develop a new drug — this presumably factors in the costs of development, the costs of testing drugs, especially on human subjects, and of drug development attempts that fail.

In what follows, I will argue for the same conclusion as Swartz, that life-saving drugs ought to be treated as public goods, specifically addressing what I expect to be the main objections to that conclusion.

The argument from benefit

The usual argument for privatisation of some goods is that it benefits all concerned. For example, it is argued that patents promote innovation by guaranteeing that the incentive for which innovators have to do research (i.e. profit) is protected, and by enabling innovators to share their knowledge so that others can build on their discoveries or inventions upon payment.

In thinking about whether we should regard life-saving drugs as private or public goods, we need to pay attention to the development of drugs and not just their proper use. People who support privatising, or particular privatising schemes such as patent protection, often argue that without such schemes, there would

be no incentives to do new drug research (or to share the results of such research). However, many people do new drug research just because it is their job, and national governments such as the US government or non-governmental agencies such as the World Health Organization (WHO) fund new drug research just because it is needed.

Will people refuse to do research if they do not have the prospect of the riches afforded by patent protection? This seems unlikely since scientists doing research are happy to do so even when the only rewards are their salaries, professional recognition and benefit to humanity. The patents usually go to their corporate employers. Then, will people refuse to fund research if they do not have the prospect of the riches afforded by patent protection? This may be true, but research can be funded by taxes as well and research funded by taxes might be directed towards desperately needed drugs for tuberculosis and malaria rather than Viagra. Still, even if patents are not necessary incentives for research, they might be, on the whole, beneficial to research — for example, by protecting and enabling innovation.

Here it is worth attending to the situational details that can cause a scheme which works in theory to fail in practice. So consider who in the developing world stands to benefit by signing the intellectual property codes set by the developed world (which had no such codes when it was developing). Few developing countries have drug industries at all, and they have to fight expensive legal battles to keep first world drug companies from patenting remedies that have been passed down through folk tradition. Further, as long as drug companies are driven by the need for profit, they have little reason to invest in research to find drugs for diseases prevalent in the developing world, where the buying power is low. Thus, most people in the developing world benefit less from privatised medical research than they would from medical research driven by health needs and funded publicly. We should also ask: "Who in the developed world benefits from current intellectual property codes?" As the standards for patenting become more precise, it becomes more and more expensive to obtain patents. Some companies are choosing not to make their research public, rather than to patent their findings. Driven by profit, drug companies sometimes make cosmetic alterations in medications to extend their patents. Life-saving medicines can be unaffordable to people in both the developed and developing world — with the consumer paying not only for salaries of chief executive officers and investor returns but also for expensive advertising.

The moral argument

Many people believe that those who have discovered or invented the formulae for manufacturing medicines have a *right* to those formulae, and not just to compensation for their labour or a return on their investment. John Locke, the classical liberal defender of private property, articulated this intuitively powerful idea in his *Two treatises of government* (2) thus: "Something becomes mine, rather than the common possession of mankind, when I mix my labour with it." The reasoning seems to be something like, "My body is my own, so my labour is my own, so the products of my labour are my own."

However, Locke held that the justification for my appropriating any part of the commons is, in the first instance, that this is the condition of my benefiting from it. For example, I need to make the fruit I find lying on the ground part of my body to benefit from it; this need is what first justifies my private appropriation of the fruit. Further, when I labour, my labour so increases the value of whatever it is mixed with that I do not, by appropriation, decrease what is available for others; instead, I also increase the common stock.

Two consequences of this justification of private property in terms of benefit are that: (i) in cases where appropriation does diminish what is available for others — for instance, in the case of enclosures of the commons in England in Locke's time — Locke opposed appropriation and (ii) if the goods I have appropriated to myself spoil because I am not able to use them, then these goods are no longer serving the purpose of property, which is for the benefit of mankind, individually and collectively.

We can see that Locke did not treat private property as "a moral and legal right to exercise exclusive influence and control over a material object", come what may. He traced the transgression of the natural limit on appropriation to the invention of money: money makes it possible for one to appropriate more and more to oneself without spoilage and to the detriment of the commons. Under these circumstances, Locke argued, private property is no longer justified by its benefit to mankind, but by a tacit agreement to the property system. If this describes our circumstances, then we may ask: Did we agree to this system of property allocation? What system should we agree to? One that allocates property rights to the "first"

discoverer, or one that spreads the benefits of discoveries and inventions, or some other system?

We need not take Locke's views as authoritative, despite his influence on our thinking about property. I cite them because they are sensible, for they recognise that property allocation arrangements must be justified, either in terms of their benefits to all concerned, or on the basis of some agreement – which had better be fairly made, if it is to justify anything. (In contrast, it looks as though developing countries are being strong-armed into conforming to the WTO's codes for trade-related intellectual property rights by 2006.)

Finally, let us consider the position that ownership rights should reside with those whose labour has created a given physical or intellectual product — whatever be the overall social consequence. Note that this position does not support the status quo, since currently corporate entities rather than researchers usually own patents. However, this position posits an unsupportable relationship between labour and entitlement. Some people argue (following one line of reasoning from Locke but not the others) that if you labour on something, you have a right to that thing, because your labour is the source of its value. However, this is simply false: natural resources are an obvious source of value — the value of wood, for example, does not derive from logging alone, but also from the trees that may have grown up on their own. Labour may add value to things found in nature, but it does not create their value. (Marx's "labour theory of value" does not say that labour is the source of value, but that a thing's exchange value is determined by the amount of labour it would take to produce that thing — the thing in question can actually have fallen from the sky.) I am not denying that people ought to be compensated for their labour; I am denying that people have a right to what they mix their labour with.

Reflection on these considerations should, I believe, begin to dissolve the hold of the intuition that discoverers and inventors, and "makers" in general have some right to what they make. They may have the power to share it or not, but that power and right are not the same thing.

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General Agreement on Trade in Services and the health sector

B Ekbal

Until the World Trade Organization emerged in 1995, there was no multilateral agreement on services. Negotiations at the WTO led to the General Agreement on Trade in Services, a comprehensive agreement on the international trade in services. GATS explicitly provides for successive rounds of negotiation with a view to achieving progressively higher degrees of liberalisation. An increase in trade in health services offers a handful of developing countries a limited set of export opportunities, predominantly in attracting foreign consumers to their health facilities. These gains seem trivial when compared with the effects that the increased trade in health services could have on people's right to health. Trade in health services risks exacerbating many of the problems which already plague health systems across the world. The damage may outweigh the benefits, particularly for those with little ability to pay more for publicly provided health care.

The last round of the General Agreement on Tariffs and Trade (GATT) in 1994 gave rise to a multilateral agreement on trade under the World Trade Organization (WTO). The WTO identified two areas for multilateral agreement: goods and merchandise, and trade in services.

Until the WTO emerged in 1995, there was no multilateral agreement on services. Some services were exchanged but no arrangement existed for trade in services. Services tend to be place-specific and were considered non-tradable. By the 1990s services constituted a major part of the economy of some countries and became an important portion of international trade.

Negotiations at the WTO led to a comprehensive agreement on the international trade in services. The objective of this agreement is progressive liberalisation of trade in services. It aims to provide a secure and more open market in services like the GATT does for trade in goods. The resultant document is the General Agreement on Trade in Services (GATS). GATS explicitly provides for successive rounds of negotiation with a view to achieving progressively higher degrees of liberalisation.

This agreement covers several services, specified in 19 categories, including services related to health and education. It provides the legally enforceable right to trade in all services. Only those services provided entirely by the government do not fall within GATS rule. When the services are provided either partially by the government or by private providers, as is the case for the health sector in India, they come under GATS. Any institution that requires a payment or fee falls under GATS.

The scope of GATS

Article I, Paragraph 3 of GATS defines the scope of the agreement as follows:

(b) " 'Services' includes any service in any sector except services supplied in the exercise of governmental authority. It may appear therefore that countries where health care is mostly provided by government may be exempted from implementing GATS in the health sector." However the article further clarifies that (c) "a service supplied in the exercise of governmental authority" means a service that is supplied neither on a commercial basis nor in competition with one or more service suppliers. In most countries health services are also provided by the private sector, and even the government sector charges for certain services. Therefore, under these sections of the agreement, the health sector is invariably covered by GATS. Unlike many other services, however, the direct impact of liberalisation on the priorities of the public health sector makes this kind of trade a critical issue in terms of people's right to health.

Under GATS, supply can take four modes: one, "cross-border supply", where the service is provided remotely from one country to another (e.g., international telephone calls, Internet services, telemedicine); two, "consumption abroad", where individuals use a service in another country (e.g., tourists travelling abroad, patients taking advantage of health care in foreign countries); three, "commercial presence", where a foreign company sets up a subsidiary or branch within another country in order to deliver the service locally (e.g., banks, private health clinics); four, "presence of natural persons": where individuals travel to another country to supply a service there on a temporary basis (e.g., software programmers, nurses, doctors).

Modes of supply under GATS: cross-border supply

The most important example of cross-border supply or trade in health services is telemedicine: the provision of medical services from a practitioner in one country to a patient or practitioner in another, predominantly via the Internet or satellite transmission of medical images. While still at an early stage, the potential benefits of telemedicine are already evident, especially for remote diagnosis and treatment. Based on evidence of its use among remote rural communities in Japan and Australia, telemedicine could expand the capacities of doctors in developing countries.

But the effective implementation of telemedicine projects presupposes a communications infrastructure developed to a level far higher than is currently found in most remote areas of the developing world. It is true that several examples already exist of non-commercial telemedicine projects working within developing countries on an experimental basis. Still, while a growing body of evidence attests to the clinical benefit and cost effectiveness of telemedicine, there is less proof of its commercial sustainability.

Telemedicine includes the remote provision of medical education. Teleconferencing has already been established between institutions in Canada, Kenya and Uganda to enable health care workers in Africa to benefit from the latest medical knowledge. Internet sites such as the University of Iowa's Virtual Hospitals provide free online information on a wide range of adult and child health problems – a valuable resource for doctors otherwise reliant upon outdated collections of medical journals. In all these cases, the expansion of cross-border supply of telemedicine offers potential gains for health care. However, concerns remain about the confidentiality of patients and the applicability and relevance of medical information generated in industrialised countries to situations in the developing world.

In addition, there is the problem of regulatory control over telemedicine, as noted by the 50th World Health Assembly in its 1997 resolution on the uncontrolled sale of prescription drugs over the Internet. The resolution focused on the public health hazard of counterfeit products being passed off as genuine, and on the inappropriate use of potentially dangerous medicines without medical supervision. (The WHO had already exposed four companies selling prescription drugs over the Internet without the detailed information that should accompany the sales.) Telemedicine poses regulatory challenges on the demand as well as the supply side. Even the most advanced regulatory systems will be unable to prevent doctors or clinics from ordering medicines over the Internet which are not included in a country's essential drugs list. Such practices might give those practitioners a perceived commercial edge over rivals who keep

within treatment guidelines, but would undermine national policies promoting the rational use of drugs.

The potential drain which commercial cross-border trade in telemedicine could have on limited health care budgets in developing countries is also a matter of great concern. At present almost all trade in remote health care is from North to South, and the expense of entering into commercial relationships would be prohibitive for poorer nations. While the technology of telemedicine offers potential benefits in some cases, few would suggest its commercial development offers more general solutions to the health problems of the majority.

Of more immediate significance is the development of cross-border private medical insurance and managed health care. Private health insurance is mostly provided by companies with a commercial presence in the country (and thus covered by mode three, or "commercial presence", under GATS), and the potential is increasing for such services to be provided across national borders. However, the issues remain substantially the same as those discussed later in connection with mode three: the increased commercialisation of health care and the growing involvement of the private sector.

Modes of supply under GATS: consumption abroad

Patients consuming medical services abroad represent a more significant source of international trade in health services. They may have travelled abroad especially to seek medical treatment in another country or they may happen to need treatment while visiting that country for other reasons. The majority of the USA's estimated $872 million in health care exports in 1996 came from foreigners being treated in the country.

The potential for developing countries to gain economic benefit from attracting foreign consumption of their health services is limited. However, certain countries have identified the provision of health services to foreigners as a potential growth area. India offers significant cost advantages for patients travelling from industrialised countries, with major treatments such as liver transplants or coronary bypass surgery priced at a tenth of what individuals would be charged in the USA. In addition, certain countries offer culturally-specific health services. Traditional medicine draws a substantial number of patients to China every year. The majority of them are overseas Chinese but there is also a growing number of individuals who have turned away from the western medical tradition. India has a similar advantage in its

extensive network of ayurvedic practitioners, who attract a steady trickle of foreigners every year. States like Kerala are already encouraging health tourism based on traditional knowledge.

Another aspect of consumption of health services abroad is the training of medical students at foreign educational institutions. Countries such as the UK and the USA have long traditions of providing such education to foreign students on a commercial basis. Certain countries have the ability to attract foreign students for culturally-specific courses, such as training in ayurvedic or traditional Chinese medicine. Some German universities now give students credits for courses taken in institutions in China. In these limited cases, the consumption of domestic services by foreigners represents a potential source of export earnings for the host countries.

However, these benefits will be outweighed by the social costs if limited investment is drawn away from national health priorities. In the vase majority of countries, an expanding private sector will draw medical personnel away from the public sector. Favouring foreign patients will come at the expense of the local population. While extra investment financed by charges on foreign consumers has the potential to upgrade services for local users, in practice the two groups often use separate facilities, with little opportunity for crossovers. Worse still, the public sector often has to bear the cost of building the new hospitals and clinics to treat foreign patients, which is a further diversion of resources away from public health needs.

A lesser threat applies to those countries which provide education to foreign medical students, given that there is greater elasticity of supply than in the case of health care. However, the economic imperative to raise numbers of paying foreign students has the potential to drive down the quality of training as a result of declining teacher-to-student ratios and rising pressure on resources.

Ultimately there may emerge a parallel threat to that experienced by patients: reduced opportunity of access for domestic students and a consequent contraction in the numbers of qualified nationals. The reverse situation pertains for those countries which send medical students for training abroad. In such cases the training represents an import in balance of payment terms, but can be seen as an investment in terms of the obvious potential for skills transfer. However, the extent to which those skills can be deployed to the benefit of the wider society depends on how many of the trainees

return to their home country once their courses are over. Only half of the Indian doctors trained in Europe and the USA return home at the end of their training.

Modes of supply under GATS: commercial presence

The establishment of commercial presence in a foreign country differs from the other three modes of GATS in that it is essentially an issue of investment. In health care, this investment relates primarily to foreign commercial presence in hospitals, health clinics and health insurance, and to a lesser extent to the provision of medical education. As noted, GATS aims to generate new opportunities for companies to invest and operate in the service sectors of other countries. But the prospect of increased foreign commercial presence in the health sector has raised serious concerns about people's right to health, given the negative experience of fees in the sector.

In developing countries, much of this experience has come as a result of the liberalisation process, which has involved structural adjustment programmes under the International Monetary Fund and the World Bank. The introduction of cost recovery programmes in the health sector is now widely accepted to have been disastrous, forcing many poor families and their children into a "medical poverty trap" characterised by untreated illness and long-term impoverishment. Even the World Bank, while it continues to support user fees for health in its national poverty-reduction strategy papers, has acknowledged that user fees are responsible for denying poor families access to health care.

Structural adjustment programmes have introduced cost recovery principles into the health care sector in many countries. Yet GATS goes one stage further, as it represents the commodification of health care for trade on the open market. Just as internal liberalisation prepares the way for commercialisation of the health sector, so too, external liberalisation locks in commercialisation through the long-term presence of foreign investment.

For developing countries with failing health systems, this foreign investment may seem an attractive source of capital and medical technology at a time when other sources are thin on the ground. Yet involvement by the foreign private sector in health care has the potential to marginalise the poor even further. Companies seek markets in which they can be assured sufficient returns, and this typically concentrates investment in more affluent areas. Loans granted to private health care providers by the World Bank's International Finance Corporation, for instance, are predominantly directed towards facilities for the richer communities of the country or for expatriates, not the majority of the population. This practice of "cream skimming" by the private sector is already familiar in the field of private health insurance, where insurance companies and health maintenance organisations (HMOs) typically favour the healthy and wealthy over high-risk customers, excluding the latter by means of prohibitive premiums.

In terms of direct health care provision, similarly, the private sector's profit-making imperative limits its relevance to those sections of society who are unable to pay for its services, even though it is they who need the extra investment the most. Yet private investment in health care is not irrelevant to poor people. In many countries, as noted, an expanding private sector will draw personnel away from public health systems and exacerbate shortages of trained and qualified staff. Often it is the most skilled staff that makes the move to the private sector, lowering the overall quality of personnel in the public health system. Worse still, cream skimming undermines the very ability of public health systems to sustain themselves financially, as it denies the basic principles of cross-subsidisation and risk-pooling by which the healthy support the ill, the young the old and the rich the poor:

Foreign investment also brings with it the risk of domination by transnational corporations to the exclusion of domestic development. In the hospital sector, the overwhelming majority of these corporations are powerful companies based in Europe and the USA. Only Singapore's Parkway Holdings and South Africa's Afrox Healthcare are exceptions.

As well as the equity issues raised by commercialisation, liberalisation also risks compromising the quality of health care delivery. The introduction of private sector companies into public health systems raises potential conflicts of interest between commercial pressures and public health goals. In industrialised countries this has commonly meant a reduction in quality as a result of cost cutting, often through a substitution of casual for skilled labour amongst nursing and ancillary staff. It has also led to the planning of hospitals on the basis of financial rather than clinical need, with accompanying reductions in the clinical workforce and service capacity.

In the USA, where the health care market has become increasingly competitive over time, HMOs have responded by pressurising doctors to withhold treatment from their patients. By means of performance-related pay mechanisms linking their incomes directly to the clinical

costs they incur, doctors are encouraged to refer the lowest possible number of patients to specialists or to hospitals. The HMO awards bonuses to those who minimise such expenditure, while doctors who generate above-average costs risk expulsion.

In developing countries, commercial pressures lead to similar profit maximisation strategies. One study of private clinics in Malaysia revealed that many fail to assess new clients properly in their provision of family panning services, and cervical screening is undertaken only if requested. Conversely, private practitioners in Egypt have been found to be less likely than public sector workers to administer (inexpensive) oral rehydration solution, and more likely to prescribe anti-diarrhoeal drugs even though the latter are contraindicated in the country's national programme.

The decision to involve foreign companies in the health sector requires very definite structural conditions if it is not to damage the quality of health care delivery in systems which are already under severe strain. As many commentators have stressed, national and regional health authorities need highly developed regulatory, analytical and managerial capacity if they are to see any benefit from the challenges of working with foreign companies.

In the majority of poorer countries, however, this capacity is simply non-existent. As a result, the introduction of private sector investment threatens to divert care away from public health priorities and further compromise the quality of health care delivery. Concerns that profit-led health care is excessively focused on curative rather than preventive measures are familiar and longstanding, as are fears of over-prescription and unnecessary treatment undertaken for financial motives. Even joint public-private initiatives based on donations or price discounts have revealed their own shortcomings, distorting national health strategies and diverting funds towards non-priority areas, as well as hindering the development of national health systems as a whole. The acknowledged difficulties of integrating private sector companies into public health care have sown doubts among even the most pro-liberalisation commentators.

Moreover, as far as the objectives of health services are concerned, the efficiency of the private sector is unsubstantiated. Patterns of health care consumption resemble those for luxury goods, with high-income households spending a higher proportion of their income on health care than poor households. Poor households therefore account for the majority of health needs but

a disproportionately small share of health expenditure, so that the use of resources in the private health care market is doubly skewed away from need. Precisely this inverted relation between supply and demand renders the market inefficient.

Modes of supply under GATS: presence of "natural persons"

If the establishment of commercial presence is primarily of interest to transnational corporations from industrialised countries, the temporary movement of "natural persons" to provide a service abroad has generated most interest among developing countries. There is already substantial movement of medical personnel from South to North and between countries of the developing world (health services, unlike many other professional services, being largely based on universal principles). However, the perceived economic benefits of this trade raise serious concerns about people's right to health, especially in the poorest countries.

The potential for exchange of medical personnel between countries is attested by experience from across the world. Developing countries – particularly in Asia – supply over half of all migrating physicians, with about 100,000 doctors of Indian origin settled in the USA and the UK alone. Active international recruitment by national health systems has generated a particularly high level of cross-border mobility among nurses. A large number of countries which export doctors or nurses experience severe shortages themselves, and can ill afford to send their services abroad. Increased trade in health services risks exacerbating this transfer of medical personnel from poor to rich countries, thereby placing an even greater strain on health systems in the poorest. Since these are often the countries with the most acute health crises, the public health consequences of expanded trade can be considerable. Weighed against these losses, the remittances that medical personnel send home and the enhanced skills they bring with them if and when they return are poor compensation.

Trade in water and sanitation

In addition to trade in health care, trade in water and sanitation services also raises significant issues for people's right to health. In India the Pepsi and Coca Cola companies have already been marketing "mineral water". Here there are no balance of payment incentives encouraging developing countries to engage in increased trade: almost all the transnational corporations in the water and sanitation sectors are

European and none are from the developing world. Clean water and proper sanitation facilities play a particularly important role in maintaining health during infancy and early childhood. Yet 1.1 billion people across the developing world still lack access to safe drinking water and 2.4 billion people – two fifths of the world's population – do not have adequate sanitation. As a result, more than two million children die from sanitation-related diseases every year.

As with health care, commercialisation has further restricted poor families' access to water and sanitation in many parts of the world. Cost recovery and water privatisation schemes have typically involved significant price rises, often putting water beyond the reach of low-income households. Such developments raise similar problems of equity to those encountered in health care – except that with water, as with education, demand for the service is continual, not intermittent.

Most Favoured Nation and national treatment

Apart from the problems discussed above regarding the various modes of supply, there are other provisions in GATS that can adversely affect the interests of poorer nations. According to the WTO agreement, if favoured treatment is given to one country it should be extended to all the countries which have signed the agreement under WTO. The principle is: favour one, favour all. Most Favoured Nation means treating each trading partner equally. Under this provision of the GATT, if a country allows foreign competition in a sector, equal opportunities in that sector should be given to service providers from other WTO member countries. This in effect means that a country cannot be selective in permitting a foreign country in offering services based on its national interest.

The principle of National Treatment relates to treating one's own nationals and foreigners equally. In services, it implies that once a foreign service provider has been allowed to provide a service in one country there should be no discrimination between the foreign service supplier and the national/local service provider. For example, if a foreign group is allowed to set up a hospital in India, it should be given the same treatment that is given to national/local health service providers in the country. This means that it may have to be given the subsidies to which a national institution is entitled. Since the public health system is already starving for funds this provision can further take away the meagre government funds it receives. In this situation the easier option for the government would be to withdraw subsidy altogether from the public sector.

Balance sheet: meagre gains, high risks

GATS aims to increase the global trade in services with progressive liberalisation. An increase in trade in health services offers a handful of developing countries a limited set of export opportunities, predominantly in attracting foreign consumers to their health facilities and in sending their own health professionals abroad. Yet these gains look trivial when compared with the effects that an increased trade in health services could have on people's right to health. While there may be individual cases in which patients benefit from the development of telemedicine, the potential impacts of increased trade in health services are overwhelmingly negative. If developing countries divert health care resources and personnel towards foreign consumers for the sake of balance of payment gains, whether in their own health facilities or abroad, it can only lead to increased pressure on health systems that, in most countries, are already overstretched.

Attracting foreign investment in the health, water and sanitation sectors may initially seem like a promising option. Yet the commercial presence of private sector companies is unable to address the central problems of access and quality which challenge health, water and sanitation systems across the world. Instead of adding extra capacity to beleaguered public services, the private sector threatens to undermine them by taking over the most profitable parts of the system and drawing key personnel away from the public sector. In addition, it threatens to increase existing inequalities, given that the poor are commonly excluded from services provided on a commercial basis.

Trade in health services, then, risks exacerbating many of the problems which already plague health systems across the world. The main thrust of GATS towards increasing trade and greater liberalisation seems inappropriate for the health sector and the damage may outweigh the benefits, particularly for those with little ability to pay more for publicly provided health care.

Recommendations and conclusion

Several organisations like Save the Children, Medicins Sans Frontieres, the International People's Health Council and Oxfam have made recommendations to deal with the challenges in relation to GATS. These include a full and independent impact assessment of GATS and other WTO agreements, recognition of national sovereignty over

liberalisation commitments, stronger exemption for public services and exemption of subsidies from national treatment standards.

The expansion of trade liberalisation poses serious challenges to people's right to health. While some people may benefit from the increased economic opportunities which globalisation brings, many more stand to remain marginalised from its gains. Communities whose food security is undermined by exposure to international markets are directly at risk from increased trade liberalisation, and measures must be taken – in the context of the Agreement on Agriculture and elsewhere – to protect their livelihoods. As all commentators acknowledge, it is the most vulnerable who are most at risk.

Increased trade in health services offers meagre economic benefits to a handful of developing countries. Diverting resources and personnel towards foreign consumers threatens to put extra pressure on health systems which in many countries are already at breaking point. The commercial presence of transnational health corporations risks exacerbating existing problems of equity, quality and capacity. Given the low level of regulatory capacity in many countries, increased foreign investment in the health sector may well be a poisoned chalice. These conclusions argue against the suitability of the trade liberalisation model for basic services as a whole.

An international call for a full and independent assessment of GATS and trade in services is necessary. In view of the effective irreversibility of GATS-related market access and national treatment commitments, countries should not be under pressure to liberalise their basic services. Developing countries, in particular, should avoid making liberalisation commitments on basic services under GATS. A reassessment of GATS should form part of a wider review of WTO agreements, a review called for by the government of developing countries and civil society organisations around the world.

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Techniques of population control

Neha Madhiwalla

My most poignant memory related to contraception is of an encounter with a couple in rural Maharashtra during a household survey. The man, in his late 30s, was married for the second time, his first wife having died in her youth. He had three adult children, both sons and daughters, from this marriage. His second wife was barely in her early 20s and had just given birth to her second daughter. After a while, as the interview progressed, he announced, "In a few months, we will get her 'operation' done." The woman, who till then had been participating shyly in the discussion about her last childbirth, fell into an impassive silence. It would be hard to describe what she was thinking about—the denial of the opportunity to have a son, or being forced to give up her fertility choices so early in her youth, and, at the very basic level, not having any say in an act on her own body. And it went through my mind that none of the healthcare workers with whom this couple would undoubtedly come in contact would bother to listen to her silence.

This seemed to represent to me all the moral questions on modern contraceptive technology. On the one hand, people, across class, caste and religion, have accepted the use of sterilisation to determine the number of children they want, quite ignoring the opposition that they may face from religious ideologues and politicians. In a way contraception has played a big role in emphasising the importance of the individual's choice in personal and sexual matters. On the other hand, the manner in which the state and the medical profession have shaped the discourse on contraception has done little to promote the empowerment of women and the liberalisation of marriage.

It is against this background that we need to examine the specific moral/ethical questions about contraceptive technology. The most dominant concerns in this area relate to consent and freedom. Historically, the women's movement has been campaigning against "coercion" as a moot issue in the family planning programme. They have clearly drawn links between an anti-natalist state and patriarchy, both of which exercise their power over women to meet their ends, a point so eloquently demonstrated in the

aforementioned incident. In the case of contraception, both research as well service provision, consent is an extremely tricky issue. Women often are willing to put their well-being at risk in order to obtain some control over their fertility. The wide prevalence of illegal abortions is a case in point. Women, at the very outset, are making contraceptive choices in the context of unequal, and often conflict-ridden, relationships. Thus, one finds that they are deeply appreciative of husbands who just permit them to use contraception and, even more rarely, accompany them to the healthcare centre. Few men actually participate in the process of contraception beyond this. On the other hand, a large number of women find that their desire to use birth control is not supported by their partners.

Thus, it is not surprising that women have been enthusiastic about trying out injectable contraceptives in place of other long-acting methods. As the paper by **Hirve** points out, many women who start using injectables do not continue. Very likely the high dropout rates are a result of the fact the adverse effects that usually follow take them unawares. This is largely the result of healthcare workers deliberately concealing information or trivialising problems out of anxiety of losing their clients. Unfortunately, the system continues to prioritise increase in "prevalence" of contraception usage over increase in its free and informed acceptance and use.

An interesting point mentioned in the paper by Hirve is the discussion on the issue of menstrual chaos, a common adverse effect of injectable contraceptives. For women, the menstrual cycle, its regularity, frequency and intensity are the most reassuring signs of good health. A point that medical experts have refused to take serious regard of, sometimes offering the argument that amenorrhoea is actually good for women as they are, generally speaking, anaemic.

While it is not true that birth control is the only domain where medical experts tend to make decisions and choices on behalf of their clients, it seems to be particularly prone to this kind of violation of autonomy. Birth control in the Indian context is, largely speaking, seen as a women's issue and medical professionals often position themselves as benevolent patriarchs protecting women, sometimes even from themselves, by enforcing what is good for their well-being.

However, this is not to negate the fact that there is a huge need for contraceptive services, which requires, along with good ethics, good management. Thus, the other most important ethical concern

in contraception is standard of care. An important point made in the paper by **Murthy, Sarojini and others** in this regard is that a contraceptive is not a drug. Its users are healthy, young adults. Thus, the potential harm involved must be extremely minimal in order to justify its use. Harms emerge from two sources: first, the technology itself, and, second, from its use. As brought out clearly in the paper by **Das**, the relatively safe method of tubal ligation is rendered hazardous by the conditions in which it is conducted. In camp conditions even the basic minimum standards of clinical and patient care are dispensed with, apparently to cope with the numbers. It would be facetious to point out that this problem would not arise if we did not herd women together at regular intervals for camps, but rather provided these facilities on a routine basis in accessible primary care centres.

The fact that the "camp approach" has made a comeback is a telling sign of the erosion of the public health system. In several parts of the country primary health centres are lying unstaffed and abandoned, victims of state neglect. Quite predictably, the provision of family planning services as part of routine service is becoming difficult. This is not unlike the scenario in other fields such as immunisation. All over we find that preventive and promotive health services are becoming one-day-a-month affairs, whether it be antenatal care, postnatal care or immunisation.

This poses ethical problems at several levels. First, the multipurpose worker is fast becoming a misnomer. These workers have become de-skilled—reduced to the mechanical delivery of anti-tetanus shots, oral contraceptive pills, intrauterine device insertions and iron and folic acid pills, without the time or expertise for providing clinical services or good patient care. They have virtually no curative role left. They are not even able to provide effective referral as they are rarely available in the village when women develop problems or complications. Few of them have ever conducted a delivery in their entire career. They have virtually no scope for building rapport with the communities they serve or enhancing their own interpersonal skills, both of which are critical aspects for delivering quality family planning services. Thus, the women's group argument about the inability of the public health system for effective screening of women and providing follow-up is still the strongest reason for opposing the introduction of injectable contraceptives in the family planning programme. This problem affects a large number of services, such as the tuberculosis control

programme or the malaria control programme. These too have suffered due to the fact that clients are not offered any care for adverse effects and very little, if any, counselling and emotional support. However, given that contraception is not a life-saving measure, as for example, anti-TB treatment is, it is not unreasonable to insist that introduction of this technology be preceded by the provision of adequate standards of care.

This brings us to the final and, perhaps, most basic ethical/moral question in this area—which is of accountability. A very formal (though very important) enforcement of accountability is through the payment of compensation to those harmed by way of suffering disability, experiencing unwanted pregnancy after sterilisation, or, in extreme cases, death. However, for the large majority who suffer minor harms—such as humiliation, rude behaviour and poor quality care—there is no redress mechanism. The system reacts to any assertion of rights and claims of violations by denying any wrongdoing. As pointed out in the editorial by **Rao**, government agencies blatantly violate standard guidelines for quality of care that are laid down by their own department of health and family welfare. As a result, communities have developed a deep distrust of the public health system's motives. They turn, quite desperately, to the private sector, with the hope that as consumers they will have more rights than they do as citizens, in spite of the knowledge that private sector providers are equally able to manipulate the system.

This has resulted in a self-perpetuating cycle of abusive practice. It is quite common for people to articulate opposition to the coercive mode of delivery of family planning services as opposition to family planning itself. This prompts the healthcare system to devise more and more ingenious methods of circumventing the process of seeking free and informed choice. What is forgotten in the bargain is that the expansion of family planning services should ideally be a component of the overall movement towards a more equitable society, where individual autonomy is respected and there is a conscious affirmation of the rights of women and vulnerable groups to respectful and empowering treatment from the service providers.

Supreme Court judgement on sterilisations

Mohan Rao

A recently reported Supreme Court of India order (1) has far-reaching implications for one of India's largest public health programmes. In response to a Public Interest Litigation, the Court noted: "For the time being, no doctor without gynaecological training for at least five years' post degree experience should be permitted to carry out the sterilisation programme." A three-judge Bench also instructed state governments to pay a compensation of Rs one lakh per patient dying due to sterilisation. Further, noting that there were no uniform guidelines for the conduct of these operations, the Court also ordered that the Centre should lay down such guidelines within four weeks.

Given that critics of the family planning programme have frequently drawn attention to the appalling conditions under which target-driven sterilisations are conducted in the country, this judgement can only be welcomed. At the same time, it draws attention to several other issues that equally need consideration.

Sterilisations, whether male or female, are among the safest of surgeries. But they carry, in our country, the burden of the largest mortality toll ever imposed by a welfare programme in the history of the world. During the years of the Emergency official sources admit the death of 1,740 persons, predominantly male (2). These were largely poor people, drawn to undergo sterilisations by the "compensations" offered, or coerced into undergoing sterilisations. They were disproportionately from among the marginalised and minorities which meant that that the issue did not receive the attention it deserved. But as male sterilisations proved politically costly attention turned to female sterilisations, often in camps, something evocatively described in Deepa Dhanraj's powerful documentary on the family planning programme, *Something Like a War*.

Despite being a signatory to the International Conference on Population and Development, despite the fact that the National Population Policy (NPP) explicitly renounces targets and emphasises issues of quality of care, it is no secret that states were scarcely influenced by the "paradigm shift" that the NPP is said to have brought

about. This shift emphasised the need to meet unmet needs for health services, including reproductive health services (3).

That there continues to be a single-minded focus on numbers is indisputable. Several state population policies link health personnel's performance assessments with family planning target achievements. Family planning performance has also been made a condition for the release of development funds in a range of schemes. A two-child norm has been implemented for contestants to the Panchayat Raj institution elections in several states. This mocks efforts to bring deprived populations into the political mainstream at the grassroots level, since these population policies take away from dalits, adivasis, women and the poor in general the political space that the 74th Amendment sought to provide. Studies have shown that this has led to women being forced to seek sex-selective abortions followed by sterilisations (4). Ironically, the Supreme Court, in another judgment, upheld this two-child norm (5).

Over the same period, there has been a state-led collapse of the under-funded public health system. The National Health Policy (NHP) admits that India has the dubious distinction — at 0.9 per cent of the Gross Domestic Product — of the fifth lowest public health spending in the world, lower even than countries of Sub Saharan Africa (6). It is no surprise then that we continue to have the largest morbidity and mortality load among countries with similar per capita incomes. The collapse of the public health system has meant that more and more people are driven into the private sector. And thus, again as the NHP admits, medical expenditure has emerged as one of the leading causes of indebtedness. Indeed, the NHP also notes that poor families typically reduce even their basic nutritional requirements to meet their medical expenses.

It is these two factors above all — the collapse of the public health system and the single-minded focus on target achievements in family planning — that lead to sterilisations under unhygienic conditions, with little care to screen prospective patients, or to provide some semblance of quality of operative procedures. Sterilisations are also performed with poor equipment, and the system has no use for follow-up (7). To focus on the training of doctors alone is therefore to miss the woods for the trees. Is there not an urgent need to address the overall conditions and context in which such procedures are performed?

Must matters of quality of care be decided by the Supreme Court? Why is the Indian Medical Association silent? The Department of Health and Family Welfare drafted standard guidelines for quality of care for sterilisations years ago. Of course in their quest for targets, states are not following these guidelines.

There are other concerns raised by the Supreme Court order that need debate. There is an acute shortage of doctors in the public health system. MBBS-trained doctors are perfectly capable of carrying out sterilisations. But if a specialist is now required, does this mean the public health system ceases offering these facilities? Would this then not mean that more patients are pushed into the exploitative arms of the private sector?

It is presumed that quality of care can be guaranteed by specialisation. Specialised obstetricians and gynaecologists in the private sector perform significantly more — and most often unnecessary — Caesaerean sections (8). We only have to remember the silence of the Federation of Obstetricians and Gynaecological Societies of India on sex-selective abortions — to which they contribute disproportionately — to realise that this faith in specialisation may be misplaced.

Reports are legion about poor patients being rendered blind following operations for cataract. Will this too have to be attended to by the Supreme Court? In short, what are the implications for other procedures, from Caesarean sections to coronary by-pass surgery, carried out by the public health system in India? Will norms for training be laid out for all of them? Will these norms apply to the private sector in medical care, the largest and least regulated in the world?

Further, what are the financial implications of the order for the public health system, ailing for lack of funds? In the early 1960s the issue of quality of care hindered the development of the primary health care system in the country. It is also frequently raised to open up Indian markets for multinational companies that equate quality care with high-tech care.

It is widely accepted that the problems with health care in India are systemic in nature; the solutions too must take a systemic view.

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Why women's groups oppose injectable contraceptives

N B Sarojini, Laxmi Murthy

The following statement is based a letter to Mr A Ramadoss, Union Minister for Health and Family Welfare, signed by 62 individuals and health organisations in India. It was written in response to a national workshop on October 27-29, 2004, organised by Parivar Seva Sanstha in collaboration with the government of India, UNFPA and the Packard Foundation through the Population Foundation of India, to expand contraceptive choices with the introduction of injectable contraceptives.

As concerned scientists, women's groups and health activists, we are advocates of voluntary birth control and the right of a woman to control her fertility with safe contraceptive choices, which are user controlled. With this conviction, for the last two decades we have opposed the introduction of injectable contraceptives in the family planning programme.

In the bid to meet unrealistic population control targets and as part of liberalisation policies, Indian authorities have relaxed drug regulations in order to expedite the introduction of long-acting, invasive, hazardous contraceptives into India. This will subject millions of Indian women to long-acting hormonal contraceptives such as injectables (Net En and Depo Provera) and sub-dermal implants (Norplant), likely to cause irreversible damage to their own and their progeny's health.

The injectable contraceptive Depo-Provera was approved for marketing in India in 1993 without the mandatory Phase 3 trials. The American multinational Upjohn (since bought over by Pfizer) thus gained access to one of the largest markets for contraceptives without following requirements.

Women's groups, health groups and human rights groups have opposed the introduction of injectables given the potential for abuse, non-completion of mandatory trials and the lack of accountability of pharmaceutical agencies. An analysis of major studies calls for a complete ban on injectable contraceptives and particularly their introduction in the public (National Family Welfare Programme) sphere.

Adverse health impact

Severe side-effects of Net-En and Depo-Provera include menstrual disorders, cessation of the monthly cycle or irregular bleeding, general weakness, migraine headaches, and severe abdominal cramps. In a country where a large percentage of women in the reproductive age suffer from anaemia, irregular and heavy bleeding can have catastrophic consequences. Studies have shown that injectable contraceptives like Depo-Provera can also lead to osteoporosis. This can have grave consequences for poor women with low bone density due to poor nutritional status. Depo-Provera has been indicted for climacteric-like syndrome; irreversible atrophy of the ovaries and endometrium; deaths due to thrombo-embolism; increased risk of HIV infection from an infected partner; increased risk of Down Syndrome in babies born to women users; increased chances of still births; increase in the risk of breast cancer, cervical cancer including carcinoma *in situ*; doubts regarding the return of fertility after discontinuation of the drug, and so on.

Inadequate infrastructure and accountability

In the case against the injectable Net En, filed in the Supreme Court in 1986 against the Union of India, the Indian Council of Medical Research, The Drugs Controller General of India and others by Saheli and other women's groups, the government admitted at the close of the case in 2000 that mass use of Net En in the FP programme was not advisable. This is a recognition of the potential risks and the need for close monitoring and follow-up.

Depo-Provera is hazardous for women in all circumstances. Moreover, administration requires ruling out contraindications and close monitoring over long periods. Such monitoring is totally absent in this country. Poor women who visit government hospitals where injectables would be offered in the family planning programme would be treated as "living laboratories".

As for the nongovernmental organisation (NGO) sector, the government of India has not evolved definitive standards for NGOs in terms of care, follow-up or accountability. Hence, our core concerns on women's health and safety remain unaddressed here as well.

Dubious post-marketing surveillance in India

A five-year post-marketing surveillance study (PMS) was to have been done in place of the final stage of clinical trials. Its results have not been made public. In this case, post-marketing surveillance has translated into private marketing of the drug. This is hardly surprising given that PMS was conducted by Upjohn, which profitted from the results of the research. This raises serious doubts about the scientific objectivity of the data and its analysis. Scrutiny of PMS data reveals that each woman user is included in the study for five injections, three months apart. Thus, the study covers each woman user for 15 months only — though Depot Medroxyprogesterone Acetate (DMPA) or Depo Provera is intended as a spacing method for at least two to three years. Further, 15 months is not adequate to assess long-term effects. It is unscientific to declare Depo Provera as "safe" on the basis of inadequate data.

The following serious concerns remain unaddressed in the PMS:

* The potential side-effect of bone density loss and subsequent increased risk of osteoporosis has not been studied, though the PMS had a separate budget to monitor bone densitometry. This is of great significance in India where bone density among women is likely to be low.
* Cancer risk has not been studied, though studies in other countries show that increased risk of breast cancer — especially in younger women — cannot be ruled out. Assessment of return of fertility has not been incorporated in the study design — in a contraceptive being promoted as a spacing method. The effect of DMPA on progeny conceived immediately on cessation of use of DMPA has also not been studied.
* Problems such as amenorrhoea, irregular bleeding, generalised weakness and lethargy, migraine headaches, pain in the abdomen and severe abdominal cramps have been considered by the researchers to be "non-serious" medical events. From a user's perspective, these side-effects could be debilitating and hamper daily activities and affect one's well-being. Contraceptives are targeted at healthy women in the prime of their lives, and such side-effects cannot be side-lined as "non-serious". Similarly, the study does not even look into possible side-effects like mood changes, loss of hair or loss of libido which are also of concern to women users.
* Breast-feeding is a contraindication for DMPA. The administration of DMPA during lactation could have a serious adverse effect on the health of breast-feeding women because of its association with demineralisation of bone. This is in violation of international norms and ethics as put down by WHO and CIOMS guideline number 11.

Many studies quoted in favour of Depo Provera have been scrutinised and challenged for their veracity. We believe there is no scientific/ medical justification for the introduction of injectable contraceptives like Depo Provera or Net-En.

Dr C Sathyamala in her monograph (1) articulates the problems associated with DMPA and concludes that it is hazardous to the health of women and their progeny. It is not suitable for nulliparous women, adolescents, breast-feeding women, women who have completed their family, and women in the reproductive age group. The evidence available is already damning and it would be unethical to subject more women to clinical trials with these contraceptives.

Drugs Technical Advisory Board recommendation against Depo Provera

The recommendations made at the Drugs Technical Advisory Board meeting held on February 16, 1995 state that: "Depo-Provera is not recommended for inclusion in the Family Planning Programme." N H Antia, one of the members of the DTAB, in a separate note states why it should not be included:

* The target-based approach may lead public health personnel to impose DMPA on women without checking for contraindications or explaining hazards including permanent sterility.
* Because of the almost superstitious belief in the power of injections, "gullible women would be more than willing to use this injection thus rendering themselves vulnerable to misuse of DMPA".
* The health of the DMPA user has to be monitored for an array of disturbing side-effects. The Indian public health system is inadequate for this work.
* Up to two-thirds of women on DMPA experience menstrual chaos, which may be culturally unacceptable to women.

Lack of informed consent

Right from the experience in Patancheru in Andhra Pradesh in 1985 (leading to the filing of a writ petition in the Supreme Court), where poor, illiterate women were recruited in clinical trials and administered the Net En injectable without their informed consent, women's groups have monitored the violations of informed consent while administering contraceptives. A study (2) reveals that women in Delhi were put on injectable contraceptives in a public health set-up without informed consent. Vital information regarding its safety and adverse effects was withheld from women, depriving them of the right to make an informed choice.

The empowerment of women is not simply a matter of offering them more contraceptive technologies without complete information, proper screening and follow-up. The attempt to justify the introduction of injectable contraceptives on the plea that it would provide women with a wider range of contraceptive "choice" makes a mockery of the concept of "choice" given that an overwhelming majority of women have no choice regarding access to health, education or employment.

We urge you to consider these issues very seriously before considering any proposals that recommend the inclusion of injectable contraceptives in the National Family Planning Programme. We hope you will reject the interests of private profit and work instead to formulate a policy that ensures the overall good for women and their progeny.

This memorandum has been endorsed by the following organisations and individuals: Aalochana Documentation and Research Centre, Pune: Simrita Gopal Singh • AIDS Awareness Group, Delhi: Elizabeth Vatsayan • Akshara, Mumbai: Nandita Gandhi • All India Democratic Women's Association (AIDWA): Brinda Karat • All India Progressive Women's Association (AIPWA): Srilata Swaminathan • Anandi, Gujarat: Neeta Hardikar • Catholic Medical Association of India • CEHAT, Pune: Sunita Bandewar • Centre for Social Medicine and Community Health, JNU: Mohan Rao • Centre for Social Medicine and Community Health, JNU: Imrana Quadeer • Chetna, Ahmedabad • Community Health Cell, Bangalore: Thelma Narayan • Delhi Science Forum: Amit Sengupta • Dynamic Action Group, Lucknow: Ram Kumar • Amar Jesani, Mumbai • Anant Phadke, Pune • Dhruv Mankad, Nashik • Mira Sadgopal, Pune • Navsharan Singh, independent researcher • Vandana Prasad, Delhi • Veena Shatrughna, Hyderabad • Eklavya, Dewas: Anu Gupta • Ekta, Madurai: Bimla • Explorations, Mumbai: Jaya Velankar • Forum Against Oppression of Women, Mumbai: Sandhya Gokhale • Forum for Women's Health, Mumbai: Meena Gopal • Gramya Resource Centre for Women: Ashima Roy Choudhury • Hanif Lakdawala, Gujarat • Health Watch UP, Bihar: Abhijit Das • Jagori, Delhi: Abha Bhaiya • Jashodhara Bagchi, Chairperson West Bengal State Women's Commission • Jan Swasthya Abhiyan, Madhya Pradesh: Ajay Khare • Jan Swasthya Abhiyan • LABIA, Mumbai: Shalini • Maati, Munsiari, Uttaranchal: Malika Virdi • Madhya Pradesh Mahila Manch: Lorry Benjamin • Magic Lantern Foundation, Delhi: Gargi Sen • Majlis, Mumbai: Flavia Agnes •

Medico Friend Circle • Masum, Pune • MPVS: Ajay Kumar Khare, Bhopal • National Federation of Indian Women: Sehba Farooqi • Nirantar, Delhi: Jaya Sharma • OLAVA and Muslim Women's Rights Network: Sabah Khan • People's Health Movement (India): B Ekbal • Prabir, Godda, Jharkhand • Prayas, Rajasthan: Narendra Gupta • Rahi, New Delhi: Anuja Gupta • Ravi Duggal, CEHAT, Mumbai • Sanchetana, Kolkata: Rajashri Dasgupta • Saheli, Delhi: Laxmi Murthy • Sahiyar, Baroda: Trupti Shah • SAMA, Delhi: Sarojini N B • Sangram, Sangli: Meena Seshu • Stree Adhikar Sanghatan, Delhi: Anjali Sinha • The Ant, Assam: Sunil Kaul • Halo Medical Foundation, Anadur, Maharashtra: Shashikant Ahankari • Tamil Nadu Women's Collective: Sheelu • Tathapi Trust, Pune • Vacha, Mumbai: Sonal Shukla • Vimochana, Bangalore: Donna Fernandes • Women's Centre, Mumbai: Ammu Abraham.

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Injectables as a choice — evidence-based lessons

Siddhivinayak Hirve

Newer, better contraceptive methods may not result in increased reproductive choice if health systems cannot ensure quality of contraceptive services.

Though extensively researched and used by over 16 million women in 130 countries Depot Medroxyprogesterone Acetate's controversial history has restrained its use by national family planning programmes worldwide. Early clinical trials were abandoned due to the adverse US FDA ruling and opposition by health advocates in India. After US FDA approval Depot Medroxyprogesterone Acetate (DMPA) was licensed for use in 1993 in India conditional on post-marketing surveillance by its manufacturer for side-effects. Since 1994, injectables are available through commercial and social marketing channels but not in the public sector. In 1995, a panel favoured the use of injectables rather than levonorgestrel or Norplant in India, because of the ease of dispensing injectables and the prohibitive expense of Norplant. A recommendation was made in 1998 to introduce injectables in suitably equipped centres in the public sector with appropriate screening, counseling and medical backup, and emphasis on good clinical practice and post-introduction surveillance for side effects and management. Women activists opposed its introduction in the national family welfare programme for reasons of safety and fundamental inadequacies in providing quality contraceptive care, ensuring informed choice and consent. The debate on injectables touches wider issues of gaps in existing population and drug policies, a lack of male responsibility and involvement in reproductive health, and vested interests of multinationals.

Injectables have the lowest failure rates among methods of contraception. This efficacy is dependent on appropriate timing of the first injection, and repeat injections. The typical acceptor is a woman in her early 30s, with two or three living children, who wants to limit rather than space her children. Women prefer injectables to pills or IUDs. Acceptors include first-time contraceptive users because of the convenience, effectiveness and perceived safety. They also include women who switch to injectables after experiencing side-

effects with other contraceptives. An initial high acceptance of injectables is not sustained as most women experience menstrual disturbances resulting in one-year discontinuation rates of 15 to 50%. Menstrual disturbance as a reason for discontinuation is context- and culture-specific, with high discontinuation rates seen amongst women in Pakistan, where women are less likely to accept amenorrhoea; in contrast, infrequent bleeding was less likely to result in discontinuation than frequent heavy bleedings in Indian women. Tolerance thresholds and partner attitudes to menstrual disruption need to be studied. Protagonists of injectables seek to underplay the side-effect of menstrual disturbances as not being harmful or life-threatening. This is not to underplay the women's perception of side-effects as a reason for discontinuation. High discontinuation rates may be due to poor selection of method, poor attributes of the contraceptive or just the inability of the services to ensure continued use of the injectable. Alternately, it may be seen as a measure for the woman's freedom of choice to opt out of the method, if she dislikes it.

Another concern is the reversibility of injectables. The median delay to return to fertility (8-9 months after last injection), as expected, is higher than barrier methods, oral contraceptives, or intrauterine devices. Large variations are seen amongst women from different populations, reflecting differences in the nutritional, metabolic and fertility status. Return to fertility is not affected by duration of injectable use or by parity, implying that women can safely use injectables for even delaying their first pregnancy.

How safe are injectables?

This is probably the most controversial and researched aspect. Studies of Chinese women show bone mineral loss to be much lower than previously projected (0.4-1% per annum) and unrelated to duration of DMPA use. Debates on DMPA-induced bone mineral loss and its effect on pubertal skeletal growth in adolescence, or the risk of aggravation or acceleration of osteoporosis in lactating women *vis a vis* the benefits of contraception, have been largely speculative. Though WHO recommends its use amongst adolescents and lactating women, India chose to play it safe by recommending that use of injectables be avoided in adolescents.

Adverse effect on blood pressure and thrombosis has not been reported. One study has shown glucose intolerance following long-term DMPA use. There is no link between breast cancer and long-term DMPA use. An increased risk was seen in recent users but not in long-term users suggesting that DMPA may trigger the growth of existing breast tumours rather than turn normal cells cancerous. Prolonged use of DMPA may cause *in situ* cervical carcinoma but not invasive cervical carcinoma; hence the need for periodic monitoring for cervical cancer.

In utero exposure to DMPA shows equivocal findings of its effect on birth weight and birth defects. DMPA and norethisterone enanthate (NETEN) are secreted in breast milk in lactating women. There is no effect, or insignificant effect, on breast milk or subsequently on infant development. Pubic hair development was delayed significantly in girls. Increased aggression responses in adolescents and an enhancing effect on female sexuality have been seen.

Service delivery issues

Screening, counselling on mode of action, side-effects and their management are crucial. Poor follow-up of clients, lack of motivation, and lack of knowledge on side-effects management are programme weaknesses. Standardised protocols for counselling and better provider skills are needed. Women attending FP clinics in the Philippines were not well informed about the range of services available. Studies amongst private providers in India showed that they did not promote indiscriminate use of DMPA. However, there was a need to develop standardised protocols for counselling and improve provider skills. Medical procedures were not explained, while 16% of clients reported that providers did not inform them about side-effects resulting in most women with side-effects not returning to the clinic for assistance. Many DMPA programme dropouts reported that clinic staff were not caring or courteous. Findings indicate poor counselling of women by providers in terms of content and quality. Periodic orientation for providers on issues related to medical eligibility, side-effects management and counselling and skills to counter rumours were some strategies suggested by providers to improve quality of care.

Preference for a female provider and supply shortage often turned away would-be DMPA acceptors or resulted in method switching. Distance and inconvenience of clinic timings sometimes resulted in clinic switching or DMPA discontinuation. Client costs can adversely affect DMPA use. Acceptance is highest when DMPA is offered free. However, free services cannot sustain continued acceptance.

Though DMPA and NETEN may have similar effectiveness, continuation rates and side-effects, the service delivery implications are very different. To avoid field worker confusion, error and disruption

of field worker routines, and to simplify managerial and supply logistics, it is recommended to use either DMPA or NETEN (not both) in the same geographical area as there are significant differences (different dosage regimes, needles etc.) that affect service delivery.

The Thailand experiences highlight the need for diligent follow-up, surveillance for side-effects, and accurate records. The Sri Lanka experience illustrates the need for transparency and flexibility of the health system to respond to concerns voiced by the community. The initial uptake of injectables is usually high; sustaining it is difficult because of inadequate preparation, poor training and poor logistics management. This resulted in poor counselling, lack of informed choice, poor selection of women and other concerns. Injectables were prematurely withdrawn from the national programme in the Philippines, to be re-introduced more successfully later.

Ethical concerns

Whether injectables undermine or further a woman's reproductive rights needs to be examined in the context of policy and practice. An injectable has to be evaluated from a rights perspective in terms of who controls it, its purpose, safety, effectiveness, risks and benefits, reversibility, and equally important concerns of availability, accessibility, affordability and quality of service delivery. Since its inception, India's FP programme has been driven by demographic goals of population control resulting in promotion of provider-controlled contraceptives. Recently we have a policy environment which reflects a commitment to widening contraceptive choice in the broader framework of reproductive health and reproductive rights. The National Population Policy 2000 seeks to provide gender-sensitive quality services and supplies, information and counselling and widening contraceptive choice to enable women and couples to make informed choices and access quality health care services.

Women's groups have opposed injectables because of the potential for violation of reproductive rights as well as of informed consent, autonomy and safety. Addressing resource constraints, removing informational, physical and economic barriers and strengthening the quality of reproductive health care delivery — putting a reproductive rights framework into practice — present a challenge and an opportunity to offer injectables and widen contraceptive choices for women. It is time to ensure a health system which is sensitive to social and gender inequalities, one that respects women's dignity and autonomy.

This paper derives from a scientific literature review, by the author, on the use of long-acting, progestin-only contraceptives in the South Asian context. The review was commissioned by the UNFPA. A report of the review, Progestin-only injectable contraceptives facts file*, was published by UNFPA India on October 15, 2004, and was available at www.unfa.org.in/reports/17_Facts_File.pdf when accessed on December 18, 2004.*

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Ensuring quality of care in sterilisation services

Abhijit Das

Female sterilisation is the mainstay of contraceptive methods in India. Every year over four million female sterilisation operations are conducted in the country. Like all surgical procedures, female sterilisation, despite being a relatively low-risk procedure, has its attendant risk and failure rates. According to international authorites, the failure rate, i.e. the chance of becoming pregnant after the operation, is around one in 200, the rate of complication around one in 100 (1), and the risk of death around three in 100,000 procedures (2). According to these estimates, there is a possibility of over 20,000 failures, 20,000 women with complications and about 150 deaths due to these operations. However, there are no specific provisions for dealing with these acceptable risks within the programme.

Healthwatch UP Bihar is an advocacy network on women's health and rights in four states — Uttar Pradesh, Bihar, Uttranchal and Jharkhand — which originally comprised UP and Bihar. Healthwatch UP Bihar is actively involved in tracking the changes in the delivery of the state family planning programme after the adoption of the Target Free Approach and after the Reproductive and Child Health Programme (3). The state unveiled its population policy in July 2000 and this policy had a set of escalating annual targets that ranged from 600,000 to 1.2 million cases per year. While reviewing the policy directives, members of the network came across a large number of cases of sterilisation failures, complications and deaths (4). Site visits to sterilisation camps revealed that bicycle pumps were being used to introduce air into the abdomen for laparoscopic ligation (5).

Public interest litigation for ensuring quality of care in sterilisation services

The Department of Family Welfare of the Government of India had prepared a manual of standards in the case of female and male sterilisation (6). The quality of care in 10 sterilisation camps was documented using these standards. It revealed that most of the standards were not being followed. The average operating time was between two and five minutes for laparoscopic ligation. Against the prescribed limit of 20 operations per team per day, teams were found to perform 75 operations.

Using the study by Healthwatch UP Bihar and another study as evidence, and the Department of Family Welfare guidelines as the basis, a public interest litigation (PIL) was filed in the Supreme Court by Healthwatch UP Bihar under Article 32 of the Constitution. The PIL (Writ Petition (Civil) No 209 2003) was admitted and the Supreme Court asked all states and union territories to file their affidavits. The Supreme Court gave its order to states in May 2003 and since then only seven states and union territories have filed their affidavits. These include Daman and Diu, Dadra and Nagar Haveli, Andaman and Nicobar islands, Sikkim, Manipur, Haryana and Orissa. Except for Haryana, none among these have acknowledged that there are any cases of failure, complication or death and have solemnly sworn that all procedures are following the standards. Haryana has been the sole exception because of the well-known Santara case (7) where the government had to pay compensation for the failure of a case of tubectomy.

It is interesting to note that a performance audit by the Comptroller and Auditor General on the National Family Wefare Programme in 2001 reported that nine states had reported 762 failures and no investigations had been carried out to establish the reasons for the failure. A five-district study in Uttar Pradesh conducted in 1999 had reported a failure rate of 4.7% which would amount to over 15,000 failures in that state alone (8).

Quality of care, ethics and law in the case of sterilisation

Sterilisation campaigns have been in the centre of controversies. Forced sterilisations in Nazi Germany, in the US in the early 1940s and the Sterilisation Act of Sweden are well-known cases of human rights violations. There were forced sterilisations during the Emergency in India too. However, after the International Conference on Population and Development (Cairo 1994), family planning programmes have supposedly become more development-centred and women-friendly. India too has changed its policies and programmes through the adoption of the National Population Policy (NPP 2000), the Reproductive and Child Health Programme (1997) and the Community Needs Assessment Approach (1999). In the wake of these changes, the findings of the two studies raise a number of legal and ethical questions regarding the conduct of individual operations, mass sterilisation camps as well as programme design and accountability.

There are close relationships between quality of care, ethics and legality. While quality of care can be considered to relate to technical aspects, ethics relate to moral responsibility and law binds with legal accountability.

Sterilisation operations are non-therapeutic procedures and therefore warrant extra care and caution (9). The ethical responsibility of the practitioner is more in the case of non-therapeutic operations because it is possible to cause harm to someone who did not have a problem to start with. Many women undergo tubectomy as a result of the subtle pressures of health workers and the absence of knowledge and access to other services. The ethical considerations in the case of female sterilisation have more than one dimension. First, one has to consider the manner in which women are recruited for the procedure. While this is the responsibility of paramedics and outreach workers, it is finally the responsibility of the team headed by the operating surgeon to ensure that all medical eligibility criteria and ethical (informed consent) requirements have been met. The operating surgeons must ensure that the minimum acceptable technical standards are met. Besides, women who come to camps deserve to be treated with dignity. The author's experience at the camps is that a heavily sedated woman is picked up roughly and dumped on the operation table. In the operation theatre, there is little concern for the woman's privacy and at the end of the operation she is picked up and dumped outside equally unceremoniously with little concern for post-operative care. As a programme of high national priority, the family planning programme owes the women who agree to undergo sterilisation operation minimum respect and quality services and medical personnel associated with these camps need to ensure this.

Doctors often justify the shoddy treatment of women at sterilisation camps by referring to the pressure of targets that they have to fulfil, or the lack of time. This is a dilemma that doctors must resolve at the personal level as well as through professional organisations such as the Indian Medical Association and Federation of Obstetrics and Gynaecology Societies of India. The accountability to the employer (the government) in terms of the various pressures has to be balanced against the ethical responsibility towards the individual patient. Besides ethical principles, the consequences of poorly conducted operations have legal dimensions as well. Indian courts have admitted cases of tubectomy failure and deaths, and have taken steps to compensate women for medical negligence. They have also fixed the state's accountability for the doctor's negligence in cases of failure (7) as well as deaths from tubectomy (10).

It is time that the simple tubectomy operation is examined more closely, not only because it is perhaps the most widely conducted surgical procedure in India but also because this major surgical procedure, if improperly performed, has the potential to cause harm.

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HIV/AIDS programmes: philosophy and practice

Bebe Loff, Brad Crammond

To none will we sell, to none deny or delay, right or justice. (Magna Carta)

Each of the articles in this collection raises, in some form, substantive and procedural aspects of justice. What we would like to address in this brief commentary is the movement of these ideas from the academy to practice. In doing so we will examine the environments in which fair process might promote distributive justice.

Jesani et al have described the World Health Organisation's 3-by-5 initiative and its implementation in India. NACO's guidelines indicate that the first phase will cover sero-positive mothers who have participated in the Prevention of Parent to Child Transmission Programme co-sponsored by UNICEF, sero-positive children below the age of 15 years, and people with AIDS seeking treatment in government hospitals. The reasons why NACO has prioritised these populations as opposed to others are unclear.

It is of interest that despite promoting the view that prevention and treatment should proceed in tandem, NACO's priority groups for prevention are sex workers, intravenous drug users, men having sex with men, migrant labourers and street children. The linkage between these groups and those prioritised for treatment is not established in the documentation. One can only assume that these groups are perceived as the primary vectors for the transmission of the disease.

Jesani et al are concerned that without commitment to a rights-based approach, inclusive of procedural justice, the current imbalances with respect to access to services and treatment will remain. It is difficult to see how, without resort to law, redress will be possible.

Macklin describes the criteria for procedural fairness and various principles of distributive justice. She notes that given that principles for distributive justice may conflict and that there is no correct way

of determining how to choose between or balance these principles, the requirement of a fair and open process becomes even more necessary.

Sahay and **Mehendale** examine ethical concerns in Indian HIV vaccine trials. They describe the general ethical standards and note matters of relevance to the Indian population. For example, they describe the position of one community advisory board that states, controversially, that the involvement and concurrence of men would be needed for married women to participate in trials. This is in conflict with international guidelines. Apparently, a national consultation produced a consensus that sponsors should be liable for trial-related injuries, presumably including sero-conversion. The possibility of providing insurance to cover injuries occurring during the trial was explored with an arbitration board to determine disagreements between participants and the sponsor concerning the cause of lasting injuries. (Unfortunately, where arbitration is formalised, those who are unable to represent themselves are unlikely to succeed. Nonetheless, Indian courts and tribunals have a surprisingly good record in upholding rights.)

Gore's article reveals how at the personal level, despite the challenges posed by living with HIV, the support of family and friends combined with education will more likely promote an outcome that is the best possible given the circumstances. Attitudes such as this can be supported by sound policy. Otherwise, potentially positive community responses may be undermined, reinforcing stigma and lessening the possibility of access to necessary services.

It is the theme of fair process and its implementation that will be examined in what follows. If the government is the body most able to provide institutional support for distributive justice, utilising fair procedures, what methods will convince it to do so?

Let us take transparency as an example. Governmental transparency is in the interests of the populace because the opportunity is provided both to know what the government is doing and to judge whether what is done is appropriate. But transparency is not in the interests of those in the ruling party in government because it lays bare their actions and opens them to criticism. Why then would a government embrace transparency when it threatens its operation and may reduce its potential to contract services to friends rather than those most qualified? Almost universally, governments have done so only when they enter office or take

power, often in reaction to the abuse of secrecy by a previous ruler. This is true in the case of the English, French and American Revolutions, of post-colonial India, and of the recreation of South Africa post-apartheid. In each case a history of political opposition combined with a long build-up of popular resistance that ultimately caused catastrophes of varying degrees. In the aftermath of governmental change each set of new rulers introduced charters of rights designed to prevent the abuses of the previous regime—some have lasted, some have not.

But how does the world of public health or of human rights advocates engineer such change without the need for catastrophic events?

In a case entitled Shri Subodh Sarma & Anr. v. State of Assam & Others (2000) in the Gawahati High Court, a public interest litigation was pursued by the family of a person with HIV. The complaint targeted an AIDS project funded by the central government. The latter provided finances to the state government, but the state had failed to spend the money on AIDS prevention. A further complaint was that the local state-run hospital had no procedure for treating AIDS patients.

The court decided that:

* NACO guidelines and strategies must be implemented in letter and spirit; the funds released by the central government for AIDS prevention must not be allocated to any other area; the state government must ensure that no other agencies are misusing funds earmarked for AIDS prevention or treatment; blood banks must operate with a licence or be closed;
* AIDS counselling centres should be opened at state hospitals; people should be appropriately trained to deal with AIDS;the implementation of the system should be monitored; and people with HIV/AIDS must not be refused treatment in a state hospital.

Unfortunately, the decision was provided without substantial reasoning. However, it is an indication that an active court can attempt to counter systemic inequity.

The National Human Rights Commission of India may similarly inquire into such matters. For example, in the case entitled Medical Treatment to XXX, an HIV-positive patient at Lok Narayan Jaiprakash (LNJP) Hospital, New Delhi (Case No.:1698/30/2003-2004), the Commission received a complaint alleging that XXX had been denied treatment both by government and non-government hospitals. He was admitted to the All India Institute of Medical

Sciences, and discharged after 15 days. He complained that during his stay at the LNJP Hospital from September 2 to 9, 2003 he was refused treatment (dialysis).

In response to the Commission's notice, the medical superintendent of AIIMS submitted a report stating that the patient was examined by urologists and nephrologists on various occasions and was found to be clinically stable, and did not require dialysis immediately during his admission. His renal function too showed an improvement and was consistent with standard clinical care. The patient was discharged only when his condition was found to be stable and was asked to report after 15 days for review and follow-up, but he did not return.

The medical superintendent of the LNJP Hospital had also sent a report together with an updated status and progress report of XXX. Upon considering the progress report, the Commission found that subsequent to its intervention, proper medical treatment had been given to the patient and no further action was called for at this stage. However, the Commission informed the medical superintendent that it should continue to provide proper treatment to XXX and other such HIV-positive patients, and that the hospital should continue to offer adequate treatment to poor patients so that they may not approach the Commission in future.

Proper process is possible with an active civil society that has the necessary mechanisms available. However, even with these features in place, neither fair procedures nor just outcomes are assured.

To call upon an extreme example from a country that prides itself upon its observance of rights and due process, the experience of the United States' response to Hurricane Katrina is a salutary illustration of failure in all regards. One year before the hurricane, the state of Louisiana requested government funding "to develop an in-depth contingency plan for a powerful hurricane" (1). The funding was refused. Instead, $500,000 was awarded to private consultants to devise a hurricane disaster plan. The final cost of the project doubled to $1 million and the consultants completed a detailed plan. By the time the hurricane hit, no part of that plan had been implemented—with $1 million spent on creating it, no money available for its execution.

Haliburton reconstructed military bases, Blackwater were hired to protect the Federal Emergency Management Agency from looters, and other companies active in Iraq have been contracted with no open bidding to perform the reconstruction of New Orleans.

Congressional investigations found gross overcharging and mismanagement by these companies, just as they did when reviewing their operations in Iraq. During this period and subsequent to the urging of Milton Friedman, the public school system in New Orleans had with "military precision" been almost completely replaced.

The strength of social institutions with the facility to combat corruption, be they courts, commissions or other means of open scrutiny, is as crucial in the case of hurricanes as in establishing processes for decision making surrounding access to treatments. Debate should occur around the nature of those social institutions just as it should about their guiding philosophies. The reasoning behind resource distribution as determined by governments or other agencies should be open, available and subject to challenge. Ultimately decisions will be made. Not all will be content with these decisions, but openness and ability to appeal may make such decisions more palatable.

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Government-funded anti-retroviral therapy: new ethical challenges

Amar Jesani, S P Kalantri, George Thomas,
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In September 2003, an international initiative was launched to treat 3 million people living with HIV/AIDS by 2005-the 3-by-5 initiative. According to WHO estimates, 95 per cent of the 40 million people living with HIV/AIDS (PLHA) are in developing countries. Less than 8 per cent of those needing anti-retroviral therapy (ART) receive it — compared with 84 per cent in the West (1). The Director General of WHO described the lack of access to ART as "a global health emergency" and declared: "To deliver anti-retroviral treatment to the millions who need it, we must change the way we think and change the way we act." (1)

The 3-by-5 initiative found its echo in India where there are an estimated 4.58 million PLHA as of 2002. On the World AIDS Day 2003, the Indian government announced that from April 1, 2004 it would provide free ART in six high prevalence states: Andhra Pradesh, Karnataka, Maharashtra, Tamil Nadu, Manipur and Nagaland. Later, the government added Delhi to the list, a low prevalence state, due to its "high vulnerability" (2). The National AIDS Control Organisation's (NACO) draft guidelines on the internet state that the first phase would cover sero-positive mothers, sero-positive children below the age of 15 years and people with AIDS seeking treatment in government hospitals. An estimated 0.1 million patients would be covered by the end of 2005 (3).

Two factors are responsible for these major announcements. First, organisations of PLHA all over the world have pressurised governments and international organisations to recognise their right to treatment and care. Second, there is a growing realisation of the economic and social impact of the HIV/AIDS epidemic, as well as of its human rights implications. In fact, HIV/AIDS has been responsible for orienting the public health community to human rights — particularly the right to health.

The obligation to care and treat

The medical profession has extensively practised discrimination against PLHA. Hospitals test patients for HIV infection without their knowledge or consent, without pre-test counselling contrary to national and international guidelines. In the private sector, patients found to be HIV-positive are shunted to government hospitals, discharged on some pretext or charged extra for treatment with "special protection". In government hospitals, patients with HIV infection are referred to the sexually transmitted diseases (STD) wards regardless of the source of their infection. Some are refused emergency treatment while others are isolated, thus making their HIV status public.

Interestingly, the private health sector has for long delivered ART to those who can afford it, while also increasing its discriminatory practices. This makes one sceptical of the claim that stigma and discrimination will reduce as treatment options become available. More important, the government's programme commits to cover only around 2 per cent of PLHA. It is not clear how the technical guidelines and medical criteria will make the selection of this 2 per cent impartial. How can the selection process be impartial and objective if the profession that is supposed to implement it has shown discriminatory behaviour? The introduction of free ART to a select few must be accompanied by the strict enforcement of the fundamental obligation of health professionals to treat patients without discrimination.

Being just and seen to be just

Justice and ethics are the casualties when political choices favour corporate profit over patients' lives. Current policies pricing essential drugs out of people's reach are responsible for the public health and ethical crises in HIV/AIDS. The problem of justice is also evident at the micro-level of the new policy.

Clearly the new ART strategy does not intend to cover all those needing treatment. PLHA living in states other than the seven named are left out. Even within the seven states, only certain categories are eligible. Unless the government explains and justifies the logic of its policy, it faces an enormous ethical crisis. For instance, Delhi's belated inclusion is not due to medical vulnerability but political power.

The policy also needs to be seen as just, or what Norman Daniel describes as having "perfect procedural justice". If the states are selected on the basis of sound public health logic, it must be strictly adhered to without giving in to political exigencies *. The location of treatment facilities ought to be such that physical access is easy. Ten of the 15 institutions identified in the NACO guidelines are in Maharashtra and Tamil Nadu. This physical imbalance carries forward the past unjust distribution of health services.

Another issue relates to the prevention of drug resistance due to poor adherence to the treatment protocol and compliance to treatment. NACO needs to clarify whether, besides the medical selection criteria, there will be a value judgement of patients who are best placed to comply with treatment. Further, the private health sector has been irresponsible in the treatment of other communicable diseases. Irrational prescription practices, discarding patients half-way through the therapy when they run out of money, etc., have contributed to the development of drug resistance. Since the private sector has long used ART and will continue to use them, stringent regulation of its prescription practices must be brought in the policy agenda. Without this, the policy will suffer reversals, again jeopardising PLHA's right to treatment.

There is also the danger of corruption leading to the rejection of deserving patients and the availability of "free" treatment for a bribe.

Other health needs

Finally, just process demands an explanation of why people suffering from other diseases — many of them life-threatening — should be made to pay in government centres for drugs and user charges when ART will be freely available. The new health policy and even the Common Minimum Programme of the new government has promised that the government expenditure on health care will be increased from 0.8 per cent of the gross domestic product (GDP) to over 2 per cent of GDP. Just process demands transparency about when this increase will be achieved and whether the increased funding will go primarily for HIV/AIDS programmes or distributed fairly across suffering patients of all types.

For all this, the medical ethics movement in India must make the connections between ethics, human rights and public health and keep a sharp eye on this programme. This will not only prevent its unethical implementation but also make the ethics movement learn from public health and human rights concerns.

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* *The authors thank Norman Daniel for his insights through discussions as well as by sharing a draft of his to-be-published paper "How to achieve fair distribution of ARTs in 3 by 5: fair process and legitimacy in patient selection."*

Challenges confronting the WHO/UNAIDS 3x5 Initiative

Ruth Macklin

Efforts such as the World Health Organization's 3x5 Initiative bring with them new challenges, along with the hope and promise of expanding access to antiretroviral treatment (ART) in developing countries. Some challenges are practical or technical: Will a sufficient number of volunteers undergo HIV tests to determine their eligibility for treatment? Will there be enough rapid test kits available for all the people who will have to be tested? Equally challenging are questions of ethics and equity.

The editorial in the July-September 2004 issue of the Journal (1) describes some of the ethical challenges this initiative faces in India. This includes the ongoing discrimination against people living with HIV/AIDS in both public and private sectors, the injustice evident in the selection of the sites where free access to ART will be offered, and the potential for corruption due to bribery in rejecting or selecting patients for free treatment. Although these and other ethical challenges are not unique to India, they are based on evidence from current and past discriminatory practices and unjust distribution of health care resources.

The editorial asks, "How can the selection process be impartial and objective if the profession that is supposed to implement it has shown discriminatory behaviour?" The only way to accomplish this is to adhere to procedural fairness while selecting both the sites where free ART will be available and the individuals who will be eligible to receive the treatment. Elements necessary for achieving procedural fairness are discussed below.

Community involvement

Involvement of communities is a prerequisite for procedural fairness.

Transparency

Groups involved in setting priorities must use democratically developed, unambiguous criteria in taking decisions about the individuals or groups that will receive treatment. "Public accountability in the form of open, democratic processes is a fundamental requirement of justice because people must understand what principles and reasoning are used in choices that affect their basic well-being (2)."

Decisions about which categories or groups should have access to ART and the rationale for these decisions should be "reasonable" in that they should appeal to reasons and principles that are accepted as relevant by the stakeholders. Such decisions must be publicly accessible (3).

Inclusiveness

Those involved in the decision-making process at all levels should include a wide range of individuals and groups. Policy makers and members of advisory boards should include persons with HIV infection and their family members, people from different backgrounds — language, cultural, educational and class.

Impartiality

This criterion is required to avoid conflicts of interest. For example, stakeholders should not be involved in the decision-making process which sets priorities for their own group to receive ART.

Due process

There should be a mechanism for challenge and revision of the chosen scheme, including the opportunity for revising decisions about priorities in the light of further evidence and changing circumstances (3).

Accountability

There should be some form of accountable regulation of the process to ensure that the above conditions are met (3). In addition to embodying elements of procedural fairness, implementation of the 3x5 Initiative must also respect human rights and adhere to substantive principles of ethics and equity. Although adherence to human rights provisions in scaling up treatment programmes is essential, none of the various human rights treaties or declarations provides specific criteria for setting priorities or choosing among potentially relevant principles of equity. As treatment programmes are rolled out, it will not be possible for every eligible person to be treated at once. What criteria should decision makers use to set priorities for access? Are there ethically acceptable grounds for choosing special groups, such as health care workers, to ensure effective implementation of treatment programmes? Can giving preference to children or pregnant women

be ethically justified? There is no clear and uncontroversial way of determining which groups in a population should be given the priority when all cannot be treated at the outset.

Ideally, the 3x5 Initiative should provide ART free of charge through public health care institutions. This would ensure not only that the poor will not be excluded from the scaling up of ART, but also that priority will be given to the large number of people in developing countries for whom existing treatments have not been affordable and who would continue to be excluded if they had to pay out-of-pocket. Moreover, practically, evidence from existing programmes in which people in developing countries have had to pay for some or all the cost of antiretroviral drugs reveals an array of negative medical and social consequences, including interruption of therapy, deterioration of health status, poor adherence, and development of drug resistance.

An argument in favour of giving priority to the poor is supported by a leading ethical principle: concern for the worst-off or the least advantaged. In the context of health care delivery, this is usually understood to refer to those who are worst-off in terms of health status, but it could also apply to the poorest members of society; the lowest socioeconomic class; the most vulnerable (for example, children, especially orphans); or groups that are marginalised or most discriminated against. The principle that favours the least advantaged and the most vulnerable groups does not, however, call for giving strict priority to these groups.

Other ethical principles are potentially relevant and can provide justifications for choosing one or the other scheme for access to ART. The utilitarian principle, applied specifically to health policy, aims at maximising health benefits for society as a whole. For example, treating health care personnel or teachers would have the additional benefit of ensuring that needed personnel are available for providing treatment and for health promotion, which produces additional health benefits for society. Similarly, treating factory workers rather than children or unemployed people produces economic benefits for the country which, in turn, could be used to increase treatment access. However, giving priority to the more productive members of society would perpetuate the exclusion of individuals and groups who have historically lacked access to health care.

An egalitarian principle of equity in this context would call for distributing resources equally among persons, or distributing health care services equally among different groups. This principle is the basis for schemes that emphasise health equity over health

maximisation. There is thus a conflict with the utilitarian approach. The goal is to reduce disparities in health status among different groups or strata in society: the poor, women, people living in rural areas, ethnic or racial minorities, and others.

The three principles described here point to criteria or concerns that must be considered, but the principles can lead to conflict, and it then becomes necessary to balance competing concerns. There is no unique, correct way of achieving this balance. For this reason, leading commentators have urged that the emphasis has to be on fair processes (4). The aforementioned principles can serve to justify the decisions to the extent that decision makers in each country can agree on principled ways to set priorities for equitable access among those eligible for ART.

A different option for setting priorities could focus initially on applying principles of equity to institutions that provide health care services to individuals and groups likely to be HIV-infected. These would include both urban and rural health facilities, general public hospitals, and specialised clinics or facilities. Whichever approach is chosen, the use of the fair procedures described earlier remains necessary, since equity demands adherence to both substantive and procedural aspects of ethics.

This article is adapted from a background paper prepared for a WHO consultation on Ethics and Equity in the 3x5 Initiative, Geneva, Switzerland, January 26-27, 2004. The background paper, Ethics and Equity in Access to HIV Treatment-3 by 5 Initiative*, can be accessed at http://www.who.int/ethics/en/background-macklin.pdf.*

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Addressing ethical concerns in the Indian HIV vaccine trials

Seema Sahay, Sanjay Mehendale

Ethical practice requires that researchers should ensure the safety and welfare of participants, and protection of their rights.

Vaccines are considered the most cost-effective prevention tools for infectious diseases such as acquired immunodeficiency syndrome (AIDS) where behavioural change may not always be successful. There are some advocates of a therapeutic vaccine (1), but in view of the relative success of antiretroviral therapy (ART) in suppressing viral load and opportunistic infections, and in improving the quality of life, it is difficult to imagine how therapeutic vaccines would work better – though they might act as an adjunct to ART. Further, recognising the limitations of secondary prevention, an ideal public health prevention strategy should focus on primary prevention directed at a much larger vulnerable population.

Even with increased financing for HIV/AIDS prevention and treatment, the AIDS vaccine effort remains grossly inadequate (2). Nevertheless, there is a global endeavour for the development of AIDS vaccines.

AIDS is a chronic, currently incurable and inevitably fatal disease that carries social stigma. Ethical concerns in AIDS vaccine trials are related not only to the nature of the virus, but also to the social stigma (3). They focus on the physiological and psychosocial risks to trial participants, issues related to informed consent, and complex trial design, access to treatment within a trial and access to an effective vaccine afterwards (4). The research must have high social value and scientific validity, and should be conducted fairly and with appropriate independent review. People from the target population should be included in decisions on the design and implementation of the trials (5). Further, when research is conducted in developing countries, it must be based on true partnerships and respect for local investigators, participants and the community (6).

Undertaking HIV vaccine trials in developing countries

The AIDS epidemic in some developing countries in Africa and Asia has led to an eagerness to initiate AIDS vaccine trials. Trials may be initiated even with economic constraints, sub-optimal infrastructure and technical capacities, low levels of awareness among politicians and the community, inadequate experience on protection of human rights and limited access to health care (7). Policy-makers, programme managers, researchers and the community should decide to initiate a vaccine trial only after carefully reviewing the level of programmatic, scientific and community preparedness in the host country.

Ethical review of research

There are international guidelines for ethical conduct of research and clinical trials. Although international trials are sometimes reviewed by international ethics committees (ECs), ethical review has to be done in the country hosting the trial (8). The Indian Council of Medical Research (ICMR) has published a set of guidelines for biomedical research on human subjects that are on par with other international guidelines (9) and will be applicable to Indian HIV vaccine trials.

Ethics committees reviewing research must examine the safety and protection of vulnerable human participants, value of the research, appropriateness of the methods, balance of the risks and benefits, and arrangements for taking voluntary, informed consent from participants. They must ensure that research is not restricted to specific populations, it is inclusive of future beneficiaries and that local regulations are followed.

The guidelines of the International Council of Harmonization on good clinical practice in research recommend that the ECs should provide public assurance that research participants are protected (8). Other international guidelines note that local ECs must focus on questions such as whether the researcher is suitably qualified, the research environment is appropriate, facilities are available, and information is provided in the local language (10).

The process of informed consent

The ethical guidelines of the Council for International Organizations of Medical Sciences (CIOMS) require that ethical standards governing human subject research be no less stringent in developing nations than in developed nations (11). This can be difficult if the levels of literacy are lower, understanding about the nature and causation of diseases is sub-optimal, and personal identity and individuality are not considered important (12-13).

The following information must be made clear to potential participants of a clinical trial:

1. They are being asked to participate in a research study to test a vaccine against HIV.

2. They have the right to refuse to participate or withdraw at any time without losing any benefits at the trial site.
3. They will need to commit to a specified number of visits involving certain procedures and collection of specimens.
4. The vaccine being tested is of an experimental nature with no proven safety and efficacy in humans.
5. In a placebo-controlled trial, they may receive a placebo. In a blinded trial, they will not be aware of what they receive
6. They may experience some expected and/or unexpected side-effects of the experimental vaccine.

Potential participants should also be told about the kind of care that would be provided to them during and after the trial, and steps that would be taken to maintain confidentiality, with details of who would have access to trial-related data.

Informed consent of competent potential participants must be taken without fraud, inducement or coercion. Investigators should document informed consent, which may be subject to both external and internal monitoring, and audit.

Researchers must also confirm that trial participants have understood the information given to them. In the case of AIDS vaccine trials, they must understand that the vaccine is experimental and not yet proven to be protective, and hence they must always practise safe behaviour. Comprehension tests can range from multiple choice tests to essays and oral questionnaires. Community advisory boards can advise on the appropriate method in a particular population.

Use of placebo controls

There are generally no concerns about the use of placebos when testing interventions for conditions that have no proven treatment or prevention effect. There is an overall agreement that trial participants who received a placebo in the clinical trial of a vaccine should be offered the vaccine once it is licensed.

Inducement

It is universally accepted that subjects may be paid for the inconvenience caused to them, the loss of wages and the time spent, and they should be reimbursed for expenses incurred in connection with their participation in research. They may also receive free medical services. However, the payments should not be so large or the medical services so extensive as to induce prospective subjects to consent to participate in the research against their better judgement and wishes.

Standard of care for trial participants and treatment of those who get infected with HIV

Though trial participants will be counselled to engage in safer sexual practices, initial test vaccines are not likely to be 100 per cent effective. There will be a predictable and unavoidable incidence of HIV infection among vaccine recipients. There will be infections among those in the control arm who practise risk behaviour despite counselling. There are different views on researchers' responsibility to provide treatment in such situations. These range from providing the "best proven treatment" to "the prevailing standard of care available in the host country". Antiretroviral drugs are expensive, their availability is limited, and need to be taken lifelong. Among the ethical questions to be considered is: When the intervention being tested is a vaccine and not therapy, are sponsors or investigators ethically obliged to provide treatment? (7) Requiring provision of the best treatment available globally can undermine biomedical research aimed at improving global health (14, 15). On the other hand, in many developing countries, the prevailing standard of care can be equivalent to no care at all.

If ethics demand that treatment be given to individuals infected with HIV in vaccine trials, should vaccine trials be conducted in developing countries if the cost of therapy is prohibitive? Will a decision to provide the best available therapy constitute unreasonable inducement? If ART is initiated, should the commitment be for the duration of the trial, for a specified time after the termination of the trial, or for life? There are no definitive answers. The CIOMS guidelines state that provision of services beyond those necessary for research, including treatment of an infectious disease contracted during the trial of a vaccine against that disease, is not required but is "morally praiseworthy" (11).

Provision of insurance and ART for a stipulated period has been advocated by many (16-18). Developing countries hosting a vaccine trial should have a clear policy on these issues. They should negotiate the required arrangements with the trial sponsors and share some responsibility as well. If researchers and sponsors cannot make adequate commitment for treatment and care, this should be clearly explained during the informed consent process.

Compensating for injury

International ethical guidelines require that participants be compensated for research-related injuries since they put themselves at risk in these trials. Although there is often a provision for

compensation for physical injuries, non-physical injuries or "social adverse events" such as loss of a job, housing, income, insurance, medical care or reputation, often cannot be materially compensated. Further, provisions for survivors in case of uncommon events such as a participant's death (likely to be a rare event in a vaccine trial) need to be delineated in the trial protocol. The CIOMS guidelines suggest that financial or other assistance should compensate participants and the survivors equitably for any temporary or permanent impairment or disability related to the trial (11).

Potential participants should be aware of the provision for compensation in case of physical injury, and the circumstances in which they or their dependants would (or would not) receive it.

Post-trial access to a vaccine

There is a general agreement that any vaccine which is proved effective must be made available to the populations in the countries where the trials are conducted at an affordable cost. However, two questions arise: How can accessibility be ensured and how broadly can the product be made available? Should access be limited to those at risk for acquiring the infection or be extended to the general population? Even before initiating the trial, the host countries should review their economic and political mechanisms and their infrastructural abilities to determine if they can ensure such access. Some strategies to ensure availability of vaccines to populations that need them the most are financial rewards to enable manufacture, technology transfer and negotiation of intellectual property (7).

Conducting HIV vaccine trials in India

Sustained advocacy at the socio-political level is needed to prioritise resources for development and testing of HIV vaccines in India. The community must be informed and involved for the success of the trials. Acquiring truly informed consent will require engagement of the communities in which the trial has to be done (18). The trial will be influenced by stigma, illiteracy and gender norms. For example, members of our Community Advisory Board stressed that involvement and concurrence of men would be needed for married women to participate.

While India is on the verge of initiation of Phase I HIV vaccine trials, there will always be questions about the ability of Indians to make informed decisions to participate in vaccine trials, the use of vulnerable populations, the quality of the regulatory infrastructure,

safety monitoring mechanisms and transparency (1). It is important that the government, researchers, sponsors and the community have a clear understanding of how various ethical issues related to the HIV vaccine trial will be addressed in the upcoming trials.

In India, trials involving investigational products come under the purview of the Office of the Drugs Controller General of India. The Indian Council of Medical Research approves biomedical research and also convenes a national EC for ethics review of all protocols of national importance, and local institutional ethics committees also provide their approval. These bodies should ensure that information sheets and consent forms are appropriately designed with in-built mechanisms for the research team to verify comprehension by the research subjects. The study materials should be simple, adequately explanatory and informative. It is important to involve the community from the beginning in the whole process. To ensure transparency, the mass media should be closely involved. Community members and potential volunteers need to be fully informed about the vaccine trial process, the use of placebos, randomisation and blinding. This could be done through peer educators (19).

Lengthy documents, such as consent forms, requiring signatures might be viewed with suspicion in India. Every consent form ends with a disclosure statement which states that the purpose of the research, risks and benefits, information related to procedures and rights of the participating individual have been explained to the participant, that questions or doubts have been cleared and he or she is willing to participate in the research study of his or her own free will. This is followed by the signatures of the participant and a witness. While this signifies protection of individual autonomy, it also makes assumptions about people's legal status, literacy and capacity to comprehend medical information. In India, people often equate signatures with legal documents. Therefore, it might be necessary to develop pictorial or audio-visual consents to facilitate the informed consent process.

In a traditional society with overall low levels of awareness, trial participants may be considered at "high risk" of AIDS and thus face discrimination (20). Researchers should ensure that participants of a vaccine trial are protected from such harm by disseminating information and keeping in touch with the community.

Participants of a vaccine trial will need sustained risk-reduction counselling, which is a scientific and ethical requirement. Sensitive monitoring of trial participants' behaviour would ensure adequacy of counselling procedures (21).

A major challenge, if the vaccine proves effective, is to set up mechanisms to ensure a sustained supply of the vaccine to the population. Fortunately, India has the expertise, and the biotechnological and pharmaceutical infrastructure to make this happen with the support of trial sponsors. Some Indian industries, with a proven track record of vaccine manufacture, have been recently involved in discussions to explore the possibility of their manufacturing the HIV vaccine, if it proves to work.

The government will have to take decisions on post-trial care and providing ART to trial participants thoughtfully and with caution because decisions once made need to be adhered to in future larger trials as well. Merely talking about global access does not help. In spite of the major research achievement of ART, these drugs are not easily accessible in resource-poor countries. In view of the proposed Indian AIDS vaccine trials, this issue was discussed in a national consultation involving public and private agencies. There was a consensus that a corpus fund should be raised for the purpose and the sponsors, government and society should make contributions. There was also a consensus on sponsors supporting trial-related injuries and on exploring the possibility of providing insurance to cover injuries occuring during the trial. The mechanism to decide the causality of lasting injuries and to address disagreements through an arbitration board has been defined in the context of the upcoming HIV vaccine trial in India.

It is necessary to establish a national HIV vaccine policy outlining a vaccine development plan, an operational plan and an action plan to steer the country from Phase I to Phase III of the clinical trials and beyond.

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Reflections of an HIV-positive doctor

Deodatta Gore

In 1991, I was a consultant general surgeon practising in Ratnagiri. The events that followed turned our lives upside down. Patience, faith, determination, devotion — every possible human quality in my family — was tested. I am glad to say that they met this challenge.

It began on October 17, 1994 in Ratnagiri. I had high-grade fever, which I thought was flu. The fever disappeared with a single dose of ciprofloxacin and I resumed work the next day. However, in the following weeks, I started feeling extremely weak and began to lose weight. A few months later, I started getting fever in the evenings but I ignored this and took symptomatic treatment. By June 1995, I started getting a dry, hacking cough and painful deglutition. But no alarm bells rang and I continued to work. Then I came down with an acute sore throat and fever. A tablet of crocin produced severe sweating that drenched my clothes and bed sheets. Finally, I realised that something was seriously wrong with my health, and consulted a local physician. By then, I had become severely dehydrated and had to be admitted to a nursing home. I had high-grade fever, I was not responding to antipyretics, and I could not sleep. It was at this stage that the consultant physician advised a test for HIV infection. Shockingly, the result was positive.

Forget counselling, the physician had no time to talk to me. The diagnosis devastated my life. In one moment, whatever I had achieved in the past 30 years fell apart. I was transferred to Pune where another physician confirmed the diagnosis. Even today I am unnerved by the memories. When I asked about my prognosis, the consultant just shrugged his shoulders and walked off.

After some days, I was discharged against medical advice and came home to Ratnagiri. I was treated for pulmonary tuberculosis and candidiasis, and also started on zidovudine. However, I suffered from severe diarrhoea that did not respond to any medication. I could not tolerate zidovudine and it had to be stopped eventually.

I had lost my will to survive. But my wife and family members encouraged me to fight the disease. Their daily encouragement boosted my confidence.

The medical community was shocked to hear the news but knew my family for years and that helped me a lot. People were considerate and helpful. Some offered me a job. Others offered a place for my wife to start her general practice. They did not even charge any rent for the first three years.

I recovered gradually, and began working as a lecturer in medical laboratory technology. I could no longer practise medicine since Ratnagiri is a small place and everybody knew my HIV status. I accepted my fate.

I did not even try to trace the possible route of infection, forget blaming someone else for my misery. I simply accepted it as my destiny. My wife, parents and in-laws were also supportive and that helped me calm down.

The disease resurfaced a year later, on April 30, 1996 to be exact. The first indication was pain in the epigastric region, which radiated to the thoracic vertebrae. Then I started getting severe herpetic ulcers in my mouth. The pain was unbearable. As my condition worsened I became unable to eat even semi-solid food. I was losing weight rapidly. My brain had become affected. A few months later, I was transferred to Pune once more. At this point my CD4 count was 39. I was treated for herpes virus infection and put back on anti-retroviral therapy (ART).

The dementia associated with this disease made our lives horrible. My wife and family made a huge effort to see me through. They ensured that I took medicines and food regularly as I had lost orientation in time and space. This time my recovery took more than six months. My abnormal behaviour continued for almost a year. Fortunately I survived.

In July 1997, my father passed away. This was another setback in my life. My life was in shambles. I lost the will to live.

In August that year I met my spiritual guru who has transformed my life since then. There are no words to explain what I got from him. I was at peace with myself, my HIV status and health. I gained the confidence to fight back, live with it and maybe one day overcome it. I changed my lifestyle after this meeting. I started praying regularly. I do *yogasans* and *pranayama* daily. I have developed my own diet, which is quite different from what is usually prescribed.

In 1998, I developed resistance to the ART regimen and had to be put on a new regimen, which I have been following for the past six years. “Touch wood”, I have not encountered any resistance or side-effects so far. I owe this to the lifestyle and diet that I follow, and the spiritual guidance of my guru.

All these years I had not practised medicine. Initially my poor physical health prevented me from doing so. Later it was the fear of exposure

to communicable diseases. On May 4, 2002, I started running an outpatient department (OPD) exclusively for HIV-positive people. It was a quantum leap for me, considering what I had been through. For the past two years I have run the OPD without interruption. I have also brought together HIV-positive people in my district and formed a group of people living with HIV/AIDS, the Guruprasad Trust. Today HIV-positive people from all over Ratnagiri are referred here. We offer them counselling services, treatment of opportunistic infections and ART. We also accept donations to help HIV-positive people.

It has taken a long time and massive efforts for our group to reach this stage. People in the medical/paramedical fraternity affected by this disease face serious professional, economic and social setbacks. I appeal to those affected to come together. The idea is to form a group of affected healthcare providers to help themselves as well as other HIV-positive patients.

I have now lived with HIV for nine years. The local medical fraternity has seen me suffer. They have seen me with dementia and cerebral atrophy. They have seen me fight it out every day. Today they are seeing me as a consultant in HIV medicine. They respect my fight back and support me by referring HIV-positive patients to me.

Ethics and psychiatric practice in India

Vikram Patel

In recent years the *IJME* has published a series of articles and correspondence pieces on the ethical basis for the use of electro-convulsive therapy (ECT), particularly "direct" or "unmodified" ECT for people suffering from severe mental disorders in India. Let us first clarify what these terms mean. ECT refers to the induction of a generalised seizure in a patient through the use of an electric current applied via electrodes pressed on to the scalp. "Direct" implies the use of ECT without any medication to relax the muscles, which must be given along with general anaesthesia. "Indirect" or "modified" ECT, thus, refers to the use of muscle relaxation medication, along with general anaesthesia, which causes the motor component of the seizure to be attenuated.

The discourse published in the *IJME* may perhaps be described as combative, or at least as a strident disagreement of views. On one side in support of the use of direct ECT, albeit under very specific and circumscribed contexts, are two hospital-based psychiatrists. On the other side are representatives of civil society, including a community-based mental health rights NGO, and psychiatrists. Ironically, in a country where there are grave concerns about the irrational use of pharmaceuticals and medical technologies, particularly in the private medical sectors, including by psychiatrists, here the arguments in support of the use of direct ECT—possibly the only intervention "technology" in contemporary psychiatry—are not from private psychiatrists, but from two of the country's leading practitioners based in two outstanding institutions renowned for high-quality research and public service. I use the term "ironically" because the areas of agreement between these two groups of apparent adversaries are, I think, likely to be far greater than areas of disagreement; because it is through a coalition of psychiatrists like **Andrade** and **Tharyan** joining forces with civil society groups like the Bapu Trust that we must challenge the grotesque ethical violations taking place under the name of mental health care and psychiatric research in India.

But returning to the ethical basis of direct ECT, I must state my views unambiguously. I am against its use under any circumstances. As **Waikar et al.** state in their article, unmodified ECT was banned

in the state of Goa some years ago. I was one of the expert witnesses for the trial that led to this judgment. At the same time, I respect the views of Andrade and Tharyan because I am convinced that their motivations are entirely driven by their concerns for patients. Neither they nor their institutions can be categorised as commercially-driven or as institutions that are likely to abuse medical technology for personal profit. However, I differ with them about their interpretation of the apparent need for direct ECT in India, not least because it is often carried out by practitioners with far more dubious motivations. Arguments presented in support of direct ECT focus on the apparent "urgency" of the treatment and the "cost-effectiveness" or "accessibility" to the treatment to the poor for whom the additional cost of an anaesthetist or lack of access to one may become an obstacle. I think both these arguments are flawed.

First, let us consider the issue of urgency. There is absolutely no indication or evidence that ECT, direct or indirect, is a life-saving procedure. Indeed, it is a treatment that is reserved for patients with severe depressive disorder (though in India it is also used for people with schizophrenia, an indication for which this treatment is not approved in any country) who are often in-patients in hospitals and have failed to respond to routine outpatient trial of conventional treatments for several weeks or even months. The latter should include a full trial of an antidepressant drug and a psychological treatment. We must ask why many psychiatrists opt for ECT as opposed to offering psychological treatment or completing a full medication trial, as stated in international practice guidelines. I wager that apart from the likely response that patients do not like "talking therapies" or need to get back to work urgently, the other less well-acknowledged responses are that ECT is more lucrative and conforms to the biomedical model of mental disorders most psychiatrists are comfortable with. In other words, the clinical indications for which ECT is used are often not evidence based or following international practice guidelines.

The second argument is about access and affordability. Given that ECT must only be given to very ill patients in a hospital setting, it seems unclear to me what the justification for it being used without anaesthesia could be. Shouldn't every hospital have an anaesthetist, and if they don't, should they be accredited for procedures that need anaesthesia? As far as affordability is concerned, surely we must provide an ethical treatment first, and then let the patient choose

whether they can afford it? In any event, in a public hospital where is the additional out-of-pocket cost for modified ECT? Furthermore, if affordability is a morally justifiable argument, why do we never hear surgeons justify emergency abdominal surgery for a burst appendix—most definitely a life-saving procedure—without anaesthesia on the grounds that no anaesthetist is available or that the cost of the anaesthetist diminishes the affordability of the procedure? How can the lack of an anaesthetist be a justification for the use of direct ECT on people suffering from mental disorders, then? Are there different ethical standards for them? Furthermore, in many instances direct ECT is given in large general hospitals, notably government hospitals despite there being entire departments of anaesthesia in these hospitals. It is in such hospitals that all psychiatrists from India are trained and where they observe the hospital-based use of this procedure.

Put plainly, there is no justification at all for the use of direct ECT in any individual, either on the grounds of clinical urgency or lack of access or affordability of anaesthetic facilities. Both of these are spurious arguments that are not valid in any other country in the world, including those with much weaker health systems than India. Why are they valid in India, even in extreme circumstances? At the very least, we must provide our patients with severe mental disorders the same basic rights and quality of care afforded to patients with severe physical disorders. **Rajkumar, Saravanan** and **Jacob** describe the experiences of people who had received modified ECT and those of their relatives. Even in this, arguably one of the best medical institutions in the country, this largely involved fear, coercion, lack of informed consent and unpleasant adverse effects, to the extent that despite functional improvement, the majority would not contemplate ECT as a treatment in the future. One can only imagine the plight of patients being given direct ECT in institutions with far less quality assurance—the norm in India.

Thus, I am equally surprised, as are Waikar et al., that any justification can be made for direct ECT today. However, I disagree with them that there is no place for indirect ECT, which, without a shred of doubt, has a firm place as one of the less commonly used, but critically valuable, treatments for people with severe depressive disorders, resistant to conventional treatments. Put plainly, modified ECT has a robust evidence base that clearly indicates its place as a cost-effective and safe treatment for some severe mental illnesses. I

agree with Tharyan's prescription for ways to phase out direct ECT such as changing from a thrice-a-week to twice-a-week regimen to reduce anaesthetist demand, or forming group facilities with shared ECT facilities. But these must be implemented within a short time-frame to ensure the practice ceases quickly. I also believe there is a need for psychiatrists to follow the clearly structured practice guidelines on trials for antidepressant drugs (including use of second-line medications) and psychological treatments before considering ECT.

However, as **Pathare** has argued, the issue of ethics in psychiatric practice needs to go beyond the issue of direct versus indirect ECT. There are a number of other major ethical issues in the practice of psychiatry in India today, such as the near-complete absence of psychosocial treatments and community care for the vast majority of the mentally ill, and the irrational use of psychotropic drugs. Consider, for example, the use of the latest antidepressant or antipsychotic drugs by Indian practitioners as soon as they are released in the market, even though these cost 10 times more and are just as effective as older drugs. It is not surprising that in our work in Goa we found that women suffering from depression are significantly more likely to experience catastrophic health expenditures than those with other health problems (such as reproductive tract infections). Consider too the recent trial of risperidone, a widely used and available antipsychotic drug, in a clinical trial for severe acute mania. This condition is perhaps the most severe form of mental disorder. In this trial patients already receiving a cheap effective treatment were randomly allocated to a placebo or risperidone arms. This trial raised many serious ethical concerns, not least the moral justification for allocating patients with such a severe mental disorder to a placebo arm (1).

For me, though, the biggest blot on Indian psychiatry is that, as the recent survey of mental hospitals in India showed, human rights abuses of people with mental disorders in mental hospitals are rampant—and worse, they go largely unchallenged by the profession, requiring civil society groups to advocate for the most vulnerable of the mentally ill. The use of direct ECT as "punishment" for patients is just one horrifying example of such abuse. Until the psychiatric profession stands up and demands a wholesale reform of these institutions, its moral stand on issues of care of the mentally ill will always lack credibility and appear largely self-serving. Sadly, today, as with many branches of medicine in India, the most glaring barrier to mental health reform is not necessarily the lack of resources, but the perspectives of medical practitioners. The combination of commercial interests and lack of any public health perspective create the dangerous situation we now witness: that health care, far from alleviating poverty as it does in most countries, is now one of the leading causes of household poverty in India. It is time for the psychiatric profession to join mental health advocacy movements to improve the quality of care for people with mental disorders. This advocacy needs to start by ensuring that we actually practise evidence-based and ethically acceptable medicine—rather than only give it lip service—which includes insisting on the rights of our patients for whom ECT is indicated so that they have the right to access affordable indirect ECT.

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Unmodified ECT: ethical issues

Chittaranjan Andrade

Electroconvulsive therapy (ECT) is an important treatment in psychiatry; despite the myth that it is a barbaric and outdated practice (1), it is as relevant today as it was over six decades ago, when it was first introduced. This is because ECT can be life-saving in catatonic, suicidal, or otherwise highly disturbed patients (2); because it is of exceptional benefit in patients with psychotic depression (3); and because it can be both therapeutic and prophylactic in patients who do not respond to antidepressant or antipsychotic drugs (2,4).

During ECT, a small electrical current (0.5-0.8 A) is passed through the brain via electrodes applied to the scalp. The current stimulates the brain and elicits a generalised seizure. This has two elements: the central seizure, manifested as characteristic EEG activity, and the peripheral seizure, or convulsion (2).

The exact mechanism of action of ECT is not known for certain; however, it is definitely known that, in the absence of the central seizure, electrical currents applied to the brain are therapeutically ineffective (5). It has further been established that, as long as the electrical activity in the brain which corresponds to the seizure is allowed to develop, the peripheral seizure is unnecessary (2,5).

Why would psychiatrists want to abolish the peripheral seizure? For one, the convulsion looks frightening to the viewer; this perpetrates the myth that ECT is a barbaric treatment (1). More importantly, research conducted during the early decades of ECT suggested that the convulsion is associated with a 20-40 per cent risk of subclinical compression fractures of middle thoracic vertebrae. The risk was observed to be greater in males, in older subjects, and in those with osteoporosis (6-8). Although such fractures did not appear to be clinically significant (6,9), it was nonetheless considered that morbidity avoided is safety promoted.

While muscle relaxation during ECT had been attempted as early as in 1940, it was not until 1953 that succinylcholine was established as a suitable agent for peripheral muscle relaxation during ECT (2). With the use of succinylcholine, the peripheral seizure is abolished, and the musculoskeletal complications of ECT are minimised. Such administration of a muscle relaxant is known as modification of the ECT procedure.

At this stage, it is worth noting that unmodified ECT is, rarely, associated with other risks, such as dislocation of various joints, minor muscle or ligament tears, cardiac arrhythmias, aspiration of secretions into the respiratory tract, haemorrhage at various sites, and anxiety (10). The prevalence of such complications with unmodified ECT is very low, and precise prevalences are unknown.

The administration of succinylcholine to a conscious patient, immediately before ECT, is frightening because succinylcholine paralyses all voluntary muscles, including those of respiration. It is therefore necessary to administer anaesthesia before ECT; however, the administration of anaesthesia is associated with its own risk, making the presence of an anaesthesiologist necessary.

This is where practitioners of ECT in India find themselves in a bind: on the one hand, their experience is that unmodified ECT is associated with virtually no risks to the patient; on the other hand, they find that anaesthesia cannot be administered safely to many categories of patients, and the presence of an anaesthesiologist cannot always be assured.

It is difficult to recruit anaesthesiologists in many parts of the country because these specialists are few and are monopolised by surgeons. Furthermore, involving anaesthesiologists raises the expenses of ECT from a negligible sum to a high, and (to many) hard-to-afford sum. Some, but not all Indian practitioners therefore continue to administer unmodified ECT. A survey of the medical membership of the Indian psychiatry association found that, in 1991, only 44.2 per cent of practitioners who administered ECT always administered modified treatments; however, only 24.2 per cent invariably administered unmodified ECT (11). More recent data are unavailable.

Whether unmodified ECT is ethical or not depends upon a risk-benefit analysis. On the one hand, modified ECT reduces musculoskeletal risks, haemorrhage at various sites, pre-ECT anxiety, and the other but rare adverse effects of unmodified ECT that were listed earlier. On the other hand, modified ECT could be beyond the means (or the reach) of a large segment of Indian society, and introduces the risks associated with anaesthesia.

There is now further evidence upon which decision-making can be based. Tharyan et al (12) observed from a chart review that only 12 patients experienced fractures with unmodified ECT in a series of 1,835 patients who received a total of 13,597 ECT treatments across

a span of 11 years. And, we found that only 1 of 50 patients experienced an adverse musculoskeletal event with unmodified ECT in a systematic, radiological investigation of the adverse effects of the procedure (13). It therefore appears prudent to conclude that while modified ECT may be the ideal, there can be situations in which unmodified ECT may be preferable to no ECT. Examples of such situations are those in which ECT is strongly indicated but anaesthesiological facilities are unavailable or unaffordable; in such situations, the expected gains with ECT are likely to far exceed the risks with unmodified treatments.

The stage is now set for a systematic audit of modified as well as unmodified ECT so that better data may be made available upon which more valid decision-making can be based.

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ECT without anaesthesia is unethical

Aparna Waikar, Bhargavi Davar, Chandra Karhadkar, Darshana Bansode, Deepra Dandekar, Seema Kakade, Sonali Wayal, Yogita Kulkarni

We are shocked that Dr Chittaranjan Andrade should make a case for direct ECT (electroconvulsive therapy) in your journal (1). We want to place before your readers the facts that are unreported or otherwise masked in his article.

Direct and modified ECT

In direct ECT, an electric current of 70-170 volts is passed for 0.5-1.5 seconds. It throws the body into epilepsy-like seizures. While the patient is conscious in the beginning, he is rendered unconscious when the grand mal seizure starts. He is held down physically to prevent fractures and internal injuries, as the risk of injury is high. As the procedure is given in series, this hazard is experienced again and again. In an ideal situation, the procedure is repeated 6-10 times, but continuous dosing up to 20 times or more is not uncommon. This procedure has recently been placed as a controversial and contested issue before the Supreme Court, through a petition filed by Saarthak, a mental health NGO based in New Delhi. A verdict on this issue is awaited.

In its "modern" or "modified" form (modified ECT), the patient is not allowed to eat or drink for four hours or more before the procedure, to reduce the risk of vomiting and incontinence. Medication may be given to reduce secretions from the mouth. Muscle relaxants and anaesthesia are given to reduce the overt epileptic/muscular convulsions and patient anxiety. The muscle relaxant paralyses all the muscles of the body, including those of the respiratory system. The patient does not breathe on his own while the relaxant works and he is put on an artificial respirator during the procedure. A "crash cart" is kept handy, with a variety of life-saving devices and medications, including a defibrillator for kick-starting the heart in case of a cardiac arrest. The brain is subjected to seizure activity induced by the electric current. The causal mechanism by which the treatment works is not known. It is believed that the electricity itself and the seizure activity it produces is the curing element.

Evolution and phasing out of ECT

Ugo Cerletti, an Italian, invented ECT in 1938, drawing inspiration from the fact that pigs being prepared for slaughter in an abattoir were first rendered unconscious by passing electricity through bilateral placement of electrodes against the head. After much brutal experimentation and research, the developed world banned direct ECT in the early 1960s. Many European countries have phased out even modified ECT, while in the US its usage has come down drastically after the 1980s, following class action. The 1978 American Psychiatric Association (APA) Task Force reported that only 16 per cent of psychiatrists gave (modified) ECT. ECT research does not receive funding from government bodies, or from large foundations. It is largely funded by private business. International journals do not publish articles on direct ECT.

To make a case for direct ECT in this day and age establishes a fresh, new low for psychiatric ethics in India. Instead of debating the issue of "whether or not ECT" and what community alternatives we can create in mental health, we are placed in this ridiculous situation of debating direct ECT.

Dr Andrade claims that direct ECT is "virtually" risk-free. However, neither in his article nor in any of the relevant research in India, some of which is mentioned herein, has anyone vouchsafed even the relative safety of ECT, whether direct or modified. The only argument made is that modified ECT is even worse than direct ECT.

Side-effects and risks of ECT

In the West, two important factors led to the phasing out of direct ECT: one was the discovery that between 0.5 per cent and 20 per cent of patients suffered from vertebral fractures, and the second was their evident terror and trauma. Dr Andrade admits that direct ECT is associated with the risk of vertebral/thoracic fractures, dislocation of various joints, muscle or ligament tears, cardiac arrhythmias, fluid secretion into respiratory tract, internal tears, injuries and blood-letting, other than fear and anxiety.

Kiloh et al (2) give this long list of common "complaints" following ECT, which are more acutely experienced when given direct: headache, nausea, dizziness, vomiting, muscle stiffness, pain, visual impairment due to conjunctival haemorrhages, tachycardia/bradycardia, surges in blood pressure, changes in cardiovascular activity, alteration in the blood-brain barrier, ECG changes, arrhythmias and dysrhythmias, cardiac arrest, sudden death, transient dysphasia, amenorrhoea,

hemiparesis, tactile/visual inattention, homonymous hemianopia. Among the "risks" mentioned are : myocardial infarction, pulmonary abscesses, pulmonary embolism, activation of pulmonary tuberculosis, rupture of the colon with peritonitis, gastric haemorrhage, perforation of a peptic ulcer, haemorrhage into the thyroid, epistaxis, adrenal haemorrhage, strangulated hernia, and cerebral and subarachnoid haemorrhage. Infrequent "complications" are fractures (vertebrae, femur, scapula, humerus) and dislocations (jaw, shoulder), cardiac arrhythmias, apnoea and "tardive" convulsions. Among the inevitable "side-effects" are cardiovascular responses, postictal clouding of consciousness and memory impairment. With modified ECT, the effects are "less likely" but not completely ruled out.

What is it about being mentally ill that permits society and medical professionals like Andrade to argue that being exposed to these risks repeatedly is all right? Even professionals never considered ECT to be a "cure", it is only palliative. This means that in practice, professionals can use it as and when they like, as palliative care can be seen as an ongoing need, unlike curative care.

Andrade cites "further evidence" of research by Tharyan et al (3), highly (mis)quoted studies done in the early 1990s on direct ECT. He writes that in this study only 12 patients experienced fractures out of a total of 1,835 patients receiving 13,597 treatments. This sounds as if a few of the patients walked out of the ECT room with a slight twisting of the middle finger. He fails to mention relevant data from this study that these were thoracic/vertebral fractures involving almost a third of the body vertebrae. Andrade also fails to mention that in this study, there was one reported death due to cardiac arrest (i.e. 1 patient out of 1,835 died), a good percentage experienced bodyaches, both local and generalised, and another 1 per cent of patients had cardiac complications. These data, especially the spinal injury and the mortality rate, which from the consumer point of view seem horrific, are not considered "clinically significant" by the authors of this contentious study nor by Andrade. In Andrade's own study (4), 2 per cent of the patients experienced a "musculoskeletal event".

Findings and recommendations

APA Task Force reports on ECT (5, 6, 7) note that, contrary to earlier evidence, they have to now acknowledge that mortality rates with ECT (modified) may be as high as 1 in 10,000 patients. Consumers (8) say that mortality rates may be as high as 1 per cent with modified ECT. The mortality rates are probably higher among the elderly,

making it a highly contested procedure among them. The Task Force report also notes that 1 in 200 may experience irretrievable memory loss. The Bombay High Court ordered against the use of direct ECT way back in 1989, following the Mahajan Committee Recommendations. In Goa too, legal advocacy and the proactive role of psychiatrists has resulted in the ban of direct ECT.

Death in the case of ECT is usually due to cardiovascular or cerebrovascular complications, followed by respiratory failure. Shukla (9), in discussing a case report of death following modified ECT, reviews the mortality data associated with the procedure. Rates between 0.003 per cent and 0.8 per cent have been reported in the western literature. Shukla, finding it a curious fact that deaths have not been reported at all in the Indian professional literature, observes that fatalities are not always publicly reported, particularly in India, but every psychiatrist would have experienced such cases in his practice.

The European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (10) prohibits the use of direct ECT as a form of torture. One of the reasons cited is the terror experienced by patients during the use of the procedure. The suggestion in this Convention and other relevant literature is that ECT affects the limbic system of the brain, the same system that is affected by deep trauma. Medical narratives regarding direct ECT highlight the very understandable horror of experiencing ECT effects as well as accidents and disabilities following a procedure which is supposed to "cure" (11). The motor, physiological and cognitive effects on ECT recipients following treatment are the same as trauma victims. The terror is a sign of trauma, and not a sign of insanity. Victims of direct ECT should be considered as victims of medical torture and brought within human rights and medicolegal jurisprudence.

In the study by Tharyan et al (3) a high percentage of patients (7.5 per cent) reported fear and apprehension of the procedure, and 50 patients refused the treatment. How did the researchers proceed with the study? They did so by actually sedating the patients! Quoting them in full: "Fifty of them [patients] refused further ECT due to this fear while in the remainder (100 patients) the fear was reduced by sedative premedication enabling them to complete the course of ECT. In the earlier half of the decade under review, barbiturates, oral diazepam, parenteral haloperidol and even thiopentone were used to allay anxiety; in recent years, this has been effectively managed by pretreatment with 1 to 4 mg of lorazepam given orally." The authors of this study

find it an interesting observation that those who refused were not among those who were sedated. Their study also suggests that it is common practice to sedate patients who refuse ECT. Amazingly, they recommend the use of sedatives to minimise the fear of ECT. Such is the prejudicial approach to mentally ill patients that fearful refusal of a hazardous and life-threatening procedure is considered as a mere symptom of insanity, to be further "treated" with sedatives. How do professionals reconcile ethical issues of consent in such instances?

In many countries, giving even modified ECT to children, the elderly and pregnant women is prohibited. The State of Utah is recently working on a bill which will ban ECT within institutions (where its highest abuse is possible) and on children. In Tharyan et al's study (3), direct ECT has been administered to the age group 14-70 years, including women in all trimesters of pregnancy. How did the institutional ethics committee of Christian Medical College, the site of this study, allow this study to continue uninterrupted for 11 years?

Tharyan et al further reassure that "trained" professionals were used to give direct ECT. What does training mean in the context of direct ECT? One merely needs some physically strong people to tie down the patient at strategic points to keep the jaw and joint areas from major injury. The composition of the full "team" used to prevent injury were: four orderlies, three nurses, two postgraduate trainees and a consultant psychiatrist, a total of 10 "trained" people! The argument concerning the cost-effectiveness of the procedure is not validated by this study. Even with a full load of 10 people tying down a patient from the convulsions, the reported injury rate was not insignificant. Have the costs of disability-days following ECT been taken into account? Kiloh et al (2) reported studies where the ECT took only a few hours, but the patients had to be hospitalised for a week after that, waiting for the confusion and suicidal ideation to clear up!

Why is ECT given?

Why would presumably rational scientists produce such irrational arguments to safeguard a scientifically dubious and highly hazardous procedure? The fact is that in nearly every city, a majority of private practitioners give ECT in their private clinics. A recent survey in western India showed that nearly 80 per cent of private psychiatrists give ECT, costing anywhere between Rs 500 and Rs 1,000 for one. ECT is the only piece of technology that psychiatry can boast of. We have reports of psychiatrists who ask the patient to first take an ECT even before a consultation (12). ECT has been given to cure "Naxalism" (13). In private practice, it is difficult to have the medical back-up necessary for anaesthesia or resuscitation. ECT guidelines do not exist in India, making it conducive for doctors to engage in rampant abuse of the procedure. The situation here is similar to sex selection tests, as the private market rules the roost.

Conclusion

In our view, direct ECT is a matter for human rights law, prevention of torture instruments, regulation and consumer litigation, and not for academic discussion. Andrade suggests that there must be further research on direct ECT. We have serious objections to the future conduct of such research. Statutory authorities, the human rights commision and medical regulatory bodies must proscribe such research.

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ECT: A measured defence

Chittaranjan Andrade

Waikar et al express forceful opinions about ECT. I am duty bound to inform readers that their article contains at least 25 serious factual errors, and 17 serious errors of perspective and context. Space constraints do not allow me to provide a point-wise, scientifically-referenced refutation of their article; however, if readers with specific concerns write to me, I will provide clarifications supported by research published in journals of repute.

I am aware that nongovernmental organisations require a drum to beat to make their presence felt; however, I would prefer to ascribe more ethical motives to these authors, and believe that they think as they do because they have no (stated) medical or psychiatric background nor direct experience with ECT. My response will therefore be measured and good-tempered.

The views of Waikar et al can be resolved under two headings: that ECT is barbaric, and that unmodified ECT is especially unethical. I will consider each of these views.

Is ECT barbaric and should it be discontinued?

From an emotional perspective, a seizure-inducing treatment could certainly seem barbaric. However, if ECT is barbaric or unattractive, so too are cardioversions, abortions, Caesarean sections, radical mastectomies, open heart surgeries, orthopaedic and neurosurgical procedures, and countless other medical and surgical interventions; so, where does one draw the line? The answer is simple: if the risk-benefit ratio favours the treatment, and if the treatment is better than existing alternatives, in the interest of the patient the treatment must survive. This cold logic has guided medical practice for decades, and is the reason why ECT remains a valuable treatment more than six decades after its introduction.

There are certainly countries, such as Japan and Italy, in which the practice of ECT is dying out for idiosyncratic reasons (and not because of legislation). However, in countries in which a high quality of care is assured to patients, ECT continues to be practised. In the USA, where the standards of medical care are higher than anywhere else in the world, the use of ECT is, in fact, increasing (1). During the past decade millions of dollars have been allotted in over a dozen research

grants from the US Government through the National Institute of Mental Health (NIMH) to study different forms of ECT (2). A multicentre consortium, funded by more multi-million dollar NIMH grants, is currently examining wider indications for ECT such as the extension of ECT into the maintenance phase of treatment (3).

We therefore ask: why do Waikar et al express the views that they do? Perhaps it is because they have come across instances of the sub-optimal practice of ECT. If so I have two responses:

1. If a treatment is abused, the practitioners are to blame, and not the treatment. Readers will know that treatments ranging from antibiotics to Caesarean sections are over-enthusiastically used by unscientific or unscrupulous practitioners; yet, this is not an argument for withdrawing antibiotics or abolishing Caesarean section. By targeting the treatment because of its misuse, Waikar et al compromise their own judgement and credibility.
2. A treatment is best evaluated at centres at which it is well practised. I encourage Waikar et al to visit centres, such as the one at which I am employed, where ECT is administered only after obtaining informed consent and in accordance with international guidelines. Waikar et al will discover that patients who receive ECT are grateful for the intervention. None of my colleagues, nor I, have encountered patients who considered that we used ECT as a form of punishment or torture. If Waikar et al form opinions from a few patients who have felt ill-used by ECT, they have a moral duty to moderate these opinions with the views of the large segment of patients who appreciate the treatment.

In this context I ask Waikar et al how many patients they have personally interviewed who have resented receiving ECT. Were these patients identified through systematic sampling or did they form a disgruntled, unrepresentative subgroup? Scientifically, only patients identified through a recognised method of sampling can be considered representative of the population. This is because dissatisfied patients can be found for all treatments.

True, ECT is associated with adverse effects; the commonest problems are transient memory disturbances, headache, and bodyache. Less commonly, more severe or longer-lasting memory disturbances may occur. Taken out of context, these adverse effects argue against the use of the treatment. However, taken out of context, the brutality of open heart surgery and the cognitive impairment that the procedure produces (4) should, similarly, argue against the practice of such surgery. As stated earlier, treatment decisions are based on risk-benefit ratios and on comparisons with existing alternatives. Thus, when the common and uncommon adverse effects of ECT are compared with the common and uncommon adverse effects of drugs, and when the superior benefits with ECT are measured against the unimpressive effects of drugs in selected sub-populations of patients, it appears that, for these sub-populations of patients, adverse effects notwithstanding, ECT can be the treatment of choice.

Is unmodified ECT unethical?

Early during my research career, I found that only 44.2 per cent of Indian psychiatrists who administered ECT always administered modified treatments, and that as many as 24.2 per cent invariably administered unmodified ECT; I was appalled (5). When Tharyan et al (6) published data which suggested that risks with unmodified ECT were fewer than earlier believed, I reacted with the same horror that Waikar et al presently show (7).

I received mixed support. Practitioners in large institutions, such as my own, supported my views. Practitioners in small psychiatric facilities, however, chose to disagree. They believed that I had no right to preach from an ivory tower, ignoring the ground realities of the environments in which they worked. Their arguments were reasoned. If a patient who is stuporous or suicidal requires ECT as an emergency intervention, would it be more ethical to allow him to die because an anaesthesiologist is not immediately available to supervise ECT? If a patient is psychotically depressed in a town in which the anaesthesiologists are burdened with surgical caseloads, would it be more ethical to allow the patient to suffer for weeks to months, receiving drugs which are less effective, because the anaesthesiologists did not have time for minor procedures such as ECT? If a poor patient suffers from an illness for which ECT is the treatment of first choice, would it be more ethical to allow him to suffer for months or longer with less effective drugs because he cannot afford the extra hundreds of rupees per ECT that the use of anaesthesia necessitates?

In the face of these arguments, I realised that the only way to convince my colleagues against unmodified ECT was to obtain and publish hard data on the morbidity associated with it. My colleagues and I chose to focus on spinal fractures with the treatment, the most common complication recorded in western literature. The study was conducted in a hospital in which unmodified ECT was routinely administered because of unavailability of anaesthesiology support. Anterio-posterior and lateral X-rays of the thoraco-lumbar spine were routinely obtained

before and after a course of unmodified ECT, and after every complaint of backache in 50 consecutive patients who received the treatment. To our utter astonishment only 1 patient (2 per cent) experienced an adverse spinal event; this was considered relatively minor by the consultant orthopaedist, and was treated with non-steroidal anti-inflammatory drugs alone (8).

I no longer shrilly condemn unmodified ECT. However, to reassure Waikar et al I do not condone the procedure either. When we published our unmodified ECT study, we concluded with several paragraphs on the limitations of unmodified ECT; we added a strong caveat that our findings were not an endorsement of its routine practice. Waikar et al completely misread my views in my commentary (9); to quote.

"It therefore appears prudent to conclude that while modified ECT may be the ideal, there can be situations in which unmodified ECT may be preferable to no ECT. Examples of such situations are those in which ECT is strongly indicated but anaesthesiological facilities are unavailable or unaffordable; in such situations, the expected gains with ECT are likely to far exceed the risks with unmodified treatments. The stage is now set for a systematic audit of modified as well as unmodified ECT so that better data may be made available upon which more valid decision-making can be based."

I stand by my statements. If Waikar et al wish to outlaw the practice of unmodified ECT, they may be shutting the door for effective treatment for a number of patients who seek psychiatric care in situations in which anaesthesiology facilities are unavailable or unaffordable. Will Waikar et al take the responsibility for the suffering, or possible death, of these patients? I remind readers that we are living in a country in which even minimal standards of health care cannot be assured to enormous segments of the population; under these circumstances, a sub-optimal form of treatment could be better than no treatment. On the subject of "sub-optimal form of treatment", I add that there is insubstantial evidence that unmodified ECT is as bad as it is made out to be.

The inevitable conclusion is that it is necessary to objectively compare the benefits and risks of modified and unmodified ECT, as well as patients' experiences with and subsequent attitudes towards these two forms of treatment because, in an era of evidence-based medicine, only when the results of such research become available can truly informed, scientifically and ethically valid opinions be expressed.

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Audits of electroconvulsive therapy

Prathap Tharyan

Waikar et al (1), in their diatribe against ECT (electroconvulsive therapy) in general, and unmodified or direct ECT in particular, were shocked that our institutional ethics committee permitted an 11-year "study" of unmodified ECT (2), where patients whose "fearful refusal of a hazardous and life-threatening procedure" was "considered as a mere symptom of insanity, and further treated with sedatives". They were appalled that ECT was given to children, elderly and pregnant women. They contend that our report trivialised the "horrific" physical complications with direct ECT and "the costs of disability days following ECT". They wonder "why presumably rational scientists produce such irrational arguments to safeguard a scientifically dubious and highly hazardous procedure", concluding that it is because we "make a lot of money by giving ECT".

ECT is an invasive procedure, like neurosurgery, and considerations of morbidity or mortality must therefore be viewed in this context. Untreated or treatment refractory mental illness kills and wastes precious lives. There is incontrovertible evidence that ECT is an effective treatment for depression (3), and substantial evidence that it is effective in mania (4) and schizophrenia (5), especially when other treatments fail. There is no credible evidence that ECT causes brain damage (6). ECT is not contraindicated, and may be especially effective, in pregnant women, children or the elderly (7).

Ours was not a prospective research study but a retrospective chart audit of clinical practice (2). Over 11 years, 6.3 per cent of the 28,929 patients registered at our centre were treated with ECT, hardly the overenthusiastic and indiscriminate use implied by Waikar et al (1). Of the 13,597 individual treatments given to 1,835 patients, the physical morbidity included spinal compression fractures and transient myalgia in less than 1 per cent, resulting in short-lived pain but no disability, neurological deficits or long-term sequelae over up to 8 years of follow-up. One patient died (mortality rate 0.05 per cent) of a cardiac arrhythmia, though the subsequent 12 years and approximately 2,000 additional patients treated have not seen additional mortality.

In spite of this low complication rate for an invasive procedure, all treatment conducted here since 1995 has been modified under anaesthetic supervision, and our practice, frequently audited, conforms to international technical and ethical standards. No patient has ever received ECT without personally (or a responsible relative) consenting. Fear of ECT is less with modified than with unmodified ECT but in both situations an unknown and reputedly hazardous procedure does generate apprehension, just as with tooth extraction or brain surgery. Pre-ECT sedation reduces apprehension. ECT, as practised in our centre, is hardly a lucrative enterprise since costs are low (Rs 180 per modified treatment, excluding anaesthetic drug costs) and many patients' treatments are free or heavily subsidised. Finally, our patients and their relatives have endorsed our use of ECT (8).

Unmodified ECT is aesthetically less appealing to patients and clinicians alike than modified ECT. Consideration of ways to phase out direct ECT such as changing from thrice a week to the equally effective twice a week regimen to reduce anaesthetist demand, or forming group practices with shared ECT and anaesthetic facilities, or deputing psychiatric personnel to get specialist anaesthetic training is inevitable, if ECT is to survive another 50 years. However, banning direct ECT overnight by legal action without ensuring the continued and effective delivery of ECT is tantamount to closing down mental hospitals without ensuring adequate community care. Many clinicians, without access to anaesthetists, would face denying seriously mentally ill patients an effective treatment. Such "collateral damage" resulting from well-intentioned action is unethical and unacceptable..

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Unmodified ECT vs modified ECT

Nischol Raval

This letter refers to the article by Chittaranjan Andrade regarding the use of unmodified ECT (1). The author has discussed the obvious advantages of modified ECT over unmodified ECT. He also highlights the ground realities and difficulties in practice of modified ECT. The author concludes that the use of unmodified ECT may be preferable to no ECT, as in the case when ECT is indicated but anaesthesiological facilities are unavailable or unaffordable.

Though I agree in principle with the points raised and this discussion may be scientifically correct, we need to know the views of the people who are going to be recipients of such treatment. It has been seen that doctors show remarkably little interest in their patients' views of the procedure and its effects on them (2). I think that in this discussion on the ethical issues of administering unmodified ECT, a patient's perspective is not being considered.

Though no data are available, most of the patients who refuse ECT do so because of the fear associated with the procedure. This fear may be attributed to the gruesome and barbaric picture of ECT projected by the media in which patients are shown screaming and refusing ECT and later on convulsing.

The use of unmodified ECT would only increase this fear and lead to rejection and disrepute of this really effective modality of treatment for psychiatric disorders at the hands of the media and anti-ECT lobbies.

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Unmodified ECT: what is the patient's perspective?

Chittaranjan Andrade

Raval has correctly indicated that, when prescribing a treatment, it is necessary to be aware of the views of the recipients of the treatment. There is much literature on patients' experiences with and attitudes towards modified ECT in developed countries (1,2) as well as in India (3). There is, unhappily, no literature at all on patients' experiences with and attitudes towards unmodified ECT in any part of the world; in fact, it is uncertain whether, today, unmodified ECT is indeed practised in any other country!

Data on the subject should help form a more sound judgement about unmodified ECT. Unfortunately, such data are best obtained only through a study in which patients are randomised to receive either modified or unmodified ECT. If the data were to be obtained in any other way, adherents of unmodified ECT would claim that, in the absence of a control group, the experiences and attitudes documented merely reflect experiences with and attitudes towards ECT in general.

Raval additionally suggests that the practice of unmodified ECT may fuel the fears of patients who see ECT portrayed as a gruesome and barbaric treatment by the visual mass media. With apologies to Shakespeare, the fault, dear Brutus, lies not in unmodified ECT, but in its distorted portrayal. For example, an open heart surgery is well known to result in short- and long-term cognitive deficits; if the mass media were to use this knowledge to vilify open heart surgery, would it be justifiable to abandon the procedure? Sadly, in expressing his opinion, Raval is actually right. The strongest case for the abandonment of unmodified ECT is that its continued use may provide grist to the mill of publicity-hungry, self-important civil rights activists and sensationalistic film producers, and thereby jeopardise the survival of ECT itself.

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Beyond ECT: priorities in mental health care in India

Soumitra Pathare

The Supreme Court petition (1) by the voluntary organisation Saarthak has triggered off a debate on the treatment of persons with mental disorders in India.

Some of the requests made in the petition are: to issue directives banning direct (unmodified) ECT and establishing a process for sanctioning modified ECT without informed consent; to strike down, as unconstitutional, section 81 (2) of the Mental Health Act, 1987 (MHA, 1987) which permits research on persons with mental disorders; to direct states to comply with section 4 of the Act which requires the setting up of state mental health authorities to regulate mental health care; to regulate the use of physical restraints and limit their use to extreme cases; to guarantee proper sanitary facilities to institutionalised persons; to ensure that institutions provide facilities for rehabilitation; to set up a mechanism to protect the rights of institutionalised people; to ensure that essential drugs are made available at all institutions, and to set up a scheme for legal assistance for patients in exercising their right of discharge under section 43 of the MHA, 1987.

Unfortunately, the debate has focused entirely on the issue of ECT. For the uninitiated, direct ECT is the administration of ECT without general anaesthesia, while modified ECT is the administration of ECT with general anaesthesia and muscle relaxants. This debate is a non-starter: it is accepted the world over that ECT must be administered in a modified form. It has been argued that there is a special case for permitting direct ECT in India because of the lack of facilities for anaesthesia, and to reduce the costs of treatment. Both these arguments are spurious. ECT is a major procedure and must be carried out under reasonably safe medical conditions.

An assault on clinical autonomy?

Three demands in the petition have raised the hackles of the psychiatric community: to establish a procedure for administering ECT without consent, for a ban on research on medical research on patients with mental disorders, and for regulating the use of restraints. These have been perceived as an assault on clinical autonomy. One may argue that the procedures suggested in the Saarthak PIL are difficult to implement in Indian conditions. However, it is difficult to argue against the principle of regulation of involuntary treatment and of the use of restraints.

Other points in the petition, such as the provision of rehabilitation facilities in all institutions, have attracted little attention, though they are probably the most important and can have far-reaching effects on the quality of life of persons with mental disorders.

The real issues in mental health

Almost everyone agrees that the most important issue in the field of mental health is the lack of access to high quality care for a majority of the population. Treatment, when available, is based on a purely medical model focusing on the provision of drugs and ECT. There is a dearth of psycho-social therapies, counselling and psycho-therapy services and rehabilitation facilities. It is well accepted that mental health care needs to be multi-disciplinary, involving professionals such as psychologists, psychiatric nurses and psychiatric social workers. However, such care is limited to a few centres in our country.

Mental disorders account for nearly 15 per cent of health-related disability but most countries, including India, devote less than 1 per cent of the total health budget to mental health services. Mental health services are labour intensive and human resources make up a significant proportion of the costs. However, there is an acute scarcity of adequately trained mental health professionals in the country. This is unlikely to change in the near future given the shortage of training facilities.

Most countries have between two and three times as many psychologists, social workers and psychiatric nurses as psychiatrists. In India, it is estimated that there are more psychiatrists in active clinical practice than there are trained psychiatric nurses, clinical psychologists and psychiatric social workers. No systematic efforts are being made to address this distortion, by professional organisations or by the government.

For mental health care to become accessible within existing resource constraints, it must be provided through primary health services. This approach has many advantages. Clinical outcomes of primary care for most common and acute mental disorders are as good as in specialised psychiatric services, if not better (2). Primary health services are less stigmatising than psychiatric services, and there is

also a lower risk of human rights violations. They are geographically closer to the user, increasing the likelihood that people seek help early in the illness. Finally, mental health care through primary health services is less expensive (and more cost-effective) both for service providers and recipients.

However, primary health care professionals will have to be trained to detect and treat mental disorders. It is unreasonable to expect already overburdened staff in the state-run primary health system to take on more labour- and time-intensive interventions. It may be necessary to increase the number of general staff if a mental health care component is to be added. Other issues that need addressing include supervision of primary health care staff, adequate infrastructure and equipment and, most important, the availability of psychotropic medication.

Internationally, there is a movement away from providing institution-based care. This change will not take place in India unless alternatives are put in place including rehabilitation facilities, long-stay homes in the community and community psychiatric services. The primary health care-based community mental health programme in India covers only 22 districts with a population coverage of 40 million, which is less than five per cent of India's population.

A public health approach needed

Mental health treatment and care must be integrated within and outside the health services. In health care, it needs to be integrated into the various levels of health care. There are also opportunities for integration into vertical health programmes. For example, a programme to tackle post-partum depression (which affects 25-30 per cent of mothers in the first year after delivery), can be integrated into the Reproductive and Child Health programme.

Outside health care, mental health services must work in collaboration with agencies dealing with housing, employment, social welfare and the criminal justice system. They can also be integrated into social programmes; for example, a programme to tackle depression among women can be integrated into programmes addressing domestic violence. Finally, integration demands collaboration between the government medical sector, private providers, non-governmental organisations and traditional health providers. There are good examples of non-governmental organisations participation in the provision of good quality mental health care in India; these need to be replicated across the country (3).

Protection of human rights

The National Human Rights Commission's inquiry into the functioning of mental hospitals in India documents serious human rights abuses in many mental institutions across the country (4). International standards such as the UN Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care (5), though not legally binding, represent an international consensus on standards of good practice. International human rights covenants provide legally enforceable protection of human rights in signatory states. For example, Article 7 of International Covenant on Civil and Political Rights (6), to which India is a signatory, provides all individuals, including those with mental disorders, protection from torture, cruel or inhuman or degrading treatment or punishment and the right not to be subjected to medical or scientific experimentation without informed consent. The Saarthak PIL asks for implementation of many of these internationally agreed standards and covenants.

The role of legislation

Mental health legislation has an important role to play in the protection of human rights. Mental disorders sometimes affect people's decision-making capacities and they may not always seek or accept treatment for their problems. Rarely, persons with mental disorders may pose a risk to themselves and others due to impaired decision-making abilities. Most important, persons with mental disorders face stigma, discrimination and marginalisation.

Legislation must strike a fine balance between the individual's rights to liberty and dignity, and society's need for protection. It must address issues such as integration into the community, access to high quality care,and protecting the rights of persons with mental disorders, including in areas such as employment, education and housing.

From this perspective, MHA 1987 is woefully inadequate as it focuses entirely on the provision of treatment in what it calls psychiatric hospitals and psychiatric nursing homes. The chapter dealing with human rights contains only one section on research on persons with mental disorders. There is little understanding of the need to protect the rights of persons with mental disorders when treatment is administered without their consent.

The Saarthak petition mentions only involuntary ECT. Many would argue that it does not go far enough. In most countries, an independent authority (not the family) on a psychiatrist's recommendation must sanction and supervise involuntary treatment of all kinds.

Mental health legislation in many countries also gives persons under involuntary treatment the right to review. Under the MHA 1987, the State Mental Health Authority is charged with this supervisory function. But as mentioned in the Saarthak petition, such bodies have not yet been established by many states.

The Saarthak petition has to be viewed in the broader context of provision of mental health care in India. The petition and the consequent debate presents an opportunity to discuss the (lack of) provision of mental health care, and related human rights issues. This opportunity should not be lost by limiting the debate to ECT.

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Voices of people who have received ECT

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Electroconvulsive therapy (ECT) is controversial but widely practised in India. We elicited perspectives, using qualitative interviews, from patients who received ECT and their relatives. Ethical issues related to personal autonomy, right to information, competence, informed consent and consent by proxy are discussed. We suggest strategies to ensure a basic minimum standard for obtaining informed consent for ECT in India.

Introduction

Electroconvulsive Therapy (ECT) is widely practised in India to treat severe psychiatric disorders. However, ECT is one of the most controversial treatments in medicine and opinions regarding it are often polarised (1). Recent debates have focussed on the choice of ECT without anaesthesia (2), the practice of maintenance ECT and the clinical indications of ECT following the guidelines published by National Institute of Clinical Excellence (NICE) (3). Practitioners of ECT have always been challenged by sceptical arguments against its safety and efficacy. Perspectives on ECT have ranged from those who consider that it is probably ineffective and causes brain damage (4) to those who think it is the most effective treatment available in psychiatry and is completely safe. Systematic reviews of available efficacy studies conclude that ECT is an effective short-term treatment for depression, and is probably more effective than drug therapy. They acknowledge the propensity to cause short-term memory deficits, which are more common with bilateral supra-threshold ECT (5). However, systematic reviews of patients' perspectives of ECT claim that at least one-third of patients suffer from persistent memory deficits (6). They suggest that a similar proportion of patients perceived that they were coerced into giving consent for the treatment and they were not given enough information about ECT (7).

Despite these disputes and the dearth of data regarding its long-term adverse effects, the use of ECT is relatively common in India due to its clinical efficacy, the relative absence of negative perceptions and cost effectiveness. A recent Indian survey reported that 52 per cent of institutions still use ECT without anaesthesia and only eight institutions have facilities for routine electro-encephalography (EEG)

monitoring (8). Continuation and maintenance ECT are also widely in use. Those favouring direct ECT claim that facilities for anaesthesia are neither available nor affordable in many settings (2). Institutions in India also differ in their standards of practice and technical specifications while delivering ECT (9). Recent Indian studies have predominately focussed on clinical efficacy of ECT (10). There have also been legal attempts to ban direct ECT in India (11). Though opinions and controversies about ECT are often vociferously expressed and debated, systematic research on such perspectives in India is sparse. We describe a qualitative investigation into perspectives about ECT among patients and relatives.

Methods

The department of psychiatry, Christian Medical College, Vellore, is a tertiary referral centre rendering mental health services for patients from many parts of India. The 122-bed hospital provides short-term care for patients with organic disorders, substance abuse-related disorders, psychoses, mood disorders, anxiety disorders and adjustment problems. Patients and members of the family stay in independent cottages during the period of hospitalisation, which often ranges from three to six weeks. The emphasis is on a multi-disciplinary approach and eclectic care using a wide variety of pharmacological and psychotherapeutic approaches. The outpatient clinic serves about 20-25 new and 350-400 review patients per day. It employs 15 consultant psychiatrists, 20 psychiatric residents, and 30 psychiatric nurses in addition to clinical psychologists, social workers, occupational therapists, speech therapists and special education teachers. ECT is administered twice a week under general anaesthesia. Ten to 15 patients receive ECT per session and the number of ECTs given per patient ranges from eight to 12.

We conducted qualitative interviews with 104 people: 52 consecutive patients who received ECT, and their relatives. The details of the study are described elsewhere (12). All respondents were interviewed individually after the completion of their course of ECT using a modified version of the Short Explanatory Model Interview (13), specially adapted to elicit perspectives related to ECT. We selected 10 more articulate patients for the in-depth interviews. A discussion guide was developed based on eight major issues raised in the literature (6, 14). They were: (i) fear of ECT, (ii) perceived adequacy of information provided about ECT, (iii) the process of informed consent, (iv) perceived coercion, (v) perceived benefits of ECT, (vi) attribution of cognitive deficits to ECT, (vii) suggestions from patients and (viii) whether they would accept ECT as treatment for future episodes of illness. At the end of the interview, information was provided regarding ECT and support services available for people with severe psychiatric illnesses and their caregivers. One investigator (APR) conducted all interviews in Tamil. These lasted for 45 to 60 minutes with an additional 15 minutes for informal conversation. The interviews were audiotaped, with the consent of each participant, and transcribed verbatim.

We used a framework approach to data collection and analysis of the in-depth interviews (15). The framework approach has been used for applied or policy-relevant qualitative research in which the objectives of the investigation are typically set in advance. Although the framework approach reflects original accounts and observations, it starts deductively from our preset aims and objectives. We employed thematic analysis for the assessment of the themes that emerged during in-depth interviews. We identified themes which recurred with high frequency and themes with high emotional load. The analysis was designed so that it could be viewed and assessed by people other than the primary analysts (APR, BS). We generated notes and open codes, organised them manually, and grouped similar codes into categories. We discussed any disagreements regularly to reach consensus regarding coding. Though we did not enhance rigour by multiple coding, the analysis was improved by constant comparison with the transcripts. We identified and discussed a hierarchical scheme of specific themes, issues, and problems that emerged from the qualitative data. The information was translated into English after the analysis.

Results

The majority of the patients were women (29; 56.8 per cent), younger adults (mean age 32.1; SD 9.9 years), married (33; 73.5 per cent), literate (46; 88.5 per cent), employed (35; 67.3 per cent) and from rural backgrounds (32; 61.5 per cent). They had affective illness (30; 57.7 per cent) or schizophrenia (22; 42.3 per cent) with high suicidal risk (25; 48.1 per cent) and with an average duration of illness of about four years. A quarter of the patients (13; 25 per cent) had received ECT in the past. The semi-quantitative data are presented elsewhere (12). Five men and five women who were more eloquent participated in the in-depth interviews within a week after the completion of their course of ECT. Details of the qualitative data are presented here.

The voices of people who have received ECT are discussed under the following heads:

Fear of ECT

Fears about general anaesthesia, the ECT procedure, possible brain damage and memory impairment and the stigma related to ECT were mentioned during the interviews.

"When I thought of what would happen during ECT, my body was trembling in fear."

"I feared that my brain would be damaged by this. I worried whether I would become useless and unable to do any work."

An unmarried woman added, "I feared that I would be unable to do the household work or to marry."

Patients also reported hitherto unaddressed fears about the anaesthesia. "I knew about anaesthesia right from my school days. We used to anaesthetise frogs with chloroform during our dissection. I thought that I was in the place of that frog."

Another patient reported that her fear of ECT was short-lived. "I felt the difference after the first ECT. My fear had gone away. I developed the confidence that I could work."

Perceived adequacy of information provided about ECT

Many patients were unaware of the ECT procedure, its purpose, and possible risks and benefits even after completing their course of ECT.

"I went inside, they made me lie down. They stuck a needle in my hand. I thought that they were taking a blood sample."

"I did not know what was happening inside the room. But I did not have the courage to ask questions."

Patients wanted their psychiatrists to provide more information about ECT as evidenced by the following views:

"No one explained the details to me. I would stand in the queue to pay for and then receive the ECT. They also gave me a prescription for medicines…"

"They should provide some more information. They should at least tell the patient that they are getting 'shock treatment'. "

Patients, especially those from the rural areas, the less educated and the poor were hesitant to talk to their doctors and to clarify their doubts.

"I do not have the courage to talk to the doctors. I will tell you the truth: I am really fearful when I am talking to any doctor. I hold the doctors in high esteem. How can I ask them questions?"

Other patients had implicit faith in the doctor's judgment.

"Doctors are the people who are going to treat me. They are equal to God. I have not seen God. I am seeing God in them. How can things go wrong?"

Some of them felt that the information provided was adequate:

"I think that the information they provide now is enough. Of course they are giving ECT first, and only then are they telling patients that they have been given ECT. The patients are getting cured, so we cannot say that this is wrong."

Process of informed consent

All consent forms for ECT were signed by the relatives and some were also signed by patients. Even the patients who signed their consent forms were unable to recall the details about the consent process.

"I signed without knowing what form it was."

"I do not remember anything. I cannot recall who talked with me, what they said and whether they got my signature. I remember standing in the reception of the ECT room…. I also remember lying down on the bed. Otherwise, I do not remember anything else. Now, the doctors are saying that I opted for ECT. I do not remember …"

"My daughter signed the form. She is quite ignorant. She does not know anything about this treatment."

"My brother told me that we were going to the hospital. His decision was final and cannot be disputed. So I agreed and came to this hospital. I did not know that he was bringing me for this."

However, one patient summarised the process as follows:

"I could have been cured or I could have died. Both could have happened. So they got my signature. I told them that I would not die and then I signed the form."

Perceived coercion

Some patients felt coerced into agreeing to undergo ECT. However, many stated that other treatment choices were given and that they were not unhappy with the ECT. One patient said:

"No, ECT was the only option given..."

Many patients were passive and admitted that their doctors made the decision.

"It was my doctor's decision. He said that I would be alright after this treatment."

A mother of a patient (she was present during the interview with the patient) said:

"My daughter will be cured only if she accepts ECT. How can we leave her if she does not want this? We should make her get the treatment with compulsion."

Others were aware of alternative treatments. "Yes. I got a choice. My doctor gave me ECT after getting my consent."

Perceived benefits of ECT

Many patients admitted to positive experiences and benefits due to ECT. However, patients assessed benefits of ECT in global terms with particular emphasis on recovering functional ability, rather than mere recovery from clinical symptoms.

"My condition was so bad. Now there is a definite change… My health is better now."

"There is good improvement after ECT. I am able to go to work now."

"I can enjoy my life to some extent. This was not possible earlier. You know, when you are depressed, the mood and the way of thinking are completely different. I was like that. I can control that unnecessary thinking now… I was thinking about a lot of unwanted things. I thought of committing suicide. I do not have those thoughts now."

Attribution of cognitive deficits to ECT

Many patients spontaneously reported cognitive deficits.

"I am unable to remember anything. Who will bear that? It is really unfair. I do not remember anything about my uncle's visit to the hospital. I do not remember even a millisecond of that."

Patients were more concerned about the functional limitations caused by their cognitive deficits.

"My memory is becoming dull. After ECT, I cannot find any job. That is my first concern."

"…I do not remember what I talked about with my doctor. I have forgotten my doctor's name… I wonder why ... I used to have a good memory. Now I am very forgetful. This affects my life very much. I am unable to go to work. I have difficulty in managing my household work."

Other patients felt differently:

"I would rather be forgetful than be depressed."

"It is fine. There is a price for everything... There is no treatment without side effects. I have forgetfulness. I cannot deny that, but can I get any treatment without adverse effects?"

Patients' suggestions

Most of the patients were surprised when they were asked to provide suggestions to improve the treatment procedure. Many acknowledged that they had never been presented an opportunity to share their views.

"I feel it's OK. What has been done is good enough."

Patients suggested that they should have been provided at least the minimum information regarding ECT.

"Doctors prescribe ECT to patients who may be severely ill. So they need not explain all the details about the ECT at that time. It will be better if they explain when they improve."

One patient aptly suggested that psychiatrists do more research in this area to enlighten people regarding ECT:

"You should do more research. You should know all the good and bad things about ECT. Only if you know them all can you do any good for people like us."

Whether they would undergo ECT again

Four of the 10 patients who participated in the in-depth interviews stated that they would accept ECT as treatment for future episodes of illness. Many who refused to accept ECT in the future mentioned their concern about cognitive deficits.

"I am forgetting too many things. If I am asked to undergo ECT again, I will not agree…"

"I would not like to have ECT anymore… I will negotiate with the doctors not to get ECT."

One patient, a surgeon by training, strongly resisted the option of ECT.

"I will not accept ECT. They need my consent. I have read psychiatry books saying ECT is a good treatment… But I cannot find anything good in ECT. I did not find any benefit from ECT."

However, those who were willing to accept ECT in the future approved of it as a useful treatment.

"Yes, definitely, if someone has experienced ECT once, they will never say no to it later, because there is much improvement."

More than half of the patients were not aware of the details of ECT even at the end of the course but were not unhappy about receiving ECT. An analysis of the semi-quantitative data gathered in interviews of patients and their relatives (12) revealed the following: The majority of relatives felt that enough information was provided about the treatment. They knew of its benefits and risks and felt that they were offered a choice of treatment but also admitted to feeling coerced.

Patients and relatives assessed benefits and risks of ECT in global terms with an emphasis on recovering functional ability rather than merely recovering from clinical symptoms. Individual patients and relatives differed in their willingness to receive more information, the perceived adequacy of their knowledge about ECT, their ability to recall the details, and their belief systems. All relatives had signed the consent forms while a minority of patients had also given their signed consent. Even patients who had signed their consent forms were unable to recall the details about the consent process.

Discussion

This study was part of a broad-based qualitative investigation on the perspectives of patients who received ECT, and those of their relatives (12). Qualitative research methods were chosen to explore attitudes and perceptions in detail. The need for more information on subjective perceptions of ECT and the need for new insights into this issue justify the choice of qualitative research. While 52 consecutive patients were enrolled for the study, in-depth interviews were conducted on a small and selected sample of patients who were verbal, communicative and cooperative. The other methodological limitations include the short interval between treatment and interview and the setting of the interview. The short follow-up after the course of ECT does not allow for views on its long-term effects. Medical personnel in the hospital conducted the interviews and this might have influenced the views of patients. The lack of multiple coding for the in-depth interviews was overcome by constantly comparing with the transcripts and with available research in this field. The personal bias of the researchers was minimised by avoiding directive questions to elicit cognitive side effects, by allowing discussions to develop naturally, and by reporting the wide range of perspectives.

We recognise that qualitative research has its own limitations, notably limited generalisability due to the recruitment of a small convenient sample. The concept of transferability, introduced as an alternative to generalisability, is probably better suited for such research. It implies that the onus is on the reader to evaluate the methods, setting, and results and decide if these are transferable to their own situation. We believe that the findings of this study can be transferred to other settings, not only in India but also elsewhere.

The perspectives and opinions expressed by those interviewed for this study highlight the complex nature of the issues faced by people with psychiatric illness, by their relatives and by the treating team.

The ethics of informed consent for medical procedures is a complex subject. There are many reasons for the polarisation of views on, for example, informed consent in ECT. We have chosen here to discuss five ethical issues related to ECT, using the qualitative data presented here and the semi-quantitative data from the same study published elsewhere (12). We leave it to readers to arrive at their own conclusions.

1. Standards for informed consent

The two criteria commonly employed as standards for consent are individual freedom (and the patient's right to refuse treatment) and society's right (and its right to impose therapy), which are mutually exclusive. The western world favours individual rights when the patient's "competence" is intact; society may take over decision-making when this faculty is considered to be impaired. The actual decision depends on the clinical situation and represents a compromise between these two rights. Similar ethical dilemmas exist in many clinical situations in the care of people with severe mental illness, including compulsory admission and the use of parenteral medication in acutely disturbed patients.

With the increasing value placed on personal autonomy in many cultures, many patients and societies have demanded that the individual be given the legal right to decide on medical procedures and treatments. However, in many countries including India such legal requirements are often met if the individual signs an informed consent form for a medical procedure or treatment. This practice may violate the spirit of informed consent, as even educated patients may not fully understand medical jargon; also there is a certain amount of doubt and uncertainty in medicine. Similar issues regarding the validity of informed consent during the conduct of randomised controlled trials are being debated (16). In reality, the ethical choices related to informed consent are complex and difficult to make.

Another issue that has an impact on informed consent is the value systems of people. Many people in rural India continue to value health over personal autonomy and often request the doctor to decide about treatment options. In India the doctor-patient relationship is often viewed as similar to a guru- sishya or teacher-disciple relationship. The fiduciary nature of the doctor-patient relationship allows doctors to make decisions on their patients' behalf, when their patients permit them to do so. In such contexts, the ethical decision would be dependent on the physician and would be part of the burden of caring for patients. However, doctors need to assess the patient's value system.

Treatment choices and basic information should be offered to all patients and discussed in detail for patients (and relatives when they have to give consent) who value individual autonomy. Treatment decisions can be made for patients when they permit doctors to decide on their treatment. The psychiatrist should recognise that the guru-sishya relationship not only empowers the guru to decide but also enforces more responsibility on him/her to respect the welfare of the patient. "Accountability" is the other side of the coin of "autonomy". When a psychiatrist transgresses autonomy because of the context, he or she is expected to accept the added accountability.

2. Patient competence

Competence encompasses the cognitive capacity essential for therapeutic decision-making. It is fundamental to the process of informed consent. When this faculty is considered to be impaired, society devalues personal autonomy and takes over the individual's rights to decide on treatment options. Every adult is considered competent unless otherwise proved and psychiatric illness per se does not infer the lack of competence. For example, many patients with severe depression have been found to have adequate decisional capacity to consent for ECT (17).

Nevertheless, the assessment of competence often hinges on clinical judgement. Psychiatrists have demonstrated poor inter rater reliability (with kappa values as low as 0.31) for their clinical judgement on competence (18). Competent refusals of ECT may be confused with lack of competence, and the acceptance of ECT in people who lack competence may be misinterpreted as informed consent. In the context of the fiduciary nature of the doctor-patient relationship, the treating team and doctor often have the last word.

The study clearly demonstrates that informed consent was not obtained from the majority of patients and was obtained from their relatives instead. In addition, many subjects who signed consent were not able to recall the details of the process. The results of the semi-quantitative investigation (12) reveal that patients who were admitted and received ECT "voluntarily" differed from those who were admitted as involuntary patients. Those who were admitted to the hospital as voluntary patients held medical causal explanations, agreed that an alternative treatment option was given, felt that adequate information was provided, perceived more benefits, were aware of possible memory problems and gave personal consent for the procedure. Those who were admitted to the hospital as involuntary patients held nonmedical causal explanations, were unaware of alternative treatment options, felt that information provided was inadequate, perceived fewer benefits and were unaware of possible memory problems. Their relatives provided the consent for the procedure (12).

The minimum requirements for competence include understanding that ECT is offered, consciously deciding on whether or not to undergo ECT after considering its risks and benefits, and having the ability to communicate one's decision. The need for a standardised assessment of competence is increasingly being recognised. Instruments such as the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) can assess an individual's competence to consent for ECT, but they have not yet become routinely used in clinical practice (19). The instrument consists of four domains: understanding information relevant to one's illness and the recommended treatment, reasoning about the potential risks and benefits of the choices presented, appreciating the nature of one's situation and the consequences of one's choices, and expressing a choice. When a psychiatrist doubts a patient's competence, he or she must clearly document the rationale for this opinion. It is also desirable to call for further detailed assessment and an independent second opinion regarding competence. The assessment that a patient lacks competence affects only the right to decide on treatment; it does not take away basic human rights of safety, dignity and good quality medical care. Hence, doctors should take additional effort to ensure the care and rights of those patients whom they declare to lack competence.

3. Consent by proxy

When an acutely or severely ill patient is judged to lack competence to consent for ECT and is at risk to him/herself or others, psychiatrists seek surrogate consent or consent by proxy from the patient's legal representatives. In this study, all consent forms had space for the relative's signature and the relatives were asked to give consent on behalf of those patients who were considered to lack competence. Many relatives mentioned their responsibility to ensure the best possible care for their ill relatives and many stated that they would seriously consider forcing their ill relatives to get ECT if it benefited them. Women who participated in in-depth interviews reported that they had to abide by the decisions made by their male relatives.

The World Medical Association (WMA) allows consent by proxy but emphasises that the patient must be involved in the therapeutic decision making to the fullest extent allowed by his or her capacity.

The WMA also empowers the physician to act in the patient's best interest in situations of emergency (20). In the West, such situations are mostly handled by advance directives, substituted consent of the court, and consent by proxy by institutional ethics committees, treatment review panels or a team of psychiatrists. The situation in India is different. The cost of treatment and the burden on the family play a major role in deciding on the choice of treatment here. Unlike in the West, the cost of treatment in India is not paid for by insurance or by the government health service; it is borne by patients and their families. The absence of a state-sponsored social security net and the responsibility on the family to provide for care and treatment make the family responsible for providing consent by proxy. When a psychiatrist seeks consent by proxy from a patient's relative, the dyad (psychiatrist and relative) is governed by all the issues related to autonomy, right to information and informed consent.

4. Personal autonomy and perceived coercion

The study shows that while all relatives signed consents, many reported that the details of ECT were discussed with them and alternative treatments offered and they were happy with the outcome. Yet many relatives also perceived that they were coerced to provide their consent. Even the minority of patients who signed the consent form could not recall the details of the procedure. Many patients also reported coercion. It suggests a power differential between doctors and patients. Such unequal power balances within the doctor-patient relationship exist even in the West. The West sanctions the devaluing of personal autonomy when there is a threat to society, possible harm to others, a need for partner notification of an HIV positive person, and a conflict with the physician's own moral standards (21). Personal autonomy in the context of Islamic society has also been evaluated and it is concluded that a universal declaration of biomedical ethics may not be possible (22). In psychiatric settings, personal autonomy is frequently challenged in clinical situations such as compulsory involuntary admission and the use of parenteral medication while caring for the acutely and severely ill. Often such decisions contain elements of subtle and even overt coercion (23).

5. Right to information

In this study more than half the patients interviewed were unaware that they had received ECT and the majority reported that they were not given essential information regarding the procedure while their relatives admitted to having received information about the treatment. The patients in this study expected their psychiatrists to provide more information about ECT but many of their relatives considered that providing more information could do more harm than good (12).

The WMA asserts that every patient has the right to receive all information about his or her medical treatment. Such information should be provided in a culturally appropriate way that ensures adequate comprehension. The World Health Organization (WHO) has discussed the three general models for providing information: non-disclosure, full disclosure and individualised disclosure (24). The non-disclosure model provides false hope and denies the patient an opportunity to come to terms with the treatment. It also undermines the doctor-patient relationship, precludes patients' and relatives' participation in their treatment and creates barriers within family units. It also leads to information gathering from uninformed sources. The full disclosure model is based on revealing all available information to patients. This too is paternalistic, as the provider decides on what information to provide, and the timing. It is culturally insensitive in a culturally heterogenous society because the provider does not consider the needs of the individual patient. The individualised disclosure model suggests that information should be provided according to the patient's needs: how they will cope, and the amount of information they want. Such a model may not provide complete information to everyone but will attempt to convey information appropriate to each person. For this reason, the individualised disclosure model has received wide support.

ECT has a special status among psychiatric treatments and requires specific written informed consent. The term "informed consent" implies that a person understands the facts, benefits and risks of ECT and then voluntarily indicates willingness to receive ECT. Such complete understanding and true voluntarism are rarely attained in actual practice. In the context of a dependent therapeutic relationship, informed consent almost always contains an element of coercion (25). In India, the process is complicated by a reduced emphasis on personal autonomy and a lack of awareness of human rights, with roots in illiteracy and poverty. Submission to authority is often considered appropriate. In this situation the patient voluntarily yields to the physician's authority. Informed consent becomes a mere formality, given in order to maintain harmony in the doctor-patient relationship. It is difficult to ensure the spirit of informed consent.

Suggestions to improve the practice of ECT in India

The difficult issues related to informed consent must be addressed in routine clinical practice. A protocol needs to be in place, employed religiously and audited regularly.

Techniques to enhance the transfer of information use a graded stepwise approach. Information is provided after obtaining a clear signal to proceed with the details. Discussion should be held within the context of an empathetic, supportive therapeutic relationship. There should be no intimidation or curbs on clarifications. Patients should be provided enough time to absorb the information. It is also important to discuss the patient's feelings.

The specific components of the transfer of information include: (i) finding out what the patient already knows, (ii) assessing and bridging the gap between patient understanding, expectation and reality, (iii) providing details that the patient wants to have, (iv) stating the issues in simple language, (v) allowing time to absorb the information, (vi) encouraging patients to express their feelings (vii) clarifying doubts, misconceptions as well as fears and (viii) being available for further clarification.

A minimum standard for the practice of ECT in India should include the following strategies regarding informed consent and competence assessment:

(i) Adoption of the individualised disclosure model to provide information. Patients should repeatedly be given information about ECT using the techniques described above to maximise comprehension.

(ii) Informed consent is not an event but a process. Patients and their relatives have difficulty assimilating details on ECT in a single interview. The psychiatrist should provide regular appointments for education and clarification of doubts. Patients should be facilitated to ask more questions.

(iii) If the psychiatrist believes that it is inappropriate for certain information to be provided to the patient at a particular time or context, this should be documented in the medical records. The justification for those concerns should be reviewed periodically during the course of ECT.

(iv) Written information in the form of fact sheets on ECT should be provided to patients and their relatives. Fact sheets cannot replace verbal discussion but they can act as efficient adjuvants. They serve as reminders for discussed information and as templates for framing further questions. They should be written in simple language devoid of technical jargon. They need to be provided in the patient's mother tongue. Institutions can develop their own fact sheets keeping in mind the cultural and contextual specifications of their patient population. Ensuring accuracy and maintaining a neutral perspective are desirable but arduous while formulating a fact sheet. Even the Royal College of Psychiatry had to withdraw its fact sheet following controversies related to NICE guidelines (3). Hence, an honest attempt to maximise quality may fail to produce the ideal fact sheet on ECT but will result in the construction of one that is sufficient to strengthen prevailing practice. Liberal support to ask further questions should also be offered. A basic framework for the topics to be covered in a fact sheet is presented as supporting online material in the journal website.

(v) Written informed consent should be obtained from patients who are competent or from the legal representatives of patients who lack such competence. When a patient is judged to lack competence, his/her decision-making capacity should be reassessed during the course of ECT. If the faculty of competence is restored, specific consent should be obtained from the patient to proceed with further ECT.

(vi) Patients' comprehension of conveyed information regarding ECT, its risks and benefits should be assessed independently by a medical or non-medical professional who is not involved in the treating team.

(vii) A checklist should be formulated to ensure that treating psychiatrists have attended to essential elements of the informed consent process. The routine use of such checklists will help subsequent audit of the informed consent process. An example of such a checklist is also provided as supporting online material in the journal website.

These strategies, when employed in the context of the grossly unequal power equations of doctor-patient relationships, will not result in equality for patients; nor will they remove all coercion. However, we hope that they will improve the current practice of ECT in India and move it towards the ideal.

Conclusion

ECT remains as a controversial treatment but is widely practised in India. The current practice of ECT in India has many lacunae due to complex sociocultural factors. The application of a universal bioethical model and arguments on ethical standards of ECT have not produced any tangible progress. Hence, we favour a holistic approach to understand the ethical quandaries related to the use of ECT and have devised feasible strategies to ensure a basic minimum standard to obtain informed consent for ECT. Future research on patient perspectives, long-term cognitive adverse effects and the effectiveness of differing models of educational interventions on ECT is desirable.

Conflict of interest: *The authors employ ECT in their clinical practice.*

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Privatisation and transplant programmes

Sanjay Nagral

Liver transplantation is a life-saving procedure for those dying of advanced liver disease. It has been clearly demonstrated that it also restores a good quality of life in the long term. However, the procedure can be performed only if a liver is available for the transplant.

In countries like India where the usual source of such organs from brain-dead cadavers is extremely rare, living related liver transplantation (LRLT), where a part of a living person's liver is removed and transplanted, is increasingly being performed. However, this is a formidable operative procedure for the donor,and has the potential for complications, including death.

It is also clear that family members are often willing to undergo the procedure to save the life of a close relative who is on his or her deathbed. Given the circumstances of the donor's consent, it is not surprising that living related liver transplant is a subject of ethical inquiry.

In countries where liver transplants were pioneered, the operation was first performed from deceased or cadaveric donors. Over a period spanning almost three decades, the procedure was standardised and fine-tuned, and gained wide acceptance. The results of the procedure improved dramatically from its inception in the 1970s up to the1990s. Most of these procedures were carried out in the developed world, mainly in North America and Europe.

In 1989 the living related transplant procedure was described from Brazil and Australia. In the early 1990s centres with a strong background of cadaveric liver transplant and/or liver surgery started performing the living related procedure in small numbers in paediatric patients. In a prospective comprehensive protocol, supported by an institutional review board at the University of Chicago, 20 donor–recipient pairs underwent transplantation. This study incorporated elements such as research ethics consultation, assignment of a donor advocate, demonstration of field strength of the institution and physician team prior to undertaking the procedure, and a cooling-off period with multiple steps in the informed consent process.

However, the living related procedure really gained numbers in developing countries under two circumstances: either there was no law permitting removal of organs from cadaveric donors, like in Japan, or cadaveric donations were very rare for cultural reasons, as in Hong Kong. The other feature common to these countries was that they all had a large experience in resectional surgery of the liver, mainly due to the wide prevalence of hepatocellular carcinoma.

In the mid-1990s in the USA, multiple small centres, all of which did not necessarily have a background of cadaveric transplantation, started performing LRLTs. On the other hand, in Europe, where liver transplant is performed as a component of national health programmes (and, therefore, strongly regulated), LRLT has been performed in very limited numbers and at few centres. In the UK, which pioneered liver transplantation in Europe, the role and relevance of LRLT is still being debated. One of the largest LT units in Europe, the Queen Elizabeth Hospital at Birmingham, has as yet not ventured into this procedure. Similarly, many centres with a strong record of deceased donor transplants have been cautious in embarking on LRLT.

Most centres starting LRLT procedures first applied it to children, where the donor procedure is less formidable and, therefore, less risky. Also, there was a greater need for this procedure in children since age-matched cadaveric donors were not easily available. It was only after the procedure had been performed in children successfully, with a low incidence of donor-related problems, that gradually adult-to-adult procedures were conducted.

However, unlike the paediatric experience, the introduction of adult-to-adult living donor liver transplantation did not benefit from a prospective, well-defined, single-centre study. In fact, the majority of institutions performing adult-to-adult living donor liver transplant did so without ethics committee approval. Consequently, the risks and benefits associated with the procedure were difficult to quantify and not applicable across programmes.

The single most important difference between deceased and living donor procedures is the performance of a potentially life-threatening operation on a healthy person. Whilst the issue of donor safety is not the focus of this debate, it is relevant to mention that not only is donor mortality a critical ethical issue, it has the potential to destroy the public image and acceptance of liver transplantation. The much-publicised donor death in

Mount Sinai Hospital in New York a few years ago not only led to a huge public outcry, but also affected organ donation rates in the US.

Donor mishaps early in the evolution of liver transplant in any country are likely to do significant damage to the development of the procedure as a whole. The issue of donor mortality is still plagued by hazy information and a lack of transparency. The precise worldwide number of donor deaths is as yet not clear. It is accepted by many experts that the figures are often underestimated. Although there is a debate over the precise figure, it is significantly higher that that for kidney donors.

Equally important is the morbidity of the donor operation. It is estimated that around 20 per cent of LRLT donors suffer complications, some of which can cause significant morbidity and lead to a prolonged recovery and occupational disability.

One of the reasons for the performance of LRLT before the establishment of cadaveric programmes in countries like India is the lack of cadaver donors. Whilst this argument seems obvious, it needs to be carefully examined in the light of the actual experiences reported. It seems that if there is a concerted effort by any institution to promote organ donation and identification of brain-dead donors by ICU personnel, the consent rate is likely to be fairly high. In cities like Mumbai, Chennai and Bangalore cadaveric kidney transplants have been performed in much larger numbers than liver transplants. It is unusual for donor families to consent for kidney donation and not for liver donation.

It seems, therefore, that the reason that very few cadaveric liver transplants are being performed is not the unavailability of cadaveric organs but because of a lack of infrastructure, recipients or organ sharing mechanisms, all potentially correctable problems.

It may also be worth looking at the setting in which living related programmes are currently developing in India. Most of these are in the private sector where the market is the prime determinant of how specialty medicine develops. Thus, transplant teams are in a competitive environment and have to deliver quickly. In some institutions teams and doctors from abroad periodically fly down to perform the procedure, but may not be available for post-operative care. Further, liver transplantation is becoming a part of the medical tourism phenomenon, attracting patients from other countries, especially South Asia.

Whilst all this is an inevitable fallout of the way health care is evolving in liberalised India, it is prone to practices that may produce immediate results but can result in mishaps.

There have already been three donor deaths in India. In at least one of them the donor was unrelated to the recipient. What distinguishes the Indian situation is the secrecy that surrounds such incidents. It is not difficult for anyone familiar with the style of practice of medicine in India to understand that the solidity of two critical components of the ethical basis of LRLT—donation based on true bonding with the recipient and genuine informed consent—will be severely tested.

While the ethical debate on LRLT is relevant internationally, it is especially important in the Indian scenario. On one hand, liver transplantation in India is unlikely to make a significant impact on the management of the huge numbers of patients with end-stage liver disease. On the other hand, health care is unregulated and increasingly privatised. Naturally, when an individual faces imminent death and this death could be prevented by a family member (or any other individual) donating a part of the liver—and when medical teams are willing to perform the procedure and cadaveric organs are in severe short supply—LRLT will continue to be performed in increasing numbers.

The articles reproduced in this section highlight these important ethical concerns in live related liver transplant. They must be viewed in the context of the growing privatisation of health care in India. The ethics movement in India will need to highlight such issues in order to protect the interest of the donor.

Note: Substantial parts of this commentary have been reproduced with permission from an article published in the *Indian Journal of Gastroenterology*: Nagral S. A deceased donor liver transplant programme must precede a living donor programme. *Indian. J. Gastroenterol* 2006; 25 (6): 302–4.

Ethical dilemmas in living donor liver transplantation

A S Soin

Liver transplantation is accepted worldwide as the only cure for terminal liver failure. Although the recent tragic death of a liver donor at a hospital in Delhi underlines the need for caution, a knee-jerk reaction to liver transplantation or liver donation is inappropriate.

In Asian countries where cadaveric donation is practically non-existent, living donor liver transplantation (LDLT) is the only viable way of performing liver transplants in reasonable numbers to treat patients with end-stage liver disease. However, several ethical issues need to be addressed before a hospital embarks on a LDLT programme and, indeed, before every such transplant.

The most serious objection to LDLT is the violation of the principle of non-maleficence, or to do no harm. The donor is at risk from a lengthy and potentially dangerous surgical procedure without accruing any health benefit. It is unethical to perform LDLT at a centre with sub-optimal facilities or expertise. The minimum requirements to start LDLT should be set out by the Indian Society of Organ Transplantation, ratified by established foreign teams and followed rigidly by all new centres.

Donor issues: coercion, consent and acceptable risk

There is concern about whether live donation can ever be without emotional or financial coercion. While emotional pressure has been more or less accepted or overlooked, financial incentive is illegal. Although donation should be motivated only by altruism, the real reason behind it is difficult if not impossible to determine. Some have lobbied for paid donation but the transplant community at large has been strongly opposed to it due to the danger of abetting exploitation of the under-privileged.

If the family of the prospective recipient is considered to be one ailing unit, donation by one of its other members (a first-degree relative or the spouse) may be justifiable since the family accrues a benefit for a calculated risk. However, this argument cannot be extended to unrelated donation.

Genuine informed written consent is central to the safe and optimal use of LDLT. However, even if every detail is given, the understanding of prospective donors will vary with their level of awareness, social and educational background. An overzealous and detailed description of possible complications can be misconstrued, putting off donors needlessly due to ill-founded fears and denying the recipient a chance to live. While we explicitly inform all our prospective donors (and their kin) about the mortality and major morbidity, we tailor the details of the explanation according to the perceived level of their understanding.

Some centres take informed consent in two sessions, spaced apart, to enable the donor and family to ponder over the pros and cons without time constraints (1). Although we do not do this in two defined sessions, our policy is to inform the donor of all possible consequences over three-four counselling sessions in the outpatient clinic, and then take informed written consent before the operation.

To avoid bias, it has been suggested that donor evaluation be done and informed consent be taken by a physician who is not from the transplant team (1). However, we believe that only a doctor from the transplant team can evaluate and inform the patient with the correct perspective and should be the one assigned this task in good faith. Detailed psychological testing is essential to ascertain the donor's willingness to donate the organ free of coercion and also enhance his/her understanding of the various psychological issues. Finally, the relationship between the donor and the recipient, and the non-coercive nature of the donation, must be confirmed by a government-approved, non-partisan authorisation committee before the transplant is permitted.

It is well established that liver donation is safely possible because of two unique qualities of the liver — reserve and regeneration. Due to its enormous reserve, a person is able to function normally with as little as 25 per cent of the liver. Within a few weeks, the liver actually regenerates to its normal (pre-removal) size (2).

Still, in spite of careful preoperative work-up and the best surgical techniques, there remains a very small risk to life (0.3 per cent) from donor hepatectomy (3). The risk is higher in a right lobe donation than in a left lobe one. The risk of donor hepatectomy may be higher than non-donor hepatectomy since removal of the diseased liver leaves behind much more functional liver than does a donor hepatectomy. A small risk is expected in any major surgery. This risk may seem justifiable for the family in which a terminally ill person is restored to normalcy. However, there remain detractors from this view.

Recipient issues: use of scarce resources and deciding priority for transplant

Even when cadaveric donors are available, there are ethical dilemmas over the use of a scarce national resource for patients who may have inflicted the primary disease or a co-morbid condition upon themselves (alcohol- or paracetamol-induced liver failure), those who may not have prolonged survival after transplantation (those with hepatocellular carcinoma or AIDS), those who may not be "useful" working members of society (elderly recipients), and those who are not likely to have good graft survival (those with recurrent hepatitis C). The successful use of partial livers obtained from living donors can reduce waiting periods and mortality, and also offer a choice of transplantation to the above categories of patients who may otherwise be deemed to be low priority candidates due to societal or ethical considerations. In this way, they do not compete for the limited national pool of cadaveric donors. However, whether healthy donors should be put to risk to benefit this medically sub-optimal group of recipients is open to debate. Most centres would accept this risk.

Recommendations

* The first priority of the transplant team should be to ensure the well-being of the donor and exclude a person from donation if he/she is not an optimal candidate.
* At the hospital level, detailed psychological assessment and an interview with an impartial authorisation committee are essential to enhance the donor's understanding of the various psychological issues, confirm the relationship of the donor with the recipient and ascertain the donor's willingness to donate free of coercion. Detailed written informed consent must be signed by the donor before surgery.
* All recipients considered for compassionate transplants outside the accepted clinical criteria should be approved by the hospital's ethics committee.
* A regular medical audit should be routine in all hospitals. All centres should send all donor data to donor registries at the national and international levels.
* The State and National Departments of Health should empower the Indian Society of Organ Transplantation to prepare LDLT

guidelines in concordance with international norms, which must be rigidly followed by all centres. These should cover: the minimum requirements for a team to perform LDLT; maintenance and submission of detailed records of recipients and donors for all transplants; unrelated and non-directed donation; donor compensation, and a definition of acceptable donor risk.

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Living donor liver transplantation

A V Srinivas

There was some debate within the editorial board about the appropriateness of carrying the following exchange in an ethics journal. At one level it is a complaint from a patient's relative and an institution's defence of the allegations. However, at another level the story raises some larger issues which are relevant to contemporary ethics.

The field of organ transplantation is no stranger to ethical controversy. A particularly complex issue involves living related transplantation where a healthy donor is at some risk, including the risk of death. In other words, in an attempt to save one life two lives can be lost. It is obvious that such a potentially dangerous situation needs the highest level of informed consent. And if things do go wrong there must be a sound and transparent mechanism of dealing with the situation.

This journal has previously carried an editorial on the issue of living related liver transplantation.

This unfortunate incident also points to the potential danger of an increasing trend, in the globalised world, of foreign doctors flying in, performing procedures and flying back, leaving their local counterparts to face the complications.

Hence we finally decided to put before you the story of a family bravely facing a tragedy of immense proportions. It also highlights the problems of high technology medicine where high-risk, complicated and costly procedures are marketed and performed with a promise of cure. ***—Editors***

Mr AV Srinivas wrote to IJME *describing his parents' experiences. Mr Srinivas' father was diagnosed as suffering from liver failure and advised a liver transplant. The transplant was carried out in April 2003, in Global Hospital, a private hospital in Hyderabad. The donor was Mr Srinivas' mother. The transplant was done by a team of surgeons headed by Dr Nigel Heaton and Dr Paolo Mueisan from King's College Hospital, UK. The Global Hospital team included Dr Kancherla Ravindranath, managing director of Global Hospitals and head of its department of surgical gastroenterology; Dr Dharmesh Kapoor, hepatologist; Dr PBN Gopal, anaestheologist and intensivist;*

Mrs Lalitha Raghuram, chief liver transplant co-ordinator, and the support staff.

Mr Srinivas' father died within two weeks of the transplant, in the hospital ICU. His mother suffered a cardiac arrest within 48 hours of the surgery and has been in a persistent vegetative state since then.

Mr Srinivas feels strongly that the hospital and staff behaved unethically in promoting adult-to-adult live transplants without having the necessary experience to conduct this procedure. The hospital and staff did not indicate that adult-to-adult live liver transplants are more risky than those from adults to children. Further, Mr Srinivas states that he was not made aware that this was the first adult-to-adult live donor liver transplant in India. Finally, he notes that adult-to-adult live donor liver transplants are not permitted within the UK National Health Service (NHS) because of the risks to the donor. Kings College, with which Dr Nigel Heaton and Dr Paolo Mueisan are associated, is part of the NHS. Such transplants are done in the UK only in the private sector, mostly on foreign nationals.

Mr Srinivas provided IJME *with replies to letters he wrote to the BBC, the UK General Medical Council and Professor Roger Williams, director of the Institute of Hepatology, Royal Free and University College Medical School. The BBC's reply notes that it had a policy of not releasing untransmitted footage but would consider his request if he would indicate what was contained in the footage that might be of his interest. The GMC replied that his complaint had been forwarded to Drs Heaton and Muiesan. Professor Williams indicated that adult-to-adult live donor transplants are not done in the UK under the NHS, but UK doctors do make this available in the private sector, mostly to people from outside the UK. He added that as a person working with the doctors named, he could not comment further but suggested the names of others who could.*

Mr Srinivas also provided the journal with a photocopy of an advertisement by Global Hospitals (undated, apparently published in the Hindu, December 2002), calling for people to "register fast for liver transplants to be done by UK doctors".

The following account is based on Mr Srinivas' statement as well as some documents sent by him.

My father's health problem – cirrhosis of the liver — was identified in late 2001. Over 2002, we visited Dr Nageshwar Reddy at the Asian Institute of Gastroenterology. Dr Reddy spoke about the transplant option but said the success rate was not good in India.

Towards the end of 2002, we saw media reports that experienced liver transplant surgeons from King's College Hospital, UK, would be doing liver transplants at Global Hospital, Hyderabad. In December 2002 we visited Global Hospital for the first consultation with Dr Dharmesh Kapoor of Global Hospital, who told us to continue the previous medication with a few changes. We were told that Dr Mohammed Rela, a liver transplant surgeon from King's College, UK, would be visitng Global Hospital and we took an appointment with him. Dr Rela examined my father and also went through his medical records. He said the only option was a liver transplant, and that he was a suitable candidate.

Both Dr Kapoor and Dr Rela said many transplants were being done in the West and that in the UK they had a good success rate.

In early March 2003, we consulted Dr Hector Vilca Melendez, also of King's College, during his visit to Global Hospital. This was shortly after the media reported on the first liver transplant done there, by Dr Melendez. Dr Melendez went through the medical history and told us transplant was possible, and described the success rate in the UK. We discussed the matter again with Dr Dharmesh Kapoor and on his advice my father went for pre-operative investigations for which we paid Rs 95,000.

On March 28, 2003, Mrs Lalitha Raghuram, chief transplant coordinator in Global Hospital who also heads the Hyderabad branch of the MOHAN foundation (an NGO promoting organ donation/ harvesting), called us to say there was a prospective (cadaver) donor available. She asked us to make a deposit of Rs 10 lakh immediately, and indicated that the surgery could be done any time as the surgeon from the UK was in Hyderabad. She also said that unless the patient was operated upon immediately, his condition could worsen and he could become unfit for surgery. We borrowed the money from various people and deposited it but then we did not hear anything more on the matter. Some days later, we were informed there was a cadaver liver available in Chennai. We were told to decide within half an hour if we could pay Rs 7 lakh for the chartered flight from there. We said we could not afford it.

In the meantime my father's health deteriorated and we took him back to the hospital. This was when we were first advised to consider a live donor transplant, from a family member. My mother was counselled. My parents did not consider my brother or me as potential donors, I suppose because of our career and marriage future.

I do not have any documents on the informed consent process. Family members were also spoken to, but I do not recollect much counselling. They explained that the donor's liver would grow back to normal size within two weeks, and she would be back to her normal self in 4-6 weeks. They did not describe any risks. They did not mention the difference in risk between an adult-child live liver transplant and an adult-adult live liver transplant. They used the term "live liver transplant" only.

They also said the search for a cadaver liver would continue and if it were found the live donor transplant would be cancelled. We were also assured that we would not be charged for the donor's expenses and my mother was asked to undergo investigations. My mother was hesitant but she saw this as my father's only hope. She was found to be fit for the transplant.

The surgeons were Dr Nigel Heaton and Dr Paolo Mueisan of King's Hospital, UK. Dr Heaton checked on my mother before the surgery. He said it would be major surgery for the donor – this was the first time we heard the word – but that everything was fine. He also said he had done about 55 live liver transplants and none of the recipients had died. The doctors also said my father was in good shape for surgery and would survive the operation. No one used the term "adult to adult live donor liver transplant". They described it as "live liver transplant" We did not know that there are different success rates – and risks – for partial liver transplants from live donors and total liver transplants from cadavers.

Dad's was the third liver transplant at Global Hospital; the previous two were cadaver transplants.

In the early hours of April 22, 2003, both our parents went into the operation theatre. We were told the surgery went well. It took 22 hours. Then on April 24, within 48 hours of the surgery, my mother had a cardiac arrest in the ICU. By the time they got her heart beating again, she had suffered brain damage. We believe this happened because a delay in resuscitation led to irreversible brain damage. They kept telling us that she would recover, but the extent of damage could not be known until she regained consciousness. It is now more than two years.

My father died in the ICU within two weeks of surgery. The death report, signed by Dr PBN Gopal, anaesthetist, states that the cause of death was multi-organ failure due to fungal septicaemia. We believe that he was operated upon when he was unfit for surgery.

A team from the BBC had accompanied the UK doctors. They interviewed my parents before the surgery; they videotaped the surgery and also interviewed the family after the surgery. The hospital and BBC termed it the first Indian related live donor liver transplant (my parents are related). The BBC team left a few hours after my mother went into a coma.

The UK doctors are aware that my father died within two weeks of the transplant and that my mother went into a coma. One of them was there when my father passed away. Neither of them has called back to ask how she is.

We had been told that the total cost would be Rs 12 lakh. In March 2003, we paid Rs 10 lakh and another Rs 95,000 in pre-operative tests for my father. The doctors indicated that they would not charge for the donor's expenses. When she was being taken into the operating theatre we were asked to sign a form committing to pay Rs 23 lakh, including donor expenses. We objected but Mrs Lalitha Raghuram advised us to sign so the surgery could proceed, and said this would be settled during the final billing. Even as our parents lay in a coma we were repeatedly pressurised for the payment, including with threats that medication would have to stop. Later they indicated that they would bear the cost of treating my mother. In January 2005 they sent us a bill of Rs 45 lakh, towards the cost of mom's treatment for the previous 20 months.

Did the Global Hospital have staff skilled and experienced to perform the surgery and advise the patient's family on whether the patient is suited for the transplant? I believe that they advocated a complicated and expensive surgery without giving the family sufficient information on the risks associated with the transplant, especially for adult donors.

In the US, there are regulations and some action is taken when things go wrong. Should hospitals in India here not have the same level of scrutiny?

Response: Living donor liver transplantation

M Veera Prasad

Several patients are dying in India because of the lack of a world-class facility for liver transplant. There had been instances of Indian patients waiting for their turn to receive an organ abroad. Organs are allotted to foreigners only when resident nationals are not suitable. Hence, with the noble thought of helping Indians waiting for organs, Global Hospital put out an advertisement to benefit end-stage liver disease patients and then sought registration of patients. The Global Hospital is well equipped with state-of-the-art facilities. Global Hospital doctors involved in liver transplantations are well trained in the UK. The hospital follows the King's College protocol for liver transplants. To enlighten the public and doctors about the availability of the facility, we advertised in newspapers. As a result we received several inquiries from patients and doctors. There is no need for the hospital to promote anything unethical. We will do everything in good faith.

Mr Jagannathan was a patient suffering from end-stage liver disease (due to alcoholic liver disease). He was in a very bad condition and terminally ill. He was under treatment with doctors in another hospital. He had been advised liver transplant by another doctor in 2002 itself. As mentioned by the other doctor, probably during that time the results were not so encouraging. Precisely for that reason we started the transplantation programme by taking the help of the world-renowned liver transplant team from King's College Hospital, UK, which does about 200 liver transplants a year.

Mr Jagannathan approached Global Hospital for further management in December 2002. He was put under the treatment of a hepatologist and other concerned doctors were closely monitoring the case. As he was deteriorating, the liver transplantation option was thought of.

Initially, cadaver liver transplantation was discussed with the patient and his family members. As the patient's condition was fast deteriorating, the family members were also given the option of live liver transplantation, as a last resort. Mrs Prameela, wife of Mr Jagananthan, had come forward to offer part of her liver. She was counselled thoroughly, and all problems and implications were discussed with all family members. Meanwhile, a cadaver liver became available at a far-off place. We discussed with family members the option of getting the liver by arranging a chartered flight. But as the family members were not interested, we could not do the cadaver liver transplantation.

The doctor's team explained everything thoroughly and in detail to the patient and to all family members. We have a very good "transplant co-ordination" department, which explains the process in detail to the family members including the patient. In transplantation surgeries, unlike other surgeries, we counsel the patient, spouse, close relatives and friends. Without counselling, we do not undertake even a small procedure.

Apart from that, Dr Mallikarjun, son-in-law of the patient and a general surgeon with an MS qualification working as assistant professor in a reputed government teaching hospital, is the main spokesperson of the family. How can a surgeon say that he is not aware of the risks and complications of a complex surgery like liver transplant? It is highly absurd to say that the family members were not informed about the high risks involved in adult-to-adult liver transplants. The internet-savvy family members had equipped themselves with all the information on liver transplants and in fact discussed the implications of liver transplants with us. The allegation is baseless. Feigning ignorance about the major and most complex surgery planned for their parents is an afterthought. Global Hospital follows all rules and regulations very strictly and does things ethically only

The UK National Health Service (NHS) may not be doing live adult-to-adult liver transplants for its own reasons. Guidelines of the NHS dictate the King's College Hospital policies, but adult-adult liver transplants are being done in the private sector, in the UK. Even in India, some procedures may not be done in the government sector but are done in the private sector. The private sector takes up challenges because of its expertise, facilities, technology, etc.

The main surgeon, Dr Nigel Heaton, is a world-renowned liver transplant surgeon and had done about 21 such live adult-adult transplants, and total of about 1,000 liver transplants, before doing it here. Dr Paolo, with good experience, assisted many cases.

Professor Roger Williams heads the unit in the private institute where these transplants are done by Dr Heaton's team. He refers to the high calibre of Dr Nigel Heaton. This itself shows Professor William's faith in the team as he is allowing them to operate on his patients.

We did not invite the BBC team to record the liver transplant. The BBC was engaged in producing a documentary on Dr Nigel Heaton. The team came here and shot the liver transplant programme with the permission of family members.

Once a patient is willing to undergo transplantation, as per hospital policy, the patient has to pay Rs 95,000 towards the pre-operative work-up. The work-up was done as all family members including the patient had given consent for it, after understanding the problems, complications, pros and cons, etc. In our usual practice, we cannot initiate the transplant process until the patient makes some financial commitment, as the liver transplant involves lots of activities/ commitments from the hospital's side. As a cadaver liver may be available at any time, transplantation has to be done on an emergency basis. That is why we collect an advance from the patient. After all our vigorous but unsuccessful efforts to get a cadaver liver organ, we discussed live related liver transplantation as a last option as the patient's condition was deteriorating fast. All the pros and cons, complications to the patient and to the donor, were explained to the family. Only after a thorough explanation did the patient/family members give consent. After obtaining valid consent the surgery was performed. We indeed waived the donor surgery charges, investigations, etc, on humanitarian grounds (but not the charges for complications, if any, that might arise)

We discussed adult-adult live liver transplant, in detail, with all the concerned family members. The patient's son-in law is a general surgeon. He was the main person and represented the family. The allegation that we said the search for a cadaver liver would continue and if a cadaver liver was found the live donor transplant would be cancelled reveals that the patient and his family had been told about both options. This means they had been thoroughly counselled about all options.

Mrs Prameela, the donor, was not hesitant. Dr Anurag Shrivasthava, the psychiatrist who examined her during the pre-operative work-up, certified her fitness. It was very clearly mentioned that she was very strong in her decision to donate a part of her liver to the husband. This shows they are hiding the facts.

Mr Jagannathan was in end stage liver disease and terminally ill. He was prepared/ stabilised to the best possible condition for surgery. He was never in good shape. They opted for live related transplant because he was deteriorating fast. He survived the surgery. If the patient was unfit, he would have died on the operation table itself or during the

immediate post-operative period. Everybody knows that liver transplantation surgery is a most complex surgery. It is a false allegation that they heard the words "major surgery" for the "first time" just before the operation. He lived for two weeks after surgery. The donated liver worked well; it was not rejected. He did not die of a surgical complication. Surgery was successful but later he died of sepsis, which is one of the commonest causes of death in post-liver transplant cases all over the world, as patients are kept on immunosuppressive drugs to prevent graft rejection.

We did explain that the donor's liver would grow back to normal size within two weeks, that and she would be back to her normal self in 4-6 weeks. And it usually happens. Her liver after donor surgery attained optimum size and even today her liver is working normally. There is no failure of donor surgery.

The donor was kept in the Liver Intensive Care Unit after surgery. This is a fully equipped, ultra-modern facility. Trained and highly skilled nursing professionals and intensivists are there round the clock to take care of any complications. The donor had a cardiac arrest, which may happen in some patients, especially in the post-operative period. Our doctors and other team members immediately attended on her and resuscitated her. Because of the immediate attention, she survived the cardiac arrest. But unfortunately, because of ischemic hypoxia of the brain, she slowly slipped into a persistent vegetative state. All the reasons for the cardiac arrest have been explored, but no conclusion could be made. This is quite unfortunate but there is no medical negligence as they allege.

The main UK doctors who performed the surgery were here to manage the immediate post-operative period. The second UK surgeon was here for about one month. It is all teamwork. The UK doctors were enquiring about her health status, even today and we are appraising them. We also consulted some very good neurophysicians and others and continued the treatment as per their suggestions. Recently the complainants brought a renowned senior neurophysician of their choice to examine their mother. He was highly satisfied with our treatment. She is receiving the best treatment, he pointed out. That much special care is being bestowed on her. Because of our best treatment, she is still surviving. It is one of the good examples of teamwork and untiring efforts in patient care.

It is a false allegation that they did not know there were different success rates and risks for partial liver transplants from live donors and total liver transplants from cadavers. There is nothing to hide. In

transplantation surgery, there is no money to be made. It is a highly cost-intensive procedure. With the noble intention of giving a "second life" to the needy, Global Hospital started the programme. Many hospitals have not started the programme because of the cost implications.

Transplantation is not new to us and the results are good. We are doing different varieties of liver transplantation, such as cadaveric, live related (adult-to-adult and adult-to-child), split liver transplant, etc. Prior to this case we did two cases and both are doing well. So far, we have done 21 liver transplants of different kinds and 18 survived. Our success rates are on par with those of the best hospitals in the West.

The usual package is Rs 12 lakh and approximately Rs 3 lakh for blood products (at actuals), and extra costs, at actuals, if any complication occurs. They paid only Rs 10 lakh before surgery. We did not insist on their depositing the entire amount. We have not charged the donor's surgery and investigation expenses. It is another false allegation that when the donor was being taken into the operating theatre we asked the relatives to sign a form committing to pay Rs 23 lakh, including donor expenses. Why would we undertake the surgery if they were supposed to pay another Rs 23 lakh? Regarding the allegation that we pressurised them for payment, this again is false. We never told them that we would bear the cost of treating their mother. Everything has been done ethically. We neither pressurised them to pay the bills nor threatened to stop medication. We are treating the case on humanitarian grounds. The fact that we issued the bill in January 2005, nearly 21 months after initiation of treatment itself, establishes that we never exerted any pressure. In fact, we issued the bill at their request, unaware of the fact that they had filed a case in the AP Consumer Forum.

The hospital has highly skilled and reputed doctors, many of them trained in world-renowned centres. The facility and infrastructure are on par with the best in the world. We have done liver transplants with success rates on par with those in the West. Some patients for liver transplantation have come from abroad, after enquiries in different parts of world. We did our first heart transplant on February 6, 2004, and the patient celebrated his "first re-birthday". We are one of the major centres for kidney transplantations, both live and cadaver. We did our first bone marrow transplant. Now, a patient from the UAE is waiting here for her lung transplantation, which again will be the first

of its kind. We are also planning to do the "first" small bowel transplantation and the first pancreas transplantation. The hospital has a good reputation for transplantations. With *mala fide* intentions they are making false allegations to besmirch our reputation.

It is unethical to say that we advocated a complicated and expensive surgery without giving the family sufficient information. Can anybody believe this? Extensive counselling was done not only to the patients and also to all the family members. They are highly educated and knowledgeable. The main spokesperson of the family, the son-in-law, is a practising general surgeon who does a number of surgeries daily. These surgeries have to be performed after explaining to the patients all complications and after obtaining their consent.

Not only in the US, in India also a regulatory system exists. As they filed a case in the consumer forum, we have given all records to the court for scrutiny. They filed a case in the police station. A state government committee has scrutinised the records and taken statements from us. Mr Jagannathan's body was subjected to post-mortem examination. We are ready for any "scientific scrutiny". We are co-operating with all the appropriate agencies. We have submitted the medical records to the General Medical Council, UK, as per their request. They have made false allegations against Global Hospital in the media to get public sympathy, to exploit the situation and to damage our reputation. Ethics should be followed by all. In spite of this, we are still providing the best possible care to the patient.

End-of-life care in the era of life-saving technology

Ram Rajagopalan

The nature of the care provided to patients at the end of their lives has undergone a radical change all over the world. The availability of new treatments and life-saving technologies has opened up new curative avenues, and many patients who in the past would have been candidates for compassionate, family-centred, end-of-life care are now brought to the hospital for the provision of measures that may prolong their lives. We recognise that these technologies are neither consistently effective nor universally beneficial, and often the "cure" achieved in some patients is at the expense of physical and financial misery to many others.

As these life-saving technologies have only recently become available to most Indians, there are still a lot of misconceptions about their value and limitations, in the minds of both the public and the physicians who use them. **A series of articles** (1–8) in *IJME* bring to light many of these misconceptions and conflicts that arise when the high expectations that these therapies foster are not met.

In fact, when such issues arise, the choice of an ethically dubious treatment plan is often defended on the grounds that societal or legal consensus does not exist. As the illustrative cases in the *IJME* demonstrate, we often encounter the physician unwilling to limit an ineffective, albeit "life-*prolonging*", treatment who emphatically states, "This is not done in India" (2); or another who defends his inability to maintain an ethically appropriate stance saying, "India needs valid legal guidelines."

I would argue that, from an ethical perspective, there is no uniqueness to the use of these technologies in India, and though no specific statutory laws exist to direct the patient or the physician to an appropriate course of action, the law, even in its current form, does not condone unethical conduct. It is disappointing to see how many physicians sidestep their professional responsibilities and adopt ethically untenable postures because of this perceived lack of legal support. The absence of a law cannot be justification for unethical behaviour.

Misconception of ethical principles

While making clinical decisions in critically ill patients on life-supporting technology, traditional ethical principles are applied in decision making. Thus, even in this situation patient autonomy has primacy. The patient (or his surrogate) has the right to be informed about his illness and its treatment, and to be involved in decision making, especially in consenting to or refusing the treatments offered. Most physicians feel uncomfortable about this, because considering the nature of these treatments and technology, respect for the patient's wishes may result in a threat to the patient's life. However, one must consider the fact that the goal of such treatment is not just to sustain life, but also to relieve pain and suffering, and to avoid unnecessary prolongation of the dying process.

In deciding which of these goals is important, the physician should recognise that he could only serve in an advisory role, with the patient (or his surrogate) given the autonomy to chose the preferred goal. The temptation to impose our own values in decision making (paternalism) must be avoided. Further, physicians have the ethical obligation to provide only treatments that benefit, and to avoid those that harm the patient. Respect for these rules of beneficence and non-malfeasance often comes into play when we recognise that the technologies that we use in treatment are not consistently or universally effective. Their potential to cause harm increases as their benefit in a given patient declines.

Under both these circumstances the physician has the obligation to stop (withdraw) or not initiate (withhold) treatments that may be "sustaining" the patient's life. Once again this brings discomfort to the physician, who feels that such an act may be equated with euthanasia. There is, however, a subtle but important difference between the two. Euthanasia is an act that, however well intentioned, aims to end a life. Its primary purpose is to use the termination of life as a mode of "providing relief" from discomfort. In contrast, the act of treatment limitation (by withdrawal or withholding) provides relief by minimising or eliminating treatment options that do not enhance survival or that create patient discomfort. Though the cessation of certain processes (for example, mechanical ventilation) may accelerate the death of the patient, this is not the intended goal; nor is it an inevitable outcome. It is the intent of the act of treatment limitation (to enhance comfort and to respect patient preferences) that morally justifies it, and differentiates it from euthanasia (that intends to terminate a life).

Misconception of the law

Ultimately, even when these ethical principles are understood, their application to patient care is often limited by a fear that that current Indian law is not explicit enough to support ethical acts related to end-of-life care such as withdrawal of support (1). While it may be true that these issues have not been discussed in Indian courts, international precedents, constitutional guarantees and protective clauses in the Indian Penal Code (IPC) provide adequate support for ethical practice (9).

An individual's right to consent to or refuse medical treatment is implicit in Article 21 of the Indian Constitution (which deals with the fundamental right to life and personal liberty). While it is routine to seek informed consent and to respect a patient's refusal in most other areas of medical care, concerns arise in the context of life-saving technology. Refusal of such technology may be associated with life-threatening consequences, and a patient who refuses such treatment could be seen to be attempting suicide, an offence under the IPC. A physician who concurs with such a decision may be accused of abetting suicide, and unilateral or surrogate decisions to withhold or withdraw therapy may be regarded as homicide.

The ruling of the Indian Supreme Court in the Gian Kaur decision (10) may be the most relevant counter to the aforementioned concerns. In this case the court drew a clear distinction between the illegality of the "unnatural curtailing" of the span of life and the legitimacy of a "right to a dignified life up to the point of death including a dignified procedure of death". Thus, the court's objection to the "unnatural curtailing" of the lifespan and its unwillingness to legitimise abetting of suicide implies that it will not permit euthanasia or physician-assisted suicide. On the other hand, its focus on the right to a "*dignified* life" and to a "*dignified* procedure of death" could be interpreted as approval for the withdrawal or withholding of ineffective therapies, and an acceptance of the importance of effective palliative care, which aims to restore such dignity at the end of life. While examining the medico-legal precedents to their decision, the court concurred with prior judgments that made a "crucial distinction between cases in which a physician decides not to provide [a treatment that] might prolong [the patient's] life, and those in which he decides, for example, by administering a lethal drug, actively to bring his patient's life to an end".

Physicians who continue to remain unconvinced by these indirect references to end-of-life care can seek protection under the statutes of the IPC. Consequently, a physician cannot be punished for the unanticipated adverse effects of an act done in good faith to benefit a patient (Section 88 IPC, e.g., sedation or analgesia intended to relieve pain, but leading to an unanticipated respiratory arrest) or for an act that has potential harm, but is performed to prevent another harm (Section 81, IPC, e.g., withdrawal of a ventilator) (9).

The Indian legal system, with its roots in English law, predominantly relies on common law decisions (court decisions made by judges). In the absence of Indian case law, our courts would not only consider the individual's constitutional rights and the IPC, but would also explore international precedents on issues related to end-of-life care. Courts in other countries have passed judgments in a number of cases and have evolved important legal principles that have universal relevance. However, it is difficult to predict how Indian courts would interpret the available international legal precedent (that predominantly supports treatment withdrawal and withholding).

In civil suits the courts look for conformity of the physician's actions with the standards prevailing in the profession (9). Though there is a lack of a wide consensus on the standards of end-of-life care, professional societies such as the Indian Society of Critical Care Medicine have published statements of their ethical position on this issue and have proposed guidelines (11) that could serve as the standard. Wider adoption of such guidelines and their dissemination to practising physicians will go a long way in engendering high-quality end-of-life care without the fear of prosecution.

However, as some of the commentaries and articles in the *IJME* (1, 3, 4) point out, many nuances still remain to be addressed. For instance, the role of surrogate decision makers for patients who lack capacity is unclear. There is no established hierarchy of surrogates, and conflicting opinions may be difficult to reconcile. Modes of promoting patient autonomy, mainly by legalising "advance directives", "living wills" and "DNR orders" will enhance the quality of care. The article by Adhikary and Raviraj (3) raises these concerns and also points to the need to recognise conflicts of interest in the proxy decision maker. Methods of resolving conflicts, especially the role of institutional ethics committees, also need to be clarified.

In most countries the legal consensus on these issues has been built up in common law from decisions related to landmark test cases. While India can go through a similar process, it could be very long-drawn-out and tedious. The alternative would be to develop statutory laws (enacted by the legislature) that could take into consideration much of the consensus that already exists elsewhere (12) to develop appropriate legal guidelines related to end-of-life issues. Recognising this, the 17th Indian Law Commission has worked on and filed a draft report related to the Medical Treatment to Terminally Ill Patients (Protection of Patients and Medical Practitioners) (2006) that has recently been forwarded to the government of India (13). It will be in the best interests of all concerned parties to lobby Parliament for quick action on this issue.

With this understanding of current Indian law, it becomes clear that physicians are more concerned than necessary about the legal implications of decision making at the end of life. When there is a concordance of opinion between physicians and the patient or his surrogates, and when such a consensus has been achieved without paternalistic or coercive methods, I see no problem in following the ethical path to end-of-life care. It is only when conflicts arise and remain unresolved despite frequent discussion that we will need the guidance provided by the statutory laws that are currently being developed.

Misconception of the physician's duty

Amongst the *IJME* reports, the two first-person narratives (2, 6) are the most interesting because they raise major concerns about the duties of the physician in dealing with end-of-life issues. While they provide illustrations of a disregard for patient autonomy, paternalism, lack of empathy, inadequate communication, coercion, collusion and abandonment (2, 6, 7, 8). I am particularly provoked by the act that Dr Rastogi's family was forced to accept (2): being coerced to sign a request for "leaving against medical advice", or "LAMA".

Though, superficially, the term LAMA would seem to imply that this is an ethical deed aimed at respecting patient autonomy, it is in reality a euphemism for an act that flouts every ethical rule and undermines every professional obligation that a physician has in providing compassionate care to his patient at the end of life.

It usually begins with the doctor misunderstanding that his duty to his patient is to guarantee "life at any cost" and typically occurs

when the physician believes that saving a life is the only goal of medical care or at least one that supersedes all other goals, including the relief of pain and the provision of comfort. Compounded by the erroneous assumption that medical technology can save every life it is used on, the physician takes on a paternalistic attitude and overrides any request by the patient or his surrogates to limit care, even when the harm associated with such care seems to exceed any benefit.

While it is likely that such an attitude may arise when "a patient's death is viewed as a personal failure" (7), it is also likely to be one that is propagated by confusion about the physician's ethical obligations and legal restrictions. This physician is often unable to distinguish between euthanasia and the limitation of ineffective care, and avoids any act that may ultimately end in the patient's demise, often out of concern that the law will hold it against him. Even as he realises that his patient is not showing signs of recovery, he is unwilling to admit to the family that his initial judgement of prognosis was erroneous and he does not engage in communication to ascertain the patient's wishes or the surrogates' desires. This results in a persistence or even acceleration of potentially uncomfortable treatments despite the downward spiral of the patient's clinical status. The deteriorating vital signs further increase the physician's anxiety about the imminent death of the patient, despite his best efforts, and he becomes increasingly belligerent, handling the family's request for comfort care with increasing brusqueness.

Then, just as he seems to be excelling in his disregard for patient autonomy and reaching the pinnacle of inappropriate professional behaviour, he resorts to the most unprofessional conduct of all—he decides, unilaterally, to abandon the care of his patient while transferring all the responsibility of this decision to the patient and his family. He reiterates his "unwillingness" to withdraw ineffective treatments and technology, but "generously" offers the family a "benign exit", that is, to sign the patient out "against medical advice", absolving the doctor of any responsibility in the death of the patient. LAMA is a coercive and paternalistic method of breaking away from one's responsibility to a dying patient and an act that only promotes mistrust of the medical profession. A physician with an adequate understanding of ethics, knowledge of his professional duties, and trust in the judicial system, will never resort to such a disingenuous act.

There is no doubt that decision making is quite complex in end-of-life care in this era of life-saving technology. However, a physician with a clear understanding of ethical principles, unafraid of the aberrations in current law and mindful of his professional obligations can help to preserve a patient's dignity in his final hours and restore the public's faith in a profession that is increasingly perceived as being uncompassionate.

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Impact of life-prolonging technologies on end-of-life care in India

Sunil K Pandya

The debate on end-of-life care is just beginning in India but has been going on in developed countries for some decades. Since our conditions are markedly different from those in Europe or America, it is good that we are charting our own path.

In the opening paragraph of his first person account (1), Dr Rastogi highlights a fact that all of us must ponder. Advances in medical technology have now made it possible to keep the heart beating far longer that it would have in decades gone by. The crucial questions Dr Rastogi asks — and, indeed, all doctors looking after seriously ill patients must ask — are: At what cost are we keeping the patient's heart beating? Is the ultimate outcome likely to bring happiness or sorrow to the family?

I see, all too often, patients in our intensive care wards who are sarcastically but realistically referred to as cabbages. There they lie, in deep coma, oblivious to the world and likely to remain so. Relatives come, offer affection, encouragement and hope but the recipient of this outpouring of concern and love will never know of their attendance or their sentiments. The irreparably damaged brain has rendered the patient insensitive in all senses of the term.

Even when doctors are certain – from their tests and assessments – that the patient will never regain meaningful consciousness, they persevere in their ministrations. Deep coma and attendant paralysis renders the patient vulnerable to a variety of complications – infections, pressure sores on parts of the body bearing weight, clotting of blood in the veins of the lower limbs and danger of these clots suddenly breaking loose and invading the veins of the lungs. Often these patients cannot breathe and are therefore made to do so by a machine. All this care comes at a horrendous cost.

No relative would begrudge cost if the outcome were likely to bring happiness. Even the poorest of the poor at hospitals such as the K E M Hospital in Parel, Mumbai will manage to gather the required funds, often by selling the small plot of land owned by the family or the mangalsutra adorning the mother's neck.

Decisions on whether or not to continue such expensive care should, rightly, be made by the relations. Unfortunately, faced with the prospective loss of a loved one, emotion overpowers reason. "Please do whatever you can to save his life, doctor," is the statement most doctors hear from the responsible relation.

It is only when days and weeks later, after paying huge sums that the family often can ill afford, when the family sees the patient in almost exactly the same condition, that questions on efficacy of treatment emerge. When searching questions elicit information from the doctor to the effect that no one can predict whether or not the patient will improve beyond this stage, panic sets in. At this stage, the law will not allow termination of life and so the tragic drama must be played out till, eventually, infection or some other complication calls the finale.

Dr Jindal (2) discusses some of the questions that we must consider in all strata of our society, now. Does an individual possess the right to refuse treatment? Who else can decide on treatment options? Who is to bear the costs of life-prolonging treatment? To what extent is the medical team responsible for the terminal care?

India needs legally valid guidelines on these and other crucial issues. We need to know the conditions under which a person in full possession of his/her senses can dictate that doctors should not embark on dramatic, expensive measures to save his/her life when the prospect of meaningful existence is virtually non-existent. Such a person is in dread of being a "living corpse" with tubes sticking out of every imaginable and unimaginable orifice in his/her body. He/she also wishes to spare his relations crippling costs and prolonged agony.

We also need legally valid guidelines on whether, under specified circumstances – such as the presence of widespread malignant cancer or a mercilessly progressive disease that paralyses the patient and will eventually render him/her unable to breathe or swallow so that he/she may choke to death – the doctor can be empowered to follow the patient's order to stop any further treatment. This is not termination of life. It is a decision to prevent tragic and soul-deadening prolongation of a life that has lost all meaning and, in any event, is soon to end.

Western countries have legally valid empowerment of the patient such that he can issue an "advance directive", "living will", "do not resuscitate" (DNR) order and "durable power of attorney for health care". We desperately need such empowerment of our citizens.

Guidelines already laid down need to be widely disseminated and acted upon. The definition of brain death is now part of an Act passed by Parliament and yet we see so much misconception on it. Endless tragedy has followed the decision by hospital administrators to refuse

clinicians in their institutions to take off all life-support systems once the diagnosis of brain death has been made.

Finally, we need to consider the dilemma posed by the death, some months ago, of 25-year-old K Venkatesh from muscular dystrophy in Hyderabad. Aware that he would soon die no matter what his doctors did for him, he pleaded that they be allowed to harvest his organs for transplantation so that other lives would be saved. This heroic gesture was fully supported by his mother, K Sujatha. Since there was a grave risk that Venkatesh, in his enfeebled state, would suffer widespread infection that would make transplantation of organs impossible, Venkatesh and Sujatha pleaded that his organs be harvested by terminating his life.

Venkatesh did not seek an escape from an ordeal or from suffering. He wished to perform a final act of service to his fellow beings before his inevitable and imminent death. As Sujatha put it, "euthanasia" and "mercy-killing" were mere terms that meant nothing for them. Alas! Venkatesh's wishes could not be respected. His organs could not be used to save other lives.

The crucial factor to be underlined is that all that needs to be done – some of which has been briefly referred to above – must be achieved by society at large and not by the medical profession. Rightly, doctors have been criticised for their paternalistic attitude towards patients and relatives. It is therefore fitting that the movement to bring the necessary changes in our law and practices into being must be made by society.

Who forms society? The masses, desperately concerned about their next meal, are unlikely to spearhead changes. The responsibility must, perforce, fall upon our intelligentsia – professors, scientists, lawyers, philosophers, social workers, media experts, civil servants and others – to arrive at a consensus on each of the various issues after honest, practical and soul-searching discussion and debate. The consensus decisions can then be discussed among widening circles before being incorporated in law.

We are already far behind the rest of the world in empowering our citizens to make their own decisions on the ending of their lives. It is high time we catch up.

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End-of-life issues neglected in India

Anil Kumar Rastogi

As an invasive cardiologist in the US I deal with end-of-life issues almost daily. It is my experience that many elderly patients survive cardiac arrests with a very poor quality of life or in a vegetative state. I have seen too many such patients living a miserable life for months in a hospital or nursing home bed, with the family suffering too. With advances in intensive medical care and life support systems, life can be prolonged indefinitely making it difficult to die in peace.

I was worried about similar suffering when my 81-year-old mother was admitted to a private hospital in Delhi, having suffered a stroke and spine fracture. She stayed there for over three weeks. She was seen and followed by two internists, a spine surgeon, a general surgeon, a cardiologist, a neurologist, a dermatologist and a gastroenterologist in addition to an intensive care specialist and an anaesthesiologist.

I felt that the doctors did not work with the family to make proper end-of-life decisions for my mother. It appeared that they were more interested in prolonging life (by machines) regardless of the continued suffering even when there was no hope for recovery, indirectly to collect the daily intensive care charges.

This was a well-reputed private hospital in South Delhi, but the doctors were very difficult to communicate with. When I called from the USA — after postponing my own scheduled surgery— they would shut off their cell phone or ask me to call later, at times requiring me to place a call after midnight US time. When my mother went into a coma after an episode of cardiopulmonary arrest, all the doctors, including the specialists, told the family and me that there was no hope of her coming back to a meaningful life. They felt that even if she lived she would be bed-ridden permanently. At this point the family decided to request that no life support or repeat intubation be performed. Care would be restricted to providing comfort. I personally communicated this to the attending physician.

My mother was still in a coma but was able to breathe and hence the ventilator was removed. The family had already decided not to place her back on the ventilator so as not to prolong her suffering. The doctors were informed of this decision. We were even willing to give our wishes in writing to the doctors to avoid any legal liability.

However one morning we were surprised to see her tied to the bed, intubated and placed on the ventilator again. The physicians were rude to the family. The attending physician said that he was obliged to keep her alive with machines even if this was against the family's wishes. I personally begged him not to make her suffer, and not to artificially prolong her life since he had determined that there was no hope of her coming back to a meaningful life after cardiac arrest and coma. He seemed to have no idea of the concept of "end-of-life care". He said, "This is not done in India."

Finally, the attending physician advised the family to sign a form indicating that she was leaving against medical advice. With no other option, the family signed a "discharged against medical advice" form – on the advice of doctors! This was the only option we had to avoid further suffering. My mother was still in a coma, intubated and on oxygen when she was taken home transported by an ambulance. She passed away peacefully surrounded by the entire family within two hours of arrival in our family home on February 13, 2005.

For the last 25 years that I have practised in the US I have always made sure that in similar circumstances I go out of my way to help the family. I call one family member every day so he/she does not have to hunt me down. I make sure that the family's wishes are carried out. I return every phone call promptly, especially when it is from out of town. When there is no hope for the patient's life or quality of life, it is my feeling that everything possible must be done to make the patient comfortable and avoid suffering. The family becomes very important, since the family survives the death and deals with the doctor and hospital afterwards.

End-of-life or hospice care in the US is very important — so important that recent regulations require that doctors wishing to renew their medical licenses must spend many hours of continuing medical education in the field of "end of life care" and "pain control". Now there are many lawsuits connected to similar issues where life support was implemented or continued against the wishes of patient and family. Ironically studies have shown that approximately 80 per cent of health care expenses are spent in the last few weeks of life.

I am sure that in future years, Indian medical education will recognise the importance of end-of-life care. We all know that when it comes to us personally we do not want to live and suffer in a hospital or nursing home before we die. We all want to die quickly without suffering. When we cannot make such decisions for ourselves we depend on our family members to decide for us. This is a very difficult decision

for the family but it has to be made. Once this decision is conveyed to the doctor, it is the doctor's duty to carry it out and work with the family to make patient pain-free and comfortable.

Our family was very unhappy with the attitude of doctors with their hostile nature and lack of cooperation, especially during the last few days of our mother's life. After her death I did have a long talk with the medical director of the hospital and he did agree that they could have done better. He told me that this could be a learning experience for the doctors. He was very receptive and apologetic.

It is time to take action now, or others will undergo a similar ordeal. I suggest that every hospital in India should have an ethics committee, similar to what we have here in the USA to deal with such matters. The committee must include physicians, nurses and also someone non-medical from the community such as a priest or well-respected volunteer. It should advise the attending physician who has the ultimate authority. Hospice services should be available to patients and families in India. My family and I are writing this to improve conditions in India, a final gift from our mother to our motherland.

Do Not Resuscitate orders

Sanjib Das Adhikary, R Raviraj

The Do Not Resuscitate (DNR) order is still not documented legal practice in India. It is a verbal communication between the clinician and the patient's relative or caregiver. The autonomy of the patient also remains a weak concept. Even the right to live a dignified life or die a dignified death has not been extensively discussed. The law is silent or ambiguous on most issues related to end-of-life care. The financial status of the patient appears to be the deciding factor. In most cases health care expenses are entirely borne either by the patient or by the patient's relative (1).

The DNR order is a well documented and accepted concept in most developed countries. Nearly 15 per cent of patients with DNR orders have undergone surgical procedures including tracheostomy, gastrostomy, and central venous catheter insertion (2). In 1993, the American Society of Anaesthesiologists adopted guidelines for the anaesthesia care of patients with DNR orders, as well as other directives that limit care. These were subsequently updated and emphasise the importance of the autonomy of the patient and shared decision-making between patients and clinicians about the limitations of treatment in the operating room (3). The Limited Aggressive Therapy Order, evolved in 2003, offers the patient the option of giving consent for cardiopulmonary resuscitation, particularly in situations in which a response has a higher rate of success, such as a witnessed cardiopulmonary arrest (4).

In India such guidelines are not followed in their entirety, or are difficult to follow when treating terminally ill patients. Guidelines were recently proposed for limiting life-prolonging interventions and providing palliative care towards the end of life in Indian intensive care units (5). However, similar guidelines are lacking in an operating room set-up where the chance of survival in "witnessed arrests" is high. We present a case which illustrates some of the ethical challenges likely to be encountered while resuscitating in the operating room.

The case report

A 45-year-old man with hepatitis and features of hepatic encephalopathy was admitted to the department of gastroenterology and hepatology after a two-day history of disorientation, passing of blood in the stool, and generalised swelling of the body. A central venous access in the operating room was planned to administer antibiotics and monitor central venous pressure, as peripheral venous access was difficult. The attending physician made this decision after discussions with the patient's relatives. Although he was diagnosed to have chronic hepatic failure, he was not treated as terminally ill and hence there was no discussion of DNR orders at this stage. The patient's relative was taking care of him financially.

Before being shifted to the operating room (OR) the patient was clinically "sick" but haemodynamically stable, with a heart rate of 103 per minute and blood pressure of 110 /60 mm of Hg with Glasgow coma scale of 13 /15. He was shifted to the OR with administration of oxygen by mask at the rate of 5 litres per minute, with a pulse oximeter continuously measuring the arterial oxygen saturation. According to the ward nursing staff, who accompanied the patient to the OR, he had signs of life while being shifted; he was moving, but this movement affected the accurate recording of saturation. This is often the case when patients are being transferred.

When he arrived at the OR's reception desk, we noticed that he had no pulse and no signs of spontaneous respiration. Considering this to be a witnessed arrest, that is, an immediate event, external cardiac massage was started and the patient was intubated and ventilated. After intratracheal and intravenous administration of drugs and resuscitative measures for four to five minutes, he had cardiac activity and after about 20 minutes he reverted back to sinus rhythm. We established a central venous access through the right femoral vein and the radial artery was cannulated for invasive pressure monitoring during the resuscitation process. His pupillary reflexes at the end of resuscitation were found to be intact. Because of the timely intervention, the patient could be resuscitated in the controlled environment of the OR. After the resuscitation, we discussed this critical event with the concerned physician and the patient's relatives. However, the relatives were unhappy about the resuscitation and declined financial support for the resuscitation efforts as well as for further terminal care measures.

The patient was shifted to the gastroenterology High Dependent Unit (HDU) and was mechanically ventilated. After arriving at the HDU inotropic support was withheld, following the relatives' request. The patient died after 24 hours.

Discussion

The constraints and pertinent ethical questions in this case, we feel, are: the limited time for discussion with the patient's relatives and treating physician during an acute event in the OR; obtaining advance directives for DNR in such a case for any procedure in the OR (issues related to autonomy of the patient); who is eligible for giving consent in such a situation (issues related to proxy consent), and who is financially responsible for the whole process, the institution or the relative?

One of the first questions to be asked in such a case is: should the patient have been resuscitated at all? This question addresses a major concern of medical ethics and law, about the patient's right to choose the form and nature of his or her medical care, including the right to informed consent or informed refusal. In our case neither the patient nor the relative had given or indicated informed refusal when the patient was taken to the OR for the procedure. In addition the patient had been haemodynamically stable until the procedure. DNR had not been discussed and was not considered till that time. Consent to high-risk (death on table) procedure prior to taking the patient for the procedure had not been obtained. Considering all these factors, resuscitating the patient would be justified. However, the absence of high-risk consent and preliminary discussion before the procedure increases the gravity of the event and poses a major dilemma regarding resuscitation. The medicolegal implications of such an omission can be severe and this incident emphasises the point.

In a witnessed cardiac arrest, every second plays a role in determining the post-resuscitative outcome. There will always be constraints of time to discuss the patient's condition with the relatives and the concerned physicians prior to or during the resuscitation. There are guidelines for DNR orders in such scenarios in developed countries. In the absence of a DNR order it is usual practice to resuscitate the subject without losing any time in discussing the terminal condition of the patient. We followed the same strategy in our case because we aimed for a favourable outcome. As described by Mani et al (5) in these circumstances it is important to initiate an end-of-life discussion which should guide the resuscitation team on management plans even in witnessed arrest situations.

When the patient is not in a position to give consent, the consent given or obtained in such circumstances is called proxy consent. Ideally the patient's relative or caregiver gives proxy consent. Proxy consent involves both substantive and procedural questions (6). Ideally, a person with the most accurate and intimate knowledge of the patient's recent wishes and lifestyle should give proxy consent. S/he should have a maximum stake in the decision and should be responsible for the consequences. In this case, however, proxy consent was not possible. In developed countries people's daily needs and medical care at the end of life are usually looked after by government agencies or insurance companies. This is not the case in India. Caregivers here may feel that the death of the person they care for will relieve them of a burden. This can lead to a conflict of interest arising from the treatment decision.

Another point to be noted in such cases is the term "withdrawal" or "withholding" of treatment. In this case, following the instructions of the treating physician, inotropic support was withheld after the relative's intervention. This resulted in a deterioration of the patient's cardiovascular status and in his eventual death. The difference between withholding treatment and withdrawing treatment has ethical implications, though the final event in both cases is death.

Withdrawal of a treatment may lead to death. In such situations, it can be stated that the patient's death was directly related to the withdrawal of the treatment. On the other hand when the treatment is withheld, it seems natural that the patient died of the disease. This is important because the practitioner may be relieved of a sense of guilt when the treatment is withheld rather than feel guilt when the treatment is deliberately withdrawn.

In our case, the treating physicians called it withholding of the treatment because they did not continue to add to the inotropes once the infusions got over. Thus inotropic support was withheld. However it can be argued that as inotropic support was already started in the OR, its discontinuation in the HDU amounted to withdrawal rather than withholding of treatment. Such terminology is relevant when finalising guidelines.

Conclusion

What emerges from this discussion is the deficiency in applying ethical concepts and principles of decision making to terminally ill patients in operating rooms in India. Clear guidelines for the care of terminally ill patients in the operating room need to be drafted, keeping in mind the financial and emotional burdens to the family. The medical community, particularly critical care physicians, must work towards evolving legislation appropriate to the Indian scenario.

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The team had no options

Sunil K Pandya

As noted by the authors, DNR is not yet recognised by law in India. There is, thus, no legal validity to such a directive. Under the circumstances the physician must tread carefully between legal imperatives and the principles of humane behaviour. Where there is reasonable ground to make a poor prognosis regarding recovery and survival, the physician is justified in obeying instructions issued by the patient or legally recognised next-of-kin to refrain from resuscitative measures and artificial means of propping up blood pressure or making the patient breathe. These instructions must be recorded on the patient's case paper and witnessed by a representative each of the family and of the hospital.

Where there is a fair probability of recovery and survival, everything possible must be done to help the patient unless specific instructions are given by the patient or legally recognised next-of-kin to stop treatment and resuscitation. These instructions must be recorded on the patient's case paper and witnessed by a representative each of the family and of the hospital. The instructions must record that the patient (if conscious) and family have been told in no uncertain terms and have understood that depriving the patient of treatment recommended by the medical team will harm him/her and may even result in his/her death.

The differentiation by the authors between withholding treatment and stopping treatment that has already been instituted is important and legally relevant. Where the prognosis is bad (an example is widespread highly malignant cancer), withholding resuscitative measures merely permits nature to take its course without interference by the medical team. If, however, someone has already inserted an endotracheal tube and started artificial respiration using a ventilator, removing the ventilator leaves the doctor open to the accusation of acting to terminate the life of the patient. The argument that the patient has advanced cancer and that death is to follow soon will be countered by the query: "If that be so, why was the patient intubated and ventilated?"

In the case under discussion, the medical team had no option but to do what they did. Any other action – or inaction – would have laid them open to the charge of grave misconduct and medical negligence.

As is correctly pointed out, a sudden collapse of the patient demands immediate resuscitative efforts and there is no time to be lost. Consultation with the patient's family is impractical and even unwise under the circumstances.

The team treating the patient were right in discussing with the family the patient's collapse and the measures successfully adopted to resuscitate the patient after the patient was in a stable condition.

The family's decision, based on purely financial considerations, is their prerogative. As noted above, instructions issued by them in writing, after they have understood the ill-consequences to the patient stemming from these instructions, have to be followed and were followed in this case with fatal results. The responsibility for the death, however, rests entirely with the family. The medical team cannot be faulted.

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Guiding light at the end of the tunnel

Vijaylaxmi Kamat

The most important issue here is obtaining informed consent for any procedure. Informed consent should be patient- and procedure-specific; otherwise there is a gap between what has been explained to the patient and what s/he has understood. A mere signature does not signify full comprehension. The process of informed consent must be one in which the patient and the relatives are taken into confidence and the risks involved in the procedure are explained to them. The process should envisage acute events that might occur and their subsequent treatment. The occurrence of a cardiac arrest was obviously not anticipated in this case, and because it was sudden, resuscitative efforts were attempted without having the time to take the relatives' consent. As the authors themselves state, "…the absence of high-risk consent and preliminary discussion before the procedure increases the gravity of the event and poses a major dilemma regarding resuscitation. The medicolegal implications of such an omission can be severe and this incident emphasises the point." (1)

The second important issue is that of obtaining advance directives for Do Not Resuscitate (DNR) orders when this type of case comes up for any procedure in the operating room (issues related to the autonomy of the patient). An advance directive is a document signed by the patient nominating the spouse, relative or other person who is entrusted to make medical decisions when the patient is unable to do so. In the directive, the choice of treatment in certain situations is given. For example, it might ask that the patient not be resuscitated in the event of a cardiac arrest. Both advance directives and DNR orders are not commonplace in India. Hence it is very difficult for physicians to decide on continuing or withdrawing treatment in many situations, while also respecting the patient's autonomy.

In February 2005, The Indian Society of Critical Care Medicine (ISCCM) (2) published guidelines for limiting life-prolonging interventions and providing palliative care towards the end of life. Guideline 2 states:

"When the fully informed capable patient /family desires to consider comfort care, the physician should explicitly communicate the available modalities of limiting life-prolonging interventions. If the patient or family do not desire the continuation of life-supporting

interventions the available options for limiting the supports should be identified as follows: (i) do not resuscitate status (DNR), (ii) withdrawal of life support and (iii) withholding of life support."

What are the legal implications of limiting support? The Indian judicial system has no clear stand on end-of-life issues except that suicide and abetment to suicide are punishable offences, hence withdrawal of life support even with the expressed consent of the patient or next-of-kin can be misinterpreted as physician-assisted suicide.

However, with the publication of the ISCCM guidelines and constant interaction with the law ministry, some changes are apparent. Justice M Jagannadha Rao, chairperson of the Law Commission of India, states that the commission has recently taken up the study of legal issues relating to "limiting life support" in patients in intensive care units (3).

This is important because until now, the law has been contradictory on such issues. For example: In P Rathinam and another vs Union of India and others JT 1994 (3) SC 392, the Supreme Court held that punishment for attempted suicide is unconstitutional. The Court ruled that an attempt to hasten death may be viewed as a part of a natural process. "A person cannot be forced to enjoy the right to life to his detriment, disadvantage or dislike." The Supreme Court thus recognised "the right to die" in that case. If a person has a right to live, he has a right not to live.

The above judgement of the Supreme Court stands overruled by a Constitution Bench of the Supreme Court in Gian Kaur vs the State of Punjab, in JT 1996 (3) SC 339: The judge ruled that permitting termination of life in the dying or vegetative state is not compatible with Article 21 which states: "No person shall be deprived of his life or personal liberty except according to procedure established by law."

Citing these two judgements, Justice Panachand Jain observes, "The patients who are in a permanent vegetative state may be allowed to die by seeking direction from the Court for the removal of the feeding tube. Law must march, in a changing society, in tune with the changed ideas and ideologies." (4)

There seems to be some light at the end of the tunnel, and fear of litigation should not deter physicians from honestly discussing end-of-life issues with family members.

The third important issue relates to who is eligible for giving consent (issues of proxy consent). In the case of an advance directive, the living will or durable power of attorney is automatic, and the patient

names the surrogate who is eligible to make decisions. In most US states, the surrogates are: spouse, adult child, parent, sibling and nearest relative.

The decision to withhold and withdraw life support in a comatose patient, in the absence of an advance directive, becomes problematic in India, where the term "family" is loosely applied. If the spouse is female, she is rarely allowed to make decisions, while several male members of the extended family can have conflicting opinions.

It is therefore all the more important for the primary physician to have an excellent rapport with all available family members, as effective communication is the key. Even in the US, Puri states, "The families are often hopelessly confused and divided, as the physicians concentrate on the technical aspects of life support devices. Thus, every patient-family faced with withdrawal of treatment goes through a process of making decisions, when least prepared." (5)

Guideline 6 of the ISSCM states, "The overall responsibility for the decision rests with the attending physician/ intensivist of the patient, who must ensure that all members of the caregiver team including the medical and nursing staff represent the same approach to the care of the patient."

The fourth important issue is: who is responsible for taking care of the financial aspect of the whole process, the institution or the relative? This is the most contentious issue of all. Unlike in advanced western countries, 82.2 per cent of the total health care bill in India is paid out of pocket by the patient or her/ his family. Public hospitals, which offer free treatment, have a severe shortage of intensive care unit (ICU) beds. Socio-economic considerations complicate the delivery of intensive care and especially end-of-life decisions.

In their study of four hospitals in Mumbai, Kapadia et al (6) showed that limitation of treatment and withdrawal of treatment were at least twice as common in private hospitals than in the public general hospital, which probably reflects the financial constraints of the patients' relatives. Taking into account the financial burden on the patient's relatives, the ISCCM guidelines assume importance.

Guideline 1 states, "The physician has a moral obligation to inform the capable patient/family, with honesty and clarity, the poor prognostic status of the patient when further aggressive support appears to be non-beneficial. The physician is expected to initiate discussions on the treatment options available including the option of no specific treatment." Thus, the relatives are spared the guilt of withdrawing or

withholding treatment when such expensive interventions will not alter the outcome.

I end with a quote from an article (7) in *The Hindu* by the immediate past president of the ISCCM, Dr Ram E Rajagopalan:

"...India stands out as one of the few countries in the world that have no laws on limitation of treatment. It is this issue, not euthanasia, that is being addressed by the Law Commission. As we recognise the burdens imposed by modern medical technology and realise that the constitutional guarantees of individual liberty are being neutralised by an antiquated Penal Code, we come to appreciate the urgent need to formulate new laws. These laws will go a long way in minimising the emotional and financial hardships faced by patients who are condemned to unwarranted therapeutic excesses."

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The friend

Kishore Shah

Suresh and I [KS] were called the Siamese twins. We went to the same school and college. We branched off later — I became a doctor and Suresh an engineer — but we kept in touch. When he told me of his daughter's marriage I was overjoyed, but then my son's college entrance exam was in Mumbai on the same day. Suresh instantly forgave me even while warning, "Come home as soon as you return; you are always late… "

The marriage went off smoothly and Suresh was sitting with his brother discussing the day's events when he suddenly collapsed. By the time he was shifted to a hospital, Suresh had suffered from brain anoxia for 15 minutes. He arrived in the hospital without a pulse and respiratory effort. The doctors knew that they were treating a dead patient but, out of formality, they intubated Suresh, resuscitated him and admitted him to the intensive care unit (ICU). The relatives gave them my mobile number and I was phoned and told to break the news. I rushed back from Mumbai and went directly to the ICU.

Among the most difficult tasks that a doctor faces is that of telling someone that their loved one is dead. That medical science is not all that it is made out to be, that in some cases doctors are helpless. This becomes doubly difficult if the dead person happens to be one's dearest friend.

Worse still, there was no apparent explanation for this tragedy. There was no embolus in Suresh's airway. His CAT scan did not show any infarct or clot. His ECG was perfectly normal. In fact, except for absent neurological reflexes, there were no positive findings.

When I stepped out of the ICU everyone looked up with hope, despite my serious expression. Suresh's wife came rushing to me and said, "Kishore bhaiyya, thank God you have come." Suresh's brother whispered, "Kishore bhaiyya, if you want, we can transfer Suresh to your hospital. We are so relieved that you have come. We were so confused until now." How could I tell these trusting people the truth? I took Suresh's brother to one side, looked at him with brimming eyes and said, "Look, there is hardly any hope for Suresh. His brain did not receive any oxygen for a long time. His brain is dead."

"Kishore bhaiyya, I just saw his chest moving up and down. He is breathing. How can he be dead?"

"What you see is the machine pumping air in and out of his chest."

His face became confused. I was supposed to have come and waved a magic wand. He turned away from me.

Bhabhi asked, "Kishore bhaiyya, there is still hope, no?"

An outright denial was not humanly possible. I dumbly nodded, "Yes, there is a little hope."

She did not hear the word "little", or she didn't want to hear it. Her tense face broke into a crumpled smile.

The newlywed daughter came up to me and chided me, "Kishore uncle, this happened because you were not here."

I did not sleep that night. Each relative would corner and question me. I tried to be factual and harsh. Nothing worked.

The next day brought with it a plethora of unknown relatives. A gentleman from Dhulia asked, "Where is the doctor? They are not doing anything for my dear nephew." I told him that I was a doctor, though I was in the hospital more as a friend than a doctor. I told him that Suresh had undergone a prolonged period of brain suffocation. The doctors had tried their best but nothing could be done.

"Don't teach me anything!" the uncle said. "Doctors prolong treatment to extract money." He narrated the story of another nephew who was in the ICU for a month until a general practitioner solved the case. I tried to explain that Suresh's case was different. Other relatives joined in with stories of miraculous cures and I found myself fighting a losing battle. It was best to avoid confrontation and nod quietly.

Suresh's brother was sitting in a corner with his head in his hands. I told him, "Look, it is time that we accept the fact that Suresh will never come back. Let us donate his organs to someone who really needs them. At least his eyes. Let Suresh die a dignified and helpful death. I am sure he would have approved of it himself."

He looked at me aghast and burst into tears. I tried my best to console him. After some time he said, "I have heard of a doctor in Chennai who performs miracles with such cases. I am going to get that doctor."

If I dissuaded him, I would become an enemy for life. If I agreed, I would be responsible for his failure. I merely nodded and said, "It's your money."

"Don't talk about money!" he shouted. "Are a few metal pieces more valuable than my brother's life?"

I had no arguments against his statements. The next day I saw that someone had put a vermilion mark on Suresh's forehead. The number

of relatives in the waiting room had doubled. Lemons and chillies were strung here and there. Bhabhi said, "He is improving, I heard him groan."

I quickly changed the topic. "What are these lemons and chillies doing here?"

"That is what helped. Our uncle from Dhulia brought Baba Tribhuvan who has promised that Suresh will walk in 15 days."

I asked with a sinking heart, "How much did Babaji charge?"

"Babaji never charges a paisa. Uncle told us to give him some dakshina. He will donate it at Babaji's ashram."

Suresh's brother pulled me to one side and said, "Kishore, please do something. I heard that there is vast knowledge on the Internet. Ask your friends. There must be some way to get Suresh up." I knew nothing could bring Suresh back, but I searched the Internet for hours for a miraculous cure. I wrote to my alumni group. Everyone told me the same thing. There was no hope. The circus of charlatans continued for four more days. A week after Suresh was admitted to the ICU it started dawning on everyone that may be what the doctors had been saying all along was right.

Some relatives were aloof as if I were somehow responsible for Suresh's plight. Bhabhi refused to meet my eyes. She had come to know that I had advised organ donation and could not believe that I could be so cruel.

Suresh's brother came to me and said, "We have decided to stop all the life support. It has become unbearable for all of us." I patted his shoulder and held him.

The time for disconnecting the ventilator came. All the relatives were weeping. I stood next to the body of my friend of many years. The machine was switched off.

Through the funeral journey, I pondered over my failures. I had failed as a doctor. I could not revive my friend. I had failed as a friend to protect his relatives from so-called well-wishers. I had failed as a human being to convince the relatives to at least donate his organs for the benefit of humanity.

Not a personal failure

Ratna Magotra

Most doctors have faced this situation and are familiar with the writer's feelings of helplessness, pain and anguish.

We doctors take ourselves too seriously as life-givers. A patient's death is viewed as a personal failure and, when the patient is a close relative or a friend, it is difficult to resolve the mix of emotion and abstract clinical response. We often forget that our prime aim is to function as healers and discharge our responsibilities honestly and diligently. Beyond this, the results are decided by another, Supreme Power.

In this case, Suresh arrived at the hospital without a palpable pulse and respiratory effort and was therefore clinically dead. He was electively put on a ventilator while waiting for Dr Shah's arrival.

An EEG examination should have been requested, as the family would more easily accept a documented brain death as compared to verbal explanations. I find that a CT scan was done but an EEG was not asked for. It is also my feeling that the decision-making should be done strictly by the treating doctor/s after detailed communication with the family. The role of a doctor friend or a doctor relative should be limited to providing emotional and logistic support. This would ensure that interventions and decisions are made on the basis of sound and unbiased judgement, so necessary in good clinical practice. This would also prevent the doctor friend from feeling guilty. Similarly, organ donation is a sensitive topic and should only be broached by a professional organ donation team. Finally, doctors need to learn early, preferably during their training, that they are not God in a white coat.

Denial, collusion and inappropriate hope

S N Simha

The story about Kishore, a doctor, and his friend Suresh, is a classic example of what happens when there is improper communication between health professionals and the individuals they care for.

The entire problem began when the doctors admitted Suresh in the ICU even though he was brain dead. We tend to be overwhelmed by the distress and anxiety of the family and take the easier way out — admit the patient rather than counsel the family.

An important thread that runs through the story is that of hope. The subject of hope invokes emotional and sometimes violent responses from people. "Who are we to kill someone's hope?" or "How can we play God and say that there is no hope?" I liken hope to a drug. It has its uses. It must be administered in appropriate doses, at the appropriate time. It has excellent therapeutic value but also has dangerous side-effects. Hope is good, but it must be appropriate. Right through the story, the avoidable agony was created by holding on to inappropriate hope. While it is perfectly natural for the family members to do so, the health professional must use all his skills to steer the family safely at times of crises.

I understand the agony of Kishore, who had two roles to play – doctor and dear friend. When there is conflict between these two, it is best that one withdraws from one of the roles – the choice is left to the individual's comfort. Health professionals forget that they are also human and have normal feelings. One of the difficulties in communicating bad news is that we feel personally "responsible" or "guilty" for what has happened. We are loathe to "let the patient down".

Another major issue is denial. It is how one simplifies the complexities of life. It reinterprets a part of or the whole situation that is painful and looks at it as one wishes it to be. Denial is an excellent coping mechanism, used effectively by many. As you read the story, you find denial everywhere. In a situation like this, the health professional must use all his skills to break denial. It is important to know when denial needs to be broken — when it causes refusal to take treatment, prolongs expensive ineffective treatment or makes the patient commit acts that would pose grave danger or financial ruin to himself and his family. Kishore could have challenged the denial by

saying something such as, “How do you say that he is OK or improving?” or, after presenting medical facts gently, say, “I know it is difficult for you, but is it not obvious that our hope is inappropriate?” and “Keeping him on the ventilator is only prolonging Suresh’s misery and serves to make us feel less guilty.”

Relatives are well-meaning but create problems without intending to do so. One must not take a confrontational attitude or be unduly upset. The basis of their acts is love and concern for the patient. They are also in denial-unwilling to accept the truth.

Using faith healers, alternate treatments, etc, is natural. It is born out of the inbuilt desire to live on. There is no harm in allowing the family to pursue all possible channels, as long as you, as a health professional, are not responsible for leading them up the wrong path because of your unwillingness to reveal the truth.

Hiding the truth from loved ones is referred to as collusion. It is an act of love and must not be trivialised. It needs to be handled with sensitivity, as the emotional consequences of the pretence or charade are devastating.

Health professionals must learn to identify key people of the family and restrict their communication with these individuals to prevent unnecessary confusion.

And finally, Kishore’s guilt that he “failed as a doctor because he could not revive his friend” is understandable, but it was not possible for him, under the circumstances. Yes, he failed by not addressing the other important issues — that of denial, collusion and inappropriate hope.

Medical instruments of the state?

Mihir Desai

Health professionals are committed to working for the mental and physical health of their patients. However, public health crises, for instance, in the case of an epidemic of tuberculosis, may create a conflict of interest between the rights of the individual and those of the public, and health professionals may have a genuine choice to make in their capacity as providers of health care.

Does this conflict exist when medical professionals play a role in the law enforcement process? Do they have a choice to make between the interests of the patient and those of the state? And what if the state asks them to participate in human rights violations?

This section illustrates such questions with reference to two highly charged debates in India: the narco analysis test and the death penalty. Medical professionals and human rights advocates are involved in both these situations, and the ensuing debates have thrown up some important questions: Do these practices constitute human rights violations? If so, what are the implications for ethics when medical professionals get involved in them?

Narco analysis requires the presence and active involvement of an anaesthesiologist and a clinical psychiatrist. The anaesthesiologist injects the drug, which is meant to loosen the resistance of the person being interrogated, while ensuring that only the required amount is introduced into the recipient’s system. The psychiatrist asks the questions on behalf of the police.

There are four major ongoing debates regarding the narco analysis test. The first concerns its very utility—does it in fact make people speak the truth? The second question is whether such a test amounts to torture. And the third is whether the test violates the right of the accused not to be compelled to testify against himself/herself. Finally, does narco analysis amount to an invasion of privacy? Running through all these debates is the issue of ethics of the medical professionals participating in the interrogation.

There has not been any discussion in India on the utility or accuracy of the narco analysis test, perhaps because this has not been studied here. However, the question of legality of these tests has been raised in cases before various high courts in India, and the courts have upheld their constitutionality. In one of the matters, which was carried to the

Supreme Court from the Bombay High Court, the former stayed the test. But this was an interim order and one awaits the final determination of the issue by the Supreme Court.

Under Article 20(2) of the Constitution, which is part of the fundamental rights chapter, no person who is accused of an offence can be compelled to be a witness against himself or herself. The accused has a right to remain silent. He or she cannot be forced to give statements that are self-incriminatory.

The courts have commented on whether a narco analysis test can be treated as asking a person to be a witness against himself or herself. The high courts have interpreted this to mean that only if the accused is forced to make a statement in court in evidence would it be hit by Article 20(3), and not otherwise. So a narco analysis test does not amount to breaching the principle of testimonial compulsion.

This appears to be very convoluted logic. The accused has a right not to answer any question that may incriminate him or her. This is a fundamental principle of criminal law. To say that this right is not being whittled away because he or she is not in court, or because the statements may or may not be used in court, appears to be totally wrong.

The other ongoing debate on narco analysis concerns compulsion and torture. Does the test amount to inflicting torture on the person? Torture is barred not only under Article 20(3), but also under the judicial interpretation of Article 21, which guarantees right to life. **Jesani**, by relying on various international commitments and interpretations, has argued that giving drugs to persons against their will can lead to psychological issues and definitely to inflicting torture. Again, the high courts have disregarded this argument. While **Mohan**, a medical professional and head of centre that conducts narco analysis, raises a number of objections to Jesani's argument, another medical professional, **Jagadeesh**, supports the viewpoint that narco analysis is a violation of rights, and against medical ethics.

The third argument concerns invasion of the right to privacy of the accused. This right has been judicially recognised as a fundamental right under the Indian Constitution. Can anybody be subjected to invasive action merely because they are suspects in a criminal case?

All these issues now await the decision of the Supreme Court, but on the face of it, narco analysis test appears to be totally unconstitutional.

The second debate dealt within this section concerns the death penalty, especially in the context of participation by medical professionals in executions.

Since the beginning of the 1990s, the death penalty has been abolished in three new countries every year. There are a number of other countries where, though it exists on paper, it has not been used for decades. Many others have abolished the death penalty for most offences except for wartime crimes. In India, on the other hand, every year newer offences are being added for which the death penalty is permissible.

One of the major controversies on this issue has concerned the participation of medical professionals. As Jesani points out, execution by hanging requires the presence of a medical professional, who must periodically examine the person being executed to see if signs of life exist, and then tell the hangman to continue with the hanging till the person is declared dead.

Now there is a strong move to introduce the lethal injection as a more "humane" method of execution in India. If this happens, medical professionals will have to play an even more active role in executions. As **Hiremath** points out, this brings to the fore the question of ethics of doctors, whose cardinal duty is to safeguard life, and who will now be actively participating in bringing about death.

Unlike the question of narco analysis, which is currently being decided upon for its constitutionality, there has been little legal opposition to the Law Commission's proposal on introducing the lethal injection as a method of execution.

The involvement of medical professionals in the execution process has been debated extensively in the West, especially in the US. However, medical associations in India have remained silent on this issue.

Indeed, they have not spoken out on either narco analysis or execution, both practices of the state in which they have played an important role.

There are a number of other situations in which medical professionals need to remember that their paramount responsibilities are to the patient: when providing health care to prisoners, when examining survivors of sexual assault, when treating political activists, and so on. As human rights activists and as those concerned with medical ethics, we need explore the implications of all such situations in which the health care system intersects with the representatives of the law.

Medical professionals and interrogation: lies about finding the "truth"

Amar Jesani

For some time now, a set of scientists has been glorifying the "magic" of a "truth serum". They insist it can make hardcore criminals talk and spill the truth about their misdeeds. Medical professionals are often involved in experiments, for many decades now, with the various technologies that are used in "lie detection", including brain mapping (polygraph and functional magnetic resonance imaging) and the so-called truth serum (use of sodium pentothal) in narcoanalysis.

Experiments with narcoanalysis were reported as far back as 1950 and with lie detection in 1953. The September 11, 2001, terrorist attack in the United States of America was a turning point in scientific research on lie detection. A PubMed search found 26 references from 1997 to 2001 (or 5.2 publications per year), but in less than five years (2002 to July 2006) the number has more than tripled to 83 or 16.6 publications per year. Many of these are randomised controlled trials.

September 2001 may have marked a radical break from the human rights commitments of the powerful nations of the world, but the police and intelligence agencies have been interested in lie detection techniques for decades. In the 1950s and 1960s the Central Intelligence Agency (CIA) of the USA funded and was directly involved, along with medical professionals, in covertly using drugs to study "behavioural modification".

In an infamous project called MKULTRA, the CIA promoted the use of Lysergic acid diethylamide, or LSD, on unknowing subjects, which resulted in the death of one subject. The uproar and subsequent investigations in the 1970s, some of them by committees appointed by the US senate, confirmed these activities of the CIA. But they could not provide evidence against individuals because, in 1973, at the order of the then chief of the CIA, important records of the experiment were destroyed (1).

Appendix A of the senate committee documents says that another experiment by the CIA called Project ARTCHOKE, using sodium pentothal, was "ended in 1956, but evidence suggests that the Office of Security and the Office of Medical Services' use of 'special interrogation' techniques continued for several years thereafter." (1) So

it was not surprising that after September 11, former CIA and FBI chief William Webster was quick to assert that the administration should look at the use of drugs such as sodium pentothal or other invasive tactics, which are just short of torture (2).

The Bangalore Forensic Sciences Laboratory (BFSL) has been conducting lie detection tests and narcoanalysis in India since 2000. The turning point for narcoanalysis in India came in 2002. In June 2002, three months after the burning of a train compartment by a crowd at Godhra in Gujarat, and the subsequent massacre of Muslims, seven persons accused of burning the train were brought to the Sree Sayaji General (SSG) Hospital in Vadodara.

They were interrogated and doctors from the medical college departments of anaesthesia, surgery and psychiatry carried out a narcoanalysis. The chief of the SSG Hospital, Dr Kamal Pathak, reportedly said, "I can't reveal anything because this is something that pertains to national interest." (3) Dr S Malini, who left the premier National Institute for Mental Health and Neuro Sciences to join the BFSL, supplements this argument by stating that such tests have a "scientific and a humane approach". (4) This echoes the former CIA chief's assertion that they are "short of torture".

The efficacy and ethics of narcoanalysis

Torture has made a renewed comeback in today's conflict-ridden world. However, sophisticated intelligence agencies know that not only is torture a violation of human rights, it does not yield the desired results. A person who is being tortured usually admits to any crime attributed to him or her and gives "information" that the torturer would like to hear.

Lie detection techniques and narcoanalysis suffer from the same problem. In these tests the interrogator is required to ask questions in the same way that the torturer asks questions. There is enough scientific evidence to show that a person under the effect of a drug often plays along with the suggestions made by the interrogator. The machines used for lie detection have also often led to the wrong conclusions. In 2005, in a case in the USA, the company manufacturing a lie detection machine, the Computer Voice Stress Analyser, was sued by the accused and forced to make a hefty payment as compensation to settle the case outside the court (5).

Legal experts have argued about the issue of privilege against self-incrimination and the involvement of torture in the use of narcoanalysis. Judgements in India and the USA on self-incrimination have given more importance to the evidentiary value

of the information obtained in narcoanalysis. But they have not given adequate weight to the fact that the law also places certain restraints on the government in obtaining information on the principle of "substantive due process".

From the legal angle we can thus ask if certain psychologically coercive interrogation techniques constitute a violation of substantive due process. Indian as well as American laws forbid torture tactics that "shock the conscience" but arguments such Dr Malini's, that narcoanalysis is a "humane method", are brought in as justifications.

The UN's definition of torture has four components: (a) it is an act causing severe physical and mental pain and suffering, that is (b) intentionally inflicted (c) for a certain purpose (information, confessions etc.), and carried out (d) by an official actor. As a result of the mind-altering effect of the drug, an innocent person may make a confession, or a machine may find his or her statement to be true or false; this is likely to lead to mental trauma for that person. Both the threat and the actual administration of narcoanalysis are intentional and involve the participation of not only the police but also of doctors.

In addition to violating the laws related to torture, narcoanalysis also violates the dignity of a person, a principle covered in the 1988 UN "Body of principles for the protection of all persons under any form of detention and imprisonment". Linda Keller (6) suggests that once we accept the truth serum as a legitimate or humane means of interrogation, we will be forced to adopt a completely new definition of torture. She argues that its use will open a slippery slope of ethics. If it is used for a "terrorist" or a Telgi today, tomorrow it could be anyone else.

The police in India have also started violating norms by airing videotaped statements made by the accused person under narcoanalysis. This is a way of masking the police's inefficiency and asserting that if the courts fail to accept the statement as evidence, the judiciary is responsible for not providing justice.

Medical professionals and interrogation

As mentioned, these interrogation methods clearly and deeply involve health care professionals in hospitals and in forensic laboratories. Luis Justo (7) has come down heavily on those participating in interrogation in the name of the "war on terror". He specifically targets the "biscuit" teams (behavioural science consultation teams), comprising psychologists, psychiatrists and other health workers, which operate in US military prisons. These are similar to teams in India's forensic laboratories. Justo writes that medical associations in the USA have strongly spoken out against these unethical actions.

The World Medical Association recently revised its Tokyo declaration (against participation in torture). It now clearly states: "Physicians shall not countenance, condone or participate in the practice of torture or other forms of cruel, inhuman or degrading procedures, whatever the offence of which the victim of such procedure is suspected, accused or guilty, and whatever the victim's beliefs or motives, and in all situations, including armed conflict and civil strife."

Justo documents a recent statement of the American Medical Association: "Physicians must not conduct, directly participate in, or monitor an interrogation with an intent to intervene, because this undermines the physician's role as healer." The American Psychiatric Association has also reiterated its long-held position against the participation in, or assistance to, interrogation by psychiatrists.

Unfortunately, not a single medical association in India has spoken out against such participation. Legal battles about the admissibility in courts of information collected by using narcoanalysis and lie detection continue even as physicians, psychiatrists and forensic doctors in India continue to violate medical ethics by participating and assisting in these interrogation sessions.

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Misconceptions about narcoanalysis

Bannur Muthai Mohan

The writer of the editorial titled "Medical professionals and interrogation: lies about finding the truth" (1) has conveyed a series of misconceptions about the technologies referred to in the discussion. Such an article should have been properly evaluated for its suitability for publication. The article has done more damage than good because of its failure to recognise the needs of the criminal justice system and its current legal position. Here are my comments on different paragraphs in the article:

Paragraph 1: The very first sentence is incorrect. It is not clear which barbiturate the author is referring to as the "truth serum". In the past, some barbiturates were used as "truth" drugs in the diagnosis and treatment of the mentally ill. Many of these, such as scopolamine, sodium amytal (ano barbital) and seconbarbital, were subsequently banned. An understanding of "truth" drugs, their characteristic actions, and their positive and negative potential for eliciting useful information is fundamental; the author seems to have lost sight of this. It is incorrect to say that the "truth serum" produces some kind of "magic". Medical professionals are not involved in "lie detection" and "brain mapping" tests but their involvement is essential for narcoanalysis.

Paragraph 2: It is true that the number of research publications on lie detection has tripled during 2002-2006. But no material has been produced that can be described as randomised controlled trials. The United States of America permits the use of the polygraph as a tool to minimise the potential for disclosure of classified information. The US department of defence is interested in increasing the use of polygraphs for security and counter intelligence (2,3,4). In addition to recent developments in the field of lie detection, the expertise of a clinical psychologist is an important factor for its acceptance as evidence before courts of law court. This has already happened in India (5).

Paragraph 5: The US Supreme Court has laid down the law and has accepted the use of the "truth serum" as an investigative technique (6). During the congressional investigation of the September 11 terrorist attack, important confessions were made by the prime accused during a sodium pentathol-aided interrogation. Pursuant to the revelations made, "The US administration privately believes that the

Supreme Court implicitly approved using such drugs in matters where public safety is at risk." (7) The US Supreme Court also says that "in cases of special government need beyond the normal requirements of law enforcement, a warranty requirement and even the requirements of suspicion may be dispensed with. The pinprick involved in delivering the truth serum [sodium pentathol] is likely to be viewed as minimal intrusion involving virtually no risk, trauma or pain, and given the special government need to fight terrorism might be justified without probable cause or a warrant (8)."

Paragraph 6: The Forensic Science Laboratory (FSL), Bangalore, has been conducting lie detection tests since 1999. The first narcoanalysis was done there in 2001 on an individual connected with offences committed by Veerappan. The author's data are incorrect.

Paragraph 7: There is no basis for the author's statement that drug-aided interrogation techniques, which are scientific and humane, are "short of torture". A clear understanding of the characteristics of the drug, its pathway of action, the technique of controlled depth of anaesthesia (9,10,11, 12), and the psychological techniques of handling a person in a "state of trance" will eliminate the ingredients constituting "torture".

Paragraph 8: The author may be aware that "third degree" methods adopted by investigating officers have failed to yield useful information in most cases and this is a major cause of the low rate of convictions. Such methods in fact make the individuals more hardened and disinclined to reveal any information, particularly in cases of organised or terrorist crimes. The author is not justified in using such words as "torturer" and such use is in bad taste.

Paragraph 9: Lie detection and narcoanalysis are based on entirely different principles. The former is based on the emanation of physiological /autonomic responses while answering the questions framed by the clinical psychologist. The latter is based on how sodium pentathol handles GAABA (gamma amino butyric acid), a neurotransmitter inhibitor. The inhibitory character of an individual is controlled by the depth of the anaesthesia and by psychological techniques specific to dealing with an individual in a "trance". A clinical psychologist may evaluate the appropriateness and efficacy of eliciting information in this manner. All the parameters required for narcoanalysis and the degree of conscious awareness are constantly measured and monitored. Quantitative data are now available to determine the concentration of the drug administered at any point of time during

the procedure and evaluate the level of confidence one can have about the outcome of such procedures. A case where the use of the machine led to wrong conclusions cannot be the basis for dismissing the technology.

Paragraph 10: The legal position about the constitutional rights of individuals against self-incrimination while subject to narcoanalysis has become clear after a number of high court decisions in India (13,14,15,16). The principle of "substantive due process" is never violated in doing narcoanalysis because permission from the jurisdictional court must be obtained prior to narcoanalysis in each and every case. The recent amendment (2005) to section 53 of the Criminal Procedure Code recognises the importance of these scientific tests.

Paragraphs 11,12,13,14: As long as the principles underlying the technologies are recognised as scientific, no parallels can be drawn with "torture". The FSL, Bangalore, has subjected more than 300 persons connected with a variety of crimes — involving organised crime by terrorist outfits, cyber crimes and other heinous crimes — from across the country, to such tests. The success rate has been 96-97 per cent as evaluated from the feedback received from investigating agencies and others. About 25 per cent of the total number of individuals subjected to narcoanalysis turned out to be "innocents". Therefore, the "rights of innocent individuals" stand established (14,15,16). When the public and human rights activists protest that investigating agencies adopt "third degree" methods to extract information from the accused, it is time the agencies took recourse to the scientific methods of investigation described above.

Investigations into the July 11 train blasts in Mumbai and the subsequent blasts in Malegaon were successful only because of the revelations made by individuals during narcoanalysis. Narcoanalysis has taken the place of not only proactive forensics but also of preventive forensics, because it has helped the administration take steps to prevent further planned blasts in Malegaon and Karnataka. Plans for these are being successfully intercepted only on the basis of revelations made by the accused during narcoanalysis.

The number of persons subjected to narcoanalysis is low when compared to the total number of crimes reported. This negligible percentage of individuals cannot hold society to ransom. The individual's constitutional right cannot override the State's interest.

This view has been upheld in the various high court rulings cited in the references.

Paragraph 15: How can the author say the police in India have started violating norms by airing videotapes of narcoanalysis? Once the investigating officer files the charge sheet, it becomes a public document.

Paragraphs 16,17,18,19: The team that conducts narcoanalysis consists of one anaesthetist, one physician and one clinical/ forensic psychologist. The responsibility of each expert in the team is well defined. The physician certifies the fitness of the person before and after narcoanalysis, the anaesthetist modulates the depth of anaesthesia required depending upon the quantum of information to be obtained and monitors the various stages of anaesthesia. Only the clinical or forensic psychologist interacts with the individual who is in a "trance" and gives reports along with videotapes to the courts on behalf of the team. No medical professional in the team is involved in interrogating the individual. This task is the exclusive domain of the clinical/forensic psychologist. There is therefore no violation of ethics by medical professionals.

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Narcoanalysis leads to more questions than answers

Jagadeesh N

I am writing with reference to the editorial "Medical professionals and interrogation: lies about finding the 'truth' " (1). Investigative agencies may have to keep looking for newer and effective methods of interrogation in an ever-changing crime scenario, but it is not acceptable if these methods violate accepted legal and ethical norms.

It is widely accepted that the correct dose of the so-called truth serum depends on the physical condition, mental attitude and will power of the subject on whom the narcoanalysis is to be conducted. It is also known that if the subject has used/abused intoxicants and other narcotics, a degree of "cross tolerance" could occur. In the absence of adequate research that indicates the exact dose for different subjects, the wrong dosage may put the subject in a coma or may even cause death. How then can this procedure be called "humane"? In such a situation, isn't the doctor violating the ethical principle of non-maleficence (above all or first, do no harm)?

A doctor participating in narcoanalysis is participating in a psychological third degree procedure. Chapter 2, regulation 6.6 of the Code of Medical Ethics (2) clearly mentions that the physician shall not aid or abet torture, nor shall he/she be a party to either infliction of mental or physical trauma or concealment of torture inflicted by some other person or agency in clear violation of human rights. If the doctor argues that they are participating because of a court directive, then why are they still taking the consent of the subject? Does that not amount to rationalising a coerced action without the free will of the subject?

A court in Kerala recently pronounced that no court order is required to do a narcoanalysis. Disposing of a petition filed by the Central Bureau of Investigation seeking permission of the court, the magistrate said that filing this type of a plea would only delay the investigation. The court said nobody could stand in the way of the investigating agency conducting tests recognised as effective investigation tools. When the technicalities of the test itself are not clear and uniform, it becomes difficult to accept the stand taken by the court.

If a doctor conducts narcoanalysis just on the basis of a directive from the police or an investigating agency, isn't the doctor violating the ethical principle of beneficence (all actions only for prevention of harm, removal of harm and for the provision of benefits) when the evidence gathered by narcoanalysis goes against the subject? Can the doctor be a party to violating established principles of Article 20(3) of the Constitution and Section 161(2) of the Criminal Procedure Code which say that no person accused of any offence shall be compelled to be a witness against himself/herself (that means they are not bound to answer questions which would have a tendency to expose them to a criminal charge or to a penalty or forfeiture)?

Another argument that is deployed in support of narcoanalysis is that the procedure is videotaped and audiotaped, which is proof that no coercion is being used. At the same time, if such tapes are made public before the judgement, are we not psychologically harassing and punishing the accused before the court has actually convicted them? Is this also not torture? Are doctors getting the accused person's informed consent, before the narcoanalysis procedure, to the possibility of the videotapes being illegally shown in public? If such consent is not obtained, are doctors justified, legally or ethically, in participating in such acts? Who should be blamed if the results of such tests are used to pressure the judiciary or if the court acquits the accused because the evidence is not acceptable?

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Response: questions of science, law and ethics

Amar Jesani

My editorial (1) criticised forensic scientists, medical professionals and behavioural scientists who are involved in police interrogation techniques that use scientifically questionable methods and technologies. I sent a copy of my editorial to the director of the Bangalore Forensic Science Laboratories (BFSL) and to some other forensic doctors and experts, asking for their comments. The responses by Dr BM Mohan (2) and Dr Jagadeesh N (3) are much appreciated as there is a need for public discussion of this subject.

Dr Mohan's comments cover three major areas of dispute: (a) the scientific aspects of forensic technologies and methods used in police interrogation; (b) the legal aspects and (c) the ethics of scientists and doctors participating in such interrogation. I will attempt a response to his statements on these three subjects.

Scientific aspects of forensic technologies

Scientific aspects of polygraph and lie detection have been examined by two expert committees. The first report was prepared by an expert committee of the National Research Council (NRC) at the request of the United States Department of Energy (4) in 2003. The second report was prepared by a working party of the British Psychological Society (BPS) in 2004 (5). The NRC expert committee was asked to review the use of the polygraph for personnel screening, but also reviewed its use in criminal investigation or "specific event investigation". The BPS working party reviewed evidence on all uses of the polygraph, and looked at its scientific validity (the extent to which it measures what it is supposed to measure) as well as its scientific reliability (its consistency across time and when used by different examiners). While neither of these reports dismisses lie detection technologies, both of them describe their limitations and note the need to use them with caution.

According to the NRC report, "Almost a century of research in scientific psychology and physiology provides little basis for the expectation that a polygraph test could have extremely high accuracy. Although psychological states often associated with deception (eg, fear of being judged deceptive) do tend to affect the physiological responses that the polygraph measures, these same states can arise in the absence of deception. Moreover, many other psychological and physiological factors (eg, anxiety about being tested) also affect those responses. Such phenomena make polygraph testing intrinsically susceptible to producing erroneous results. This inherent ambiguity of the physiological measures used in the polygraph suggests that further investments in improving polygraph technique and interpretation will bring only modest improvements in accuracy… Research has not developed and tested theories of the underlying factors that produce the observed responses." (4, page 2)

The BPS working party's conclusion on the use of the polygraph in criminal investigation is equally severe: "A polygraph does not detect lies, but only arousal which is assumed to accompany telling a lie … a pattern of physiological activity directly related to lying does not exist … (the) most popular lie detection procedures … are built upon the premise that, while answering so-called 'relevant' questions, liars will be more aroused than while answering so-called 'control' questions, due to a fear of detection (fear of getting caught lying). This premise is somewhat naive as truth tellers may also be more aroused when answering the relevant questions, particularly: (i) when these relevant questions are emotion evoking questions … and (ii) when the innocent examinee experiences fear, which may occur, for example, when the person is afraid that his or her honest answers will not be believed by the polygraph examiner." (5, page 10)

The problem of false positive and false negative findings is compounded by what are called "counter-measures": when examinees manipulate their physiological responses in order to get examiners to conclude that they are telling the truth. One well-known example is that of Floyd Fay, who was falsely convicted of murder in the USA on the basis of a failed polygraph examination. (He served two and a half years before the real killers were found.) When in prison, he learned to defeat a polygraph examination, and then taught inmates this skill. Of the 27 inmates trained for just 20 minutes each, 23 defeated the test.

Thus, polygraph and other such tests for lie detection and finding the truth do lie.

Both the USA and the United Kingdom committees came down heavily on the quality of scientific evidence. They noted that most studies were of "low" quality, and there was a significant potential for bias and conflict of interest in polygraph research as the bulk of

research had been funded by agencies that rely on the polygraph for law enforcement or counterintelligence purposes.

It is important to note that evidence from polygraph and narcoanalysis testing is not admissible in a court. Why is it being relied on? Is it that law enforcement agencies want to misguide the public that something is being done?

Interestingly, despite reports of research on narcoanalysis, and its recent increased use in criminal investigation, there is little systematic scientific review of this practice. The question is: how have narcoanalysis and lie detection technologies become "scientific" tools of police interrogation, with strong adherents among forensic scientists, without any scientific backing? Part of the answer lies in the complex relationship between the science and the law.

Science and the law

It is my impression that many of the forensic technologies that are used by police and the intelligence communities and generally accepted by the courts have not been examined rigorously by the scientific community. At some point the courts will have to look at the validity and reliability of these technologies. Research must be done in these technologies by scientists who do not have conflicts of interest in the subject.

In the meanwhile the role of forensic scientists is to assist the court in appreciating the problems in validity and reliability of the technology used in investigation. In this context I find Dr Mohan's assertions worrisome. If the forensic scientist is not candid about the limitations of the technology this will contribute to creating misconceptions among people and misguide the courts. The claim by investigating agencies that 96-97 per cent of their cases were solved using these technologies is not supported by available research data. Such agencies have an interest in asserting the "success rates" of such technologies. We need scientists who do not have conflicts of interest in this matter to make research-based comments on the technique's validity and reliability.

I must emphasise that this is not only about scientific validity. Any inquiry must follow due process — this is a right of the accused. If narcoanalysis involves a violation of human rights, then it is inhumane, however efficacious it might be or become. In fact, many torture methods are scientifically designed, just as technologies for legal executions are scientifically designed. Scientific technologies deployed for inflicting torture do not become humane just because they are scientific.

There are a number of legal opinions, like that of Linda Keller cited in my editorial, that narcoanalysis, which is a drug-induced confession, is a coercive interrogation practice and falls within the United Nations' definition of torture. This would violate substantive due process — and this goes beyond the absence of judicial order. We must keep in mind that there was a time when the judiciary did not consider torture a violation of due process. This change in the understanding of the court resulted from advances in the political and human rights spheres.

Ethics of participation

A core ethical requirement for forensic doctors and scientists is impartiality. They must not allow their conduct and opinion to be influenced by their employers, by investigating agencies or even by a feeling of "national interest". The only way forensic laboratories can stay scientific and not be reduced to police laboratories is by upholding this principle.

However, forensic doctors and scientists are often perceived as being an integral part of the state apparatus, specifically the police and intelligence agencies. The dilemma that they face, of dual loyalties, is acute but seldom discussed. If they make errors of judgment, if they are partial or have a misplaced loyalty towards law enforcement agencies, or if they succumb to an ideological temptation to fight terrorism in defence of national interests — all this can lead to compromises in ethical and human rights standards (6).

Dr Mohan describes in detail the narcoanalysis procedure and the role played by each person involved. He shows that narcoanalysis requires the actual presence and active participation of the medical team. The medical team is not absolved of complicity just because the actual questioning is carried out by a forensic psychologist and not physicians, just as a doctor witnessing a policeman torturing a victim is himself guilty of torture.

I fail to understand Dr Mohan's contention that when the medical team is so deeply involved in interrogation, it is not participating in interrogation, and thus not violating medical ethics.

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Medicalisation of 'legal' killing: doctors' participation in the death penalty

Amar Jesani

Societal support to the death penalty in India was high during the public debate preceding the hanging of Dhananjoy Chatterjee in Kolkata. Community hysteria was such that some youngsters died in mock re-enactments of the hanging, and the hangman acquired the status of a celebrity. The support base for the death penalty has only expanded over the years, with increasing violence — sponsored by both civil society and the state. This cuts across political parties and ideologies, emboldening the judiciary, lawmakers and constitutional heads to use it more often.

In 1980, in Bachan Singh v. State of Punjab, the Supreme Court, by a four-to-one majority, ruled that the death penalty was constitutionally valid and did not constitute an "unreasonable, cruel or unusual punishment". It should be kept in mind that the terms "unreasonable, cruel or unusual punishment" and "rarest of rare case" are defined not by objective criteria but subjectively by judges who are influenced by public opinion. This is also true in the USA (1).

Medical involvement in the death penalty

In the past decade, the law and judiciary have made systematic efforts to promote doctors' participation in the death penalty. In 1995, a two-judge bench of the Supreme Court decided on a petition opposing the stipulation in the Punjab Jail Manual that, after execution, the body of an executed person be kept hanging for half an hour. The petitioner also demanded that instead of hanging, potassium cyanide should be used for execution. The Court did not accept the second demand, but agreed that keeping the body hanging for half an hour was barbarous and ruled that "A convict shall remain hanging only till he is declared dead by the medical officer." As a result of this little-known judgment, a doctor must periodically examine the person after the hanging, to look for signs of life. If the person is found alive, the doctor is to ask the hangman to continue — to order hanging to kill instead of resuscitating (2).

Further medicalisation of execution was suggested in 2003, when the Law Commission of India in its 187th report recommended the

use of a lethal injection (3). It is a matter of time before the Supreme Court decides — or Parliament enacts a law — that hanging is barbarous, cruel and unusual, and should be replaced by a lethal injection. The use of a lethal injection is unique because it simulates the medical procedure; the setting of the execution looks medical, and due to the condition of the prisoner it often needs a doctor's assistance to carry out.

Historically, medical professionals have played an active role in designing execution methods and in helping make existing methods more efficient. In the eighteenth century, Dr Antoine Louis designed and Dr Joseph-Ignac Guillotine advocated the decapitating machine as a humane method of execution that became infamous as the guillotine. Dr Alfred Southwick, a dentist, helped design the electric chair that was considered "more humane" for many years. Medical expertise played an important role in the use of the gas chamber and even in hanging. Dr Stanley Deutsch, an anaesthesiologist, conceived of a lethal injection along the lines of intravenous induction of general anaesthesia. The first "clinical trial" of the lethal injection was carried out in Texas in 1982 on a 40-year-old African-American man who was injected with anaesthetic agents as two doctors watched. He was dead within minutes (4).

In the process of an execution, doctors are involved in the care of prisoners awaiting execution, in preparations such as certifying fitness, procuring chemicals for lethal injection, sedating the prisoner on the day of execution, advising on or participating in the execution itself, pronouncing death, certifying death, removing organs for transplantation, and carrying out an autopsy. Psychiatrists carry out evaluations of the prisoner's mental state, provide testimony in capital cases (including "fitness for execution" determinations) and give or recommend treatment. Other health professionals may be asked to carry out doctors' roles when doctors refuse to participate.

Doctors oppose medical participation

In 1980, the American Medical Association (AMA) and in 1981, the World Medical Association strongly opposed medical participation in the death penalty. Most other national and international associations of medical and other health professionals also forbid participation of their members. In 1992, the AMA came out with detailed guidelines on medical acts in the process of execution that do or do not violate medical ethics (5). Accordingly,

testifying on competence to stand trial, testifying on relevant medical issues during a trial, testifying during the penalty phase of the trial, witnessing an execution in a non-professional capacity, relieving acute suffering of the condemned and certifying death after someone else has already verified the death, are considered within the framework of ethical conduct. On the other hand, prescribing or administering tranquillisers or other drugs that are part of the execution procedure, monitoring vital signs, attending or observing the execution as a physician, selecting sites for injecting, starting intravenous lines to administer lethal chemicals, prescribing or administering the drugs, supervising lethal injection devices or personnel and pronouncing death (examining the executed person to ascertain life) are considered unethical.

The AMA guidelines, however, do not deal with issues such as providing evidence bearing on competence to be executed, treating incompetent prisoners to restore competence to allow execution, and issues relating to transplantation of organs following execution. Ethical problems in these areas are acute and fiercely debated. Interestingly, though the AMA adopted an anti-death penalty resolution in 1969, it subsequently remained silent on issues other than regulating doctors' participation. Medical associations from Europe, with the lead provided by the British Medical Association, consistently opposed the death penalty and played a key role in ensuring that it was taken off the law books of most European countries.

Ethical challenges for health professionals in India

The 1995 Supreme Court judgment and the Law Commission's report (2003) pose major ethical challenges for health professionals in India. The 1995 court ruling demanding that a medical officer monitor vital signs while the person is hanging severely compromises medical ethics and must be opposed by the profession. Involving medical professionals in the death penalty, or demanding that psychiatrists should treat mentally ill persons to make them fit for execution, puts law and medical ethics on a head-on collision. The ethics movement must educate the judiciary and law-makers on the subject. Finally, the Law Commission's recommendation on lethal injection should be firmly opposed as it tries to give a medical face to an inhuman punishment. Doctors, who occupy a more powerful position in the medical hierarchy, must support other health professionals, such as nurses and technicians, forced by administrative orders to participate in executions.

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Law commission report proposes lethal injection for the death penalty

Vijay Hiremath

India is currently one of only 83 countries retaining the death penalty. In India, the death penalty is imposed by way of hanging or shooting. Recently, the Law Commission of India circulated a document entitled "Consultation Paper on Mode of Execution of Death Sentence and Incidental Matter". (1) This document contained a questionnaire polling opinions on methods of execution. The questionnaire however, questions neither the use of the death penalty itself nor whether this method of punishment is necessary and justified.

The "Consultation Paper" has been confined mainly to the following three issues: the method of execution in the death sentence; the process of elimination of difference in judicial opinion among judges of the apex court in passing the sentence of death penalty; and the need to provide to the accused a right of appeal to the Supreme Court in such cases.

Method of execution

In India, the death sentence is currently executed through hanging or shooting. The Criminal Procedure Code dictates that hanging should be the mode of execution and the Army Act, Navy Act, and Air Force Act dictate that the mode of execution for all persons sentenced to death should be shooting.

In Deena v. Union of India (1983) 4 SCC 645, the apex court held that the execution of death should satisfy the following criteria: 1. It should be as quick and simple as possible. 2. The act of execution should produce immediate unconsciousness passing quickly into death. 3. It should be decent. 4. It should not involve mutilation.

Execution by hanging does not meet any of these requirements. There have been several cases reported where hanging has not immediately resulted in a broken neck and thus the convict is left to slowly strangle to death. This strangling results in the convict's eyes popping almost out of his head, his tongue swelling up and protruding from his mouth. In cases where the neck is in fact broken, the rope often tears large portions of the convict's flesh and muscle from that side of the face where the noose is. In many cases, the convict will end up urinating

on himself and defecating before death. The prisoner remains dangling from the end of the rope for 8-14 minutes before a doctor climbs up a small ladder and listens to his heartbeat with a stethoscope and pronounces him dead. Given these facts, it is clear that hanging is neither a quick and simple nor a decent method of execution as it involves mutilation of the body and, in some cases, prolonged suffering and torture before death.

Lethal injection is the method of execution currently being contemplated by the Law Commission. The proposition for using this method was first introduced in a medico-legal journal in New York, USA, in 1888. In 1977, this proposition was re-introduced by Dr Stanley Deutsch of the Oklahoma Medical School. Lethal injection is the primary method of execution used in the USA. As per the description provided in the Consultation Paper of the Law Commission, this method of execution involves the prisoner being secured on a gurney with lined ankle and wrist restraints. A cardiac monitor and a stethoscope are attached to the prisoner, and two saline intravenous lines are started, one in each arm. The saline intravenous lines are turned off, and sodium thiopental is injected, causing the inmate to fall into a deep sleep. The second chemical agent, pancuronium bromide, a muscle relaxant, follows. This causes the inmate to stop breathing due to paralysis of the diaphragm and lungs. Finally, potassium chloride is injected, stopping the heart.

This method, of all those available, appears to be the quickest and least painful. However, the reality is that even this method can result in cruel and unusual suffering. Amnesty International has documented numerous "botched" executions involving lethal injection. The case of Scott Carpenter, who was executed in Oklahoma, USA, on May 18, 1997, serves as a prime example of this. Two minutes after the injection was administered, Carpenter started making noises; his stomach and chest had "palpitations", and his body suffered 26 violent convulsions in the process. He was officially declared dead only 11 minutes after the injections were first administered.

The role of doctors in all methods of execution is very important. In cases where execution is by hanging, the doctors only check whether or not the person is actually dead. In cases of lethal injection, a medical expert is required to administer the injection and as such the doctor is directly involved in the execution. In these cases, the line between a medical practitioner and an executioner is crossed. Internationally, there have been many medical associations that have taken a stand that no medical practitioner should be asked to take part in bringing

about the death of a convict. The British Medical Association held that it was opposed to any proposal to introduce a method of execution that would require the services of a medical practitioner.

The principle behind this reasoning is that the medical profession is intended to save lives, not to bring an end to them. It seems only appropriate that the Indian Medical Association and all other Indian organisations responsible for the practice of medicine in this country should state their position on this issue and convey their sentiments to the Law Commission of India. Our medical practitioners, sworn to protect lives, should not be participating in the execution of any individual, whatever the circumstances. A statement of this kind on the part of medical associations would greatly advance the move for complete abolition of the death penalty in India.

It has been proven through research that the death penalty does not functionally act as a deterrent to violent crime. The crime rate in Canada, where the death penalty was abolished in 1998, has substantially reduced since the abolition. At the same time, in the USA, a country where the socioeconomic climate is very similar to that of Canada but which has retained the death penalty, the crime rate has been consistently on the rise for a number of years.

Unanimity in decision

It is essential, in cases where the penalty is so severe, that there be unanimity among the judges awarding the death penalty. However, there are often differences of opinion among apex court judges in such hearings. Even if only a minority of the judges differ in their opinion, in these cases it is not reasonable to impose the death penalty. Rather, such convicts should be granted life imprisonment. However small the voice of opposition may be among the judges, such convicts should be granted some form of mercy.

Right to appeal

It is of utmost importance that in all cases where the death sentence is imposed or confirmed by the High Court there must be an automatic appeal made directly to the Supreme Court. Every convict who is facing a death sentence is entitled to a chance to appeal his conviction and save himself from the gallows. There are many mitigating circumstances that may have resulted in a person being wrongly convicted and sentenced to death. The accused may be poor and may not have received competent representation at the time of the trial. In any case where the state is electing to execute and thus terminate the

life of one of its citizens the decision must be confirmed, as a matter of prudence, by the highest court of the land, and that too, unanimously.

The death penalty has existed since the beginning of recorded history. In all this time, it has never proven to be effective as a deterrent to crime in the way that popular perception would have it. No method of executing a human being can be termed as decent and humane because killing, whether it is done by the state or by an individual, constitutes an inhumane act in and by itself. The only humane solution that the Law Commission should offer the Government of India is the complete abolition of the death penalty.

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Struggles of public health practitioners

Imrana Qadeer

The initial search by the classical thinkers for a just society provided a strong moral sense of justice in their social contexts. Over time, the transition into capitalism made individualism, competition and survival of the fittest prime ethical values. Yet the desire for justice had to be accommodated, and this was done by incorporating the values of equality, fraternity and basic human rights into a universal ethics. The evolution of specific areas in ethics, such as medical ethics, is very much a part of the same historical process by which classical public health was marginalised by clinical medicine. Medical ethics evolved around the moral duties of physicians, competition between them, their relationship with their patients, and the benefit and harm they conferred through their practice.

Both in Britain and the United States medical ethics continued to develop around clinical practice till the end of the 19th century when public health projects began to raise questions about the need for ethical norms in a discipline where patients do not come to the doctor and often do not even know that things are being planned for them. The healthy, too, may be acted upon, and interventions often denied to the needy without their knowledge. Over and above this, the paternalistic nature of public health provided by the state, and governed by its ideology and resources, give undue power to professionals.

This led to a new search. Areas of ethical concern for public health have been proposed, such as population risk reduction, epidemiological research, health promotion and disease prevention, and not cure alone, and addressing structural disparities and the needs of the marginalised (1). Some have spoken of codes of conduct or tenets of public health ethics. These deal with: the fundamental causes of disease; respect for individual rights; community involvement; addressing the needs of disfranchised communities; transparency of information; emphasis on protection and promotion of health; timely action on the basis of available information; integrating a variety of approaches to respect diversity, policy and programme implementation in a way that promotes the social environment; confidentiality of information about individuals

and communities if publicity harms; ensuring professional competence; and building public trust in institutions (2).

These can be interpreted differently depending upon the choice of perspective in public health—biomedical or socio-medical. The articles in this issue represent several of the aforementioned challenges within the evolving perspectives on ethics of public health.

Interestingly enough, the four papers in this issue present a range of dilemmas that public health and its ethical values face today. While one writer highlights the ethical conundrum of the medical practitioner with faith in his vaccines but reservations about the vaccine programme itself, the other authors reflect the impatience of spirited public health practitioners who value technology but are critical of its organisation as well as the scientific basis of that organisation.

Anant Phadke, for example, is critical of the prolonged use of the obsolete Semples vaccine for rabies (which the state withdrew only after forced to do so by public interest litigation); the non-availability of the cell culture rabies vaccine at peripheral health institutions; and the government's inability to enforce the much-needed production of the 0.1 ml vials to make this vaccine cheaper, cost-effective and, therefore, easy to use in a public health system. He thus addresses issues such as irrational clinical practice and its protection by the state instead of beneficence and protection of the population, especially the poor. He exposes the unethical practices of the state in its responsibilities towards the public, and the lack of concern of providers.

Abhijit Das takes the debate from a single, technology-based intervention to the more political "targeted population programme". He raises ethical issues pertaining to policy and programme implementation. His analysis of targeting the poor, a strategy of the United Progressive Alliance, links it to the Malthusian and eugenic perspectives deeply embedded in the policies of the government of India despite all its pronouncements of population welfare through reproductive and child health programmes. The absence of ethical guidelines for the programme is reflected in its lack of concern for the disfranchised, its neglect of the fundamental causes of population growth, and its inability to generate trust among public through a transparent system of accessible and linked service institutions. Incentives (in the garb of compensation)

continue to increase and exploit poverty itself. The poor are rarely given any choice in adopting a method of contraception, with information as well as services lacking. The "client-segmented approach" gives the rich the privilege of opting for their preferences out of a range of contraceptives. Evidences of maleficence are several. The two-child norm is enforced with the full knowledge of son preference in Indian culture, leading to selective abortions, and the killing and abandoning of daughters. Though Das fears that India may go the Chinese way, one wonders why, with our given levels of dwindling female children, we must wait to call our situation serious.

In the third article in this genre **Anurag Bhargava** and **Biswaroop Chatterjee** argue for a new public health ethic by addressing the challenge of resurgence of communicable diseases. Unlike dengue, chikungunya does not kill, and this has led practitioners to view it as an avenue of profit. Its self-limiting nature has led the government to use techniques like fogging to create the false impression that it was taking meaningful action. This reveals the poor state of traditional medical ethics within public health.

Bhargava and Chatterjee raise several other pertinent issues. The first is the available knowledge in epidemiology, its use in programmes, and the neglect of research in areas that are crying to be explored. They question the present projection of the vector-borne disease control programme, pointing out that the vectors of malaria, dengue and chikungunya are different and the technologies cannot be shared by the control programmes.

Second, they argue that instead of developing alternative strategies, contemporary public health efforts have a technology fix and fail to address issues relating to development. This important set of ethical dilemmas is related to the neo-liberal policies of reforms that have undermined welfare and weakened the basic welfare infrastructure for food distribution, rural development and health services. Increasing social and structural inequalities have reduced the nutritional status of the population and damaged the environment.

This leads them to the third set of ethical issues, related to policy objectives, and the scientific basis of programme conception and implementation, and timely action based on available information. Innumerable programmatic maladies, from the ill-equipped primary health centre and the consequent uncontrolled proliferation of

falciparum malaria, to the national tuberculosis control programme that ignores, rather than addresses, the problem of multi-drug-resistant tuberculosis, are illustrative of this set of issues.

The fourth set of issues that they bring to centre stage concerns sensitivity to the needs of the marginalised, the competence of professionals, and the urgency of making public health institutions worthy of our trust. They reject the position that public health workers cannot go beyond medically defined boundaries, and ask that they create a new ethics of practice that raises issues of general development pertinent to public health, even if it is outside their field of direct activity.

A note of caution is necessary here, as in order to be scientific, we often tend to reject available though inadequate information as undesirable for planning. One of the challenges of public health planning in the Third World is to work within such constraints through projections and midway corrections in the strategy. If this process is monitored, the initial level of information can be improved over time instead of waiting for better information to begin with. The data presented in this paper show that the problem is often that the present set of planners does not address the available data if it does not suit them.

Second, those who talk of an alternative ethics have to be meticulous about their own information base. For example, it is not correct to say that "malaria was so far considered a rural disease". The change of strategy in 1977 to a modified plan of operation, to simply control death and protect industrial areas through a limited strategy of control, was only after the importance of urban malaria was recognised. Similarly, we need to be more cautious in separating nutritional (individual) and environmental factors in the resurgence of disease. To say that for malaria nutrition is important and for chikungunya only the environment requires evidence, especially when food availability is basic to one's immune status and so dependent upon environmental conditions. Since both diseases can be found in the well-fed, but it is the poor and undernourished populations that bear the brunt of both, we need more careful assumptions.

The paper by **T Jacob John John** is interesting as it shows the pain and dilemma of a public health practitioner committed to a technological route for a public health purpose. Critical of the oral polio vaccine (OPV) and yet committed to it, he takes an ethical position that may prove difficult to sustain. His epidemiological

logic is that we have come so far that there is no going back. It is necessary to point out that vulnerable populations will bear the cost of this stand, and inappropriate decisions in the past may not justify further expense. John's commitment to the programme despite its flaws leads him to focus on technical solutions for districts with low achievement levels rather than the overall public health context of health and health services. However, he does acknowledge the ethical implications of vaccine-associated polio paralysis, and the consequent responsibility of the state to provide such children care and their families compensation.

When the frame of reference of public health ethics does not include participation of people, their experiences, priorities and perception, when the social environment and the inequities in welfare of the marginalised lose their centrality, and when the prestige of technology alone needs defence, then public health practice becomes an act of control and domination over nature and people: the "war" against disease.

Whatever the future brings, one thing is clear. The new ethics of public health in India will emerge from such concrete struggles and debates. These will redefine the meaning of beneficence, non-maleficence, confidentiality, informed consent and individual rights in the Indian context. This is a context defined by inequalities of caste, class and gender, by the ecological challenges thrown up by the neo-liberal route to development, and a population where over 70 per cent are assessed to be poor and vulnerable. Hence, debates with the involvement of the public must become a part of the ethical tenets of public health.

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The ethical implications of the targeted population programme proposed by the UPA

Abhijit Das

"A sharply targeted population control programme will be launched in the 150-odd high-fertility districts."

—Common Minimum Programme, United Progressive Alliance Government

The Common Minimum Programme (CMP) lays out the agenda for governance of the present United Progressive Alliance government. This document has been hailed for being a radical departure from the earlier government's neo-liberal approach because it outlines a host of equity-oriented measures for social development. However, the section on women and children contains a single sentence alluding to targeted population control. Women's empowerment activists have protested against this.

Population control seems to emerge repeatedly as the only answer to India's poverty, illiteracy, disease, lack of resources and services. Many among the urban / middle class/ educated believe that the poor do not care how many children they have or that the coercion is justified for all round well-being. However, the very notion of population control and the way the family planning (FP) programme is being implemented in India raises serious ethical issues.

Eugenic background of "population control"

The relationship between population and food production was first outlined in the late nineteenth century by Thomas Malthus. What is not well known is that Malthus was more concerned about numbers of the poor and had even advocated hastening their death so that the desirable could continue to live and multiply (1). This idea of preservation of racial purity through selective breeding gained further ground and "eugenics" was formulated by Francis Galton. Selective breeding of one race automatically meant control of breeding and selective elimination of the "inferior" race. This form of population control was institutionalised in Europe and America (1). Forced female sterilisation was used as recently as two years ago in Slovakia for the control of the Roma gypsy population (2).

The promotion of a superior race was central to the forced sterilisation of Jews in Nazi Germany. But the idea of undesirable over-population of the poor was part of the debate in Europe and America well into the twentieth century. Research was conducted to prove that the poor were physically and morally deficient due to biological reasons. As an extension of this argument, birth control including sterilisation was advised to prevent the pollution of the national genepools. There is even controversy about the motives of Margaret Sanger, the founder of the Planned Parenthood Association of America, who some claim had eugenic motives and coined the slogan "Birth control: to create a race of thoroughbreds" (3). Even the field of demography, which guides most of our population related thinking, is said to have arisen from within a eugenic framework (1).

The ethics of targeting

The term "target" has strong military associations and the qualifier "sharply" adds images of sharp shooting. The population control mindset is associated with a contempt for poverty and a fear of the socially disadvantaged, viewed through middle- to upper-class, morally superior and a capitalistic lens. This was evident in Europe and America in the nineteenth and early twentieth centuries. It was evident in the US-sponsored population control programmes in developing countries like Vietnam, Philippines, Guatemala and India. Even today this mindset is present through the targeted approach that is present in many states in India (1). Who is the target of such population policies and norms? Usually, it is the poor who need more hands to eke out a livelihood or the rural folk living in inaccessible villages and who have no modern health services to speak of. It is also the dalits who are poor, far from health services and who do not have assurance of survival of their children. The brunt of the targets is borne by women are looking for ways to get out of the perpetual cycle of production and reproduction. It is interesting to note that while the Constitution promises liberty, dignity, equality and justice, the people who need these most become targets for the FP programme.

Enforcing restricting norms

While the two-child norm seems the only way out [endorsed now by the Supreme Court (4)], many feel the more desirable path would be to enact a one-child norm like in China. While it is true that the

population growth rate has come down in China, it is equally true that the same has happened in Kerala over the same time period. The difference is that no norms were enforced. Evidence from China shows the price that Chinese women had to pay for the success of this norm. There has been a serious decline in the sex ratio – son preference being strong there too. In addition women have to go through violations like forced abortions, sterilisation, domestic violence and other human rights violations (5,6).

This situation may now be repeated in India. Some prosperous states show a rapid decline in the sex ratio. Planners, law enforcement officers, the judiciary and doctors are involved in many ways – not only as programme managers and regulators, but also as the radiologists and obstetricians who finally ensure that sex pre-selection is successful. This situation may now be repeated in India. Some prosperous states show a rapid decline in the sex ratio. Planners, law enforcement officers, the judiciary and doctors are involved in many ways – not only as programme managers and regulators, but also as the radiologists and obstetricians who finally ensure that sex pre-selection is successful.

Incentives as coercion

An incentive is a token of gratitude which can help the family get out of its poverty. But when people cannot ignore an incentive because of financial circumstances, this gift becomes imperative for survival. Most families who are provided with incentives for adopting contraceptive measures do not have the option to refuse. Thus incentives and disincentives associated with the population programme have become tools for subtle or overt coercion in the hands of functionaries from the auxiliary nurse midwife to the Collector. Rarely an event like the one in which five men were drugged and sterilised to obtain a gun license comes to light, underlining the predatory nature of the programme (7).

Family planning programme implementation: ethical issues

Female sterilisation is the most commonly used method of contraception in India. Ethical issues around FP programme implementation can be seen at two levels – at the level of choice of contraceptive and in the provision of actual contraceptive services.

If we consider the issue of choice, we see that an overwhelmingly large proportion of family planning acceptors go in for female sterilisation. The method most widely available is the method most widely used in a country (8). Tubectomy is the most prevalent method in India. Even the more progressive women lack knowledge and awareness about the side-effects and contraindications of different methods. The study also found that though there is a demand for these services and women ask their health workers about supply of contraceptives, health providers have now started using the "client segmentation approach" to determine which contraceptive is appropriate for whom (9).

The ethical issues involved in the way female sterilisation services are being delivered in Uttar Pradesh have been described in an earlier article in this journal (10). The People's Tribunal on the two-child norm and coercive population policies (New Delhi, October 9-10, 2004) noted that consent forms are filled mechanically, surgical standards are not followed, services are not provided and records are not kept of complications or failures (11).

Conclusion

Population control programmes are inimical to reproductive rights which have been codified as human rights under article 16.1 of the Women's Convention. Designing and implementing any client-centred family planning programme thus requires a clear understanding of the eugenic and authoritarian background of such programmes and a clear focus on human rights. Unfortunately this sensitivity is not present in the CMP. If indeed it is a charter for the development of the underprivileged in our country, the sentence alluding to targeted population control needs to be revised.

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Restricted availability of free anti-rabies vaccine: unethical and criminal

Anant Phadke

More than 3 million cases of dog bite occur annually in India and hundreds of thousands of people are exposed to the risk of contracting rabies. But they are deprived of the free anti-rabies vaccine due to several unethical practices of the government and pharmaceutical companies.

Rabies is caused by the bite of animals, mostly dogs, who are themselves afflicted with rabies. The condition is fatal. An anti-rabies vaccine should be administered to people who have been bitten by a dog suspected to be rabid. The vaccine is one of the few medicines which was made available free of cost on a priority basis in public health facilities in India.

Until recently health centres used the obsolete Semple vaccine prepared from the brain of sheep. Other than the needless sacrifice of so many sheep, this vaccine had three problems. It was only 60-70 per cent effective. It usually required a course of up to 14 injections of 5 ml each. And about 1 in 5,000 persons injected with the vaccine would develop allergic encephalomyelitis, a serious brain condition.

The Semple vaccine was withdrawn in developed countries after the arrival of the more effective, safe and convenient cell culture vaccine. But its usage in India continued because it was much cheaper than the cell culture vaccine.

The Semple vaccine's cost advantage was lost when research showed that the cell culture vaccine was effective even when given through the intradermal route rather than the conventional intramuscular route. This required one-fifth the dose and therefore the cost too became one-fifth. The World Health Organisation recommended the intradermal regimen as early as in 1992 (1). It has been extensively and successfully used in Thailand (2).

However, Indian authorities continued to use the obsolete Semple vaccine. This was partly because the manufacturers of the cell culture vaccine in India promoted it only for the intramuscular route. None of the experts in the private medical sector was using the intradermal regimen. Their associations, studded with medical luminaries, have still not done anything to promote this route. This indicates the

pervasive influence of vaccine manufacturers. It is a sad commentary on the ethics of the medical profession in India.

Unethical, callous neglect

In June 2005, the Semple vaccine was finally withdrawn from the Indian market as a result of public interest litigation. When more than 3 million cases of dog bite occur annually in India, the authorities should have first ensured that adequate quantities of the cell culture vaccine were available. The budget of public health facilities should have been substantially increased to buy this comparatively more expensive anti-rabies vaccine. No such measures were taken. This was highly unethical neglect of what is, for poor patients, a matter of life and death.

The cell culture vaccine stocked now in public health centres is meant to be given free of charge to people with Below Poverty Line (BPL) cards. But the many poor people who do not possess a BPL card are asked to buy five injections of the vaccine, costing Rs 300 each. In some health centres all patients are charged Rs 50 per dose. Thousands of poor people cannot afford this expense and they go home without taking the injection.

Many amongst the poor have come to believe that people without a BPL card will have to spend Rs 1,500 in a government health centre for the vaccine. Several reports speak of poor people who were bitten by dogs staying at home rather than going to the health centre for treatment. This makes it difficult for doctors to use their discretion to waive charges for persons who do not have BPL cards.

Careful monitoring will show a rise in deaths due to rabies in India since June 2005, when the cell culture vaccine was introduced. This situation, which can be largely attributed to neglect by the authorities, persists despite protests by health groups. The Jan Aarogya Abhiyan (the Maharashtra unit of the nationwide Jan Swasthya Abhiyan) has lobbied with authorities in Maharashtra, including the health minister, to make the cell culture vaccine available free of cost to all victims of dog bites, not only to BPL card holders. Despite assurances, this measure has still not been implemented.

Double standards of multinationals

The most unethical players in this sordid story are the vaccine manufacturers, especially the multinationals. Internationally, they have registered their brands (Rabipur, manufactured by Chiron and marketed by Aventis, and Verorab by Leon) for both the intramuscular and intradermal routes. In India, they have registered these brands only for intramuscular use. Even the Indian National Dairy Development Board has registered its brand only for intramuscular use. If these companies were to register and promote this vaccine for intradermal use, vaccine costs would drop to one-fifth of the current costs. Instead thousands of Indians are being denied the life-saving vaccine.

The Drugs Controller should, in public interest, ask these companies to register their brands for intradermal use as well, or give official permission to doctors to use the intradermal route even if these companies refuse to register their brands for intradermal use. The intradermal route is scientifically well-established. Undergraduate textbooks include the Thailand Red Cross Society's intradermal regimen (3). Indian studies have shown the intradermal route to be as effective (4, 5). The current WHO guidelines also recommend the intradermal regimen. (6).

The government could have long ago decided in favour of the intradermal route. Instead it set up a committee to study the feasibility of using the intradermal route in India. The Jain Committee, set up in September 2003, is yet to come out with its recommendations. A multi-centric trial has also been launched to study the intradermal route. These seem to be delaying tactics for the benefit of vaccine companies. As these companies focus on high sales per patient, poor Indians will keep dying because free cell culture vaccine is not available in government health facilities and cheaper treatment is not available in the private sector.

There is one more hitch. In the West the cell culture anti-rabies vaccine is available in 0.1 ml ampoules for intradermal use, but in India it is available only in 1 ml and 0.5 ml vials. If a doctor opens a one ml vial of Rabipur for the intradermal route, s/he must have five patients to inject, as the dose of Rabipur for the intradermal route is 0.1 to 0.2 ml. Although research in Thailand has shown that once opened the ampoule can be used for a week by keeping it refrigerated (7), the Indian government – as the largest buyer of the vaccine – should ask companies to manufacture 0.1 ml ampoules/vials for intradermal use at a reasonable price. This will enable doctors in primary health centres or small clinics to administer the anti-rabies vaccine even if there is only one patient and there is no reliable cold storage facility.

The Jan Swasthya Abhiyan has been lobbying for these changes with government officials. It has also lodged a complaint with the National Human Rights Commission. The health minister has

announced that recent Indian studies of intradermal use have shown encouraging results and has said that this mode would "soon" be approved.

It is likely that the intradermal route will eventually be officially sanctioned in India. But will the government force drug companies to manufacture the smaller doses? We need strong public opinion to push for such changes. Any further delay means that thousands of poor patients will continue to die unnecessarily because the free cell culture vaccine is not available. Organisations working on medical ethics and human rights have not so far addressed this important issue. Will they take it up on a priority basis?

As this article goes to the press, the news is that the Drugs Controller has issued a circular permitting the intradermal route – but with the unreasonable clause that it can be given only at public hospitals getting more than 50 dog bite cases a day.

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Polio eradication and ethical issues

T Jacob John

Yash Paul's paper (1) raises several technical questions about polio eradication. The ethical issues are implicit, but must be made explicit. Although disease control decisions are based on epidemiologic and economic considerations, any intervention involving people has ethical implications.

In 1978 the Government of India decided to use oral polio vaccine (OPV) to control polio, occurring then at the average rate of 500 cases per day (2). The primary vaccination schedule was three doses in infancy. The prevailing popular belief (based on theory, not evidence) was that vaccine viruses would spread in the community, immunise unvaccinated children, induce high herd effect, and control polio rapidly. The alternate choice, the injectable polio vaccine (IPV), marginally more expensive, was believed to protect only the vaccinated. Thus, OPV was (erroneously) considered the better "public health" vaccine.

Most of the questions raised in the paper had been answered many years ago – identifying low vaccine efficacy (70 per cent for three doses of OPV) as the reason for frequent vaccine failure (3, 4); the need for 10 doses per child for 99 per cent protection (5); the advantages and high efficacy of IPV (6, 7); and the high "force of transmission" of wild polioviruses and the low herd effect of OPV (8, 9). In the West, vaccine-associated paralytic poliomyelitis (VAPP) in vaccine-recipients and contacts had been identified. Its frequency was generally low, but with geographic variations. Clearly IPV was ideal (safe and effective) for the individual. OPV was erratic and unsafe.

Here lies the ethical problem that had been ignored by the silent majority, including Yash Paul, for decades. The government chose OPV for public health, and refused to license IPV to avoid "competition". As it turned out, the putative public health advantages of OPV did not materialise. The burden of disease did not decline for 10 years. Even those with the best interests of children did not understand this twist in policy –epidemiologically subtle but ethically unsound. The lesson is: what is not in the best interests of the individual cannot be in the best interests of the community. OPV could be justified only as an interim measure, provided polio was controlled quickly by its efficient use (10).

When the polio eradication programme was established, history was repeated. Pulse vaccination with OPV (or national and sub-national immunisation days, NID, SNID) had been shown to improve the herd effect; it also provided an opportunity to give repeated doses to the same children.

From 1988 (when the declaration to eradicate polio was signed) to 1995-96 (when India began eradication efforts), the price of IPV had risen. Anticipating the future need, the National Mission on Immunisation recommended indigenous (public sector) manufacture of IPV. After much progress was achieved, the government decided to close the project. Today, the number of VAPP cases exceeds wild virus polio and ethics has once again come to the forefront. As all rich countries want only IPV, the price has become so high that it is unaffordable for public health in India. All those who ignored ethics and scientific evidence in the past (including Yash Paul), have realised their mistakes when it is too late to correct them.

Imagine choosing between an attractive but cheap boat and an older but slightly more expensive boat to cross the sea. Against local knowledge that the old boat was fast and fuel-efficient, the visitors, experts at sea, hired the former. After covering more than half the distance, the boat is found to be leaking badly, moving slowly, and consuming too much fuel. The arrival date has already been missed by a wide margin. What should be the next move? To go back and hire the efficient boat or somehow to complete the voyage in the leaky boat? Passengers can protest loudly, but achieve nothing except create ill will.

A second lesson: technical failure is why ethics is highlighted, whereas ethics should have guided intervention in the first place. Indeed, the (neglected) ethical duty of the government is to give free care, rehabilitation and compensation to all children affected by VAPP.

In times of war all citizens must remain united. Dissension must be put aside to win the war against wild polioviruses, which is our immediate collective responsibility. I do not share Yash Paul's pessimism about the eradication of wild polioviruses. The need of the hour is to plan the future tactics of completing and concluding polio eradication. We must not simply wait for others to go ahead and then to find fault in hindsight. The road map after eliminating wild polioviruses is what we must discuss (11). OPV must be stopped soon after the elimination of wild viruses, as it will be unjustified to cause VAPP when natural polio will not occur.

Both technical and management deficiencies have delayed the interruption of wild polioviruses in some 20 plus districts, mostly in Uttar Pradesh and Bihar. The low efficacy and poor herd effect of OPV at the achieved coverage levels did not match the high force of wild virus transmission. Yet, if the question is whether wild viruses can be eradicated by the tactical use of OPV, the answer is "yes". To achieve that, near 100 per cent coverage with an average of 10 doses per child will be required. Where the vaccination infrastructure is weak, this is best achieved through repeated pulse vaccination campaigns. The current use of monovalent OPV will accelerate the build-up of immunity, partly overcoming low efficacy of trivalent OPV. The setback in Tamil Nadu, Karnataka and Andhra in 2003 was clearly by imported wild viruses. Their efficient elimination attests to the advantages of a robust routine immunisation system and the feasibility of eliminating wild viruses with concerted overuse of OPV. We do not have the time to wait for the infrastructure to improve in order for polio to be eradicated

IPV should have been licensed in India long ago, but its limited use in a few immunocompromised children would not have accelerated the elimination of wild viruses. For that purpose high (greater than 80 per cent) coverage with at least two, ideally three, doses, should have been achieved. This in turn demanded a strong immunisation infrastructure. Had we used IPV in routine immunisation (combined with the DPT vaccine) and used OPV in pulses, perhaps we could have achieved eradication more efficiently. Had we achieved greater than 90 per cent coverage with IPV, perhaps polio could have been eradicated without additional efforts. But history cannot be changed, only the future can be redesigned.

Stopping OPV after eliminating wild viruses is an ethical necessity. But, epidemiologically it is unsafe to do so, for fear of the emergence of circulating vaccine-derived polioviruses (cVDPV) with regained neurovirulence and transmissibility, mimicking wild polioviruses (12). Here lies the dilemma of the future. Eradication can be complete only when it is safe to stop vaccination altogether. I believe that IPV will have to be manufactured in India (to make it affordable in the quantities needed) and used to cover the withdrawal period of OPV, to prevent the emergence of cVDPV (11, 12). Only after vaccine viruses are eliminated should we consider polio eradication complete. Let us hope that the mistakes of history will not be repeated.

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Note: *The opinions expressed here are personal and not of the organisations with which I am associated.*

Are we listening to the warning signs for public health in India?

Anurag Bhargava, Biswaroop Chatterjee

The 2005-6 epidemic of chikungunya fever highlights the weaknesses of public health in India. The failure to control mosquitoes, and the illnesses transmitted by them, has resulted in recurrent outbreaks all over the country. This is inevitable given the larger scenario: neglect of the basic requirements of health; poor political support for health; a weak public health capacity; centralised programmes for control based on selective interventions, and poorly planned development projects which have created conditions ideal for the outbreak of disease. All these issues are concerns for public health ethics and must be addressed to tackle the problems posed by mosquito-borne as well as other communicable diseases.

"If disease is an expression of individual life under unfavourable conditions, then epidemics must be indicative of mass disturbances of mass life... Epidemics resemble great warning signs on which the true statesman is able to read that the evolution of his nation has been disturbed to a point which even a careless policy is no longer allowed to overlook." (1)

Rudolph Virchow's insights are prescient more than a century and a half after they were made as we continue to wrestle with the old epidemics of tuberculosis and malaria, new epidemics like HIV disease, cardiovascular diseases and cancer, and resurgent epidemics of dengue and chikungunya fever.

This essay seeks to address the issues for ethics and public health posed by the resurgence, after 32 years, of an epidemic of chikungunya fever in India. It places chikungunya in the context of other mosquito-borne illnesses, which are taking a heavy toll of health and life in India.

The disease and the epidemic

Chikungunya fever, which takes its name from the Makonde language's graphic description of the patient's state (bent over and

unable to walk upright), is a mosquito-borne viral illness. It is spread by the bite of the Aedes mosquito, which also spreads dengue fever. The triad of symptoms consists of fever, severe joint pain, and rash. It can be confused with dengue in the early stages, but the joint pain in chikungunya is more severe, and there is usually no bleeding. The fever is self-limiting like other viral illnesses but the joint pains can be both incapacitating in the acute phase, and also very prolonged, with some people unable to return walk or work for weeks, months and, rarely, years (2).

Diagnosis is generally based on clinical features; serologic tests based on detecting antibodies to the virus are available only in national level referral centres, and newer techniques like RT-PCR are of only theoretical interest in an epidemic situation. Like most other viral illnesses there are no specific antiviral drugs and treatment is symptomatic, with non-steroidal anti-inflammatory drugs given for pain and fever. There is no vaccine and prevention and control of the disease rest entirely on control of the Aedes mosquito, and protection against its bite.

Large urban outbreaks of chikungunya have been reported in Kolkata and Chennai in 1960. It was last seen in Barsi in Maharashtra where it involved as much as 37.5 per cent of the town (3). It has continued for decades, apparently at a low prevalence (4).

The epidemic which started in end-2005 affected – according to official estimates – more than 1.3 million people in more than 150 districts in eight states (5). Karnataka and Andhra Pradesh were the worst-affected states.

Chikungunya, like most other illnesses, is not a notifiable disease and most patients went to private doctors for treatment. Informal reports from different parts of India suggest that the epidemic was even larger than implied by the government's figures. For example, doctors at the Mahatma Gandhi Institute of Medical Sciences, at Sevagram in Maharashtra, reported that outpatient attendance trebled and there were up to 90 admissions daily in medicine wards alone (6). Government health centres and even private pharmacies ran out of paracetamol and other pain-relieving drugs.

Apart from the scale of the epidemic the predominant involvement of rural areas and attack rates of up to 45 per cent in families of those affected were striking features. More than 2,300 cases of suspected chikungunya fever were reported in Nandigaon, Andhra Pradesh, a village with a population of 8,000. In urban areas the worst affected were those living in slums. Deaths have been recorded, mostly in the

elderly and usually due to other co-morbidities but occasionally to complications like encephalitis (7). However the illness itself spelled disaster for lakhs of poor families surviving on manual labour, with entire families incapacitated by joint pain, for months. There are reports of people being forced into debt and farm-related activities being badly affected (8).

Health care responses to the epidemic

Initially there was some confusion about the nature of the problem, because of a lack of previous experience with an epidemic of fever and arthralgia. But even after people started rushing to doctors in thousands, it took two months for the National Institute of Virology to confirm the diagnosis (9).

This proved to be a windfall for many private practitioners. In Nagpur district, community halls were rented to cater to patients. Patients across rural India were given the staple fare of injections, antibiotics, saline, and even steroids. Doctors in rural Haryana cashed in on the dengue panic and informed their patients that they were suffering from dengue, but that the treatment would prevent it from turning fatal.

Everyone jumped on the chikungunya treatment bandwagon. The state transport corporations distributed "preventive" homoeopathic medicines to more than 100,000 employees (10). Spiritual foundations organised free medical camps, some in association with district medical administrations (11), advocating yoga, meditation and breathing techniques – as treatment and prevention for a mosquito-borne illness.

Incidentally, the response of private practitioners to a predominantly self-limiting and non-fatal condition was in sharp contrast to their behaviour during the dengue outbreak in Delhi where patients were immediately referred to public hospitals. Similarly, patients are routinely tested for HIV without their consent and those who test positive face denial of care, discharge and discrimination when their status becomes known.

Public health response

The public health response consisted of despatching medical teams and medical camps – essentially a health care response. There was no widely publicised advisory for patients or doctors about the nature of the disease, its management, and ways to prevent it. Thermal fogging machines were used (12), though guidelines emphasise that they have limited effect on the mosquito population (13); also, spraying gives the community a false sense of security and affects their efforts to

reduce the source of the mosquito's breeding – which is the more important action. But it is a highly visible action and conveys the message that the government is doing something about the disease. Such stunts were combined with political declarations: the chief minister of Andhra Pradesh, himself a doctor, promised to eradicate mosquitoes in three years (14).

Are such practices ethical when people are not even aware of how the disease is transmitted and how they can protect their family from it?

Other epidemics of mosquito-borne dieases

The epidemic of chikungunya has to be seen as a resurgent viral illness in the context of other epidemics of mosquito-borne illnesses which have become a regular feature in the country. Dengue fever has been causing annual outbreaks in many parts of urban and rural India. When it manifests as a dengue haemorrhagic shock syndrome it has a mortality of 50-70 per cent. Japanese encephalitis kills over 30 per cent in those affected and 50 per cent of those who survive are left with neurological damage. An outbreak of Japanese encephalitis in eastern Uttar Pradesh in 2005 killed more than 1,000 people. Finally, malaria, transmitted by several species of the Anopheles mosquito, has become more difficult to treat, more expensive, and deadlier than ever before.

Almost half of malaria cases in India are due to Plasmodium falciparum, which can kill. The parasite has become increasingly resistant to the cheapest drug, chloroquine. Starting in 1994, the outbreaks of P falciparum malaria have resulted in large numbers of deaths in Rajasthan, Assam, Nagaland and Andhra Pradesh. The largest number of deaths from falciparum malaria occurs in tribal India, where we work. In just two weeks we have seen three patients die because they came in too late, and every day we see patients who might die but for care. Falciparum malaria is one of the few infections which can kill a person in the span of a day. In its severe form it requires the most intensive care, a blood bank, dialysis facilities and a ventilator, all virtually inaccessible to rural Indians.

Anopheles and Aedes: changing the rules of the game

The government's strategy to control all vector-borne diseases is based on its strategy for malaria. Malaria, the archetype of all mosquito-borne diseases, is seen more often in rural than in urban areas. It is transmitted by Anopheles mosquitoes that breed in clean water, have a long flight range, and bite at night. Anopheles mosquitoes vary in their preference for human or animal blood; Anopheles culicifacies, the chief rural vector, is happy with cattle blood.

Chikungunya and dengue are transmitted by the Aedes mosquito which used to be considered an urban mosquito but chikungunya is prevalent in both rural and urban areas today. Aedes can breed in clean as well as somewhat polluted water, has an average flight range of 100 metres, bites in the daytime, and chiefly human beings. Thus it breeds in and around human habitations, in water bodies such as storage tanks, desert coolers, even septic tanks. It can breed all year round in our cities and not simply during outbreaks (15). Aedes eggs can withstand long periods of drying and dormant eggs inside old tires are known to have been transported over great distances. In short, human activities contribute greatly to the survival and spread of Aedes mosquitoes.

The malaria control strategy consists chiefly of residual spraying with insecticides like DDT in rural areas, use of insecticide-treated bed nets, and early diagnosis and prompt treatment of patients in an attempt to interrupt transmission.

However, the Aedes mosquito is largely resistant to DDT (16). Other malaria control measures don't apply to dengue control; insecticide-treated bed nets are irrelevant when the mosquito bites during the day. The only way to prevent dengue and chikungunya is for people to know where the mosquito is breeding in each house and locality, and take individual and community action to eliminate it. Mosquito repellents are effective but beyond the reach of the poor. Space spraying to kill adult mosquitoes should be used cautiously, in exceptional cases.

The health care and public health responses to epidemics

One must distinguish between health care with public health. Typhoid may be treated with drugs but the public health response is to provide a safe water supply. Any large-scale outbreak of illness requires a health care response to address the deficiencies in the diagnosis and treatment at various levels of health care. But it also demands a comprehensive and long-term public health response, which addresses the deficiencies in public health measures that made the epidemic possible.

Most epidemics in India are not followed by a long-term response. The public and the media accept their recurrences as inevitable accompaniments of the "seasons", which can at best be contained, only to recur next year. In this model of public health, typhoid fever, hepatitis and cholera are dealt with separately rather than as diseases

caused by a contaminated water supply. Malaria, dengue, chikungunya and filariasis are similarly treated as different problems though they all point to a failure of mosquito control. There is no overarching public health response to the enormous burden of water-borne and vector borne diseases, apart from a national anti-malaria programme.

The warning signs of the epidemic for public health in India

"Microbes are nothing – the terrain everything."

Louis Pasteur's understanding of microbes and their ecology was far more sophisticated than the current view of treating "bugs" with "drugs" and vaccines. Indeed, sanitary reforms in 19th century Europe addressed the terrain -- the horrific living conditions of people -- with improvements in living conditions, water supply, sanitation and sewage disposal, reforms of wages and working conditions and access to a socialised system of education and health care. Such facilities may seem utopian in India, where people struggle to meet even their most basic needs. But they can be achieved with political will, as demonstrated by Cuba, which is far more constrained for resources than India is. However, our policymakers increasingly espouse a vision of public health that depends on newer drugs, vaccines and micronutrients and not on the basic needs of human beings that lead to a better life and less disease.

The germ-centred view of the chikungunya outbreak treats it as a separate viral disease and focuses on the purely viral or immunological reasons for its resurgence. Thus the scale of the epidemic was attributed to people's low immunity to the virus (17). But chikungunya outbreaks do not occur in Singapore, where nobody is immune to the virus either. The increasing intensity of mosquito-borne illnesses points to our abysmal failure to control mosquitoes. We must address the wider issues that make us so vulnerable to recurrent epidemics.

Neglect of the basic requirements for health: Health depends, at the barest minimum, on access to adequate food, sufficient safe water, housing and sanitation. The provision of these basic requirements dramatically brought down the occurrence of communicable diseases in the West, long before modern vaccines or antibiotics were discovered. We should address these foundations of public health while we create public health foundations.

This need is urgent because the situation is worsening. The primacy of food, safe water and sanitation was emphasised in the Alma Ata charter for primary health care. Over the years, the concept of primary

health care as all-encompassing and holistic has changed to refer to highly selective, technology-oriented, minimalist health care at the primary level.

The per capita availability of food grain in India has seen a dramatic decline of 20 kg from the early 1990s to the present day, when it stands at a level close to that seen around Independence (18). Current levels of nutrition in Indian children are below those seen in sub-Saharan Africa (19). Yet we claim a 10 percentage point poverty reduction. The reduction of food grain allocation through the Public Distribution System to only 25 kg per family, irrespective of family size, will further worsen the situation. Yet few experts in public health raise their voices against this step.

A purely germ- and vector-based view of disease tends to obscure the fundamental relationship between under-nutrition and the risk of developing diseases. The prevalence of acute hunger has been considered crucial to the intensity of an epidemic and its lethality (20).

Access to safe water and sanitation are key issues for both water-borne and vector-borne diseases. The absence of effective water chlorination and the contamination of water with sewage during its distribution inflict a host of diseases such as dysentery, typhoid and hepatitis A and E. In the absence of a reliable water supply people must store water, and the storage containers, in turn, become breeding grounds for Anopheles stephensi and Aedes aegypti mosquitoes.

But access to these basic requirements, as well as to responsive health care, is socially and politically determined and there are gross inequities across social classes in India. The poorest 20 per cent have double the mortality rates of the top 20 per cent of the population. A very small part of the total population of India bears a disproportionate burden of malaria mortality.

Ecological changes and vector-borne "diseases of development": The incidence of microbial diseases declines when economic development is associated with social development. On the other hand, when economic development is divorced from social development, the incidence of disease may increase. This is happening right in front of us in India.

The Malaria Institute of India, now the National Institute of Communicable Diseases, had clear guidelines for the environmental control of malaria. These include guidelines to be followed during the construction of drains, roads and irrigation projects. These

environmental measures for reducing mosquito breeding have been forgotten in the enthusiasm for chemical-based control.

The landscape of India is undergoing irrevocable changes with urbanisation, industrialisation, irrigation, green-revolution agriculture and infrastructure development. Many of these changes are creating new breeding sites. Falciparum malaria, earlier seen mainly in north-eastern and central India, is now endemic even in Rajasthan. Japanese encephalitis now affects West Bengal, Uttar Pradesh, Andhra Pradesh, Karnataka and Goa.

Urbanisation and vector-borne diseases: Urbanisation is seen as a driver of India's economic growth. Unfortunately, when the poor migrate to cities, they encounter a degrading environment, much worse than their homes in rural India, due to a singular lack to provision of low-cost housing. Slums inevitably arise, with their problems of inadequate water supply, drainage, waste disposal and sanitation, leading to recurrent outbreaks of mosquito- and water-borne diseases. Open drainage, which is often mixed with sewage, is a feature of most cities. New construction pays scant regard to drainage, impeding the flow of water and creating conditions of water logging every monsoon. The burden of disease in slums can be gauged from the annual parasite index (API), the number of smear-positive malaria cases per thousand population. The API calculated in a Delhi slum, during the course of a Malaria Research Centre study in 1982, was 496.6 (21). That is, every second slum dweller had malaria that year.

Irrigation: If the urban environment now breeds malaria, which was so far considered a rural disease, the green revolution, mismanaged irrigation and ill-planned infrastructure development are contributing to the emergence of the typically urban diseases of dengue and chikungunya in rural areas, in addition to worsening the malaria situation. Anopheles and Culex can breed in rice fields, slow-moving streams, and pools. Poorly designed hand pumps leave open water collections that breed thousands of mosquitoes. Intermittent tap- based water supply, which is now becoming a feature in many villages, is forcing people to store water in large containers, where Aedes aegypti can breed.

Consider the following:

* There was a 32- fold increase in the rate of smear-positive falciparum malaria and hundreds of deaths in the Narmada valley, where malaria was previously rare (22).
* The Indira Gandhi Project, with its 8,000 km of badly managed canals, has caused seepage and water-logging of 8,600 hectares of land, and completely altered the ecology of the region. The resultant heavy mosquito breeding was responsible for an epidemic of falciparum malaria in Rajasthan in 1994 which claimed 1,200 lives (23).
* Irrigation and the increasing use of groundwater have also changed the nature of crops to more water-intensive crops such as rice and sugarcane. Rice fields offer breeding sites for mosquitoes including the vector of Japanese encephalitis.

Road construction: Poorly organised road construction can also lead to mosquito breeding. Burrow pits accumulate water and serve as breeding sites. The congregation of construction workers, often from malaria-endemic zones, creates a reservoir of infection. People get bitten because there is no proper housing and as they have no access to effective health care the infection spreads unabated. All of this amounts to a perfect recipe for a malaria outbreak.

Neglect of primary health care: The difficulties of disease control are compounded by our neglect of the comprehensive primary health care approach. Without a system of responsive, first-contact care, it is not possible to diagnose a sufficient proportion of patients early enough to interrupt transmission in the community, whether of P falciparum or M tuberculosis. In the case of malaria, for example, slides take weeks to get reported and patients are given incomplete presumptive treatment that contributes to increasing drug resistance.

Wherever social and economic problems exist and the access to primary health care is poor, the malaria situation is bad. It is not surprising that 50 per cent of all malaria deaths in the country occur in the tribal areas of six states, which are also marked by poor public health indicators.

Fundamental problems with national health programmes: Another major factor in this discussion is the fundamental problems with national health programmes. This merits a separate discussion, but the following points must be noted:

Paucity of data and underestimation of disease burden: None of our national health programmes has reliable data on the magnitude of the disease, which would determine planning and allocation of resources, and serve to gauge the success or failure of the programme. The National Anti Malaria Programme contends that the incidence of malaria, based entirely on the results of blood smears collected by the multi-purpose workers, is now merely 1.87 million cases (2003 figures) from the high of 6.47 million in the 1970s (24). However, studies by the Malaria Research Centre

(MRC) have indicated such incidence data to be a gross underestimation. In a rural area, a comparison of incidence data from a single primary health centre revealed 63 malaria cases while MRC recorded, during the same period in the same population, 1,784 malaria cases (25). In an urban area, the incidence was seen to be nine times the official figure (26). A paper in *Lancet* last year provided evidence that the World Bank falsified incidence data for malaria in projects in India supported by it, which did not even correspond to the national vector-borne disease control programme figures for these states (27). How can we address critical public health problems in this scenario of denial and obfuscation?

The "one size fits all" approach: Malaria is a disease affected profoundly by local conditions of temperature, rainfall, vector and human behaviour, vector sensitivity to insecticides, topography and breeding sites. The initial success of the anti-malaria programme in the 1960s was reversed by the 1970s with six million cases reported annually. A major reason was that DDT was the "one size fits all" technological fix for mosquito control. When the vector became resistant to DDT, the programme collapsed. Non-Anopheles mosquitoes, urban areas and mosquito breeding got little attention, setting the stage for Aedes breeding.

Going against the evidence: Sixty to seventy per cent of malaria cases in the country are transmitted by A culicifacies. Widespread resistance of A culicifacies, not merely to DDT but even to other pesticides, is a fact acknowledged by the Malaria Research Centre (28). Despite this, it continues to be a mainstay of the programme. There is a need for evidence-based public health in developing countries, in this era of evidence-based medicine.

Obsession with germs and vaccines: Many strains of Streptococcus pneumoniae, which is responsible for a large part of childhood mortality, are now resistant to cotrimoxazole and, less often, to penicillin. Multi-drug resistant tuberculosis is a major problem in previously treated patients with TB. Falciparum malaria is resistant to chloroquine in many parts of the country, leading to proposals for changing the treatment of falciparum malaria to the much more expensive artemisinin-based combinations. Infections once thought to be treatable are becoming untreatable. New antimicrobial drugs are being followed by drug-resistant strains with equal rapidity. And the response to the emergence of drug-resistant strains is to look for new drugs.

All these organisms spread through the same old pathways. Surely it is more cost-effective to tackle the conditions that favour the spread of the pathogens, and conditions that promote the development of disease, rather than get lost in the details of individual agents. For example, it is cheaper to provide safe drinking water to the entire population than to vaccinate every individual with the Hepatitis A vaccine, the typhoid vaccine and the cholera vaccine (the list leaves out many diarrhoeal pathogens for which there, at present, is no vaccine). It is cheaper (and, of course, better, from the starving person's viewpoint) to have enough food to eat than to wait for some new vaccine to prevent tuberculosis. Most new vaccines are univalent, which means that they protect against the one disease for which they are meant. On the other hand, adequate food and safe drinking water and vector control protect against multiple diseases at the same time.

The talk of vaccines and newer drugs is a politically convenient ploy to divert attention from the failure of basic public health measures, a failure that makes epidemics possible. It is also an excuse for not doing anything. Vaccines cannot be a stand-alone intervention; they are only one of the tools of public health to complement other public health measures.

Lack of capacity to respond to public health problems: There are vast lacunae in our current ability to respond to an outbreak of a communicable illness, or manage our public health programmes, due to the lack of facilities and trained personnel. Though tuberculosis is the single most important killer disease in the country, it is only in the past decade that microscopy facilities for the diagnosis of tuberculosis have been created at the primary health centre level. Earlier sputum samples had to be examined at the district level centre. Even now, there are no state facilities to diagnose drug-resistant tuberculosis, though medical colleges may have a magnetic resonance imaging machine and a state-of-the-art intensive care unit. Malaria diagnosis at the village or sub-centre level is still marked by long delays. In a situation of an outbreak of cholera, there is a lack of facilities for confirming the diagnosis at the district level and, sometimes, even at the state level. We routinely isolate and identify Vibrio cholerae at our rural hospital, but the district medical officer told the local press that diagnosis could only be made by the National Institute of Communicable Diseases.

At the district level, clinicians who are uninitiated in the practice of public health hold the post of district medical officers. It is

disconcerting to find that many states do not have entomologists to guide interventions in the national vector-borne disease control programme. One entomologist remarked in the context of the chikungunya epidemic, "Fumigation failed to wipe out mosquitoes, but entomologists have been virtually eliminated from India's public health system." (29) We need environmental engineers familiar with interventions for reducing mosquito breeding sites in relation to infrastructure projects, and we need anthropologists and social scientists who can chart new directions in malaria control with community participation.

The way ahead

"It isn't that they can't see the solution. It is that they can't see the problem." - G K Chesterton

These epidemics offer to all of us concerned with the health of the Indian people a moment of truth. Shall we ignore the messages? If so, at what cost? Shall we continue to find it acceptable that a child saved from the disability of polio dies of a pneumonia made severe by underlying malnutrition, or is killed by the next wave of Japanese encephalitis or dengue? Shall we land poor families into debt because severe typhoid requires now a third generation cephalosporin for its treatment? Shall we merely supply rapid diagnostic tests and artemisinin-based combination treatments to tribals with malaria acquired by a poorly executed irrigation project?

The refrain of health care and public health professionals is that the social and political factors are outside their domain. But are we even articulating health problems to our administrators and politicians as problems that cannot be solved by medical technology of drugs and vaccines but also require the application of social technology? In our own domains, do we do all that we can to reduce the economic cost of disease to our people? At other levels, did we protest when the government in 1981 allocated only Rs two crore to a TB programme for more than a million patients – as a result of which half a million died prematurely in India? Or when funding to the malaria control programme was cut by 40 per cent in 1994? Shall we protest now when a severely undernourished people are further deprived of food security? Should we in public health continue to be apologists for faulty social policies and processes, cloak results in terms of germ and diseases, and push pills, micronutrients and vaccines? Public health in India needs skilled professionals but it also requires strong advocates.

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