

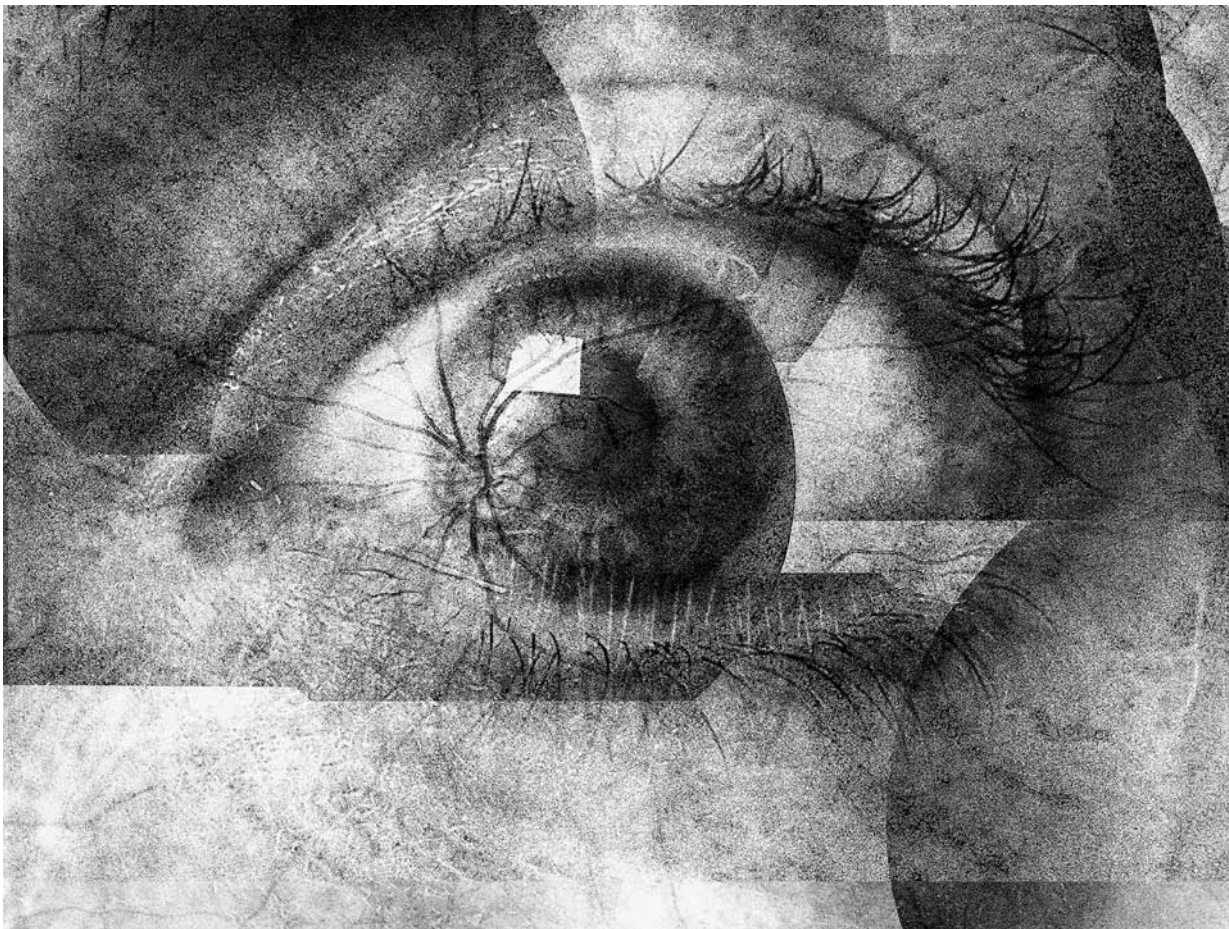
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## ***DHARMA AND MEDICAL ETHICS***

**The making of myths in Indian healthcare**

**The murder of Dr Narendra Dabholkar: a fascist attack on rationalism**

**Parliamentary report on the HPV vaccine trials: vindication of a campaign**

**Discussion: Were the cervical cancer screening trials ethical?**

**Film review: *Ship of Theseus***

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## Opening a can of worms

In India today, attempting to claim one's democratic rights, or even to seek information about them, is met with blatant stonewalling and even violence. The revolutionary potential of information and its increasing speed are both feared by vested interests and appreciated by the public. An editorial commends the Parliamentary Committee on the PATH HPV clinical trials for exposing the systematic breach of every norm meant to protect participants. Another analyses the proposed reforms in the Medical Council of India. Narendra Dabholkar devoted his life to exposing those who abused the people's faith and paid with his life for his daring. In this issue, an editorial pays tribute to this man committed to science and public awareness.

Alongside this, the growing clout of the media lends itself to the marketing of myths and dreams, to which healthcare is no exception. An author traces the creation of a myth around a powerful chain of healthcare facilities. Other articles assert the need for pandemic preparedness, for medical regulation, and for strict norms in the conduct of clinical trials in India and abroad.

However, even the best laid plans need conviction and commitment to be implemented effectively. The need for a philosophical basis to strengthen medical ethics is explained by an author, while a research study demonstrates the link between the ethical climate at work and the job satisfaction of nurses. We also have a stimulating exchange of views in the Discussion segment.

The *Indian Journal of Medical Ethics* (formerly *Issues in Medical Ethics*) is a platform for discussion on healthcare ethics, with special reference to the problems of developing countries such as India. It hopes to involve all cadres of, and beneficiaries from, this system, and strengthen the hands of those with ethical values and concern for the underprivileged.

The Journal is owned and published by the Forum for Medical Ethics Society, a not-for-profit, voluntary organisation. The FMES was born out of an effort by a group of concerned doctors to focus attention on the need for ethical norms and practices in health care.

Contributions to the journal, in the form of original papers, research findings, experiences in the field, case studies, debates, news and views on medical ethics, are welcome. All submissions must be in English and are subject to editorial review.

**Contributors are requested to refer to the detailed guidelines for submission available on the journal website, [www.ijme.in](http://www.ijme.in)**

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## EDITORIALS

# The Medical Council of India – change necessary, apprehensions persist

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The Government of India superseded the Medical Council of India (MCI) with effect from May 15, 2010 by an amendment to the Indian Medical Council Act, 1956. The supersession followed reports of financial irregularities and corruption in the Council. A board of governors was put in place. By two further amendments in 2011 and 2012, the powers of the MCI continued to be exercised by reconstituted boards of governors. The term of the current board of governors expired on May 14, 2013. An extension of 180 days has been granted and, therefore, the Central Government should reconstitute the MCI by November 10, 2013 at the latest. On March 19, 2013, the government introduced a bill, The Indian Medical Council (Amendment) Bill, 2013, for the purpose (1). However, the government has inserted an escape clause that would allow it not to adhere to the time schedule. This is Section 3AA, which states, "The Central Government shall, *as soon as possible* [italics added], after the commencement of the Indian Medical Council (Amendment) Act 2013, by notification in *The Gazette of India*, reconstitute the Council.....: provided that the Board of Governors constituted under sub-section (4) of Section 3A shall continue to exercise the powers and perform the functions of the Council till the new Council is reconstituted." So, do not hold your breath. With Parliament's recent record of performance, it will be surprising if the Bill gets passed in the monsoon session.

### Explicit government control over the MCI

The overriding theme of the Bill is that the Central Government is to have explicit powers over the Council. One can argue that the 1956 Act did grant such power, under Section 32 (Power to Make Rules). Sub-section (1) of this states, "The Central Government may, by notification in *The Gazette of India*, make rules to carry out the purposes of this Act."

A new Section, 30A, has been added in the Amendment Bill. Sub-section (1) provides for the manner of resignation of any member of the Council. Sub-section (2) empowers the Central Government to remove any member of the Council on seven grounds, which are as follows.

- Insolvency
- Physical or mental incapacity
- Being of unsound mind, as declared by a competent court
- Being convicted of an offence judged by the Central Government to involve moral turpitude
- Having a financial or other interest likely to prejudice the exercise of functions
- Abuse of position, as judged by the Central Government
- Being guilty of proven misbehaviour

For removal under the last three clauses, the person involved has to be given a chance to be heard.

The last two clauses are subject to interpretation, which means that the government can remove a person on vague grounds.

Further, by changing subsection (2) of Section 32, the government has explicitly stated that it can make rules on the following.

- The manner of electing the representatives of medical colleges
- The mode of election to the Council of persons holding qualifications recognised in Part I of the Third Schedule of the IMC. These are licentiate qualifications of various state governments and one wonders whether many of them still exist.

Also, the Bill introduces amendments to Section 33 (Power to Make Regulations):

Amendment A 1 states that the Council shall be bound by directions of policy given to it *in writing* [italics added] by the Central Government, though there is a proviso that the Council shall be given an opportunity to express its views as far as possible.

Amendment A 2 states that the Central Government's decision on whether a question is one of policy or not is final.

Amendment B states that the government can direct the Council in writing to make, amend or revoke regulations within a specified period and if the Council fails to comply, the government can make, amend or revoke the regulations as it deems fit.

These, then, are the major changes to be made in the functioning of the MCI.

Another important issue is that the number of members of the MCI is likely to go down from the present 119 to 90 or so, and the number of elected nominated members will be almost the same as that of elected members (2).

The other changes, which are relatively minor, are as follows:

- Doctors have to renew their registration after 10 years.
- Overseas citizens of India with recognised qualifications can practise medicine in India.
- The biometric particulars of all persons in medical registers have to be registered.
- The Indian medical register will also be available in electronic form.
- Specific mention has been made of the obligation to lay down the standards of professional ethics.
- The maximum number of terms in the MCI is two.
- The duration of a term has been reduced from five years to four.

### Questions

Is so much control by the government a good idea? I would argue that we have to wait and see. In recent years, the MCI has not acted in a way that inspires confidence in anybody. Governments, at least, are accountable to Parliament.

Is it a matter of concern that the number of nominated persons on the Council should nearly equal that of elected members? On this too, one must reserve judgment. At present, elections to the state medical councils and MCI are dominated by “doctor politicians,” who make enormous efforts to get elected. The majority of the members of the medical fraternity are passive observers and must be faulted for their inertia.

Ultimately, as pointed out by Dr Sunil Pandya (3), the rot in the superseded medical council lay within. When the MCI is reconstituted, we hope that the new members, both elected and nominated, will prove to be worthy of their position and exercise wisdom and circumspection to help foster an expert and caring health workforce.

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## The murder of Dr Narendra Dabholkar: a fascist attack on rationalism

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The brutal assassination of Dr Narendra Dabholkar in Pune has been a big blow to the progressive social movement in Maharashtra. A medical practitioner turned activist, Dr Dabholkar was renowned for his more than two-decade-long crusade in the state against superstitions and his efforts to promote broader social reform. However, his untiring campaign, from 1995 onwards, for the enactment of an “anti-superstition/anti-black magic bill” in the state made him the object of hatred for obscurantist forces. This fanatical hatred and the increasing intolerance and aggressiveness of these fascist forces led to his murder on August 20, 2013.

### Background of involvement in broader social reforms

Dr Dabholkar was born in Satara, then a small town, in 1945. His family was an illustrious and highly educated one, and many of its members have been renowned for their work in the fields of education and social reform. It is no wonder that in his college days, Narendra was attracted by socialist, egalitarian ideals and in the early 1970s, joined the Samajwadi Yuva Dal, a left-wing outfit of young socialists. During that time, among the causes championed by the new generation of socialists in Maharashtra was the anti-casteist movement. Dr Dabholkar became involved in the *Ek gav, ek panavatha* (One village, one water source) movement led by Dr Baba Adhav, as well as the movement for renaming Marathwada University as Dr Babasaheb Ambedkar University. He continued to be involved in the anti-casteist movement till his death. Recently, he had taken the initiative to mobilise public opinion against the stranglehold of caste panchayats, an issue which came into sharp focus following the brutal killing in Nashik

of a woman by her own father, whose action was motivated by fear of the caste panchayat's reaction to his daughter's inter-caste marriage.

Together with his wife, Dr Dabholkar practised medicine for 10 years, but from 1982 onwards he became a full-time activist. He was instrumental in galvanising a team of socially conscious theatre artistes, including the renowned Shreeram Lagoo, Nilu Phule, Rohini Hattangadi and Sadashiv Amrapurkar, to organise 25 performances of a Marathi play in different parts of Maharashtra with the aim of creating a fund through the sale of tickets and through donations. This fund, the "*Samajik Krutadnyata Nidhi*" (Social Gratitude Fund) initially amounted to around Rs 2.5 million and has now grown to over Rs 10 million. Currently, the fund is being used to support 45 full-time social activists in Maharashtra. One important contribution which helped enhance this fund came from schoolchildren, who donated Rs 5 each by skipping a meal! Dr Dabholkar was also the secretary of the India Committee of the Maharashtra Foundation's annual awards, instituted by progressive Indians in the USA to felicitate social activists, literary persons, artistes, etc. In 1998, Dr Dabholkar became the editor of *Sadhana*, a progressive, socialist weekly magazine in Marathi, founded by Sane Guruji 60 years ago.

Though he gave up clinical practice in 1982, Dr Dabholkar continued to tackle health issues at the social level. For example, as a doctor, he used to give public lectures to unravel before lay people the truth behind the claims made by Babas about 'cures' from certain medical disorders. He also drew attention to the godmen's exploitation of people with psychiatric problems, besides exposing the fraudulent medical practices of quacks. One of his last contributions was a complaint against a fraudulent doctor, which he followed up to the level of the health ministry. In July 2009, he was invited to preside over the first ever Patients' Rights Convention, organised in Pune by the Jan Aarogya Abhiyaan.

Dr Dabholkar was involved, to a considerable extent, in the movement against addictions, and led campaigns against local liquor dons in various places. He also organised protests against the Maharashtra government's liquor policy. A few years ago, he launched a campaign against the policy of granting permission for the establishment of factories that produce liquor from jowar, the staple food grain in villages in Maharashtra. He was a founder-member of a de-addiction centre, Parivartan, in Satara. This centre can admit up to 25 patients at a time. The de-addiction work is being continued by his son, Hameed, a Satara-based psychiatrist, and his colleagues. Incidentally, Dabholkar named his son Hameed in memory of his close friend, Hameed Dalwai, a renowned social reformer in the Muslim community who died prematurely. This was indeed a very unusual, bold step to take, given the overall sociocultural milieu, which coloured the attitudes of even those in the progressive circles.

Though Dr Dabholkar was better known for his crusade against superstition, he was also deeply interested in ushering in broader social reform.

### **A "rationalist" with a difference**

In 1989, Dr Dabholkar founded the Maharashtra Anndhashraddha Nirmoolan Samiti (MANS) (1), or the Committee for the Eradication of Blind Faith. MANS, which with about 180 branches, is one of the most active progressive organisations in Maharashtra. Its monthly magazine has 15000 subscribers, the largest number among the progressive magazines in Maharashtra. MANS's objectives, as articulated in its literature, are not limited to opposing superstitions and rituals which exploit and harm people. They also include cultivating a scientific attitude, skepticism, humanism, critical thinking and rationalistic moral values among the people to create a just society. Dr Dabholkar used to emphasise that MANS is part of the broader progressive, left movement.

MANS declared an award of Rs 2.1 million to anybody who could prove his/her capacity to perform "heavenly" miracles. Nobody has been able to win it! MANS confronted many *babas, buas, tantriks*, etc and has led agitations against several forms of superstition. This included debunking the myths propagated by self-styled godmen and godwomen. MANS also spearheaded the Shani Shinganapur movement, the aim of which was to make it possible for women to enter temples they are forbidden to enter. Dr Dabholkar, however, was not a "rationalist" in the sense that Abraham Kovoov was. He felt very strongly that superstition had its roots in socioeconomic factors and would not disappear through mere criticism of godmen and superstition. Unlike some other rationalists, he did not preach atheism or ridicule gods, though he was in favour of a critique of religion.

### **Tireless campaign for a law to curb exploitative, barbaric "black magic"**

Dr Dabholkar led MANS to tirelessly campaign for 18 long years for the introduction of an anti-superstition bill, which, as he used to emphasise, sought to prohibit exploitation in the name of religion through fraud and barbaric practices. Following modifications, this Bill has been christened the "Maharashtra Prevention and Eradication of Human Sacrifice and Other Inhuman, Evil and Aghori Practices and Black Magic Bill." The modifications and rephrasing were undertaken to dispel the fear fuelled by false propaganda that the Bill is against the Hindu religion. Dabholkar used to point out that the Bill did not contain a single word about any religion. The Bill pertains to fraudulent and exploitative practices such as performing *karni, bhanamati* or magical rites in the name of supernatural powers; offering ash, talismans, charms, etc for the purpose of exorcism and to drive out evil spirits or ghosts; punishing or beating mentally ill patients in the belief that they are possessed by evil spirits; and so on (2).

Dr Dabholkar fostered the first draft of the Bill way back in 1990, after which MANS began to campaign for it. In 1995, it was tabled as a non-official bill and was supported by the Congress party during the regime of the BJP-led government. A coalition government with the Congress as the major partner came to power in Maharashtra in 1999 and since then, every chief minister promised help in getting the Bill passed. However, the move was invariably stalled for one reason or the other. On August 15, 2003, the government proclaimed in the newspapers that "Maharashtra would be the first state in India to enact a law against black magic." However, this did not materialise. The saffron brigade indulged in typical double-speak. On the one hand, some of them indulged in downright false propaganda and rabid, frontal opposition to the Bill. On the other, the BJP took the official stand that *it is not opposed to the Bill, but is opposed only to some its provisions*. This BJP stand continued despite a host of changes in the text of the Bill in view of the fears expressed about misuse of some provisions.

The political bankruptcy of the ruling parties has been quite a revelation. Their leaders have, time and again, promised to enact this legislation, but succumbed to pressure from the rightist forces and postponed taking a definite stand. Perhaps they fear alienating the socially reactionary or misguided people in their vote bank. Second, their leadership has faced opposition from its rank and file in this matter. Godmen have a following among a large number of politicians in the dominant parties. Even though the Bill does not target these godmen directly, a section of politicians fears any move that would affect the cults of godmen in any way. The latest draft of July 2013 was prepared after extensive consultations, including consultations with the representatives of *warkaris* (the disciples of the saints in Maharashtra, several hundreds of thousands of whom visit the Vitthal Temple in Pandharpur every year). During the meeting with the chief minister on July 30, 2013, these representatives gave their consent to the latest draft of the Bill, which incorporated their suggestions.

Against the background of an all-pervasive degeneration of the social and political culture, and the increasingly intolerant stand of the rightist elements, some fanatic was able to carry out this murder. It is anybody's guess whether this murder has any link with Modi's ascendancy. Is it a sign that religious fanatics and propagandists are afraid that the work of MANS is weakening the stranglehold of religious superstitions on the minds of ordinary people? Dr Dabholkar was known to be an extremely soft-spoken, mature social worker who believed in dialogue. He would never lose his temper and would not personally hurt or provoke anybody during debates. He attributed his capacity to take things in his stride to his involvement in sports in his younger days. He was an excellent kabaddi player and had once been a member of the national kabaddi team. He had won several gold medals and the coveted *Chatrapati Kreedha Puraskar*. His murder was a purely ideological, political, dastardly act.

Dr Dabholkar had reportedly received threats from caste panchayats as he had called them unconstitutional and anti-democratic. Hard-line organisations such as the Hindu Jan Jagruti Samiti and Sanatan Sanstha have openly denounced the Bill as anti-Hindu and launched a vitriolic attack against it through their mouthpieces. Against this background, it is likely that the actual assassination may have been carried out by professional killers hired by vested interests.

It is heartening that people across the whole spectrum of democratic, progressive and leftist forces have vociferously condemned this murder, and that the youth formed a significant proportion of those who took to the streets in protest. In Pune, in response to the all-party call for a bandh on August 21, a significant section of traders voluntarily downed their shutters – a rare occurrence. It was this widespread protest and anger that prompted the Chief Minister to issue an ordinance to make the Bill an Act (2). The ordinance will have to be adopted by both houses of the Maharashtra legislature within six months. It is extremely tragic that one of the finest progressive reformers in the state had to sacrifice his life for the cause of a bill which aims to prohibit criminality in the name of religion.

Dr Dabholkar was known to be an extremely efficient, excellent organiser. He needed to spend no more than two days a week in Pune to edit the weekly, *Sadhana*. Five years ago, he had given a young editor, Mr Vinod Shirsath, the charge of executive editor and with time, the weekly grew in stature and financial stability. This speaks volumes of Dr Dabholkar's organisational capacity. He was a very effective public speaker without being aggressive or shrill. His arguments were clear and concise. For 30 years, he stayed at his home in Satara only two days a week, spending the rest of the time touring the state extensively. A CD containing 10 lectures by Dr Dabholkar on issues such as superstitions, god, religion, science and a scientific temper has become very popular in Maharashtra.

The second generation of leaders that Dr Dabholkar fostered has resolutely decided to continue the campaign for the enactment and implementation of the Bill, as well as the fight against superstition in general. However, we have lost one of the finest progressive leader-activists in Maharashtra—an irreparable loss.

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# Trials and tribulations: an expose of the HPV vaccine trials by the 72nd Parliamentary Standing Committee Report

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## Background

In mid-2009, the human papillomavirus (HPV) vaccine “demonstration projects” were conducted by the Program for Appropriate Technology in Health (PATH), a Seattle-based non-governmental organisation, in collaboration with the Indian Council of Medical Research (ICMR) and the state governments of Andhra Pradesh and Gujarat. The projects were funded by the Bill and Melinda Gates Foundation. The vaccines used, Gardasil and Cervarix, were donated to PATH by the manufacturing companies; in this case, GlaxoSmithKline and Merck Sharp and Dohme (MSD). These HPV vaccines were administered to approximately 23,000 young girls, of between 10 and 14 years of age, in the district of Khammam in Andhra Pradesh, and in the district of Vadodara in Gujarat.

These projects were suspended by the ministry of health and family welfare (MoHFW) in 2010, following the deaths of seven tribal girls and strong opposition from civil society groups to the unethical design and conduct of the projects. An inquiry committee was constituted to look into the “alleged irregularities” in the conduct of the projects. The committee’s report (1) agreed with the contention that there had been several violations of the rights of the participants and of regulatory procedures, but failed to apportion blame. It also remained silent on the recommendation that those involved in permitting and conducting such a trial should be punished. Despite evidence of clear violations, the inquiry absolved all involved in the project of any responsibility.

Taking a serious view of the procedural and ethical lapses in the projects, the 72nd Parliamentary Standing Committee on Health and Family Welfare recently carried out an enquiry into the studies and presented its report on “Alleged Irregularities in the Conduct of Studies using Human Papilloma Virus (HPV) Vaccine”(2), in the Rajya Sabha on August 30, 2013. This report (henceforth referred to as the 72nd Report) (2), is a clear and comprehensive vindication of the many voices and the campaign that have consistently drawn attention to violations in HPV vaccine trials in India. The 72nd Report acknowledges the unethical nature of the HPV vaccine “demonstration” project conducted in the country in 2009 by PATH (2).

## Undoubtedly a clinical trial

The 72nd Report clearly states that the “demonstration project”, as it was repeatedly referred to by PATH, was a clinical trial, regardless of what PATH called it (2). The report takes note of the observations of the MoHFW’s enquiry committee that, “the demonstration project is a study of a pharmaceutical product carried out on humans and since the primary objectives include the study of serious adverse events, it is clear that clinical trial rules and guidelines should apply” (2:p14).

The 72nd Report further states that by carrying out the clinical trial in the guise of an “observation/demonstration project,” PATH has violated all the laws and regulations laid down for clinical trials by the Government of India (2).

## Dereliction of duty and other serious concerns

Unlike the report of the MoHFW’s enquiry committee (1), however, the 72nd Report points to serious dereliction of duty on the part of many of the institutions and organisations that were involved (2:p 21), in particular the ICMR, the Drugs Controller General of India (DCGI), Ethics Committee (EC) members and PATH.

The 72nd Report questions the role of the ICMR, the apex body in the country for health research and the formulation of guidelines on clinical trial ethics, which was a complicit participant and collaborator in this project (2). The 72nd Report states that the ICMR Project Advisory Group (PAG) representative and some of the council’s officials acted as partisans of PATH and in the interest of the manufacturing companies, rather than as representatives of an institution mandated to maintain as well as ensure the implementation of the highest ethical standards in research (2:p21).

The 72nd Report also mentions that one of the roles assigned to the ICMR as per the memorandum of agreement (MOU) signed by the Director-General of the council is “advising on plans for results dissemination to support decision-making for use of the HPV vaccine.” (2). The Report expresses its inability to “understand as to how ICMR could commit itself to support the use of the HPV vaccines in an MOU signed in 2007, even before the vaccine was approved for use in the country.” It also wonders “how the ICMR could commit itself to promote the drug for inclusion in the Universal Immunisation Programme (UIP) even before any independent study about its utility and rationale for inclusion in the UIP was undertaken” (2:p19).



The Standing Committee's inquiry has proved that the DCGI played a very questionable role in the entire matter. According to the 72nd Report, the DCGI "remained a silent spectator even when its own rules and regulations were being so flagrantly violated." The report further states: "The approvals of the clinical trials, marketing approvals and import licences by the DCGI appear irregular" (2:p24).

The Standing Committee has firmly rebuked the Department of Health Research under the MoHFW. According to the 72nd Report, "the whole issue has been diluted and no accountability has been fixed on the erring officials/department for gross violations committed in the conduct of the study." The committee also felt that a very casual approach had been taken by the department in the matter and that its response reflects the lack of any concrete action to protect and safeguard the health of our people (2:p37).

Questioning the role played by PATH, the Standing Committee report states, "It is apparent that PATH has exploited with impunity the loopholes in our system, as also the absence of a nodal point or a single window for maintaining a data bank of foreign entities entering the country for setting up their offices" (2:p41). It goes on to say, "...it is established that PATH, by carrying out the clinical trials for HPV vaccines in Andhra Pradesh and Gujarat under the pretext of an observation/demonstration project, has violated all laws and regulations laid down for clinical trials by the government. While doing so, its sole aim has been to promote the commercial interests of HPV vaccine manufacturers who would have reaped windfall profits had PATH been successful in getting the HPV vaccine included in the UIP of the country" (2:p42).

The Standing Committee takes a serious view of the violations and strongly recommends that on the basis of the facts, PATH should be made accountable and the MoHFW should initiate appropriate action in the matter. This should include legal action for the breach of various laws of the land and possible violation of the laws of the country of PATH's origin (2:p30; pp 42-43).

### **Conflict of interest**

The Standing Committee sought information from the MoHFW as to whether the members of the inquiry committee were asked to file a conflict of interest declaration. According to the 72nd Report, MSD was sponsoring and funding a trial in the All India Institute of Medical Sciences (AIIMS), in the department to which a member of the inquiry committee belonged (2). The report further states: "This demonstrates a serious conflict of interest of this member of the inquiry committee" (2:p26). The Standing Committee has strongly deprecated the government's action in "appointing the committee to inquire into such a serious matter in such a casual manner even without ascertaining as to whether any of the members of the said inquiry committee have any conflict of interest with the subject matter of the inquiry" (2: p27).

The 72nd Report states: "The ministry appointed a senior official of ICMR (described as resource person) to assist the inquiry committee. The concerned individual was the main link between ICMR and PATH, and had participated actively in all discussions and meetings and helped PATH to carry out the project proactively in every respect right from the beginning in October 2006. As such, he had a clear conflict of interest and could not be relied upon to give correct information and unbiased opinions. Indeed, he should have been summoned as a witness to answer questions and not as an official resource person attached to the enquiry committee" (2:p26).

### **Flaws in "project" design, consent process**

The 72nd Report expresses its disapproval of the "project" design, which resulted in gross under-reporting of adverse events, and questions the figures for the reported non-serious adverse events (2). It is also critical of the lack of independent systems and rigorous monitoring and management of adverse events/serious adverse events (AE/SAE).

On the issue of consent, the 72nd Report observes that there were gross violations of the concept of consent and the legal requirement for it (2). This is evident from the "incomplete and inaccurate" consent forms, the failure to give comprehensive information to the participants' parents/guardians on various aspects of the vaccination, direction by the state (Andhra Pradesh) to hostel wardens to sign the consent forms on behalf of the parents/guardians, among other things. Another serious gap mentioned by the 72nd Report is the absence of insurance cover for the girls (2).

### **Funding of the trial: grey areas**

The 72nd Report notes the observations made by the inquiry committee at its meeting on September 27, 2010 (Appendix 20.5):

*....The study was initiated by PATH on its own ... without any reference from the National Technical Advisory Group on Immunisation (NTAGI), the official body of the GOI on vaccines.... It is not clear whether the state expenses were funded by PATH or came from their own resources. The monetary contributions of ICMR are also not clear. The Committee, therefore, felt that it would be in the fitness of the inquiry to document the sources and magnitude of funding of the study (2:p18).*

However, the committee's report did not delve into the matter. No mention was made of the funding from the Bill and Melinda Gates Foundation and other sources, or of the money spent by the ICMR and state governments.

## Human rights violations

The 72nd Report states that what PATH did is a clear-cut violation of the human rights of girl children and adolescents, and is a serious breach of medical ethics (2). The Standing Committee recommends that "the National Human Rights Commission (NHRC) and National Commission for Protection of Child Rights (NCPCR) may take up this matter further from the point of view of violation of human rights and child abuse" (2:p42). The Committee is of the view that since the population under study was vulnerable, the utmost caution should have been exercised in the implementation of the study.

The 72nd Report (2) emphasises that all guidelines and statutory requirements applicable to research on human participants should have been followed. It recommends that every effort should be made to expedite the preparation of a report that brings to light the real facts about the HPV vaccine trial, and to ensure that corrective measures, both in connection with the HPV trial as well as all such ongoing or proposed clinical trials of drugs/vaccines are implemented.

## Conclusion

The 72nd Report (2) validates the campaign led by civil society that has highlighted the violations committed in the HPV trials and has been demanding action ever since deaths were reported in 2010. We hope that the government and agencies concerned will act on the Standing Committee's findings expeditiously. We are living in a world in which scientific and technological advances are being made at a rapid pace and hold great promise; indeed, clinical trials are necessary if safe and effective medicines are to be developed. However, we cannot allow the pharmaceutical industry to go further in the direction in which it seems to be headed today, ie where medical ethics, rules and human rights are sacrificed at the altar of profiteering.

## References

1. Final Report of the Committee appointed by the Government of India (vide notification No.V 25011/160/2010 –HR dated April 15, 2010) to enquire into "Alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine by PATH in India". New Delhi: Gol; 2011 Feb 15.
2. Department-related Parliamentary Standing Committee on Health and Family Welfare, Department of Health and Family Welfare. Seventy second report on alleged irregularities in the conduct of studies using Human Papilloma Virus (HPV) vaccine by PATH in India. New Delhi: Rajya Sabha Secretariat; 2013 Aug 30 [cited 2013 Sep 17]. Available from: <http://164.100.47.5/newcommittee/reports/EnglishCommittees/Committee%20on%20Health%20and%20Family%20Welfare/72.pdf>
3. Department-related Parliamentary Standing Committee on Health and Family Welfare. Fifty ninth report on the functioning of the Central Drugs Standard Control Organisation (CDSCO). New Delhi: Rajya Sabha Secretariat; 2012 May 8[cited 2013 Sep 17]. Available from: <http://164.100.47.5/newcommittee/reports/englishcommittees/committee%20on%20health%20and%20family%20welfare/59.pdf>

### ERRATA: *IJME* (JULY-SEPTEMBER 2013)

1. AEFI and the pentavalent vaccine: looking for a composite picture, page 144, para 10, Line 5 should read: "350 lives will be lost to Hib pneumonia and meningitis over the next 5 years by not vaccinating one birth cohort in India."
2. National Vaccine Policy: ethical equity issue, Page 188, Figure 1: The following caption should appear below Figure 1: "From: Moher D, Liberati A, Tetzlaff J, Altman DG. The PRISMA Group (2009). Preferred reporting items for Systematic Reviews and Meta-Analyses. The PRISMA Statement. PLoS Med. 6(6): e1000097. doi.10.1371/journal.pmed.1000097. For more information visit [www.prisma-statement.org](http://www.prisma-statement.org)"
3. Innovations in monitoring of adverse drug reaction: the role of a technical advisor, Page 190: The names of the authors should read as follows: "S RAMALINGAM, TK PONNUSWAMY, YS SIVAN"
- 4a. Symposium on bioethics: empowerment of research participants/patients, Page 204: The first author's name should read: "S Swarnalakshmi."
- 4b. Pg 205, column 2, paragraph 3, line 10 should read: "Dr Nandini said that the US Commission for the Study of Bioethical Issues discussed that the US too should have a policy on compensation, as is being discussed in countries like India."
- 4c. Pg 205, column 2, paragraph 4, line 2 should read: "Dr S Swarnalakshmi, IRB Manager, YRG CARE and Organizing Secretary, TYBS 2013, spoke on PRIM&R, which had co-sponsored the symposium through the regional connections programme."
5. Evolving roles of ethics committees in India, Page 206, Column 1, paragraph 5, lines 2-3 should read: "It was suggested that Strategic Initiative for Developing Capacity in Ethical Review, of which the Forum for Ethical Review Committees in Asia and the Western Pacific is a branch, could act as a body to certify many ECs. The Indian Society for Clinical Research (a private organisation established in 2005) is industry-supported but not an industry association.."

## FROM THE PRESS

### **Lone crusader for ethics**

Fighting for ethics is never simple, as a doctor from Kerala realised during his long crusade. In 2008, Dr KV Babu, an ophthalmologist practising in Payyanur, was offended by the numerous endorsements of commercial products in the media by none other than the Indian Medical Association (IMA). His plea was that an endorsement by the IMA of a particular brand of oats or fruit juice was equivalent to an endorsement made by him, as a member of the organisation. He felt that when such an action was a direct violation of the Code of Medical Ethics Regulations 2002, laid down by the Medical Council of India (MCI), it was his duty to complain to that body. However, five years down the line, the matter is still pending before the council's ethics committee.

The MCI has delayed its decision on the issue that questions its own jurisdiction over the IMA, which has, in turn, tried unsuccessfully to expel the feisty doctor. Dr Babu has fought this battle at his own cost, spending over Rs 50,000 on trips to Delhi. He has had to file RTI applications, and write letters to the health ministry, the chief information commissioner and even the National Human Rights Commission to get the MCI to heed his arguments. Responding to the council's view that it cannot take action against associations, Dr Babu filed complaints against all 187 doctor members of the association's central working committee. Eventually, the MCI ruled against the endorsements and penalised two leading office-bearers.

Dr Babu, meanwhile, stands firm in his fight against his expulsion, saying: "It is law-breakers who ought to be expelled, not those who uphold the law."

**Rema Nagarajan, Cover story, *The Times of India Crest edition*, July 6, 2013, Available from: <http://www.timescrest.com/coverstory/the-patient-doctor-10659>**

### **Serious lapses in "welfare" schemes**

Twenty-three children died on July 16, 2013 after consuming a meal at a primary school in Gandaman village, near the town of Chhapra in Bihar. The meal of rice and soybean was served under the mid-day meal scheme, and was later found to contain the insecticide, monocrotophos. The media has analysed the wider implications of the tragedy and highlighted the callous manner in which such welfare schemes are being implemented.

An editorial in the *Economic and Political Weekly* cites a programme evaluation report, dated May 2010, by the

Planning Commission that found serious lapses in the infrastructure provided and the quality of food. The tragedy has exposed several aspects of the negligence associated with the implementation of welfare schemes in the country. These include the following.

- Programmes such as the mid-day meal scheme are characterised by class discrimination. The same goes for the public distribution system for foodgrains, in which no one takes responsibility for delivering good-quality services to the poor citizen, and for infrastructure such as clinics and school buildings, which are hopelessly inadequate. Powerful local politicians and contractors embezzle the funds provided for these purposes.
- There was a woeful absence of facilities, including transport and personnel at the healthcare centres where the poisoned children were taken, right from the local centre to a public hospital in Chhapra town to the intensive care unit in Patna Medical College Hospital.
- Primary service providers, such as cooks, helpers, midwives, contractual teachers and anganwadi workers, who are employed on contract, are not even paid the minimum wage.
- Pesticides such as monocrotophos, said to have been the culprit in this case, and butachlor, are widely used in several Indian states for crops like vegetables, fruits and chillies. The used containers are left lying around and can easily harm the unwary or children, or be misused by criminals. This continues despite the fact that monocrotophos is banned in 46 countries.

**Editorial, Dignity, not mere roti, *Econ Pol Wkly*, August 10, 2013, Available from: <http://www.epw.in/editorials/dignity-not-mere-roti.html>. Anant Zanane, Mid-day meal deaths: chemical banned by 46 countries is easily available in India, *Ndtv.com*, July 24, 2013, Available from: <http://www.ndtv.com/article/india/mid-day-meal-deaths-chemical-banned-by-46-countries-is-easily-available-in-india-396260>**

### **NEET judgment in contravention of earlier SC decisions**

A recent controversial judgment of the Supreme Court of India held that the Medical Council of India's (MCI) proposed national entrance-cum-eligibility examination (NEET) is violative of Article 19(1) (g) 25, 26 and 30, under which citizens are free to practise any profession and linguistic and religious minorities are free to set up and manage educational institutions. The majority judgment of Justices Kabir and Sen held that the MCI had exceeded its powers by declaring a single-window admission process for medical colleges all over the country,

and further, that since educational standards vary across the country the process will not ensure a level-playing field.

An article in *The Hindu* analyses how this latest verdict has gone against the principles laid down in the earlier judgments of the apex court. In the Unnikrishnan case of 1993, a constitution bench had stated that education “can neither be a trade or business, nor can it be a profession within the meaning of Article 19(1)(g). Trade or business normally connotes an activity carried on with a profit motive. Education has never been commerce in this country.” In 2002, an 11-judge bench had declared: “Inasmuch as the occupation of education is, in a sense, regarded as charitable, the government can provide regulations that will ensure excellence in education, while forbidding the charging of capitation fee and profiteering by the institution. Since the object of setting up an educational institution is by definition ‘charitable’, it is clear that an educational institution cannot charge such a fee as is not required for the purpose of fulfilling that object.” In yet another judgment in 2005, a seven-judge bench had stated: “Holding of such common entrance test followed by centralized counselling or, in other words, single-window system regulating admissions does not cause any dent in the right of minority unaided educational institutions to admit students of their choice.”

**Dhananjay Mahapatra, SC’s NEET logic contrary to constitution bench rulings, *Times News Network*, July 22, 2013, Available from: <http://timesofindia.indiatimes.com/india/SCs-NEET-logic-contrary-to-constitution-bench-rulings/articleshow/21228499.cms>**

### Malnutrition deaths in outskirts of Mumbai

Within the short period of April to June 2013, 171 children in the age group of 0–6 years have died in the tribal belt of Maharashtra, including Shahpur, Jawhar and Mokhada talukas, very close to Mumbai. During the same period last year, 184 children had died, 141 of them in the age group of 0–1 years. Of the 171 children who died this year, 131 were in the age group of 0–1 years and 40 between 1 and 6 years of age. In 2013, 173 children in the area have been diagnosed as “severe acute malnourished” and 3403 as “moderate acute malnourished.”

After 258 deaths attributable to malnutrition had occurred in Jawhar tehsil in 1992, the government had set up special projects for the tribal areas of the state. Over Rs 2118 crore has been spent on these projects over a 21-year period. The Thane zilla parishad is said to have a budget thrice the size of that of the state of Kerala and five times that of Goa.

Government health officials attribute the problem to the geographical nature of the region, early marriages, malnourishment of mothers, poor awareness about family planning practices and superstition.

Indavi Tulpule, an activist of the Shramik Mukti Sanghatana, an advocacy group, says, “The government needs to start looking at malnutrition as a symptom of a larger developmental malaise affecting this region and work holistically with [a] multi-pronged

approach. Land is being diverted from agriculture and food crops on the one hand and on the other, people simply have no work. Even if you ignore the problems in the public distribution system, this means their capacity to buy food is compromised, resulting in hunger and malnutrition.” The administration has an ethical responsibility to prevent the country’s children from starving to death. Furthermore, when this occurs so close to the metropolis, remote location and backwardness can hardly be a justification for neglect.

In Rajasthan’s tribal belt, where one-third of the children in the age group of 0–3 years were found malnourished and 80% anaemic, district officials have declared an incentive scheme. A reward of Rs 100 is to be given to government health workers who bring in a malnourished child for treatment. Officials say this will be in addition to a payment of Rs 135 being made, per day for 10 consecutive days, by the health department to the parents of a child admitted to a centre for malnourished children. The new scheme will include auxiliary nurses, midwives, anganwadi workers and *asha sahayoginis*.

Small steps of this kind may show serious intent, but a major overhaul of all such schemes is essential.

**Yogesh Pawar, Maha shame: 171 children die of malnutrition in Thane, DNA, July 30, 2013, Available from: <http://www.dnaindia.com/mumbai/1867404/report-maha-shame-171-children-die-of-malnutrition-in-thane> IANS. In Rajasthan, rewards for spotting malnourished kids, *The Times of India*, July 13, 2013, Available from: <http://timesofindia.indiatimes.com/city/jaipur/In-Rajasthan-rewards-for-spotting-malnourished-kids/articleshow/21052458.cms>**

### Government eases compensation norms in clinical trials

After drawing flak from the clinical trials industry for its reforms relating to compensation for participants who suffer adverse events during trials, the government has amended its own revised guidelines. Uncertainty regarding the fallout of the earlier reforms is said to have thrown the clinical trials industry into the doldrums, causing an estimated loss of about Rs 900–1200 crore over the last six months. The revised guidelines had stated that participants who suffered death or injury would have to be compensated even if these events were not necessarily the consequences of the trial. Under the new guidelines, a participant will be awarded compensation only if the death or injury is proved to have been caused by the trial. These modifications have been recommended by the Drug Technical Advisory Board and accepted by the health ministry. Further changes include the following.

- Medical management will be provided only in case the injury is due to activities related to the clinical trial, “as the free medical management may create undue influence for the patient to enrol in a clinical trial.”
- The period for reporting serious adverse events and fixing the quantum of compensation has been extended from 21 to 30 days.



- The deadline for an independent expert committee to establish the cause of death during a trial has been increased from 30 to 60 days.
- The “licensing authority” or Drug Controller General of India may now decide on the amount of compensation and cause of death up to two months after receiving the expert committee’s report.

**Vidya Krishnan, Govt eases compensation guidelines for clinical trials, *Live Mint* [Internet] July 11, 2013, Available from: <http://www.livemint.com/Politics/fsjKnIxaH6JKm1Ep7tnGtJ/Govt-eases-compensation-guidelines-for-clinical-trials.html>**

### **Government policy moves away from family planning**

“Maternal and child mortality are the major issues faced by India and not population growth. The days of high fertility rate are over,” according to SK Sikdar, the deputy commissioner and head of the family planning division, Union ministry of health. The health ministry has stated that it is “repositioning” its policy focus away from birth control towards maternal health and spacing of pregnancies. However, with a maternal mortality rate of 212 per 100,000 live births, the country has a long way to go to reach the Millennium Development Goal of 109 by 2015.

The new strategy is “completely free of taboos and coercion. We have also moved from a camp-based approach where our health workers had a target to achieve. Instead, we now have fixed-day services for women in clinics,” said Anuradha Gupta, the mission director of the National Rural Health Mission.

Activists have greeted these statements with caution. Jasodhara Dasgupta of the National Alliance for Maternal Health and Human Rights said, “We would welcome the policy by the government, but my personal experience shows the government still concentrates on target numbers more than the quality of services.” She pointed out that the burden of birth control is still borne by women, who also face the accompanying violations of human rights at many government-organised camps.

**Nikita Mehta, Government shifts focus from birth control to spacing, *Live Mint* [Internet]. July 10, 2013 Available from: <http://www.livemint.com/Politics/rulUdu59QejhnLgg80dssJ/Govt-shifts-focus-from-birth-control-to-spacing.html>**

### **Controversial tests on H7N9 flu virus**

A group of researchers working on the Influenza A H7N9 virus has, in a letter to *Science* magazine, put before the public its case for gain of function (GOF) studies to create viruses with varied properties in the laboratory. The epidemiologists, led by Ron Fouchier and Yoshihiro Kawaoka of the University of Wisconsin, say that their earlier experiments, on the same lines, with the H5N1 flu virus had aroused a storm of protest and been virtually shut down for a year. They now want to explain to the public the nature and importance of their work in the interests of transparency. According to them, so far, research has studied “the wild-type avian A (H7N9) viruses in terms of host range, virulence, and transmission” and they are evaluating the effectiveness of antiviral drugs and vaccine candidates.”

Researchers “use several techniques to give viruses characteristics that they don’t have in nature, such as the ability to infect new species or transmit more easily through the air. Such studies are critical to understanding the sometimes subtle changes that can make a bird virus a pandemic threat.” The Fouchier group argues that traditional epidemiological testing does not enable healthcare authorities to tackle pandemics in time. However, scholars opposing the tests are very sceptical, arguing that the justification for carrying out this research is unconvincing and that the precautions outlined by the group cannot guarantee safety.

Among the characteristics given to viruses in GOF studies could be easier transmission and the ability to infect more species. These could be potentially disastrous if the viruses were to escape from the laboratory or get into the hands of terrorists, say critics.

**David Malakoff, Critics skeptical as flu scientists argue for controversial H7N9 studies, *Science*, August 9, 2013, Available from: <http://www.sciencemag.org/content/341/6146/601>**  
**Ron A M Fouchier, Gain-of-Function Experiments on H7N9, *Science*, August 9, 2013, Available from: <http://www.sciencemag.org/content/341/6146/612.full>**

### **Survey shakes up medical teachers**

According to a survey carried out recently at the Grant Medical College in Mumbai, medical students pointed to continued absenteeism, lack of clarity in teaching and ignorance of the subjects taught as the three worst failings of their professors,.

The survey covered 900 students from the first to third years. They were asked to rank their professors, from all 12 departments, on a score of 1 (worst) to 10 (best). The students were encouraged to be frank, with no obligation being placed on them to mention their names or roll numbers. The participants were the most indignant about those teachers whom they said they had never even seen on campus.

The survey was initiated by the dean, Dr TP Lahane, who said that though the college is a reputed institution, “not many of our students are able to crack the All India Post-Graduate Medical Entrance Exams.” He concluded, “This survey gives a fair idea of where the problem lies.” In the survey, the pathology and forensic departments fared the worst, while the biochemistry and anatomy departments were rated the highest. The teachers have apparently taken the survey seriously and say they intend to improve their performance. This is a good augury for the maintenance of standards in medical education which have been a cause for concern all over the country. More colleges in India should take a leaf out of Dr Lahane’s book. There are plans for a follow-up survey after six months.

**Lata Mishra, Survey shames JJ’s Grant Medical College faculty, *Mumbai Mirror* [Internet] September 2, 2013, Available from: <http://www.mumbaimirror.com/mumbai/others/Survey-shames-JJs-Grant-Medical-College-faculty/articleshow/22222846.cms>**

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## ARTICLES

## Dharma and medical ethics

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**Abstract**

*Despite the numerous policies, regulations and laws aimed at promoting and ensuring ethical practice in healthcare, ethical misconduct remains rampant. Perhaps something more is needed to encourage a genuine and sustained moral attitude and behaviour. To a casual reader, the regulations on ethics read merely as a list of do's and don'ts and their philosophical foundation is not clear. In actuality, morality is often grounded in philosophy. Traditionally, religious and theistic philosophies drove moral behaviour. However, this is changing due to the current trend of secularism. Hindu philosophies are among the oldest philosophies that are still thriving, and this article explores these philosophies and compares and contrasts them with some of the contemporary ethical theories to assess if they can add value to the field of medical ethics. The main theme of the article is dharma or righteous conduct, the concepts related to it and how these can have a bearing on the development of an ethical attitude and the practice of medical ethics.*

**Introduction**

In the past century of medical history, innumerable policies, regulations and laws have been framed to promote and ensure ethical practice in all aspects of healthcare. Despite these measures, we are bombarded with reports of unethical medical practice and research misconduct with disturbing frequency. In the case of the few who are "caught," the penalties are punitive and the transformation in attitude and behaviour, if any, is usually more cosmetic than real. Many instances of unethical behaviour arise not from ignorance, but from an attitude of deliberately overlooking norms and regulations. Regulators, institutions, educationists, policy-makers and activists often despair over what further steps need to be taken to promote a genuine and sustained moral attitude and behaviour. While we continue to harp on more strict regulations and better enforcement, have we been overlooking any other avenues that may exist?

At present, the teaching of medical ethics focuses chiefly on principles, guidelines, rules and laws. Medical ethics is understood as a list of do's and don'ts and its practice is considered a matter of social and professional etiquette or a regulatory requirement. Even though many of the present ethical guidelines evolved from a sense of moral outrage at horrifying instances of human exploitation in the name of medical science, the philosophical foundation of these

guidelines (ie an understanding of human beings, their purpose and inter-connectedness, and how they should behave towards one another) is not really evident to the casual reader of the regulations. Despite its commitment to ethics, medical decision-making is heavily influenced by the character of individuals and this, in turn, is shaped by the person's environment, experiences and personal philosophy. For all these reasons, there is a need to reiterate the philosophical foundation of ethics.

Traditionally, the imperative for moral behaviour drew its strength from theistic beliefs. Since about the 17th century, more voices were heard in favour of basing moral behaviour on secular foundations. Immanuel Kant's categorical imperatives (1) are clearly founded on a secular philosophy. At present, too, there is a popular trend of secularism, sometimes accompanied by a disregard for religion, and the theistic imperative for moral behaviour is losing ground. Despite the popularity of the secular trend, it appears that life is not really guided by the "secular philosophies." The imperative for moral behaviour is largely dependent on personal resolve, fear of the law, or a social obligation to abide by regulations. It is well known how resolve can be weakened, the laws bent or regulations overlooked. While secular philosophies do offer scope for a categorical imperative, theistic approaches can enhance and enrich this scope. Therefore, it is worthwhile not only to revive the philosophical foundation of ethical behaviour, but also its theistic moorings.

Each religion has its own distinctive derivation of ethics and morality. There is extensive written material on the Christian, Jewish and Islamic philosophies in relation to medical ethics (2-4). However, there is meagre literature of this nature as far as Hinduism is concerned (5-7). Hindu philosophies are among the most ancient philosophies that are still flourishing and it would be interesting to see how they can contribute to present-day medical ethics.

This article dwells on some aspects of Hindu philosophies, particularly the concept of *dharma*. A seemingly elaborate account of Hindu philosophies is presented here. However, in actuality, it is only a succinct outline that is meant to provide the reader with a glimpse of the system of thought. Unless one provides a background that acquaints the reader with the depth of the philosophies, it would be difficult to make a meaningful connection to medical ethics.

## What is Hindu philosophy?

The word "Hinduism" has been conventionally used to denote a religion. However, it is also an umbrella term for a way of life, guided by a wide variety of beliefs and rituals based on Vedic<sup>1</sup> traditions. The *Vedas* and *Upanishads* are its foundational scriptures (8,9). The term Hindu philosophy actually encompasses different schools of thought,<sup>2</sup> of which *Yoga* and *Vedanta* retain their importance in the current practice of Hinduism. There are many apparent and subtle differences amongst these schools of thought, and it is difficult and problematic to comprehensively explain the terms associated with or variations between the philosophies in a short article like this. The various schools of thought are more or less in agreement that the purpose of human life is to strive for spiritual progress, towards *moksha* or *nirvana* (liberation) – be it liberation from "the cycle of birth and rebirth" or from "unhappiness and misery" – through an experience of oneness with God or the cosmic Self.

## Goals of life: the *purusharthas*

In Hinduism, life is considered to consist of four stages: *Brahmacharya*, *Grihastha*, *Vanaprastha* and *Sanyasa*<sup>3</sup>. During one's passage through these stages, one has to fulfil certain goals to have led a meaningful life. These goals, known as the *purusharthas*, are *dharma*, *artha*, *kama* and *moksha* (10). The scriptures<sup>4</sup> offer guidelines and instructions on how these goals can be attained. Most of the instructions are deontological in nature and have the tenor of categorical, moral imperatives.

In common parlance, *dharma* simply refers to a person's religion. *Dharma* is commonly interpreted as rituals, duties, caste rules or even the law, but such interpretations are reductionist. In philosophical terms, *dharma* refers to a way of life that is aligned to the natural order of things. Natural order itself refers to an orderly system in nature that is believed to be divinely established, with the purpose of ensuring sustained maintenance of life, in a peaceful and harmonious manner. While *dharma* signifies actions that are aligned to the natural order of things, *adharma* would mean actions that are against this order. It is believed that only the pursuit of *dharma* can bring about social harmony and peace in the world. *Adharma* is believed to lead to suffering, conflict, discord and imbalance. Therefore, *dharma* is also simply referred to as righteous conduct.

Human beings are said to have certain duties or responsibilities during the four stages of life that must be carried out in such a way as to sustain the natural order.

Therefore, *dharma* means *carrying out all one's responsibilities, even while maintaining peace and harmony*. The words "duty" and "responsibility" are used synonymously. Since the concept of *dharma* is part of a theistic philosophy, a person's foremost responsibility is considered to be the expression of gratitude to God and to the teacher / guru. Second in importance is a set of responsibilities arising from the roles assumed in the family, ie that of a child, parent and grandparent. These responsibilities include providing care, sustenance, protection and love. The third set of responsibilities emanates from the premise that human

beings are social beings and embedded in society. As they derive a great deal from society, they have a duty to give something back, to help others, serve those who are suffering, and promote peace and harmony in society. The final responsibility is towards nature, the environment and all forms of life.

Without material means, it would not be possible to carry out these responsibilities. Therefore, *artha*, the second goal, focuses on the need to earn material wealth as a *means* to abide by one's *dharma*. The essence of how one should achieve this goal consists of earning wealth in a congenial manner, by virtue of one's own efforts and hard work, without cheating, stealing, harming or causing loss to others, without being driven by greed, and without disturbing peace and harmony in society. Wealth should not be accumulated mindlessly; it should be accumulated only to the extent necessary for meeting one's responsibilities.

*Kama* is commonly translated as "erotic love" or "sensual desire". However, in the context of the *purusharthas*, it refers to the responsibility of love and of showing integrity in relationships. It extends to the responsibility of procreation, too. The experience of fulfilment and satiety must be at the emotional and psychic levels rather than the physical alone. Thus, *kama* signifies something more than sensual desire alone.

*Moksha* indicates "liberation from the cycle of birth and rebirth". Such liberation would be attained as a consequence of the fulfillment of the other three goals, extending across all the stages of life, and is the result of a cumulative effort over many births or lifetimes. In contemporary times, however, liberation has also been interpreted as "liberation from unhappiness and misery". It seems difficult to actually describe or experience liberation from the cycle of birth and rebirth while it is possible to experience liberation from unhappiness.

## The telos of *dharma*

An explanation of *dharma* is completely intelligible only if it also includes an account of its telos or purpose. *Dharma* focuses not merely on the action, but also on the *purpose* of the action and, in extrapolation, the purpose of human life. A lifetime of practising *dharma* allows a person to flourish and live the good life, which is somewhat similar to, though not exactly the same as, Aristotle's *eudaimonia* (11). Today, people's notions of the purpose of life and a good life are extremely varied and controversial. Aristotle's *eudaimonia* entailed living well and taking part in activities that exercise the *rational* part of the psyche, while the purpose of life was to flourish. *Eudaimonia* was the "end" by itself. The parameters for proof of a good life were wealth, power, friends and beauty. In Hindu philosophy, a good life means performing activities that exercise the *spiritual* part of the psyche, while the purpose of life is to attain *moksha* and not merely to flourish. The parameters for proof of a good life are an "experience of peace, harmony and lack of misery" (10,12).

## The world as a cosmic family

*Vedanta*, in particular the Advaita version, sets forth the concept of cosmic unity in clear terms. This concept regards all living



and non-living entities in the universe as one and the same, as mere expressions of the essence of the large cosmos (the Whole). According to Advaita (13,14), the oneness can be experienced only when one thinks of oneself not as a separate individual entity, but as a being who is integrated with the whole cosmos; and *moksha* can be experienced only when this oneness is experienced. Therefore, submergence of the self into the Whole and abnegation of the sense of separateness or individuality is celebrated. This emphasis on cosmic unity has influenced several physicists and philosophers, such as Einstein, Schrodinger, Spinoza, Nietzsche and Schopenhauer (15,16–18). Besides influencing physicists' understanding of the universe, Advaita has influenced the derivation of ethics in the Hindu ethos. According to Swami Vivekananda, "...this oneness is the rationale of all ethics and spirituality...the essence of all morality is to do good to others... whomsoever you hurt, you hurt yourself. They are all YOU...." (19). Also, "Only when one can see oneself in others, only then can one truly feel love and respect for others. The sense of universal brotherhood promoted by this philosophy is echoed in the *Upanishads* as *vasudhaiva kutumbakam* (the whole world is my family) (20).

### Translating *dharma* into daily life

While abiding by *dharma* in *brahmacharya* (student life) – the first stage of life – one's responsibility is to educate oneself, study and gain knowledge. The knowledge acquired should extend beyond technical information to a knowledge of the scriptures and philosophy. Emphasis is also laid on the practice of contemplation, as well as on efforts to understand the merits of a life of simplicity, self-discipline and the judicious use of resources. This stage is one of celibacy in thought, word and deed, so that the mind can remain focused on studying. The potential for ethical enrichment offered to a medical student, or for that matter, a student of any other health discipline, by the prescriptions of *dharma* is clearly evident. The student phase can, therefore, be regarded as a process that prepares the person to lead an ethical life in the second stage. The second stage of *grihastha* is associated with the maximum level of social responsibilities. This is the stage during which the most important contribution is made to the organisation and sustenance of the entire society. Therefore, a person in this stage is most in need of guidance. According to the *purusharthas*, this stage is of the maximum relevance in terms of promoting righteous conduct in the fulfilment of all responsibilities (*dharma*), as well as promoting righteous means of earning material wealth (*artha*) and a life characterised by integrity (10,21). Persons who are in positions of power of any kind and whose decisions can have an impact on many people have a responsibility to make fair and just decisions, free of any personal biases. This, once again, draws attention to the relevance of *dharma* in research, medical care, medical administration, policy development and governance. The role of the moral foundation envisioned in the concept of *dharma*, during studentship as well as in building a moral citizen in later life, cannot be overemphasised. The occurrence of the theme of 'righteousness' is striking in the other eastern philosophy, Buddhism, as well, in the articulation of the goals of life or the eight-fold path to salvation<sup>5</sup> (22).

An exploration of the meaning of each of these goals seems to indicate that *dharma* is the first, most important, and overarching goal, which extends to *artha* and *kama*. These three goals are the means to the ultimate goal of *moksha*. It is also evident that the aspirations of human beings are fully acknowledged and permitted – in fact, human beings are exhorted to fulfil their aspirations – but within a framework of duty on one side and spiritual attainment on the other. This is reflected also in the manner in which the goals are listed, ie *artha* and *kama* are positioned between *dharma* and *moksha*.

### Attaining the goals of life

The gap between knowledge and practice in human behaviour is well known. A theoretical knowledge of *dharma* alone does not suffice. Some attitudes and qualities are said to be needed to practise *dharma*. Guidance on how to acquire those qualities is available in the scriptures and writings of all the schools of Hindu philosophy. Such guidance is mostly in the form of prescribing the virtues to be cultivated and advising against certain vices.

Shankaracharya's *Viveka Chudamani* promotes the virtues of *viveka*, *vairagya*, *shat-sampatti* and *mumukshutva* (23). *Viveka* is the wisdom to discriminate; to discern between what has enduring value and what does not, in all affairs of daily life, ranging from mundane matters such as eating and drinking to more serious ones. *Vairagya* is dispassion or freedom from self-indulgence. Self-indulgence is considered to have no enduring value and is, therefore, discouraged. *Shat-sampatti* literally means a "treasure of six virtues". It refers to cultivation of a frame of mind which is calm and quiet, and which can control negative thoughts, endure hardship with equanimity and draw mental strength from within oneself rather than depending on external support. It also includes having firm faith in the guidance offered by one's spiritual teacher. *Mumukshutva* refers to an intense longing and aspiration for *moksha*. This intense longing appears to be the ultimate driving force of morality.

In his *Yoga Sutras* (aphorisms), Patanjali, prescribes adherence to the *Ashtanga Yoga* (24), which comprises the qualities of *yama*, *niyama*, *asana*, *pranayama*, *pratyahara*, *dharana*, *dhyana* and *samadhi*. *Yama* (vow of self-restraint) and *niyama* (disciplined daily routine) are regarded as the primary steps and the moral backbone of *Ashtanga Yoga*, as they cultivate an ethical discipline.

The purpose of developing all these qualities is to still the mind and distance it from the chaos of the myriad thoughts and desires that distract one. In this way, one's thoughts will be pure, and one will experience contentment and be able to practise austerity. This will enable one to focus on higher goals.

Some of the vices that hinder human beings from performing their *dharma* (duty) are said to be unbridled sensual desire, avarice, envy and vicious anger. It is held that these vices can be overcome through knowledge gained from the scriptures (*Jnana Yoga*), unconditional devotion to God (*Bhakti Yoga*), or detached and selfless work (*Karma Yoga*). Learning about



*Karma Yoga* (25) is useful in understanding the motivation for abiding by *dharma*.

In a literal sense, *karma* means actions and *yoga* means spiritual union. Therefore, *Karma Yoga* is described as a way of thinking, willing and acting, by which one orients oneself towards one's spiritual goal. Humans beings are supposed to act in accordance with their *dharma* (duties), giving no consideration to their self-centred desires, likes or dislikes. They are supposed to act without an eye to the fruits of their deeds. They should not think about whether they will succeed or fail, as long as the performance of their deeds is marked by complete involvement and commitment to their *dharma*. In short, *Karma Yoga* is selfless action or selfless work. When one performs one's duties or work with such an attitude, it amounts to service. The *Bhagavad Gita* (26) offers detailed explanations of and guidance on *Karma Yoga*.

It is interesting to note that the guidelines on *dharma* closely resemble the precepts of Deontology (27), in the sense that the morality of actions is judged by how far individuals adhere to their duty or responsibility or abide by the rules. The exhortation to cultivate virtues closely resembles Aristotle's promotion of virtue ethics (28,29) and Confucianism (30).

As is evident, whatever the school of Hindu philosophy, the virtues to be inculcated are very similar. Followers can pick and choose the individual philosophy according to their inclinations. The virtues embodied in Hindu philosophy have a universality, in the sense that no other religion or secular order would contradict them and, indeed, many of them find mention in the scriptures and literature of other religions, too. Practising these virtues seems a difficult task and a serious enterprise, but it appears that it would give rise to a mental attitude that promotes responsible behaviour. It promotes selflessness, an expansive worldview, moral behaviour and altruistic motives which are tangibly different from the qualities inspired by man-made regulations and constitutional law.

### **Dharma and current medical ethics**

Most medical professionals embark on their career with a commitment to morality and ethics. However, when they enter the world of competition, and a society that values name, fame, money and power more than spiritual progress, their commitment to ethical behaviour can easily weaken. The commitment to an ethical attitude needs constant reinforcement. *Dharma*, both through the ethical discipline it demands in everyday life and through its theistic moorings, may provide this reinforcement. Moreover, when *dharma* is understood and frequently reiterated as the primary purpose of life, it may serve to balance and temper a person's worldly aspirations.

It may be asked how *dharma* can actually help in the care of individual patients. Most of the existing ethical theories, be they Deontology, Utilitarianism, Consequentialism or Principlism, offer only a broad framework for action. Making an ethical decision in a particular situation still requires an interpretation of the theory. Sometimes, theories, principles or

guidelines seem to be in conflict with one another, ultimately necessitating an interpretation based on the context. The theories mentioned above offer no further guidance. The person has to depend on practical wisdom to choose the right course of action. *Dharma*, too, provides only a framework for action. However, the virtues that must be practised to abide by *dharma* also promote mental discipline and practical wisdom (*phronesis*, according to Aristotle; *viveka*, according to Hindu philosophy). On the basis of this, one can make ethical, fair and practical decisions that are aligned to one's deeply held values.

There are innumerable principles, guidelines and regulations in use today, but awakening the *ethical attitude* to honour them is the challenge. It must be stressed that *dharma* is not yet another ethical principle that can be applied to resolve ethical dilemmas – instead, it represents a way of life that awakens, promotes and sustains an ethical attitude. An awakened ethical attitude would enable a person to interpret situations wisely and judiciously apply the ethical principles and theories already in use. Guidelines, regulations and laws would then be seen as the means, and not the end, in so far as ethical behaviour is concerned. Thus, *dharma* would have an overarching influence on decision-making in healthcare, encompassing and extending beyond individual medical care.

*Dharma* could influence decision-making in many aspects of healthcare. The concept of cosmic unity (13) stresses the interconnectedness of all components of creation. Each living body is regarded as a microcosmos that is a complete reflection of the macrocosmos around, and, therefore, every human action has a consequence on the environment. An understanding of the cosmic dimension of human life may significantly influence the way we look at our world and at our behaviour in it. It may define a framework for our aspirations, be they in terms of technological progress, longevity, regenerative medicine or freedom from disease. It may provide a direction to research and scientific progress towards genuine social beneficence. Understanding the cosmic dimension has the potential to sensitise us to approach the universe with respect and awe, and to teach us to value the environment and make judicious use of diminishing resources.

When divinity is recognised in all forms of life, one will hesitate to treat any form of life merely as a means to achieve one's own ends. This is very similar to Kant's second categorical imperative (1), but it has a philosophical and theistic foundation that helps one understand the essence of respect for persons and informed consent.

It is now being realised that there are fundamental differences in the foundation for medical ethics between cultures. Western philosophies encourage discovery, as well as the enhancement and maintenance of individuality, the principle of autonomy being an expression of this individuality. Autonomy is, therefore, often regarded as the most important of the four ethical principles. Flowing from this concept is the tendency to demand moral behaviour from others as a matter of right. The Hindu philosophies, on the other hand, promote abnegation of the self and submergence of individuality. Those who are followers

of *dharma* are intensely aware of their responsibilities towards others and the impact of their choices on them. Therefore, the person is most likely to focus on making choices that are the least self-centred, the least harmful and the most beneficial to others. This seems to indicate that beneficence and non-maleficence would be regarded as more important than autonomy. When social beneficence and non-maleficence drive medical care, the potential to deliver ethical care increases tremendously.

Today, there are plenty of complaints regarding the deteriorating standards of work ethics amongst medical professionals. *Karma Yoga* (25) offers guidance on the work ethic of professionals. Its ideals are rigid self-discipline and self-restraint, total absorption in one's path of action, and setting high standards for oneself to provide dedicated service. To a follower of *Karma Yoga*, *dharma* would mean selfless service, working for the benefit of society and not for rewards, and aspiring for honesty and perfection in action. These translate into attending to one's duties promptly; delivering rational, cost-effective and good-quality medical care; focusing on care rather than monetary profits; and being genuinely committed to serving the sick rather than gaining fame, wealth, position and power. They also imply that it is important to ensure the veracity and legitimacy of the results of scientific research. Most importantly, *the ideals of Karma Yoga are supposed to be pursued for the self and not others*. Thus, moral behaviour and self-policing are driven internally, and the need for external monitoring and regulation is not so strong. This attitude has become rare in the present age, though it is extremely important, not only for practising ethical medicine and conducting ethical clinical trials, but also for creating role models for future generations of medical students.

*Karma Yoga* can influence the delivery of healthcare in other ways, too. As it requires one to perform one's duty selflessly, without an eye to the benefits of one's success, any work done in this spirit is a service to humanity. If the philosophical foundation of one's work consists of the submergence of 'I' as the achiever or doer, the submission of all the fruits of one's actions to God, and contentment and detachment, there is bound to be a clash with concepts such as intellectual property rights and patents. In this context, *Karma Yoga* translates into giving greater importance to non-economic social values in the development of drugs as well as the marketing strategies for drugs. Providing medical care and conducting research to develop new treatments are regarded as one's duty, and this duty must be fulfilled with the expectation of no more material gain than is necessary to fulfil other social responsibilities. The high cost of medical care today can be attributed partly to the pricing policies protected by patents laws and intellectual property rights and partly to personal aspirations for the accumulation of immense wealth. Would it be possible to consider a paradigm shift in which the personal benefits of research or medical skills are not demanded as a matter of entitlement, but are accepted humbly and considered a spontaneous bestowal of appreciation or gratitude by the society, based on the social worth of the achievement? Such questions are not easily resolved.

The concept of *dharma* has many areas in common with the current practice of medical ethics and further enriches it. When

one has explored and gained a thorough understanding of the virtues, it seems that the virtue of *satyam* (truth) does not refer to merely speaking the truth. It means the permeation of our thoughts, words, deeds and relationships with our fellow human beings by truth. It posits the imperative for integrity in research, maintaining an appropriate relationship with patients, disclosure of medical error, transparency in the consent process, etc. It implies opposition to plagiarism and falsification of data. *Ahimsa* is not a matter of refraining from killing alone, nor is it mere vegetarianism. It also implies kindness and care for all forms of life. It also signifies refraining from mindlessly destroying a colleague and from causing undue harm or pain during research, as well as being judicious in the pricing of services so that the "economic violence" of sickness can be reduced. The concept of *vasudhaiva kutumbakam* ("the whole world is my family") promotes a universal attitude of caring and service, which is the cornerstone of ethics in healthcare.

## Conclusion

People choose their professions on the basis of their capabilities, inclinations and circumstances. Many young medical students say they chose the medical profession because they wanted an opportunity to serve others. Society has long respected the medical profession for its commitment to service and the alleviation of suffering. It is apparent that *dharma* and medical science have a common aim – to make humanity happier by reducing suffering. So, they could be regarded as convergent or even complementary. Albert Einstein said, "Science without religion is lame, and religion without science is blind." Recognising this fact and assimilating it into our practice of medicine would lead to an intelligent combination of technical skills, compassionate understanding and spiritual/religious values, ultimately benefiting the very art of healing.

Present-day guidelines and policies have reduced ethics to a mere social etiquette and glibly articulated forms for informed consent. However, morality and ethics are a way of life and not something to be thought of only when providing medical care, running a hospital, making medicines or conducting research. Medical ethics is only one of the many expressions of a moral life. Ethics is also reflected in the way we treat our fellow beings, the choices we make and the aspirations we nurture, in all walks of life and at all times. If one interprets ethical behaviour from a "*dharmic*" perspective, ethics seems to acquire a transcendental dimension and an ontological foundation that steps beyond the domains of patient autonomy and consent forms. The *dharmic* perspective imparts more categorical strength to ethics and posits that ethics is articulated not merely as a legal or regulatory imperative, but also a spiritual imperative. Thus, there are enough merits in the philosophy of *dharma* to warrant a closer and deeper exploration of its importance to medical ethics, both in the teaching and practice of medical ethics.

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## Notes

1. Pertaining to the *Vedas*, the oldest Hindu scriptures
2. Hinduism has six orthodox schools of thought, most of which are theistic and accept the *Vedas* as the supreme and revealed source of knowledge, and three heterodox schools of thought, which draw upon traditions other than the *Vedas* too (32) (9).
3. The four stages are *Brahmacharya* (referring to student stage of life), *Grihastha* (referring to family life and / or being a citizen), *Vanaprastha* (referring to the abandonment of material possessions) and *Sanyasa* (renunciation) (10) (34). The first two are the most relevant to this article.
4. The first part of the *Taittiriya Upanishad*, *Shiksha-valli* (12), is a section providing instruction on how the *purusharthas* can be attained.
5. Eight-fold path of Buddhism: right views, right resolve, right speech, right conduct, right livelihood, right effort, right mindfulness and right meditation.
6. The *Bhagavad Gita* (28), Shankaracharya's *Viveka-Chudamani* (Jewel-crest of Wisdom) (24) and *Yoga* philosophy of Patanjali (25) are only some of these scriptures.
7. *Shat-Sampatti* – (a) *sama*: an inner attitude of tranquility and contentment, (b) *dama*: controlling wayward thoughts and actions and using the senses in a responsible way, (c) *uparati*: ceasing to depend on other persons or external objects for happiness, (d) *titiksha*: forbearance or enduring difficulties without rebellion or lamentation, (e) *shraddha*: faith in or firm conviction regarding the truth about the natural order of things, and (f) *samadhana*: remaining focused on harmony and balancing the mind, its thoughts and emotions.
8. Only an approximation of their meaning can be expressed in English. *Yama* refers to a vow of moral self-restraint. It is a vow of restraint against vices like violence, falsehood, incontinence of urges, theft and greed. In a more positive sense, it could be interpreted as restraining one's impulses and temptations so as to encourage adherence to non-violence (*ahimsa*), truthfulness (*satya*), celibacy in thought, word and deed (*brahmacharya*) and non-covetousness (*aparigraha*), and to refrain from stealing (*asteya*). *Niyama* are rituals or routines to be practised every day so that they become integrated with one's character and give one the moral strength to abide by the vow of self-restraint. Thus, *yama* and *niyama* are interrelated. The process of following the routines gives rise to a sense of discipline and focus, which is conducive to internal and external purity (*saucha*), contentment (*santosh*) and austerity. These allow one to remain focused on spiritual goals and study (*tapas and svadhyaya*). *Yama* and *niyama* are regarded as the primary steps without which the rest of *Ashtanga Yoga* will not prove fruitful. *Asana* and *pranayama* refer to controlling the body and breathing with the help of postures of meditation and breathing exercises, respectively. These seemingly physical exercises are important psychic practices which are built on the foundation of *yama* and *niyama* and are, in turn, essential for the next four steps of *Ashtanga Yoga*: *pratyahara* (withdrawal of the mind from all external objects and all internal images), *dharana* (concentration), *dhyana* (meditation) and *samadhi* (unification of the self with God).
9. The *arishadvarga* (six negative characteristics): *kama* (unbridled sensual desires), *krodha* (unjust and vicious anger), *lobha* (avarice and greed), *moha* (infatuation), *mada* (vanity resulting from egoism), and *matsarya* (envy and jealousy) (28)

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# The big Cs of the informed consent form: compliance and comprehension

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## Abstract

*The informed consent process is a shield which protects subjects from harms that may be caused by a scientific enquiry. Only a competent participant with a complete understanding of the trial can give informed consent. Although the content of a valid informed consent form (ICF) has been established, the Drugs and Cosmetics (First Amendment) Rules, 2013 have stipulated that ICFs must fulfil the requirements of Appendix V of Schedule Y. We considered 50 ICFs and analysed whether they complied with Appendix V. Our analysis reveals a gloomy picture, with 70% of the ICFs deviating from the requirements of the law. We have identified the elements most commonly overlooked in the ICFs analysed. We recommend certain points which must be incorporated into ICFs to help participants better understand the trial. Our findings indicate that adequate action needs to be taken to ensure the protection of the rights of research participants.*

## Introduction

The informed consent process is the practical application of the principle of autonomy (1). Informed consent that is given freely is central to ethically sound research. This practical application of autonomy ensures that in no instance are there elements of coercion, deceit or abuse. Informed consent must be obtained in the right manner from participants in research and patients in clinical care (2).

Informed consent is essential for upholding the patient's autonomy, safeguarding individual rights and promoting ethical research. It aims at helping potential participants who have been deemed suitable for recruitment in a particular study to reach a decision on whether or not to participate. Obtaining informed consent is not a one-time procedure limited to the time of the recruitment of the participant. The process must be a continuous one that lasts till the end of the study. The three cornerstones of an ethical and valid informed consent process are:

- effective communication,
- full information, and
- freely given consent (3).

For the informed consent process to be completely effective in protecting the patient's rights, the patient must take a decision based on complete comprehension and voluntariness.

The concept of making informed consent in research and clinical practice mandatory is based on the principle of "respect for the patient". However, there are several challenges that

impede the smooth implementation of obtaining effective informed consent. One of the obstacles has its roots in the phrase itself – the first component, 'information', comes from the principal investigator, while the other, "consent", comes from the participant. The patient–doctor relationship is fraught with many problems, including the paternalistic behaviour of doctors, as well as inadequate communication and lack of comprehension (4).

Ambrosius Macrobius once said, "Good laws have their origin in bad morals." Indeed, a long history of abuse, deceit and lack of moral fibre gave birth to the practice of informed consent. The earliest documented reference to the concept of informed consent dates back to the nineteenth century, and precedes the Nuremberg Code. The Prussian government's ministry for religious, educational and medical affairs issued a directive which mandated that people could be enrolled in non-therapeutic research only after they had been given an explanation regarding the risks they might face, and after they consented to enrol. The directive also emphasised written documentation and held the medical director responsible for ensuring the ethical conduct of research (5). The first ever documented use of an informed consent form was the one introduced by Major Walter Reed (of the US army) during his experiments on the transmission of yellow fever. He went to great lengths to ensure that the subjects were fully aware of the risks involved, even translating the consent documents into Spanish for the benefit of Cuban volunteers (6).

Although the concept of informed consent became more structured in the Nuremberg Code (7), it was never universally accepted and instances of unethical research mushroomed. Stringent action became necessary to curb this trend. Among the efforts to ensure that research involving human subjects should be ethical was the formulation of guidelines for ICFs in The Declaration of Helsinki (8). These were adopted by the World Medical Association in 1964. The declaration provides guidelines to formulate an informed consent document and conduct the informed consent process.

Informed consent is deemed necessary for most types of experimentation on humans, but may not be so in the case of some experiments. Experiments on humans in the field of behavioural studies might not require the informed consent of the participants; on the contrary, providing information for consent might defeat the purpose of the investigation. In these trials, the participants' interest is best served if they are not given any information about the trial, that is if the trial does not pose any physical or mental risk to the patient. For



example, a worker's response to a fire drill can be best studied if information on the experiment is withheld from the worker. The US Code of Federal Regulations (9) has laid down the following conditions under which the informed consent process can be waived.

- The research involves no more than minimal risk to the subjects.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- It is not practicable to carry out the research without the waiver or alteration.

It is also specified that whenever appropriate, the subjects will be provided with additional relevant information after participation. This process is often referred to as "debriefing."

In India, Schedule Y of the Drugs and Cosmetics Rules, introduced in 1988, set forth regulatory guidelines for the launch of new drugs. It was amended in January 2005 to bring about harmonisation between the Indian guidelines and the guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Schedule Y recommended formats for critical documents used in clinical research, one of which is the ICF (10). The mandatory provisions regarding the contents of ICFs are provided in Appendix V of the Schedule. Thus, it is legally binding for the ICFs of trials conducted in India to be in accordance with Appendix V. The Drugs and Cosmetics (First Amendment) Rules, 2013, in sub-paragraph 3(ii) under the section on Responsibilities of the Investigator(s), specify: "The investigator will provide information to the clinical trial subject through the informed consent process as provided in the Appendix V about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial-related injury or death." Thus, the law requires every ICF to contain the elements of Appendix V.

In this article, we have attempted to check whether the format of a sample of ICFs is in agreement with Appendix V of Schedule Y. This has been accomplished by investigating whether the contents of the selected ICFs contain all the mandatory elements specified in the Schedule Y. Schedule Y requires each ICF to incorporate 19 essential elements in their entirety. We have compared the contents of the ICFs with the mandatory elements quite strictly.

## Materials and methods

We collected 50 ICFs which were used for trials conducted between 2008 and 2013. These ICFs were collected from a site for clinical trials that was located in a tertiary care centre in Pune. The ICFs were the 50 most recent and consecutive ICFs approved by the Institutional Review Board (IRB). All the 50 ICFs considered were for drug trials and only the English versions were analysed for the study. Due permission was obtained from the hospital authorities and the IRB to analyse the ICFs. An attempt was made to check whether the contents of the ICFs

were in accordance with the 19 mandatory elements specified under Schedule Y (11). These elements are as follows:

- A. Statement that the study involves research and an explanation of the purpose of the research
- B. Expected duration of the subject's participation
- C. Description of the procedures to be followed, including all invasive procedures
- D. Description of any reasonable foreseeable risks or discomforts to the subject
- E. Description of any benefits to the subject or others reasonably expected from the research. If no benefit is expected, the subject should be made aware of this
- F. Disclosure of specific appropriate, alternative procedures or therapies available to the subject
- G. Statement describing the extent to which confidentiality of the records identifying the subject will be maintained and who will have access to the subject's medical records
- H. Trial treatment schedule(s) and the probability for [sic] random assignment to each treatment (for randomized trials)
  - I. Compensation and/or treatment(s) available to the subject in the event of a trial-related injury
  - J. An explanation about who to contact for trial-related queries, rights of subjects and in the event of any injury
  - K. The anticipated prorated payment, if any, to the subject for participating in the trial
  - L. Subject's responsibilities on participation in the trial
- M. Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled
- N. Statement of foreseeable circumstances under which the subject's participation may be terminated by the investigator without the subject's consent
- O. Additional costs to the subject that may result from participation in the study
- P. The consequences of a subject's decision to withdraw from the research and the procedures for orderly termination of participation by subject
- Q. Statement that the subject will be notified in a timely manner if significant new findings develop during the course of the research which may affect the subject's willingness to continue participation will be provided
- R. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or foetus, if the subject is or may become pregnant), which are currently unforeseeable.
- S. Approximate number of subjects enrolled in the study.

We examined the ICFs not only for their content and the presence and completeness of these mandatory elements, but also for the language, writing style and presentation of information. We identified certain key words in statements

related to the mandatory elements. When these key words/phrases were absent, the elements were considered to be "present but incomplete." Certain elements had been omitted altogether from the ICFs. In this case, the elements were regarded as "not present." Only an element which was present and complete with the key words/phrases was regarded as "present in its entirety." Let us take the example of the element: "Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled." If the word "voluntary" or the phrase "penalty or loss of benefits" is missing, we have termed it "present but incomplete." All the elements in the ICFs were grouped under the three categories mentioned above. Each instance of an element was recorded as a 'count'. It was recorded if it was missing but required, as well as if it was present but not required.

**Results and discussion**

Of the 50 ICFs analysed, only 30% adhered to the norms specified in Appendix V of Schedule Y on the content to be included in an ICF (Figure 1).

We identified a total of 950 counts of mandatory elements in the 50 ICFs analysed by us. Out of these, 873 counts were present in their entirety, in 63 counts; the element was either absent or incomplete. Among these 63, 37 were "present but incomplete" and 26 were "not present" (Figure 2). In 14 counts, the element was not applicable to the particular trial. Seventy per cent of the ICFs were found not to be in accordance with Schedule Y. These had collectively 63 absent or incomplete mandatory elements with a mean of 1.8 counts of incomplete and/or absent mandatory elements per ICF.

About 30% of the ICFs analysed lacked information on the alternative therapies available to the patient, besides the investigational product. The percentage of ICFs which had not followed this particular norm either said "alternative therapies are available" or contained no statement on the matter at all; there was no disclosure of information on the alternative therapies available to the participant. This implies that the options provided by the ICFs regarding treatment were biased

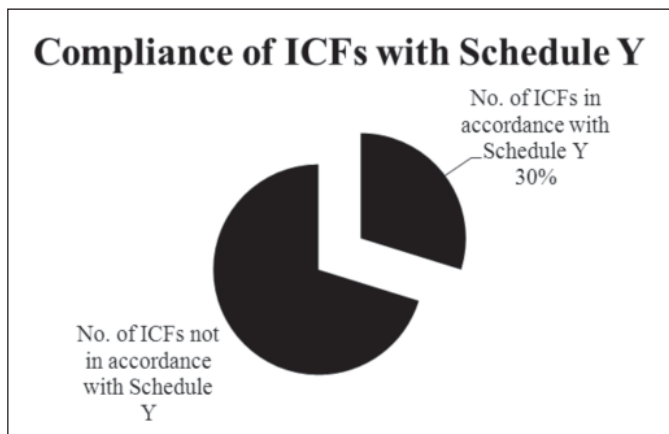


Figure 1: Analysis of ICFs in accordance with Schedule Y

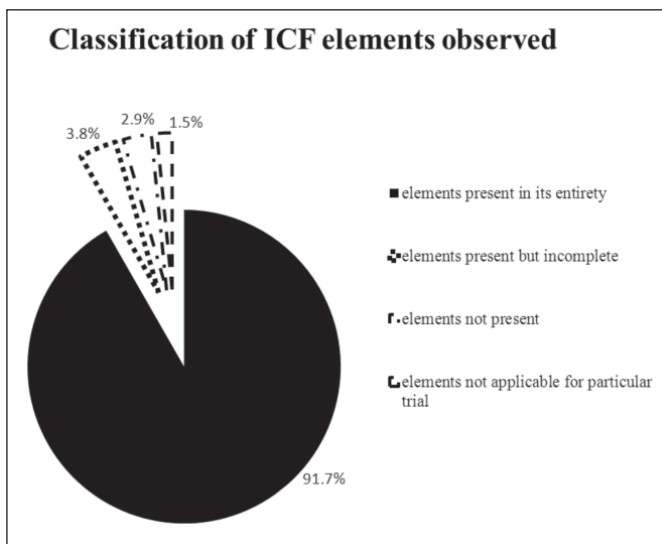


Figure 2: Classification of mandatory elements of analysed ICFs

towards the product being investigated. Although it must be noted that the ICFs asked the patients to discuss alternative treatments with their study doctor, Schedule Y clearly mentions the need to "disclose specific appropriate alternative procedures or therapies available to the subject."

About 26% of the ICFs analysed did not contain a "statement that participation is voluntary, the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled." ICFs which did not contain key words/phrases such as "voluntary" and "will not involve any penalty or loss of benefits" were deemed to have incomplete or partial information on the said mandatory element. This is an important statement which emphasises the participant's freedom of expression and action. It ensures that the participants cannot be coerced or blackmailed into participating and continuing to participate in the trial against their will. The participants are free to decide whether they want to participate or continue participating in the trial without fearing any repercussions.

Of the ICFs analysed, 14% did not contain a "statement that the subject---- will be notified in a timely manner if significant new findings develop during the course of the research which may affect the subject's willingness to continue participation." In the course of a research study, there are often instances when new information is made available to the investigator from other investigational sites. This information must be passed down to the research participant by the site investigator to keep the process of informed consent active. The new information might affect the individual's decision to continue participation in the trial. Thus, such information must be given to the participants in a timely manner. The absence of this element increases the burden of risk on participants and keeps them in the dark about the potential peril that may await them.

Around 10% of the ICFs analysed lacked information on the expected duration of the patient's participation. If the ICF does

not furnish information on the approximate time for which the participant is to be involved in the trial, there is a possibility that the participant will face exploitation due to the whims of the study doctor or the sponsor. A patient might end up participating in the trial for much longer than required and the repercussions may be similar to those in the Tuskegee trial (12).

Around 8% of the ICFs analysed did not contain the following.

- *Description of any benefits to the subject or others reasonably expected from research.* This information gives a clear picture of the therapeutic gain that participation in the trial may bring and assures the participant that he/she is not merely a pawn in a scientific endeavour.
- *Statement of foreseeable circumstances under which the subject's participation may be terminated by the investigator without the subject's consent.* In cases in which the principal investigator feels that the patient would do better with alternative therapy or the patient's condition is deteriorating, the principal investigator can terminate the patient's participation in the trial without the latter's consent. When the participant does not abide by the instructions of the study staff, the principal investigator may be forced to expel the subject from the trial without the latter's consent.
- *A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or foetus, if the subject is or may become pregnant), which are currently unforeseeable.* This statement categorically specifies that pregnant and lactating women should not expose themselves to the product being investigated as it can have a damaging effect on the foetus. Women who are taking part in the trial and who may get pregnant and men whose partners can get pregnant must practice safe sex to avoid pregnancy. This would safeguard the unborn from the effect of the product under investigation. This statement is aimed at averting a tragedy such as the thalidomide disaster (13).

About 6% of the ICFs analysed did not contain information on *the approximate number of subjects enrolled in the study.* Specifying the number of patients taking part in the experimental treatment might help to instil confidence in the subjects, as having an idea of the sheer number of participants may be a source of reassurance to them.

Approximately 4% of the ICFs analysed did not contain the following.

- The consequences of participants' withdrawal from the trial and the procedures for orderly termination of their participation. This must be explained in the ICF so that the participant can withdraw voluntarily, with no fear and reservations regarding medical care, penalties or deterrents. The procedures for orderly termination of the participation must be explained in the interest of the safety of the participant.
- The additional costs to the subject that may result from participation in the study were not mentioned. A mention of any additional costs is particularly important in the case

of add-on studies, i.e. when the trial is conducted to check the efficacy and safety of add-on therapy and not the main therapy. Clear instructions stating whether the patient must pay/not pay for the main therapy would avoid any confusion.

A small percentage (around 2%) of the ICFs analysed lacked the following information.

- These ICFs did not contain information on the *compensation and/or treatment(s) available to the subject in the event of a trial-related injury.* This is a point which is of the utmost importance, particularly in the light of the recent discussions on the compensation given to participants for trial-related injury (14). The grounds on which compensation should be given to the participant must be elucidated clearly. In case of trial-related injury, detailed information on the treatment of the injury should be supplied. If this information is not duly provided, the matter would have to be resolved in a court of law.
- There was no information on the *anticipated prorated payment, if any, to the subject for participating in the trial.* This section deals with the possibility of the participant being paid to participate in the trial. The provision of incentives to the participant to take part in a trial is a matter of controversy as this might lead to unethical exploitation of the participant.
- These ICFs did not contain an *explanation about who to contact for trial-related queries and in the event of an injury, or for an explanation about their rights.* In the course of a trial, certain doubts may arise, the participant may want more information or medical help, or may have other grievances which need to be addressed. For these reasons, the contact information of the principal investigator and representative of the ethics committee must be provided to the participants. It is important to offer participants a line of communication so that their grievances can be addressed.
- These forms lacked information on the *subject's responsibility in the trial.* This is a vital aspect of trials which reflects that the participants are an integral part of the trial and must help it function smoothly. They can do so by following the directions given in the ICF about their responsibility and the instructions given by the study staff.

However, all the ICFs analysed did contain the following elements.

- *A statement that the study involves research and an explanation of the purpose of the research.* This statement emphasizes that the proposed therapy is not being practised currently and research must be conducted to prove the proposed therapy's efficacy. The ICF must contain a brief explanation of the aim of the research.
- *Information on the trial's treatment schedule(s) and the probability of random assignment to each treatment (for randomised trials).* This section pertains to when, how and what medications will be administered to the participant during the trial. In the case of randomised trials, information

on how each participant would be placed in the treatment arms is to be explained. The failure to explain these matters would leave participants in the dark about what medications to take, as well as when and how to take them.

- A description of any reasonably foreseeable risks or discomforts to the subject. This information specifies the possible demerits of the trial that could affect the participant adversely. They must be made aware of these risks before their consent is taken.
- A statement describing the extent to which the confidentiality of records identifying the subject will be maintained and who will have access to the subject's medical records. This statement ensures that the participants' identity remains confidential during their participation in the trial. It also clarifies who would have access to this confidential information and the reason for which this access is granted to them.
- A description of the procedures to be followed, including all invasive procedures. This section provides information on all the tests and medical procedures which the participants must endure during the course of the trial. If this information is not provided, they will have no knowledge of the tests that they will be put through and the necessity of the tests. Such a situation may be exploited, to conduct tests and procedures that are not sanctioned, for the sake of medical inquisitiveness.

Our analysis has led us to believe that instituting some changes will increase the transparency of trials and build the patient's trust in a system that is essentially alien to most. The following suggestions should be considered for inclusion in every ICF. Some of these changes were observed in less than 8% of the ICFs analysed.

- The details of the insurance provider, the total cover and the conditions of claim should be made clear.

We believe it is most unfortunate that the participant has no information on the insurance policy taken out on him/her by the sponsor. There is no information on what the clauses are, the grounds on which the participant would be given compensation, when the participant can claim

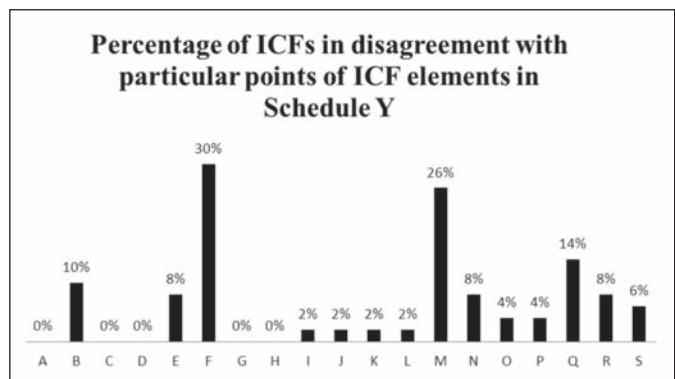


Figure 3: Percentage of ICFs in disagreement with particular ICF elements specified in Schedule Y (For significance of A-S refer to Materials and Methods section)

compensation, and when it is not permissible to seek compensation. These unresolved issues would prove to be a hurdle when seeking compensation for trial-related injuries. We suggest that the participant should be given a copy of the insurance policy (or an abstract) along with the ICF, and be made cognizant of the terms and conditions of the insurance policy before giving consent.

- Information should be provided on what to do when the participants miss their medication or visit.

Participants might sometimes forget to take their medications and/or miss a scheduled study visit. In such situations, information on "what is to be done next," ie when and how to take the next round of medication, could prove to be of vital importance. Missed study visits must be communicated to the study staff immediately and remedial measures taken.

- The participant should be informed whether any offsite services are offered by the site staff.

There may be times when the participant, for personal or professional reasons, cannot make the scheduled visit to the study site. It should be made known whether, in such cases, the study site would offer to collect biological material, such as blood, and information, such as knowledge attitude questionnaire, from the participant's place of choice. These are called offsite services, for which the participant's consent must be obtained in order to protect his/her privacy.

- The participants must be given clear information on the amount of time (hours) they are expected to spend on study visits every week or month.

When enrolling participants in a trial, the site staff must check whether they have time to spare from their regular schedules for activities related to the study so as to ensure the best possible compliance. Good compliance might increase the likelihood of the drug under study being as efficacious and safe as possible. Thus, if time is an important factor, the participant will find it easier to take a decision on whether or not to participate in the trial if he/she is given information on the amount of time (hours) that might have to be spent per week /month on study-related activities. The provision of this information would lead to better compliance, which would be good both for the study and participants.

- The ICF should contain a statement which makes it clear that participants in the trial can avail of legal assistance and which informs them that signing the ICF is not tantamount to surrendering their legal rights.

Although these ideas may seem obvious to the trial staff and those involved in clinical research, such a statement will serve as a useful reminder to the participants of their rights, since they may not be familiar with the functioning of a clinical trial. This statement may give the participants courage to seek legal help if they feel that they have been wronged in any way during the trial. This right is available to them even after signing the ICF.



- *The participant should be provided with information on the regulatory status of the drug under study in other countries.*

Information on the status of the drug the world over, including details regarding its presence in the market, efficacy and safety, will help participants assess the benefit of the drug under investigation. Information on whether the drug is available as an over-the-counter drug, only by prescription, or only in hospitals, will help them gain an understanding of the drug.

- *There should be a statement reassuring participants that the trial has been approved by the regulatory authority and the IRB/IEC.*

When lay persons come across an ICF, they are overwhelmed by the quantity of scientific literature and information on the disease itself. An assurance in the form of a statement that the regulatory authorities have examined the trial and certified it as safe for participants is of great help.

- *The ICF should contain a statement that the profits accruing from the trial are not intended to be shared with the trial participants.*

If a company has designed any product with the help of the participants' biological samples and is not willing to share the profits with them, this decision must be stated in the ICF. It should be clarified that there are no profit-sharing models in place for the products developed.

## Conclusion

The Drugs and Cosmetics (First Amendment) Rules have made the elements of Appendix V of Schedule Y mandatory for every ICF used in trials in India. We fear that there is a long way to go before ICFs become compliant with the provisions of Appendix V. In our small analysis, a meagre 30% of the total ICFs analysed were in agreement with the norms of Schedule Y. More than three-fourths were not in accordance with the regulatory norms of the country. Among the 63 counts of deviation from the elements mandated in Schedule Y, 37 fell under the category of "incomplete", which signifies partial information and even the absence of key words/phrases mandated in the statements. About 26 deviations related to the omission of the elements required. In 14 instances, a few of the mandatory elements included were not applicable to the particular trial. For example, a statement that the particular treatment or procedure may involve currently unforeseeable risks to the participant (or to the embryo or foetus, if the participant is or may become pregnant) does not apply in observational trials.

In some ICFs, the information was presented in a disorganised manner. Some were written very eloquently, though it is doubtful how far a person with an average command of English and medicine would be able to grasp the contents of such an ICF. It must be noted that some ICFs met every requirement of the Schedule Y guidelines. However, the language and

style of writing would, in our opinion, make it difficult for the average Indian patient to comprehend the information and connect with the trial. We have suggested certain elements which, when incorporated, could help the patient gain a better understanding of the issues involved.

It is worth noting that, even as the ethical and regulatory issues pertaining to clinical trials are being made more stringent, ICFs continue to be incomplete or misinformed. Most of these ICFs belonged to trials conducted between 2008 and 2013. The observations which have been made here reflect trends; an analysis of 50 ICFs may not amount to statistically significant findings. In any case, the analysis presents a grim picture and the matter is worth pursuing further. We would also like to suggest that trials must be approved by the ethics committee only when their ICFs contain all the mandatory elements mentioned in Schedule Y.

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# The relationship between ethical climate at work and job satisfaction among nurses in Tehran

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## Abstract

**Background:** This study aimed to provide an understanding of the relationship between the ethical climate at the workplace and job satisfaction among nurses.

**Methods:** 210 nurses working in selected wards in the Tehran University of Medical Sciences were asked to fill out questionnaires on their work environment and level of job satisfaction. The data collection tools included a questionnaire to obtain demographic data, the Olson moral climate questionnaire and Minnesota job satisfaction questionnaire. The data were analysed using SPSS software version 14.

**Results:** We found a significant positive relationship between the ethical climate and the level of job satisfaction among the nurses. Among the demographic variables, the working shift, income level and type of duties allocated had a significant relationship with job satisfaction.

**Conclusion:** Hospital managements should pay attention to the factors influencing job motivation among nurses, including the ethical climate of the work environment.

## Introduction

Organisations are units of the community that both affect the environment and are affected by it. Organisational ethics is a set of principles that promotes similar behaviours among the organisation's staff, and helps the organisation and staff solve problems caused by conflicts within the system, such as personal tensions and disputes related to job responsibilities (1).

Organisational ethics in healthcare is concerned with issues such as resource allocation (2), funding and setting of priorities (3), safeguarding justice and access to care (4), disclosure of risks and complaints of misconduct (5), and workplace ethics and the ethical climate in the health services (6).

The organisation's ethical climate – also referred to here as moral climate – reflects the organisation's rules and guidelines and their association with ethical consequences (7). It can also be a mediator of moral distress (8,9). Moral distress occurs when a person perceives that the right course of action cannot be implemented because of institutional constraints (10). The ethical climate determines whether decisions are based on ethical criteria, as well as how employees interpret ethical questions (11). Studies have shown that an organisation's

ethical climate affects not only the moral attitudes of the organisation's employees, but also their work output (12).

The ethical climate in healthcare settings is defined as "organizational specific conditions that facilitate the discussion on the patients' health problems and their solutions, and provide a framework for ethical decision-making in the clinical environment." Researchers have suggested that the promotion of an ethical climate in the workplace enables employees to better cope with ethical stress and other causes of dissatisfaction, and may increase their level of job satisfaction (8,9).

Employees' job satisfaction has been shown to be reflected in their attitudes towards their work. Those who are satisfied with their work have a positive attitude towards it, while those who are dissatisfied have a negative attitude (13). A positive ethical climate is also associated with high levels of job satisfaction in terms of attitudes to payment, professional progress and colleagues.

Researchers have shown that the organisation can affect the employees' level of job satisfaction by influencing the ethical climate (14).

This study aimed to determine the relationship between the ethical climate at work and job satisfaction among nurses in a university hospital in Tehran.

## Methods

### Population and sample

The study sample consisted of 210 nurses working in the emergency, surgery and internal medicine wards, and the cardiac care units (CCUs) and intensive care units (ICUs) of the Tehran University of Medical Sciences (TUMS). All were graduates with either BSc or MSc degrees in nursing.

### Sampling technique

The study used stratified sampling with proportional allocation. The wards were selected according to the number of nurses working there. The sample from each ward was selected randomly (using the lists of nurses working there).

### Instruments

A demographic form, the Olson moral climate questionnaire (15) and the Minnesota job satisfaction questionnaire (16) were

used to gather data. The moral climate is taken to reflect the ethical climate in professional settings.

The demographic form included questions on age, gender, education, type of employment, level of income, marital status and the current ward assigned.

The Olson moral climate questionnaire, which uses a Likert scale, contains 26 items on the organisation's moral climate. Each question has five options: "almost never" (score=1), "rarely" (score=2), "sometimes" (score=3), "often" (score=4) and "almost always" (score=5). The questions concern five factors, including "communicating level with the colleagues" (items 1, 10, 18 and 23), "patients" (items 2, 6, 11 and 19), "managers" (items 3, 7, 12, 15, 20, 24), "physicians" (items 5, 9, 14, 17, 22 and 26) and "hospital" (items 4, 8, 13, 16, 21 and 25). The higher the score, the more positive was the moral climate at work.

The Minnesota job satisfaction questionnaire, which also uses a Likert scale, contains 23 questions on the participants' working conditions. Each question has five options: "very satisfied" (score=5), "satisfied" (score=4), "do not know" (score=3), "dissatisfied" (score=2) and "very dissatisfied" (score=1). The higher the score, the higher is the level of job satisfaction.

The questionnaires were designed after a review of the literature, in consultation with colleagues and experts in the field.

#### *Ethics review*

The research proposal was approved by the ethics committee of the Tehran University of Medical Sciences and permission for the study obtained from the School Research Committee.

#### *Data collection and analysis*

The researcher handed the questionnaires to the unit heads, who distributed them among the nurses in their units. The participants were provided with information on the goals of the study and assured of the confidentiality of the personal information they would be providing.

The data were analysed using the statistical programme SPSS version 14.

### **Results**

90% of the respondents were women. The respondents' ages ranged from 22 to 55 years, the average age being 30.8. 61% were below 31 years of age. 207 (98.6%) had a bachelor's degree and 3 (1.4%) had a master's degree.

Of the 210 nurses, 28.1% worked in the ICU, 26.2% in the surgery ward, 23.3% in the internal medicine ward, 11.9% in the CCU and 10.5% in the emergency ward. Table 1 shows the frequency distribution of the demographic characteristics of the nurses.

Of the 210 nurses, 58.1% described their income as "average", 34.8% as "unfavourable" and 5.7% as "favourable". There are 3 missing values (1.4%).

The mean and standard deviation of the Olson moral climate questionnaire results for the investigated units was  $3.36 \pm 0.69$ , and the mean and standard deviation of job satisfaction among the nurses was  $3.17 \pm 0.63$ .

Pearson's correlation co-efficient showed a significant positive correlation between the moral climate at work and job satisfaction among the nurses ( $r=0.39, p \leq 0.001$ ) (Table 5).

The Scheffe test did not show any association between job satisfaction among the nurses and working shift ( $p=0.02$ ) (Table 2).

The one-way analysis of variance test (ANOVA) showed a significant positive association between income level ( $p < 0.001$ ) and job satisfaction among the nurses (Table 3).

The Scheffe test showed a significant association between job satisfaction and the type of duties allocated ( $p=0.02$ ) (Table 4).

### **Discussion**

The study found that the more favourable the ethical climate, the higher the level of job satisfaction reported by the nurses.

Considering the relationship between the ethical climate at work and job attrition, Hart found a significant relationship between a poor ethical climate and job attrition. Factors such as the number of patients, the adequacy of the nursing staff, and supervision of nursing activities also influenced change of job or career (17).

According to Elçi and Alpken, the pursuit of self-interest by employees has a negative influence on work satisfaction, whereas working with the team's interest in mind, social responsibility, and professional codes have been found to have a positive impact (18).

A study by Jaramillo et al found that the ethical climate has a positive effect on a salesperson's satisfaction, which, in turn, leads to a lower employee turnover, greater organisational commitment, and better job performance (19). Olson considers the ethical climate an organisational variable which can be managed and modified in order to improve the work environment.

The ethical climate provides a basis for ethical decision-making in organisations. When healthcare organisations enable their employees to talk to others about difficult issues, such as those faced by nurses in the care of patients, and allow them to feel that they can consult their colleagues, managers or clinicians, they create conditions which promote ethical thinking, ethical dialogue, hope and problem-solving. The work environment affects the behaviour and beliefs of the employees; hence, the work environment must be designed to strengthen relations between nurses and physicians, and to increase job satisfaction (15).

Sumner and colleagues, while investigating why nurses in the USA leave the profession, found that nurses sacrifice their interests for their patients' needs. They may experience

Demographic characteristics	Status	Frequency	Percentage
Marital status	Single	99	47.1
	Married	109	51.9
	Missing	2	1
	Total	210	100
Employment type	Public services	39	18.6
	Contracted	171	81.4
	Total	210	100
Service history (years)	1-4	60	28.5
	5-9	66	31.4
	10-14	43	20.5
	15<	29	13.9
	Missing	12	5.7
Total	210	100	
Position	Head nurse	18	8.6
	Ward master	45	21.4
	Nurse	147	70
	Total	210	100
Working more than one shift	Yes	155	37.8
	No	55	26.2
	Total	210	100
Working shift	Morning shift	28	13.3
	Afternoon shift	2	1
	Morning and afternoon shift	22	10.5
	Night shift	13	6.2
	Afternoon and night shift	8	3.8
	Rotating shift	137	65.2
	Total	210	100

Work shifts	No. of nurses according to work shift	Mean job satisfaction levels (± SD)	ANOVA
Morning shift (0730-1400 hrs.)	28	3.44±0.69	p=0.02*
Afternoon shift (1330-1930 hrs.)	2	3.02±0.95	
Morning and afternoon shift (0800-1930 hrs.)	22	3.16±0.55	
Night shift (1900-0800 hrs.)	13	3.13±0.59	
Evening and night shift (1330-0800 hrs)	8	3.68±0.42	
Rotating shift	137	3.09±0.62	
Total	210	3.17±0.63	

p<0.05\*=significant

Income level	No. of nurses according to income level	Mean job satisfaction levels (± SD)	ANOVA
Favourable	12	4.14±0.61	p<0.001*
Average	122	3.24±0.52	
Unfavourable	73	2.89±0.62	
Missing	3	-	
Total	210	3.17±0.63	

p<0.05\*=significant

Type of duty allocation in the ward	No. of nurses according to duty allocation	Mean job satisfaction levels (± SD)	ANOVA
Functional	46	2.95±0.59	p=0.02*
Case method	143	3.22±0.65	
Team work	21	3.28±0.47	
Missing	3	-	
Total	210	3.17±0.63	

p<0.05\*=significant

Variable	Moral climate
Job satisfaction	r=0.39
	p=0.001*

\* Correlation significant at 0.05 level (2-tailed)

Work shifts	No. of nurses according to work shift	Mean moral climate levels (± SD)	ANOVA
Morning shift (7:30 h-14 h)	28	3.44±0.56	p=0.36
Afternoon shift (13:30 h-19:30 h)	2	4.15±1.19	
Morning and afternoon shift (8:00 h-19:30 h)	22	3.38±0.79	
Night shift (19:00 h-8:00 h)	13	3.07±0.77	
Evening and night shift (13:30 h-8:00 h)	8	3.47±0.61	
Rotating shift	137	3.35±0.68	
Total	210	3.36±0.69	



Income level	No. of nurses according to income level	Mean moral climate levels ( $\pm$ SD)	ANOVA
Favourable	12	3.87 $\pm$ 0.81	p<0.03*
Average	122	3.32 $\pm$ 0.60	
Unfavourable	73	3.34 $\pm$ 0.79	
Missing	3	-	
Total	210	3.36 $\pm$ 0.69	

p<0.05\*=significant

Type of duty allocation in the ward	No. of nurses according to duty allocation	Mean moral climate levels ( $\pm$ SD)	ANOVA
Functional	46	3.25 $\pm$ 0.79	p=0.38
Case method	143	3.41 $\pm$ 0.68	
Team work	21	3.30 $\pm$ 0.45	
Missing	3	-	
Total	210	3.36 $\pm$ 0.69	

frustration and moral tension when they are unable to meet their patients' needs and also their own (20).

Among the demographic variables, the income level and type of duties allocated to the nurses had a significant statistical relationship with job satisfaction.

There was a significantly positive association between the nurses' income level and the level of job satisfaction. This result is consistent with other studies. Manookyan et al found that nurses' income was directly related to their job satisfaction (21). Studies also show that the best indicator of job satisfaction is the individual perception of the level of respect and compensation the organisation offers to acknowledge individual worth and merit (22).

As for the type of work allocation among the nurses, those who worked in a team had a higher level of job satisfaction than those who worked individually. This suggests that there is a synergy in team work (23).

## Conclusion

The results of our study indicate that hospital managements should pay more attention to the factors that motivate nurses and give them job satisfaction. Valuing the nursing profession, allowing scope for job diversification, and maintaining a respectful relationship with nurses all make nursing more productive and provide nurses with opportunities to improve their performance. The direct relationship between the ethical climate of the workplace and the job satisfaction of the nurses

covered by this study highlights the necessity of considering measures that might strengthen the ethical climate. One way of promoting the ethical climate of the nurses' workplace and increasing their job satisfaction is to establish a code of nursing ethics, disseminate the provisions of the code, and monitor and evaluate its implementation.

## Data-sharing statement

Two more articles were captured from the thesis (24), but these have been published only in the Persian language. An article entitled "The relationship between the moral climate at work and the job satisfaction of Iranian nurses" has been published in an Iranian journal (*Medical Ethics*) and its abstract is not in English (25). Another article entitled "Relationship between moral distress and job satisfaction among nurses of Tehran University of Medical Sciences hospitals" has been published in *Hayat* and its abstract is in English (1).

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## "It all changed after Apollo": healthcare myths and their making in contemporary India

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### Introduction

In the shadow of recent proposals for universal healthcare in India, discussions regarding the impact of private medical care on Indians' health have taken on a greater urgency. However, our collective attempts to evaluate the effects of India's growing private medical sector have been seriously hampered due to a lack of reliable or comprehensive data regarding (i) the size of the private healthcare sector, and (ii) its patterns of growth, particularly since the 1980s. As we formulate and assess practical strategies for a sustainable healthcare future for India in the absence of reliable statistical data, historians' tools for understanding the recent career of healthcare in the country merit consideration.

To that end, in this article, I examine myths and myth-making as central to the rise and consolidation of Apollo Hospitals, first in Chennai and later as a key player in India's recent healthcare history. Using face-to-face interviews with more than 20 prominent Chennai physicians as well as published sources, I investigate not only the myths surrounding Apollo and its founder, but also the manner in which these stories are regularly circulated within the wider medical community. The case of Apollo is instructive for two reasons: a) Apollo is seen widely as representing the new chapter in the history of healthcare in India; and b) Apollo merits attention on its own, as a case study, to illustrate how corporate hospitals established after it "manage" their own success story and thereby shape the perceptions of the common man and professionals alike. In short, I argue that the most important successes of Apollo Hospitals have been in image management. Given that much of Apollo's "success story" is based on assumptions and assertions that crumble under even the most basic historical scrutiny, we would be wise to regard the corporates' claims of economic promise and therapeutic efficiency with some scepticism.

### Apollo and the invention of the "corporate hospital" in India

At the risk of stating the obvious, the rise and spread of the Apollo Group of Hospitals from the 1980s matters because it is widely seen to represent the beginning of a new chapter in the history of healthcare in India: the rise of the corporate hospital alongside the unfolding of liberalisation in the country. Apollo's story has been told and retold among physicians, journalists, politicians, bureaucrats, and members of the general public. In this story, the career of Apollo Hospitals appears to be nothing short of miraculous: Apollo, in particular, and India's healthcare sector more generally, figure simultaneously both as the cause and effect of the country's recent economic successes. Yet, as this essay argues, this legendary status depends on accepting a set of assertions that are at best, debatable and at worst, mere myth. Not only are these stories debatable, they are also dangerous, because they obscure a set of broader historical processes that both precede and go beyond any results that can be attributed to one man or one hospital. In the light of this generally confused state of affairs, it would be useful to begin with a chronological account, both of the establishment and early history of Apollo (particularly in Chennai), as well as of the broader context – in terms of the regional and national provision of healthcare – in which Apollo emerged.

In 1980, Dr Pratap Reddy, founder and chairman of Apollo Hospitals Group, announced that he had acquired a plot of land for the first Apollo hospital, Apollo Hospitals Chennai, on the centrally located Greaves Road. At the time, the *Times of India* reported that this was the first of a new chain of large hospitals (1). This development was significant for three reasons. First, the Chennai hospital would be the first private limited hospital in India. Second, in order to move ahead with the financing, Reddy had been given permission to build a private hospital of a capacity of over 30 beds. Until then, the law permitted

only government or charitable trust hospitals to expand their bed strength beyond 30 (Chennai doctor 2). Third, this hospital raised funds through overseas borrowing and was also the first to issue public shares to finance its establishment (2,3). It was observed at that time that this was “the first [public offering] of its kind in India for financing a multispeciality medical centre to be run on corporate lines”(4).

The Chennai hospital was inaugurated amidst much fanfare in September 1983 by Zail Singh, President of India. It was only in February 1984 that it started admitting patients (5). It consolidated its reputation as the hospital of choice for the city's powerful a few months later, when MG Ramachandran, the then chief minister of Tamil Nadu, was admitted there (6). By 1988, Apollo Hospitals expanded to Hyderabad, as Reddy had initially planned. In 1996, Apollo Indraprastha was opened in New Delhi.

By 1993, Apollo Hospitals had begun to issue large advertisements in the national press to congratulate themselves on serving the nation (see Figure 2 in appendix). At the time of writing this article in 2013, Apollo has undertaken the task of continued expansion in India and beyond. The year 2013 also marks three decades of the existence of Apollo, and the occasion is to be celebrated by the Group with commemorative volumes by and about Reddy. One of the recent promotional pieces summed up Apollo's achievements as follows:

*From one multispeciality facility that he founded in Chennai 30 years ago to 54 hospitals, 1600 pharmacies, 60 diagnostic clinics and 11 nursing colleges in 2013, Dr Reddy's medical system attracts more than 100,000 footfalls daily across India. Cumulatively, more than 32 million people have been treated at various Apollo hospitals (7).*

### **Apollo: myths and myth-making**

Despite a wide range of opinions regarding the rise of the corporate hospital, there are many similarities in the manner in which its significance is described both by supporters and critics. An admirer recently wrote:

*In 1983, at a time when the government's commitment to investing in public healthcare appeared to be flagging, Prathap Chandra Reddy did something unthinkable: he launched the country's first corporate medical system. Three decades on, the argument over the pros and cons of privatised healthcare in a poor country remains unsettled but there is one thing Dr Reddy's admirers and critics both agree on: the emergence and rise of his company, Apollo Hospitals Enterprises, has altered the health-care landscape of India (7).*

Compare this with the sentiment of a critic of Apollo:

*I would say that what I noticed during the past thirty years, which is the time I have been practising medicine, the big change is that when we were undergraduates, there were no private hospitals in Chennai. There were*

*private nursing homes which was [a] big difference. Because nursing homes wouldn't take acutely ill patients. They would only take elective surgical procedures; very mild illnesses. Anything serious was referred to the government teaching hospitals. Obviously the three: Kilpauk Medical College, Stanley Medical College, and the biggest, Government General Hospital. If you had a serious illness, [in] those days it was considered that the place to go to was Government General Hospital. It all changed after Apollo (Chennai Doctor 1).*

Yet the claim that “Apollo changed everything” fails to bear the weight of scrutiny. It would be useful to disaggregate the “It all changed after Apollo” myth into its five key elements:

- Apollo came up at a time that healthcare for “ordinary Indians” was flagging.
- Apollo provided a new model of healthcare delivery in India.
- At its heart, Apollo is a patriotic project.
- In order to establish Apollo, its chairman, Prathap Reddy, single-handedly changed government policy.
- Apollo was an immediate success.

In light of this descriptive convergence among both admirers and critics, the rest of this section attempts to describe and assess these five elements of the “It all changed after Apollo” myth.

#### **1. Apollo came up at a time when healthcare for “ordinary Indians” was flagging**

Talking about Reddy, a doctor whom I interviewed claimed, “When he set up Apollo Hospitals in Chennai in 1983, private healthcare institutions were virtually unknown to the country”(8). This aspect of the myth of Apollo is often articulated through three sub-claims: 1a) that there was no reasonable healthcare available in Chennai, 1b) that the government, in particular, had either abdicated or was simply unable to fulfil its responsibility to provide healthcare for ordinary Indians, and that, therefore, 1c) only the very rich had access to high-quality healthcare, for which they travelled abroad.

Let us consider these in turn.

##### *1a. There was no good healthcare available in Chennai for “ordinary” Indians*

Although this claim is oft-repeated (that before the establishment of Apollo and other corporate hospitals in Chennai, there was no good quality healthcare in the city for so-called ordinary Indians), it is difficult to find evidence to support this claim. For the sake of simplicity, let us leave aside the vexed question of who an “ordinary Indian” is (as well as the even more vexed question of whether or not she is well served by corporate medical institutions in Chennai today). Whilst historians have yet to fully document the city's medical past, physicians from Chennai have described in interviews how the city has been the long-standing home of high-quality medical

care and medical education in India. Chennai's reputation as a "healthcare hub" far precedes the opening of Apollo Hospitals in 1983-1984. One of the doctors whom I interviewed, and who was closely associated with the Tamil Nadu branch of the Indian Medical Association, estimated that the city was home to approximately 400 hospitals and 10,000 beds.

The phrase repeatedly used both by physicians in interviews and newspaper journalists to describe the cluster of medical facilities in Chennai is "medical mecca." The use of this term is based on a detailed consideration of the various aspects of excellence in the medical sphere, including: medical education and large government hospitals; a cluster of private nursing homes run by prominent physicians (particularly along Poonamallee High Road); excellent connections to national transport infrastructure; nodes of specialist expertise; and a reputation for the provision of ethical treatment at reasonable fees.

That the medical education provided in and around Chennai is of a high quality is common knowledge. Three medical colleges in the region are consistently ranked in the top ten nationally. These are the Christian Medical College in Vellore (established in 1902 and affiliated to Madras University in 1942), Jawaharlal Institute of Postgraduate Medical Education and Research in Pondicherry (established in 1823 and re-developed in 1956), and Madras Medical College in Chennai (established in 1850). The students graduating from these institutions not only staff large teaching hospitals, but also go on to staff and manage the small, medium and large hospitals across Chennai.

Further, Chennai is famous for the high quality of treatment and research carried out in a number of its government hospitals. Special mention may be made of the Government General Hospital (established in 1664), and Stanley Hospital (established in 1792). Other hospitals of note included the Southern Railway Headquarters Hospital in Perambur (date of establishment not available), Vijaya Hospital (established in 1972), KJ Hospital and MV Diabetes Hospital (9). The same high standards of quality are maintained by several high-profile voluntary and charitable trust hospitals as well. These include the Voluntary Health Society (established in 1958), the Cancer Institute (established in 1954), and Sankara Nethralaya (established in 1978). Speaking of the high standards of government hospitals, one physician said:

*When I went to medical school [1970s], MMC was still the place you went to if you had complicated illnesses. Even private doctors would do hernias and gall bladders outside. But if you needed cancer surgery... they'd say: "Hey, listen come to the government hospitals. They are better equipped to do all those. We are academic centres" (Chennai doctor 2).*

Another physician echoed these sentiments:

*"...I think more and more people joined medical college in Madras. It was considered to be, you know, the place to go to. So it had that reputation of being something, even right from the first days..." (Chennai doctor 7).*

Apart from the extensive medical infrastructure in and around Chennai in terms of medical education and large government hospitals, over the 20th century, the city also became famous for its large number of private nursing homes, run by prominent physicians. These private nursing homes included the Pandalai Nursing Home, Sundaravadanam Nursing Home and Kumaran Nursing Home. Nearly every doctor I interviewed mentioned that, particularly from the 1960s onwards, Chennai's Poonamallee High Road came to be India's "Harley Street" among doctors and patients across India. Nevertheless, none of this is apparent in the awestruck assessment of Reddy and Apollo Hospitals cited below (an assessment which is very common).

*[Reddy's] plan for the creation of a nationwide hospital system in the corporate sector may not seem extraordinary today when private medicine has made major inroads across the country but it was dramatic 30 years ago... When he set up Apollo Hospitals in Chennai in 1983, private healthcare institutions were virtually unknown in the country (7).*

Yet, rather than being "virtually unknown," Chennai's private hospitals and nursing homes were part of a larger regional and national trend of an expanding private medical sector, a trend which emerged around 1960. As Bhat observes, "Private healthcare expenditure in India has grown at 12.5% per annum since 1960-70" (10). In rural India, the number of small private treatment facilities increased threefold between 1984 and 1992 (11). Similarly, in the small city of Mangalore in south-west India, the number of moderate-sized nursing homes jumped from six in 1986 to 20 in 1994, and to 32 in 1998 (12). Further, as Nicher and Van Sickle point out, "In the 1980s, small private labs began springing up in towns and cities..." (12).

As home to a good number of highly-trained physicians, whether practising privately or in government institutions, Chennai became well known as a centre of excellence in particular specialist areas. One doctor summed up what many others noted:

*Historically, Chennai is the healthcare capital of India... for whatever reason the primary centre is always started in and around Chennai. Cardiac units, neurosurgical units, orthopaedic units; anything that starts in India and healthcare first seems to be able to kick off in Chennai and then to somewhere else. Dr B Ramamurthy was the legend of his time - a first world-class neurosurgical centre that he put up in the seventies (Incomplete)... Like that, the Cancer Institute in Adyar still has a reputation for being a good oncology centre... In ophthalmology, [Sankara] Nethralaya is a world-class centre (Chennai doctor 2).*

In addition, many physicians noted that the practice of medicine in Chennai was marked by a high level of professional ethics, combined with relatively low costs. One doctor observed: "A kind of good temperament is there in most of the senior doctors in Chennai, they want to be helpful not necessarily just make money" (Chennai doctor 3) Another doctor elaborated



on this theme: "Medicine really exploded during the post-war years. And Madras had the reputation that it tended to be a little bit more conservative. The Bombay person is always a little bit more of an entrepreneur" (Chennai doctor 12). In this conversation, the doctor equated a broader cultural conservatism with a higher level of professional probity.

*1b. Apollo came up at a time when government support for healthcare for ordinary Indians was flagging*

Just as with the claim that good-quality healthcare was virtually unavailable for ordinary Indians before Apollo, the claim that Apollo "filled a gap" in the provision of healthcare due to the lack of government support is difficult to sustain. This is particularly the case when one considers the overwhelming evidence to the contrary. There was a substantial government health infrastructure in Tamil Nadu before the establishment of either Apollo or any other corporate hospital in Chennai.

As part of a larger project of widening and strengthening the health infrastructure in India, primary health centres and sub-centres were introduced as the "rural health" component of the Minimum Needs Programme during the Fifth Five-Year Plan (1974–1978). As Duggal explains: "During the 1980s, the public health spending peaked and this was reflected in major health infrastructure expansion in rural India via the Minimum Needs Programme" (13). Tamil Nadu was particularly successful in its attempts to implement the programme for building health infrastructure. As Muraleedharan et al narrate: "Tamil Nadu embraced the concept whole-heartedly and built the facilities much faster than almost all other states" (14).

However, there is also a possibility that Tamil Nadu was able to capitalise on the rural health agenda of the Minimum Needs Programme, at least in part, because it had already launched a robust programme of health planning prior to the implementation of the Minimum Needs Programme. KS Sanjivi (doyen of Chennai's voluntary health sector, b. 1903–d. 1994) claimed in 1973 that Tamil Nadu was one of the few states which had the requisite number of primary health centres, complete with the medical and paramedical personnel needed (15). In 1973, Sanjivi explained:

*The government of Tamil Nadu was the first to constitute a state planning commission with a task force on health ... presided over by Malcolm Adiseshiah... [It] divided itself into working parties to consider in depth the problems of health services, medical education, family planning, nutrition, sanitation, the role of voluntary organisations and indigenous medicines, including homeopathy. It handed over its report to the Chief Minister of Tamil Nadu, M Karunanidhi, in 1972 (15).*

Taken together, the pre-existing government health infrastructure and the policies prioritising planning for the provision of primary and tertiary healthcare did much to contribute to the growth of *all* healthcare in Chennai, well in advance of the establishment of Apollo.

Whereas the role of Apollo may constitute a part of these larger trends, it would be erroneous to claim that it could have

served as a catalyst for them. Many of the doctors interviewed pointed out that it was, in fact, the long-standing healthcare infrastructure in and around Chennai that created a client base for private medicine. Several doctors drew attention to the fact that, particularly by the 1980s, the region's population had been sensitised to the importance of good healthcare "habits," such as visiting doctors to address their health concerns. It is also to be noted that the relatively higher levels of development in Chennai and across Tamil Nadu over a long period meant that even before liberalisation, the state was home to a comparatively large middle class population which could afford specialist care in Chennai.

*1c. Apollo triumphed because it provided what was up till then unavailable in India or for Indians*

This aspect of the Apollo myth claims that good-quality healthcare was out of the reach of Indians, except those who were very, very rich. The corollary claim is that those who could afford international travel went either to the UK or to the USA for specialist, life-saving treatment. The following is an excerpt from an interview with a doctor from Chennai, and what he says is typical of what many physicians reported:

*Chennai doctor 7... I mean, they were doing excellent work. But there was always this thing that if you were a VIP you got good treatment, whereas if you were a common man you didn't get such good treatment. And the hospital could have been a lot cleaner. So that was one thing that did put people off. Now suddenly here was a place where everybody could go to. I mean not everybody – people who could afford it, and who did not want to go to a GH [General Hospital] could come here.*

SH (author): *Instead of going abroad.*

*Chennai doctor 7: Yes. Now let's talk about the heart. Everybody who needed a bypass would go to the US. Now suddenly here was a place that one could go to. You didn't have to go there.*

This claim, however, fails to take into account some basic developments in India's economic history. In the mid-1980s, the cost of international travel rose astronomically for Indians. This was because of changes in the exchange rate and, in particular, radical devaluing of the rupee, particularly by the late 1980s. It was at precisely the same time as overseas medical travel became prohibitively expensive that Apollo began to announce dividends via newspaper articles. In other words, it is worth considering that Apollo did not create a market, but stumbled into one.

## **2. The emergence and rise of Apollo was a catalyst for a new model of healthcare delivery in India**

This claim is predicated on the corollary claim that Apollo was quickly emulated by many others in the private healthcare sector. Certainly, the story of Apollo can be described as that of the emergence and rise of *one* corporate hospital chain in India. To be fair, from the very beginning, Apollo's promoters planned Apollo not as a single institution, but as a *chain* of large private hospitals (16). This was, indeed, a new concept in India in terms

of the scale, organisation and delivery of private healthcare. What is less clear, however, is the degree to which Apollo served as a *catalyst* for the successful emergence of other large private hospitals and hospital chains across India.

In claiming that Apollo served as a catalyst for other private hospitals and chains to emerge, many assume that Apollo was an *immediate* success. However, Apollo took at least five years (and most likely, many more) before it made any dividends. Further, there was a substantial gap (at least 15 years) between the inauguration of Apollo in 1983 and the establishment of other large, successful Indian hospital chains that continue to be in existence today. Nevertheless, Apollo did make waves in the early years. As early as 1991, Chennai was hailed as the “corporate healthcare” city of India, though it had only a total of *four* large private hospitals (compared to the approximately 20 that we have today). In 1995, one journalist celebrated Chennai’s achievement thus:

*Madras is the new “mecca of medicine”... In the last five years the hospital services sector has boomed in this city, though “for profit” hospitals exist elsewhere in the country, Madras is the only city with four corporate hospitals (17).*

Indeed the 1990s was a time of relative early growth, and, soon after this article was published, Chennai had six corporate hospitals: Tamilnad Hospital, Devaki Hospital, Malar Hospital, Dr Agarwal’s Eye Hospital (which went public in 1994), and Chennai Kaliappa Hospital, in addition to Apollo. One of the obvious factors to reckon with was, and still is, that starting a corporate hospital requires immense funds. One of the doctors interviewed observed that “the gestation period for a hospital is five to seven years, minimum, before it can make a profit,” (Chennai doctor 6). As one physician explained:

*When you borrow money [for a hospital], you’re asked to repay like an industry in like five years. [But] you cannot pay back in healthcare in the five years. Absolutely impossible. So what then happens is that people take the massive amount of money. [But] modern medical technology depreciates in four years. At the end of the fifth year, you have junk, it’s scrap... (Chennai doctor 2).*

The following tale of Tamilnad Hospital illustrates how, while it was one thing to open a corporate hospital, it was quite another to keep it going or to turn a profit.

#### *From Tamilnad to Global*

Tamilnad Hospital was incorporated in 1984 by a US-based non-resident Indian, Dr CP Velusamy. In 1985, it became a public limited company. In 1991, Tamilnad Hospital issued public shares in order to finance the cost of setting up what was at that time described as “the first phase” – a 250-bed hospital in Perumbakkam, which was in south suburban Chennai and quite remote in those days (18). In 2000, after a protracted labour dispute, Tamilnad Hospital faced a mass walk-out of physicians (19). Following the labour unrest, as well as a lengthy delay in the hospital’s plans to start a medical college jointly with the Kanchi *math* nearby, Tamilnad Hospitals folded up. In 2003,

the Kanchi *math* took over the hospital through its deemed university at Kancheepuram. The hospital was rechristened the Sri Kanchi Kamakoti Sankara Medical Hospital (20). However, in 2006, Sankara Hospital admitted defeat in being able to make the venture profitable and applied to sell the hospital, explaining that in its expansion to 450 beds on the 46 acre site, it had become untenable financially. In 2007 in an all-cash deal worth Rs 257 crore, Sankara Hospital was bought by Global Hospitals and was renamed Global Health City, which is what it is known as today as well (21).

In short, whilst Apollo was the first, it is far from clear whether it paved the way for other large, private hospitals in Chennai, or whether other large, private hospitals found it easy to succeed. If anything, time has shown that the largest organisations tend to survive, given that they can do business (and spread losses) across economies of scale.

#### **3. At its heart, Apollo is a patriotic project**

The assertion that Apollo is a symbol and an institution representative of the greatness of the Indian nation is a truism. Statements on this aspect of the Apollo myth are often repeated and it is this angle that the Apollo Hospitals Group promotes the most vigorously in its publicity material and media appearances. As Prathap Reddy regularly emphasises in his many interviews to the media, “...bringing the best healthcare within the reach of every patient is our mission and [at Apollo] we are determined to make it a reality” (22). However, this claim addresses an implicit criticism. That is, one often hears worried murmurings, even among physicians employed by Apollo, of how for-profit medicine may be profit-driven. The anxiety is that profits in medicine make for bad medicine and a deterioration in morals, which would be particularly deleterious to patients in India, a nation still wracked by dire poverty. In framing the business of Apollo as a service to the nation, this criticism is neutralised.

Apollo Hospital not only neutralises the criticism of for-profit medicine, but also often presents Prathap Reddy’s very pursuit of profit (whether in healthcare or other ventures) as patriotic. Mostly, this claim of patriotism is paired with praise for the service Apollo Hospital provides to middle-class consumers. One of Reddy’s recent interviewers wrote, “[Reddy’s] is the story of one man who set out to revolutionise the unaddressed healthcare needs of a section of India’s growing middle class. It is a tale of manoeuvring through difficult bureaucratic and complex medical systems” (7).

Indeed, much of the retrospective publicity concerning Reddy and the establishment of the first Apollo highlights a series of meetings he had with Indira Gandhi, and later, Rajiv Gandhi. The accounts of these meetings portray Reddy as one who aimed to help save the nation from what was seen as stifling regulation and bureaucracy. These accounts regularly include a version of the following story: “I told Mrs Gandhi only the rich and powerful get access to healthcare and she really gave the first impetus by telling everybody, ‘Here’s a man who wants to reverse the brain drain’” (8). However, no one mentions the fact

that Indira Gandhi, who is regularly credited with evaluating the overall effect of the first Apollo, died within the first year of its establishment. Of Mrs Gandhi's endorsement of Apollo Hospitals, another of Reddy's interviewers wrote:

*The new hospital attracted the best medical talent, including eminent non-resident Indian doctors who returned to India from hospitals in the US and UK. This prompted then Prime Minister Indira Gandhi to remark, "Dr Reddy you have brought talent back to India and reversed the brain drain" (23).*

Reddy regularly remarked that "...the man who really changed the face of healthcare in this country with his vision and clarity was none other than Rajiv Gandhi – by opening up hospitals to funding and other opportunities" (8).

However, when Reddy was preparing to open Apollo in 1982, his statements regarding the national role that the hospital was expected to play were substantially different from the stories we hear today. In 1982, a newspaper reported that Apollo was an institution primarily intended to serve foreigners travelling to India from the Gulf for medical treatment:

*A hospital being built under the corporate sector here expects a steady flow of rich Arab clients and a huge inflow of foreign exchange, since the Arabs are not satisfied with the facilities offered in the Bombay hospitals. Dr Prathap Reddy, chairman of the company behind the venture, told newsmen here yesterday that many rich Arabs had told him that they wanted to be picked up from the airport to the hospital and all investigations and treatment should be done under one roof, regardless of cost (24).*

In this early iteration, Apollo would serve the Indian nation – not by ministering to Indians –but by ministering to India's foreign exchange reserves. The avowal of such objectives echoed a statement Reddy had made slightly earlier, in which he had disclosed that the government recognised the Apollo venture as a "core economic activity" because it (the government) was aware of the potential of healthcare to attract foreign exchange(25). It should be evident that this quote is at odds with the avowed aim of Reddy and Apollo that has been commemorated subsequently. Reddy and Apollo Hospitals have been honoured with the highest accolades that the Indian nation can bestow. Reddy received a Padma Bhushan in 1991 (India's third highest civilian honour) and a Padma Vibhushan in 2010 (India's second highest civilian honour).The Indian Postal Service issued a commemorative stamp in honour of Apollo Hospitals in 2009.

#### **4. In order to establish Apollo, Reddy changed state practices single-handedly**

Many go on from the assertion that Apollo was a trailblazer, that too the only one, in crafting a new future for medicine in India, to claim that Reddy effected these changes by dint of his personal charisma. According to these accounts, Reddy charmed the "Delhi Durbar" under successive prime ministers

during the 1980s with the sheer persuasiveness of his argument that his was a national/populist project.

Indira Gandhi and Rajiv Gandhi figure prominently in these accounts. One newspaper reported: "Banks were not willing to fund hospitals. Apollo approached the Centre and found a patient listener in the then Prime Minister, Indira Gandhi. The healthcare sector gained industry status, and access to financial markets" (26). Referring to 1989 when Rajiv Gandhi was the Prime Minister, another interviewer made the following claims:

*...On Reddy's representation, the former (Rajiv Gandhi) amended in three days in the Parliament and removed all hardships leading to liberal funding And so the costliest medical equipments made inroads[sic] into Indian hospitals and were equipped on par with the western. Rajiv Gandhi also gave a tax exemption of Rs 10,000 [on medical equipment] (27).*

Finally, another interviewer risks over-egging the pudding, exceeding even Reddy's and Apollo's own claims: "Often referred to as the father of modern healthcare in India – after all, he revolutionised healthcare in India when the country was mired in babudom" (8). Reddy himself was quoted as having said the following of the first Apollo:

*...securing licences to import 370-odd medical equipment for the hospital itself took two years. Meanwhile, lowering of import duty on life-saving medical equipment also helped private healthcare during the pre-reform era. The duties came down from 100% to 5–6% over the years (26).*

The claims regarding the transformation brought about by Reddy ignore and obscure the fact that the pre-existing economic climate had already been in the process of changing. Reddy takes credit for these changes, in particular, liberalisation, first under Indira Gandhi in the early 1980s and then under Rajiv Gandhi in the late 1980s. This aspect of the myth also underplays the increasingly active role of associations such as the Federation of Indian Chambers of Commerce and Industry (FICCI) and the Confederation of Indian Industry (CII).

#### **5. Apollo was an immediate success**

The popular perception is that upon its establishment in 1983, Apollo was an immediate success in terms of therapeutic outcomes and profit margins. The publicity circulated by Apollo Hospitals gives one to believe the same. As one of the doctors who was interviewed emphasised, "[Apollo] was a place where you could be confident you get every kind of treatment under one roof. And it was available for a price, but it was there. The quality was there. That was right from the beginning. It was a foregone thing. It just took off" (Chennai doctor 7). Many attribute the success to Reddy's visionary nature. Another doctor declared, "Apollo succeeded because Reddy could see what was coming"(Chennai doctor 8). However, this was not the case, as is clear both from Apollo's own attempts to secure funding through further public share issues to underwrite further expansion, as well as the struggle of other hospitals to thrive within the same market (Chennai).



## Conclusion: the trouble with myths for writing policy

Alongside biotechnology and information technology, corporate healthcare is given pride of place within India's current "sunshine story." These industries are taken to be examples of the country's capacity to deliver and are given much of the credit for the nation's recent economic successes. Indeed, according to a recent KPMG report, rising income levels, changing demographics and shifts in disease profile were expected to double the size of spending on healthcare by 2012 (28). The industrial barons leading these fields both drive new economic policies and profit from these new policies.

Looking ahead at the role that corporates are poised to play, one final point regarding the form and meaning of medicine, as well as myths in this sphere in the era of liberalisation, requires critical scrutiny, particularly in the light of the current government's pursuit of universal health care. That is the claim that corporate "multi-speciality" and "super-speciality" hospitals both constitute an innovation in the delivery of healthcare, and the corollary of this, ie that corporate hospitals provide an extremely broad range of high-quality medical services and, as such, a template for healthcare delivery to the nation.

I found that there was widespread agreement, particularly among the doctors I interviewed, with the view that multi-speciality corporate hospitals represent an innovation in the delivery of healthcare. One doctor explained the significance of multi-speciality large private hospitals thus:

*Suppose a specialist – I am talking about 20 years back – suppose you are an eye specialist. You will have an eye hospital. Or you are a surgeon. You will have a surgical hospital. But the corporates changed that. Apollo Hospital changed that concept. They said, "All departments under one roof" That was the concept (Chennai doctor 10).*

Another doctor echoed this view:

*[Apollo] was a place where you could be confident you could get every kind of treatment under one roof... Suddenly people found that here was a place that, you know, they had all kinds of specialities. That was the first hospital that actually even had specialists coming in (Chennai doctor 7).*

Listening to these accounts, I failed to see what was so innovative. Surely, I thought to myself, the concept that one hospital could treat an entire range of ailments was the *foundational idea* of hospital medicine, as it emerged in the late eighteenth and early nineteenth centuries. Many claim that the multispeciality hospital provided something new, but surely this was simply a shinier imitation of the government and charitable institutions which were already in existence and which, too, were based on a long-standing model of comprehensive clinical investigation and treatment.

But the problem with this misconception is beyond a basic amnesia for medical history. The problem with the celebration of the corporate multispeciality version of hospital care is a lack

of recognition of the fact that, over the past three decades, this form of the delivery of healthcare has succeeded only due to its selectiveness. Indeed, even some of the doctors who praised the hospital's supposedly "innovative" model of care simultaneously recognised that most multispeciality hospitals succeeded both financially as well as in healthcare delivery, because they made very selective and strategic choices about their investments in specialisations. These specialisations allowed for very high success rates for very specific procedures, which could facilitate a high patient throughput and a corollary income stream.

In this context, we could consider the example of the Railways Hospital in Chennai. Railways offered excellent services for patients with heart-related ailments. However, because of the wide cross-section of the population that this hospital was built to serve, the heart specialists there were able to develop expertise not only in coronary bypass surgery, for example, but also in the much riskier areas of paediatric cardiac surgery and the heart ailments suffered disproportionately by the poor (eg rheumatic heart diseases that do not necessitate open heart surgery).

Mistaking the "comprehensive care" that the corporate hospitals claim to deliver for a genuinely comprehensive care is a dangerous mistake. It is evident that there is a big difference between the comprehensive care of universal health care proposals and that that large government hospitals have historically provided. This is particularly clear if one considers what corporate hospitals are being asked to, and poisoning themselves to, deliver to the general population of India under the universal health care proposals. Neither these hospitals, nor the Government of India has suggested that corporate hospitals should become involved in public (or "preventative") healthcare. But why not? One profile of Reddy says, "...As Dr Reddy himself acknowledges, primary healthcare should be the responsibility of the government, which has both the resources and manpower to reach all parts of the country" (8). Yet how can healthcare be either universal or comprehensive in the absence of primary health care? Corporate health care has a proven track record of offering quality care, but only in highly specific –and highly revenue-generating—procedures, such as heart bypass surgery. The costly business of primary healthcare is to be left entirely to a system that many consider already overburdened and under-funded. Nevertheless, Reddy's confidence that corporates should not shoulder more comprehensive care has been accepted by many of today's leaders (28). Reddy describes his goal thus: "My vision for the Apollo Hospitals Group is to touch a billion lives, and I am sure we will fulfil the dream" (22). Yet, it is hard to imagine that he wants to touch *all* parts of these lives' bodies; it is just the revenue-generating parts that interest him.

### List of doctors interviewed by author and cited in article

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Chennai doctor 2: Interviewed 11 May 2010

Chennai doctor 3: Interviewed 5 July 2010

Chennai doctor 4: Interviewed 19 July 2010



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## DISCUSSIONS

## Ethics of “standard care” in randomised trials of screening for cervical cancer should not ignore scientific evidence and ground realities

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We read with interest the recent editorial (1) in the *IJME* on the ethics of standard care in screening trials for cervical cancer in India. The author takes exception to the fact that three cervical cancer screening studies in India used no screening as the control arm, in spite of evidence that the Pap smear is an effective screening tool. The author argues that the Pap smear should have been the standard arm in these trials, and that it was unethical to “withhold” this screening method from participants in the control arm of the trial. At the outset, we wish to declare a conflict of interest in our response by virtue of being investigators of one of the aforesaid trials, but feel it necessary to clarify certain facts that have been overlooked. First, during the consent process, all women in the Mumbai trial (control and intervention arms) were counseled on Pap smear testing, given information on the centres nearby that offered the Pap smear and assured that they were free to get themselves screened if they so wished. Second, the author’s assertion that visual inspection with acetic acid (VIA) had already been proven to be effective on the basis of cross-sectional studies, and that there was no need to perform randomised trials to prove that it was effective, lacks scientific credibility. The hierarchy of medical evidence places the randomised trial at level 1, or providing the highest level of evidence, whereas that yielded by cross-sectional studies is considered to be level 4 evidence, ie evidence that is unreliable. Major national public health policy decisions are always made on the basis of randomised level 1 evidence. Prior to our study, there had been no randomised evidence that VIA performed by trained primary health workers (who are the only healthcare providers available for the vast majority of the poor in rural and urban areas) leads to cervical cancer mortality reduction. In fact, an earlier study had shown that neither the Pap smear nor VIA had led to a decrease in mortality due to cervical cancer in India (2). Should we not obtain robust level 1 evidence before making a major public health decision to offer VIA as a routine screening method to all women in India?

Before commencing with the trial, the choice of no screening for the control arm was discussed with several experts at the national level. Three points are noteworthy. First, the Indian Council of Medical Research (ICMR) and the Ministry of Health and Family Welfare, Government of India had concluded that there was a dearth of facilities for nationwide screening for cervical cancer using the Pap smear, and had made a projection

that even with a twelve-fold increase in staff trained in Pap smear, only a quarter of the eligible women in India could be screened (3). The report emphasised the urgent need for alternative methods of screening and suggested that visual examination of the cervix be evaluated (3). Second, a WHO–Government of India committee reiterated the points made in the ICMR report and, in view of the fact that the infrastructure and resources did not permit a nationwide Pap smear-based screening programme, stressed the need for the identification of an alternative method that was “scientifically correct, ethical and feasible” in India (4). Finally, a report from the Center for Risk Analysis, Department of health policy and management, Harvard School of Public Health affirmed that the Pap smear was difficult to implement in developing countries and suggested that alternative strategies be considered (5). Using mathematical modelling techniques, the report went on to compare the cost-effectiveness of the Pap smear, direct visual inspection of the cervix and human papilloma virus (HPV) DNA testing. The efficacy of once-in-a-lifetime screening with HPV DNA and direct inspection was almost identical (27% and 26% reduction in the incidence of cancer, respectively), and was superior to that of the Pap smear, which was 19%. The incremental cost-effectiveness ratio of the three techniques, when implemented three-yearly, was \$460 per year of life saved (YLS) for visual inspection, while that of HPV DNA testing was 25 times higher, at \$11,500 per YLS, and that of the Pap smear was even higher. The paper concluded that the Pap smear was the least effective and the most expensive amongst the techniques tested.

It becomes clear from the expert reports that the Pap smear cannot be considered the standard of care in India, not only because of the lack of infrastructure and trained manpower, but also because it is not cost-effective. The results of our study showed that VIA screening reduced the death rate from cervical cancer by 31%, ie 1 in 3 deaths were prevented. In addition, the study detected a very large number of pre-invasive cancers, which were easily treated by outpatient procedures. The latter suggests that in addition to a reduction in mortality, VIA screening promises to markedly bring down even the incidence of cervical cancer in this group in the future. Thus, the results of our study, if implemented widely, would save thousands of lives globally in the developing countries. In fact, the *Wall Street Journal*, while covering the plenary presentation of our study

(6) at the annual American Society of Clinical Oncology (ASCO) meeting, quoted experts as saying: "(VIA) ... can save lives, and could even be useful in low-income areas of the US with relatively high cervical cancer rates and low use of Pap tests" (7). An international expert estimated the number of lives saved by VIA screening globally to be of the order of 270,000 per year (8).

There has always existed a healthy tension between ethics and the scientific process, but a show of moral outrage only helps to vitiate this healthy relationship.

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## Screening for cervical cancer revisited: understanding implementation research

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In the editorial "Ethics of 'standard care' in randomised controlled trials of screening for cervical cancer" (1), Sandhya Srinivasan argues persuasively that a series of placebo-controlled trials on screening for cervical cancer in India were unethical. The purported aim of the trials was to study the method that uses visual inspection of the cervix following staining with acetic acid (VIA), to determine the efficacy of the method in a low-resource setting. Srinivasan notes: "The researchers in these trials have argued that only a 'no care' control arm can give definitive results and this information is essential to guide policies and programmes....VIA has been researched at least since the early 1990s. VIA is an affordable screening test, and there is evidence suggesting that it works about as well as the Pap smear" (1:p149). The author also identifies the design of the research as cluster randomised trials: "The trials actively denied care, by comparing – as intervention and control groups – entire clusters of urban wards or rural primary health centres, rather than individuals, ensuring that women in the control groups would not somehow gain access to the interventions" (1:p148).

Several issues need to be sorted out to clarify what is at stake here. First, one must determine exactly what is wrong with the researchers' defence of the placebo-controlled design of the study. Second, one must identify just what type of study is needed in low-resource settings such as India. Finally,

there is a need to assess the ethical acceptability of cluster randomised trials.

### The researchers' defence

It is simply not true that "only a 'no care' control arm can give definitive results." Although the randomised controlled trial is the "gold standard" in clinical research methodology, this does not mean that the control arm must be a placebo. In settings in which the standard diagnostic method is a proven intervention and researchers want to test a new method, or even a less expensive method, it would be unethical to withhold the proven diagnostic method from the participants. The research design would then be a non-inferiority trial, which would test the experimental procedure against the proven intervention to see whether the former is as good (or almost as good) as the latter. That is a perfectly acceptable research design, although it would involve more research subjects and take longer than a placebo-controlled trial. The idea that it is ethically acceptable to design a study in resource-poor settings in which the participants do not have access to a proven diagnostic method outside the trial is flawed. If researchers in India wanted to study VIA to determine whether it is as good (or almost as good) as the Pap smear, they could do so in a tertiary care setting which has the equipment and trained personnel to allow for the routine use of the cytology-based screening method. Using

the existing baseline data on the incidence of cervical cancer in India, the efficacy of the experimental method (VIA) could then be ascertained.

This brings us to another flaw in the researchers' defence. The efficacy of VIA was already well established. According to a World Health Organisation (WHO) consultation report in 2002, "The test performance of VIA suggests that it has similar sensitivity to that of cervical cytology in detecting CIN, but has lower specificity. Further research is required to improve its specificity without compromising sensitivity" (2). The WHO report also pointed out the need for training personnel in the use of the method, as well as that for developing standard procedures for quality control. Also needed at the time was research on the development of a simple scoring system to objectively report the results of VIA. However, the important point is that the efficacy of VIA as a screening method had already been established when these trials were conducted in India.

### What type of research is needed?

This brings us to the second issue: just what type of study is needed in low-resource settings, such as those in many parts of India? What was needed was *not* an efficacy study of VIA, but a study of its implementation in a new setting. This type of study, known as *implementation research*, is carried out frequently in low-resource settings in which the training of personnel in the use of new equipment or techniques must be studied. The WHO defines this type of research as follows: "...that area of research devoted to understanding the bottlenecks around introduction and scaling up implementation of a proven public health intervention and finding practical solutions to overcome such barriers or constraints" (3). Although some authors agree with the part of the definition stipulating that the intervention should already have been proven to be efficacious (4), the authors of a series of papers on cluster randomised trials reject it. They write: "The fact that an educational or quality improvement intervention is being evaluated in a CRT suggests that its effectiveness is unproven. Indeed, if it was known at the start of the trial that the study intervention is effective, the CRT would be unethical" (5:p11). So, a great deal hinges on whether VIA should be considered a "proven intervention." As Srinivasan argues: "By comparing the impact of the interventions with that of no treatment, they also violated the principle of equipoise on which such studies should be based, even though there is sufficient evidence that some screening is better than none" (1:p148).

Although randomised controlled trials remain the gold standard in clinical research methodology, other approaches in implementation research need not run into the ethical problem of placebo controls. One option is to use historical controls. This method is generally considered inferior in trials that seek to prove the efficacy of a new intervention because the historical controls may not fully match the subjects receiving the intervention. However, implementation research does not

study the efficacy of a new intervention; rather, it studies the ability to employ the proven intervention properly by training personnel in the use of unfamiliar techniques or equipment. A study design that compares cancer rates following the introduction of VIA in urban wards or rural primary health centres with the past rates of cancer among women who used the same health facilities before VIA was introduced could provide results demonstrating that the implementation of the new technique was successful.

Another method – one favoured by WHO as an alternative to implementation research – is demonstration projects. WHO conducted a demonstration project on VIA in six African countries: Malawi, Madagascar, Nigeria, Uganda, the United Republic of Tanzania, and Zambia. The report on the project, which ran from 2005 to 2009, says that all women were counselled and offered screening using VIA, and patients with a positive screening test were treated using cryotherapy (6). The report concludes: "This demonstration project has shown that the 'screen and treat' approach can be introduced into existing reproductive health services in low-resource countries. Screening for precancerous lesions using VIA and treatment with cryotherapy is acceptable and feasible at low-level health facilities in six African countries" (6). WHO initiated this demonstration project in 2005, while two of the placebo-controlled studies on VIA described by Srinivasan continued until 2006 and 2007. Whereas WHO considered VIA to be a proven intervention, ready for a demonstration project in six African countries, the researchers in India apparently believed it was necessary to demonstrate the efficacy of the technique against placebo.

### Cluster randomised trials

Srinivasan does not go into a discussion of this research methodology, but does describe it, as quoted earlier. While the description is not exactly a condemnation of cluster randomised trials, it implies that they are ethically suspect because they "actively denied care" and prevented women from learning about and gaining access to VIA screening.

There is nothing inherently suspect about cluster randomised trials. It is true that one motivation for using this methodology is to prevent contamination between intervention and control groups, a problem which could occur when individuals rather than healthcare facilities are randomised. This methodology is especially useful in implementation research in developing countries, to train an entire unit of physicians or nurses in a technique that is new to them but has been proven effective elsewhere. It would be difficult, if not impossible, to obtain accurate results if individuals were randomised rather than clusters. What makes the VIA cluster randomised trials in India unethical is not the randomisation method, but the fact that the control group did not receive screening for cervical cancer by VIA or any other method.

Srinivasan rightly concludes with the observation that "there are many other issues that deserve discussion in these and other trials looking at public health interventions



in resource-poor settings" (1:p149). One critical issue is the need to distinguish clinical trials designed to study the safety and efficacy of new pharmaceutical products from those that study the implementation of interventions already proven to be efficacious in other settings. Implementation research is a useful pathway for introducing and scaling up beneficial proven public health interventions in resource-poor settings. However, it is a mistake to contend that the use of placebo controls in phase III efficacy studies of new drugs or techniques is appropriate, or even ethical, in efforts to study the implementation of proven techniques in resource-poor settings.

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## Have scientists met their ethical responsibility towards research participants?

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Pramesh and colleagues (1) have not responded to my central thesis: it was unethical to have a "no screening" control arm in the VIA trials when proven screening methods existed (2).

According to national and international research guidelines, if a proven treatment exists for the disease under study, a placebo or no treatment arm is ethically acceptable only if it is methodologically necessary (3) and the disease concerned is self-limiting, such that denying treatment will not cause serious and irreversible harm (3,4).

Given the existence and availability of Pap smear screening, as well as DNA testing for HPV, the use of a no screening arm in the trials of VIA to screen for cervical cancer violated national and international ethical guidelines for research.

1. The authors' statement regarding the information given to the participants in the Mumbai trial does not contradict anything said in the editorial; the fact that the women in the control arm were "given the freedom to get screened if they so wished" is not the same as providing them screening.
2. The authors assert: "Major national public health policy decisions are always made on the basis of randomised level 1 evidence." Decisions on public health interventions are taken using multiple sources of information. The Pap smear is one of many interventions that have been established as public health programmes in the West, and the impact measured and confirmed, without randomised trials (5). The body of research on screening methods for cervical cancer (including VIA and Pap smear) includes cross-

sectional studies, evaluation of long-standing programmes, demonstration projects, and mathematical modelling of impact and cost-effectiveness (5).

3. The authors state: "Pap smear cannot be considered the standard of care in India, not only because of lack of infrastructure and trained manpower, but also because it is not cost-effective."
  - The Pap smear is available in private and public hospitals in Mumbai, the city in which the authors carried out their research, and where the infrastructure and trained manpower necessary for its use in a screening programme exist.
  - One of the authors was also part of the Osmanabad trial (6) referred to in the editorial. This trial, the ethics of which, too, were questioned because of the use of a no screening control, was conducted through primary health centres in villages and compared VIA to the Pap smear and HPV testing. We can presume that the investigators considered all three methods to be potentially fit for use in public health programmes in rural India.
  - The authors have not explained their assertion that the standard of care is determined by cost-effectiveness, with the consequent implication that this should exclude the Pap smear from trials in India. Using the authors' argument, the Osmanabad trial should not have included the Pap smear.
  - By 2001, the ICMR had already concluded that both the Pap smear and VIA were suitable screening tests for India,

and VIA was the option recommended for immediate introduction into district cancer control programmes (5). By 2005, the WHO /Government of India committee to which the authors refer had drafted guidelines for the incorporation of both VIA (at the primary health centre level) and the Pap smear (at the district hospital level) into the existing health system, starting with a demonstration programme (7).

4. The authors state: "The choice of no screening for the control arm was discussed with several experts at the national level prior to starting the trial."

This statement does not throw any light on whether the ethics of a no screening control was discussed by these national experts, and what the conclusions were. Nor is there any mention, in the three documents cited by the authors, of a no screening control, let alone the ethics of this methodology.

Further, while ethical clearance would not have rendered the trials ethical, the authors offer no evidence to suggest that the no screening arm was even discussed by the ethics committees reviewing the trials.

5. The authors describe the editorial as a "show of moral outrage" that vitiates the "healthy tension between ethics and the scientific process." For a healthy tension between ethics and the scientific process, there must be evidence that the scientific process has considered ethics and that the scientists have met their ethical responsibility towards the research participants.

I thank Ruth Macklin for her comment (8) in support of my argument and for providing clarity to the issues raised in the editorial. Regarding my reference to the use of cluster randomisation, I did not mean to imply that all cluster

randomised trials are unethical. My intention was only to underline the consequences for the women in the control arm of these trials.

Macklin's conclusion is that the placebo-controlled VIA trials were not ethical, not necessary and not appropriate research. The question we must, therefore, ask is: why were they conducted? The response by Pramesh and colleagues does not shed any light on this question.

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## Ethical issues in adapting new technologies for rapid diagnosis

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The Xpert® MTB/RIF (hereafter Xpert) is a recent technology that has "demonstrated sensitive detection of tuberculosis (TB) and rifampicin resistance directly from untreated sputum in less than two hours" (1). Many are in favour of the widespread implementation of this technology in India. In a recent article in the *IJME*, Singh, Bhan and Upshur state that "India is ethically obliged to phase in the nationwide deployment of Xpert...as soon as reasonably possible" and "is ethically obliged to provide those diagnosed with first-line drug resistance universal access to second-line TB drugs" to treat multiple drug-resistant tuberculosis (MDR-TB) (1).

The prevalence of MDR-TB in India is estimated to be about 2%. In their review of the Xpert technology, A Trebucq and colleagues make the point that the question is not whether to treat MDR-TB, but rather, when, where and how to treat it (2). Besides the limitations related to cost (~\$10 per test), the environment required (the need for a stable, regular electric supply for an air conditioner to be able to maintain the room temperature at 15-30 °C), the shelf life of the test cartridges (18 months), and supply and maintenance issues, there are other questions as well regarding the reliability of the test at different levels of prevalence of MDR-TB. When the prevalence is 1% or less, the positive predictive value (ppv) is 32%; when the

prevalence is 2%, the ppv is 49%; and when the prevalence is greater than 15%, the ppv is above 90%. Any specimen testing positive for rifampicin resistance in a low-prevalence area will have to be verified by culture and antibiotic testing.

To control clinical TB and reduce the rate of infection, a well-run national TB programme must be in place (2). This translates into the following: 70% of cases must be identified and 85% of sputum-positive cases should be treated successfully with Directly Observed Treatment, Short-course (DOTS). Second-line drugs (SLDs) used to treat MDR-TB cost at least 100–200 times more than those used in a standard DOTS programme. The patient must take the SLDs for 18–24 months and usually has to spend the first six months in hospital. The success rate is about 60%. In general, DOTS requires six months of treatment with no hospitalisation.

Scaling up treatment of MDR-TB poses its own special problems. At the moment, SLDs are not being produced in adequate amounts and the prices of these drugs have been increasing year by year. Some who advocate the widespread treatment of MDR-TB cite the example of HIV/AIDS, for which the initial cost of treatment was high and prices were slashed subsequently, following intensive lobbying. However, MDR-TB is much less common than HIV/AIDS (though the number of patients is growing), there has been much less advocacy for widespread treatment of cases, and there has been a significant delay in the development of effective SLDs. Singh et al note that South Africa has rolled out the treatment of MDR-TB nationally, even though it may not be affordable, and say India could do the same (1). South Africa has a purchasing power parity per capita that is three times that of India: \$11,375 vs \$3830 (3), and has a much more developed and efficient healthcare delivery system.

Why is the incidence of MDR-TB increasing? A high dropout rate from DOTS programmes, limited follow-up of patients on therapy, inappropriate and incomplete treatment regimens (especially in the private sector), and counterfeit drugs have all contributed to the rise in incidence. Without an excellent DOTS programme at the point of care, backed by a multi-drug resistance treatment programme which has trained staff, adequate drugs in stock and a laboratory capable of carrying out cultures for drug resistance, testing for MDR-TB will

present an ethical dilemma for the caregiver, since up to 10% of those who test positive for drug resistance will respond to first-line drugs.

Two other issues raised by Singh et al deserve comment. The authors state that the government is ethically bound to continue administering SLDs once the treatment has been started in the private sector. This makes sense if the original diagnosis is confirmed. If a few days of inappropriate treatment for MDR-TB are extended for another two years, it could place the patient at great inconvenience and risk. This would also be at a high cost to society. According to the definition of autonomy, a patient has a right to choose among treatment options (1). However, what if the patient chooses not to be treated? Does the public have a right not to be exposed to a disease that is spread by air – a common public good?

In reviewing the when, where and how to use Xpert, India would be well advised to move cautiously in rolling out this technology to diagnose rifampicin resistance. The use of Xpert should be restricted to those centres where a positive test can be confirmed in the laboratory, and where complete uninterrupted treatment can be assured. Without this basic infrastructure, the widespread use of Xpert could lead to over-diagnosis and inadequate treatment, which could lead to more cases of XDR-TB, an essentially untreatable disease within the Indian context. When it comes to the community, the most effective intervention and the most ethical approach would be for the country to continue to improve its DOTS programme to ensure effective treatment to the vast majority of TB patients, as this itself will reduce the incidence of MDR-TB. Technology does have its limits.

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## COMMENTS

# Protection is not just about preventing disease: vaccine equity and ethics in the developing world

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Vaccines are intended to prevent disease. In 1798, Jenner used the principle of an animal virus that caused a localised lesion but afforded protection against severe disease. This started the practice of “vaccination.” The idea of preventing disease and avoiding unnecessary suffering is attractive, but since vaccines are generally given to prevent disease in people who do not already have it, they must not themselves cause disease, or at least no more than acceptable discomfort (1).

It is incredible how quickly it is possible for diseases to disappear and how people are left with only a vague remembrance of them with the passage of time. They find a place only in the tales of our grandparents’ generation, and then not even that. Smallpox, which once devastated regions and countries, has been eradicated. Polio and the ubiquitous calipers and braces (and earlier still, the “iron lungs”) have been long gone from industrialised countries. India is planning a switch to an injectable vaccine to avoid the damage to one in a million vaccinated children who develop paralysis because of the oral vaccine. Neonatal tetanus, a horrible experience in which the helpless child bends and arches in ways that seem impossible, is a rare event now that mothers are immunised during pregnancy. Measles, whooping cough and diphtheria continue to afflict us, but are no longer the large-scale killers that they once were in all regions.

Vaccines have been a remarkable success story, but although there are dozens of vaccines that are available and administered to children and adults, several of them are for diseases which are restricted to certain regions, such as the Japanese encephalitis virus vaccine, and others are restricted for reasons that have nothing to do with the absence of disease. Currently, the Centers for Disease Control and Prevention, a US federal agency responsible for public health, recommends vaccines to confer protection against 16 infectious diseases, including measles, mumps, rubella, varicella, hepatitis B, diphtheria, tetanus, pertussis, *Haemophilus influenzae* type B, polio, influenza, and pneumococcal disease (2). The BCG vaccine is not recommended for everyone in the US because tuberculosis is not a disease of major public health significance there. American children are given 14 of these vaccines in the first two years of life. Of the basic package of 16 vaccines, Indian children in all states receive only BCG and five other vaccines (if they receive immunisation at all), and in some states, this may go up to eight other vaccines. This is despite the fact that all these vaccines are available in India. With the exception of the

seasonal influenza vaccine, all of them are given to children who can access private healthcare.

Why is this? Why can a country that has built its own space and atomic energy programmes not deliver a basic intervention to its children? The infrastructure for delivery exists and vaccines are not an expensive intervention for the value they deliver. Their value can be measured not just in terms of the suffering averted but also in real economic terms. Vaccines prevent disease, and the prevention of ill health and suffering is an investment in the country’s future (3). It is true that the provision of access to healthcare in India is difficult, that challenges abound and that there are enormous hurdles. However, an advantage of vaccines is that they can be delivered according to a schedule, so that the demand for them and the location where they have to be delivered are predictable. Further, since they are given generally to healthy children, other than monitoring for rare serious adverse events, little more is required than a “well-baby” check-up and vaccination by trained primary healthcare providers who follow a protocol.

Of course it would be ideal to have services available to all across the continuum of care, but if we cannot deliver curative healthcare, can we not at least try to provide services for the prevention of disease as part of primary care on the widest possible scale, with at least as many vaccines as children elsewhere receive? Bangladesh and a host of other poorer countries perform better than India in the delivery of immunisation, both in terms of the number of antigens and the coverage rate (4). It is true that there are challenges to be confronted, particularly in systems in which the same staff and structures are responsible for both preventive and curative services, but approaches to strengthen the routine delivery of preventive and primary care services will go a long way to ensure the protection of all Indian children (and not just the rich) from disease.

Accepting the responsibility for protecting its population from internal and external threats is the remit of the government. Just as protection from aggressive neighbours requires investment, there is at least an equal and considerably more urgent need to invest in protecting the population from the preventable threats of infectious disease. Compared to an annual “formal” defence budget of Rs 2,03,672 crore (12.3% of the central government expenditure or 1.79% of GDP) (5), India spends about Rs. 600–700 crore on its national immunisation programme annually. Of this, we are told that Rs 200 crore is



the cost of vaccines. The inadequacy of this investment defies any kind of logic.

We know that when vaccines are evaluated in situations in which delivery of healthcare is excellent, the incremental advantage shown by the introduction of the new vaccine is less than that of comparable interventions in previous decades, or that of interventions in areas where the access to curative health services is deficient. However, vaccines, and oral rehydration therapy, are still considered among the most cost-effective public health interventions for childhood diseases, according to the CHOICE guidelines of the World Health Organisation (WHO), which compare the relative value of investments (6).

There is clearly an ethical need for equity in the provision of access to vaccines, but it is not against preventable disease alone that protection is needed. There are three kinds of protection required for the ethical, equitable use of vaccines in India. The first is, of course, against disease. The vaccines available are considered and a case is made for or against their use in the public health programme. The second is protection from harm. For this, the immunisation programme must ensure that any possibility of damage, either because of errors in the delivery of the programme or because of the product itself, is minimised. The third is protection from misinformation, which requires that opinions are not presented as facts, and that pseudo-science or any claims that affect the introduction or use of the vaccine are evaluated and presented independently. All three of these kinds of protection require investment from the government, which should emphasise that the activities related to them are necessary and complementary to immunisation.

There are individuals and groups who argue against vaccines, who believe that the decrease in the incidence of several infectious diseases is a result of improvements in sanitation and hygiene, living conditions and nutrition. While such improvements have clearly contributed to the decline of some diseases, such as tuberculosis and cholera in the industrialised countries, the remarkable decrease in the incidence of measles, *Haemophilus influenzae*-associated meningitis and more recently, rotavirus gastroenteritis in these same countries has been too rapid to be attributable to anything other than vaccines (7–9).

Nonetheless, every intervention, whether preventive or curative, requires a cautious approach. Vaccines are administered prophylactically to protect healthy individuals against diseases to which they are likely to be exposed. Clearly, the benefit offered by a vaccine must be greater than any potential risk it poses, and this benefit and risk must be evaluated at the level of the individual and the population separately. At the level of the individual, parents seek information and make decisions on whether their child should be given a vaccine, whether its administration should be deferred or whether it should be avoided, thus taking the responsibility for decisions that affect their child's health.

However, at the population level, how should decisions regarding benefit and risk be made and who should make

them? If a disease is common and devastating, and the vaccine is inexpensive, effective and safe with no side-effects, then the decision should be easy enough to take. Again, it is not difficult to take a decision if a disease is rare and non-fatal, or easily curable or treatable, and if there is no safe and effective vaccine. However, if there is no accurate knowledge of the disease burden (and this can be the case for a number of reasons), or the vaccine is expensive or not effective enough, then both issues (disease burden and cost-effectiveness) must be studied carefully before taking a decision on the use of the vaccine. In recent times, there has been tremendous pressure from some vaccine manufacturers for the introduction of new vaccines, sometimes mis-presenting arguments as in the case of the HPV vaccines, and this needs to be guarded against (10). There are several advisory bodies, consisting mostly of independent experts, at the country level as well as internationally, that make recommendations and help governments to consider the evidence. In addition, organisations such as WHO, through its Strategic Advisory Group of Experts on immunisation, make recommendations on the introduction of vaccines into public health programmes (11).

Before licensure, vaccines are expected to undergo phased testing among an increasingly larger population. The safety and efficacy of a vaccine are the determinants of licensure by the regulatory authorities. Once a vaccine is licensed, considerations such as the disease burden it can avert, its societal value in terms of equity, the public demand for it, politics and programmatic considerations determine whether it is finally seen as a public health priority. However, concerns have been expressed regarding the safety of several vaccines which have been introduced into national programmes. Two key elements related to safety need to be recognised.

The first is that no vaccine can claim to be 100% safe. Since most vaccines are developed to mimic infection, they result in some reaction, which is usually mild. For example, there may be some redness and swelling around the site of the injection or fever following the injection. Rarely, however, serious adverse events may occur in the case of some vaccines. Some examples are the occurrence of intussusception in 1 in 20,000–60,000 recipients of the oral rotavirus vaccine, anaphylaxis in 1 in 1000,000 recipients of the hepatitis B vaccine and encephalitis following the mumps vaccine. The WHO has published the expected rate of adverse events for several vaccines (12), and these can be useful when deciding upon whether or not the risk of a vaccine is acceptable, compared to the vaccine's potential benefit, at the population level.

The second concern is that careful and constant monitoring is required for the continual evaluation of safety signals, which may have previously gone undetected or appear because of a change in the composition or administration of the vaccine. For example, it is now recognised that narcolepsy may follow immunisation with a swine flu pandemic vaccine in individuals with a specific HLA type DQB1\*06:02 in northern Europe. It was initially difficult to make a causal association with the vaccine, but following thorough studies

in several countries that evaluated large databases, a risk of 1 in 52,000 doses was assigned (13). An example of a change in composition resulting in safety issues is the occurrence of cases of aseptic meningitis when the Urabe strain of mumps virus replaced the Jeryl Lynn strain (14).

There are many instances in which the potential dangers of a vaccine have been identified and appropriate action has been taken. In all these cases, a biologically valid explanation for an event was found and an estimation of the risk made on the basis of comprehensive investigations. Unfortunately, this is not always the case. All too often, events that are related in time to the vaccination events are considered the cause of an adverse event, and no attention is paid to the possibility of whether the supposed association can be explained biologically and from the evidence available. For example, given the infant mortality rate in India, approximately 300 children would be expected to die during any 24-hour period. If the child happened to receive a vaccine on that day, it may be wrong to conclude that the vaccine caused the death, without gathering further information on the circumstances and sequence of events. Did the vaccine really cause the death? How can this causality be determined?

WHO has come up with a tool that can serve as a guide in the assessment of causality. The approach adopted lays emphasis on constructing and testing a biologically plausible hypothesis to support the association (15). However, it must be pointed out that for the assessment of causality to be satisfactory and for it to be able to provide a clear message regarding safety, it is critical that a stable, comprehensive and structured Adverse Event Following Immunisation (AEFI) reporting system is functional, capable of providing detailed data on each event. When clear data pointing to a safety concern are supported by epidemiological and laboratory evidence, a causal association is indicated and the risks and benefits of vaccination must be re-assessed.

One example of the application of this tool has been the recent developments related to the pentavalent vaccine. This vaccine contains five antigens that have been used in different combinations in millions of children around the world. As for the combination used in developing countries, it has been deployed in countries with birth cohorts of several million children, and some countries in Asia have reported safety signals, with children dying shortly after the administration of the vaccine. Sri Lanka, India, Bhutan and Viet Nam have all reported and investigated serious adverse events following immunisation with this vaccine. Each case was investigated by the national programmes in collaboration with WHO, using the criteria on the assessment of causality developed by WHO. These criteria err on the side of abundant caution, in not saying that there is no association unless a clear alternative cause is found. It was determined that there was no causal association. The Global Advisory Committee on Vaccine Safety posted a report of the discussion on its website (16). Fortunately, countries have made a re-assessment and decided to continue with the pentavalent vaccine or re-introduced it into their national programmes.

The pentavalent vaccine will need continued monitoring, but there is currently no peer-reviewed scientific report based on analysis of a complete data set in a quality journal to support a causal association. Unfortunately, not everyone who has to make a decision regarding vaccines reads the scientific literature. The notorious case of Andrew Wakefield is worth mentioning in this context, and it must be noted that it was a flawed peer review process and the media, which thrives on demonisation, that allowed him to get away with a fraudulent research paper. In his paper, Wakefield claimed that the measles, mumps and rubella vaccine could cause autism. The claim and data were flawed and there was clearly no causal association. The findings were disproved over and over again, but the damage done to public health is reflected in an ongoing outbreak of measles in Wales (17). Measles is not usually life-threatening in Wales, but a similar scare regarding vaccines has the potential to endanger lives in a developing country. There were scares following the circulation of stories that the polio vaccine causes sterility, that the measles vaccine virus results in autism and that the thiomersal in vaccines causes cerebral palsy or autism. None of these notions has stood the test of a causality assessment (18–21), but that does not stop individuals and organisations from continuing to make unproven claims. Spreading this sort of panic can deprive children of the opportunity for vaccination. The ill effects of this are bad enough in the developed countries, but in the case of countries where access to healthcare is already limited, they result in a further denial of equity.

In summary, vaccines are valuable for individuals and populations, and public health ethics requires that we ensure access to all the appropriate vaccines for all our children so that they are protected from disease. However, we also have an ethical responsibility to see to it that the use of a vaccine is monitored through a system that carefully assesses safety signals after the vaccine has been licensed and introduced. The importance of an AEFI surveillance system to promote safety, appropriately assess risk and prevent misinformation cannot be over-emphasised. Finally, we have an ethical responsibility to employ the best scientific tools available to evaluate and use whatever evidence has been collected carefully (and not use selected information and cherry-picked data), to direct decision-making so that programmes do not, without clear and compelling evidence, withdraw vaccines. The withdrawal of vaccines without such evaluation would have consequences for people who have few other opportunities to prevent illness among their children.

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## The H1N1 influenza pandemic: need for solutions to ethical problems

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### Abstract

*The rapid spread of the novel influenza virus of H1N1 swine origin led to widespread fear, panic and unrest among the public and healthcare personnel. The pandemic not only tested the world's health preparedness, but also brought up new ethical issues which need to be addressed as soon as possible. This article highlights these issues and suggests ethical answers to the same. The main areas that require attention are the distribution of scarce resources, prioritisation of antiviral drugs and vaccines, obligations of healthcare workers, and adequate dissemination and proper communication of information related to the pandemic. It is of great importance to plan in advance how to confront these issues in an ethical manner. This is possible only if a comprehensive contingency plan is prepared with the involvement of and in consultation with all the stakeholders concerned.*

### Introduction

A novel influenza virus of swine origin, A H1N1, emerged in Mexico in 2009 and spread rapidly, in a matter of weeks, across multiple countries in the four major continents. The high mortality among young Mexicans, coupled with the rapid spread of the virus worldwide, revived memories of the devastating severe acute respiratory syndrome (SARS)

epidemic of 2003. Sensing the initial panic and in view of the case fatality associated with the virus, many countries rushed to control the epidemic. Some of the most drastic steps were taken by China and Hong Kong. The former quarantined Canadian and Mexican nationals, while the latter sealed off an entire hotel when the first case of H1N1 influenza (a Mexican guest) was detected. All other guests and the staff were placed in quarantine [<http://news.bbc.co.uk/2/hi/asia-pacific/8032157.stm>]. Soon, the World Health Organization (WHO) raised the pandemic alert level to five and declared an orange alert. All healthcare workers were required to wear N95 masks at work and have their temperature monitored twice daily. Each patient could have only one visitor a day, and checkpoints were set up at all hospital entrances. The movement of patients and healthcare workers between hospitals was restricted, and rotations of junior doctors suspended. Medical conferences were cancelled, leave for healthcare workers was curtailed, and elective surgical procedures were postponed. Restrictions were placed on overseas travel by hospital employees, and quarantine or viral screening was made mandatory on their return from countries that had reported local transmission. Additionally, travellers who had returned from Mexico were quarantined for seven days. Schools were required to begin monitoring the temperature of all students. Public health



messages were disseminated on social distancing, hand hygiene, and social responsibility.

The widespread panic among the public and growing healthcare burden raised several ethical problems, which needed to be addressed ethically. Since influenza pandemics occur in several waves lasting a year or two, thus requiring the response efforts to be sustained for a prolonged period of time, it is necessary not only to address the ethical issues which may arise during the planning, preparedness or response phase, but also to understand that these problems need to be addressed within an ethical framework.

### **Are ethical issues a priority during pandemics?**

It is rightly said that a good and fair decision is one which is based not only on sound scientific reasoning, but also on the moral values and principles of society. If we fail to incorporate ethical guidelines into our planning process or respond purely scientifically to every issue, we may land up being unfair and appear untrustworthy to the public. This has already been witnessed during the SARS epidemic in Toronto (1), where the healthcare organisations learned that the costs of failing to address ethical concerns were severe. These costs included lowering of the morale of hospital staff, confusion about roles and responsibilities, stigmatisation of vulnerable communities and misinformation.

### **Role of ethics in planning for pandemic influenza**

The incorporation of ethics into plans to counter pandemics can be described as "the application of value judgments to science" (2). According to Thompson et al (3):

*While the ethics might have little to contribute to understanding the mechanism of influenza virus transmission, it can make a significant contribution to debates such as what levels of harm the public are prepared to accept, how the burdens of negative outcomes should be distributed across the population and whether or not more resources should be invested in stockpiling antiviral medications.*

Thompson et al (3) and Torda (4) proposed an ethical framework to guide sound decision-making and fair handling of ethical issues. They developed the framework after an extensive review of the literature available on clinical and public health ethics, following which they vetted it together with the stakeholders concerned. The two important components of their framework were (i) ethical decision-making processes, and (ii) ethical values.

According to the authors, the ethical process should encompass the principles of openness and transparency with regard to the decisions taken. Further, it should be scientifically and morally reasonable and rational, include inputs from the stakeholders, be accountable during the time of crisis, and be responsive to critical review and revisions. The important ethical values to be considered are the duty to provide care, the principle of equity, privacy, proportionality, solidarity, and mutual trust.

Table 1 presents the main ethical issues related to influenza pandemics, along with the authors' ethical, rational and scientific prescriptions on how these issues should be addressed. The scientific view of the importance of each of these ethical issues is reviewed in the subsequent paragraphs.

### **Ethical issues pertaining to pandemic influenza**

The following ethical issues pertaining to pandemic influenza need critical analysis and consideration.

- The development of a comprehensive contingency plan/policy, involving the stakeholders and public
- Schemes prioritising vaccination, antiviral therapy and personal protective devices
- Rationing of scarce resources for intensive care and acute care
- The obligation of healthcare workers to serve under stressful and risky conditions
- Adequate dissemination and communication of information

#### *1. The contingency plan*

The most important step towards planning or preparing to meet an impending epidemic is the framing of a "contingency plan" by the healthcare organisation. An important component of a contingency plan consists of the objectives to be achieved in the eventuality of a potential pandemic or before a pandemic emerges. This should be followed by a step-wise, escalating response as the pandemic evolves. It has been noted that though most organisations are able to design a contingency plan to face an epidemic, their plans fail to meet the institutional or public needs. This is because most of the ethical issues concerning the population likely to be affected are either not foreseen or defined clearly, or the decision-making process is marked by the absence of healthy public engagement and discussion. In his critical analysis of the contingency plans of three nations (the UK, the USA and Canada) on how to face pandemics, Kotalik (5) found similar shortcomings. The plans lacked proper and clear guidelines on how to address ethical issues pertaining to the pandemic. Most plans fail to work in an emergency situation as they are highly scientific and are not backed by moral values.

The WHO and UK pandemic contingency plans (6,7) stress that the primary objectives of an effective plan must be to save lives, reduce the health impact of a pandemic, and minimise the disruption of health and other essential services. Also essential for an effective contingency plan are a strong leadership, inter- and intra-organisational communication and coordination, as well as clear lines of accountability. Advance planning is also a must, not only to establish but also to rehearse contingency arrangements and to identify and address gaps in preparation.

#### *2. Schemes prioritising vaccination, antiviral therapy and personal protective devices*

Pharmaceutical interventions like vaccines and antiviral therapy are required to mitigate the impact of an influenza epidemic.



Until the new virus strain is isolated or characterised, stockpiling of vaccine is not possible. Once the production of the vaccine is under way, batches of the vaccine can become available only in a gradual fashion. A recent WHO report estimated that the global production capacity for current influenza vaccines is 350 million doses per year, which is clearly insufficient for supplying vaccines to all countries. ([http://www.who.int/csr/resources/publications/influenza/WHO\\_CDS\\_EPR\\_GIP\\_2006\\_1/en/index.html](http://www.who.int/csr/resources/publications/influenza/WHO_CDS_EPR_GIP_2006_1/en/index.html)). As only a limited quantity of vaccine may be available to the developing nations, either due to the cost factor or the limited resources available in these countries for mass production, the question arises as to who should get the vaccine during the pandemic. How are the large-scale logistics to be managed and from where are the human resources to be garnered to implement a mass vaccination programme? Also considering the costing of antiviral drugs, the question arises as to how much should be stockpiled or kept as a safety stock. It has been suggested that a stockpile to cater to around 25% of the target population must be maintained and that the contingency plans should clearly spell out details regarding its procurement and storage, in addition to specifying the budgetary constraints.

As per the guidelines issued by the US Centers for Disease Control and Prevention (CDC) on the 2004–05 pandemic (8), the administration of the vaccine should be prioritised in the following order:

1. Pregnant women
2. People who live with or have regular contact with infants below 6 months of age
3. Healthcare and emergency medical services personnel
4. Children and young adults between ages 6 months and 24 years
5. Those with existing health conditions which put them at increased risk of complication

It is important to weigh the disadvantages against advantages while considering a mass vaccination programme. This would include taking into account factors such as the implementation costs of such a programme and the benefits of non-pharmacological interventions, eg isolation, quarantine and personal hygiene. Antiviral drugs are the other mainstay of treatment during pandemics and their use should be prioritised, like that of vaccines, in the case of the development of early symptoms among various high-risk groups.

During an influenza pandemic, additional essential medical supplies, such as gloves, masks, syringes, antipyretics and antimicrobial agents, are required. There is a shortage of these supplies in healthcare facilities in the developing countries, even in non-emergency situations. This shortage can hamper the provision of adequate medical care to patients with pandemic influenza. In addition, it is necessary to have basic personal protective equipment, such as disposable gloves and surgical masks, for healthcare workers. An estimate of the quantity of essential supplies needed, the estimated costs of procurement, a list of local distributors/suppliers, and the

mechanism for early procurement of the supplies should be detailed in the contingency plan. The decisions on the quantity to be purchased should be rationalised on the basis of the gap between the existing resources and the ideal requirement at the time of a pandemic; and consideration should also be given to the costs involved, ie the cost in terms of human suffering or loss of life. A certain quantity of the essential supplies should be purchased and kept as safety stock in the disaster cabinets, for use by healthcare workers during an emergency. The policy-makers should issue appropriate and fair guidelines on the meticulous and judicious use of personal protective equipment and other supplies. The guidelines should give due priority to essential healthcare workers, other workers who provide life-saving services, as well as critical services necessary for society to function as normally as possible. The emphasis must shift from the individual to the general population.

### *3. Rationing of scarce resources for intensive care and acute care*

Healthcare organisations face a disaster alert following the outbreak of a pandemic, if it is severe, as an extremely large number of sick people may require care at the same time. The vital question is: how to provide the best care to all. The principle of equity states that all patients have an equal claim to healthcare, not only under normal circumstances, but under all circumstances. If the chances of survival of one out of two severely sick patients are poor, which of them is to receive care in the ICU? What quantity of the limited but costly resources, such as ventilators, needs to be purchased? To what extent does the capacity of the hospital, in terms of beds, need to be augmented?

Oshitani et al (9) reported that with an incidence rate of 35%, up to 79.1% of hospital beds are required for patients with pandemic influenza in low-income countries. In countries like Bangladesh and Nepal, more than 100% of beds would be required for patients with pandemic influenza, even at an incidence rate of 15%.

To decide upon how to allocate scarce resources and provide equal access to healthcare facilities, the approaches advocated in the several allocation theories may be considered. These are the libertarian, utilitarian, egalitarian and communitarian approaches (10). The libertarian view is that allocation is best left to the marketplace, while according to the egalitarian approach, which is based on the principle of equity, everyone should receive the same treatment, the same amount of treatment and the same opportunity to access the benefits provided. The communitarian approach emphasises consensus among the members of the community on the goals and values they wish to achieve and uphold. The author, however, suggests the adoption of a utilitarian approach, which advocates a proper distribution of resources in order to achieve the best outcomes or greatest benefit for the greatest number of people. Patients coming to hospitals can be medically prioritised into those who will probably live only with treatment, those who will probably live without treatment and those who will probably die with treatment.

Decisions on the provision of rationalised care may also be made on the basis of the quality adjusted life years technique. An ethically reasonable approach would be to reject those patients who might survive, but who would spend a long time in the intensive care unit.

During the planning process, steps must be taken to allocate an amount of the budget that has been fixed in advance for the purchase of vital or life-saving equipment. The amount fixed should be based on the number of patients who are likely to require acute/critical care, the population the hospital caters to and the level of care the hospital is expected to provide. It is also necessary to mobilise the staff and ensure that vital equipment is available for use by rescheduling surgeries / procedures fixed earlier to a later date. Further, the situation must be assessed repeatedly, on a day-to-day basis. These measures should be clearly spelt out in the contingency plan. Most importantly, these decisions or policies should involve and draw upon inputs from the community health officials, healthcare workers and the public, and be put across in a clear, transparent, fair and systematic manner.

*4. The obligation of healthcare workers to serve under stressful and risky conditions*

Kotalik (5) rightly asserts that a successful response to an influenza pandemic depends greatly on the attitudes, skills and efforts of healthcare workers.

Dr Joanna Tse Yuenman, a 35-year-old physician specialising in respiratory diseases, was the first doctor working in a public hospital to die of SARS during the 2003 Hong Kong epidemic [[http://english.peopledaily.com.cn/200305/23/eng20030523\\_117091.shtml](http://english.peopledaily.com.cn/200305/23/eng20030523_117091.shtml)]. Her death generated a great outpouring of public emotion in Hong Kong. Two quotes (11) that express the sentiments regarding her sacrifice are, "As a doctor, her duty was to save lives," and, "...the dedication and professionalism of the front-line medical personnel went far beyond the simple duties of a job."

Healthcare workers are expected to work outside their normal scope of practice, put in extra hours, fill in for workers who are ill and be prepared to move where their services are most needed. What are the healthcare organisation's obligations towards them? Is it professionally right for healthcare workers to go home and leave their colleagues to cope? Should there be legal provisions to force the staff to work during a pandemic?

Healthcare organisations should ensure the safety of their workers and protect them. They should support their staff during a pandemic. The healthcare workers should be kept informed about the situation and what is expected of them. They should be encouraged to formulate their responses, which should then be discussed in an open forum. Priority-based prophylaxis/vaccination should be administered and safety measures, such as the provision of personal protective equipment, should be taken. This helps to reduce staff absenteeism and prevents healthcare workers from becoming vectors of the infection. Though the extent to which healthcare

**Table 1**  
**An overview of ethical problems and an ethical approach to these during influenza pandemics**

Problem	Suggested ethical approach
Lack of a comprehensive contingency plan/policy document	Frame a policy document in consultation with and with the involvement of all the stakeholders concerned. Incorporate both scientific and moral viewpoints. Keep the document open-ended, subject to a process of review. Make sure the document clearly spells out the roles and responsibilities of all concerned.
Issue of prioritisation of vaccine, antiviral drugs and personal protective devices	Assess your target population and identify the rough percentages of high-risk groups. Consider the limitation of resources and the time gap until the vaccine, drugs and protective devices can become available to the target population. Stockpile the necessary items for at least 25% of the target population at any given time. Formulate strict policy guidelines on the issue of vaccines/drugs and protective devices as per priority.
Extent of augmentation of resources needed to provide best and optimal care to all	Adopt a utilitarian approach of saving the maximum number of lives. Allocate separate assessment and triage areas within healthcare facilities/hospitals. Prioritise patients to be admitted to the ICU or acute care on the basis of their age, symptoms, underlying illness or chances of survival. Never prioritise them on the basis of race, gender, religion or citizenship Lay down guidelines on an increase in the bed strength, availability of laboratory services and number of ventilators on the basis of the hospital's resources, the target population it caters to and the expected number of cases likely to be encountered.
Obligation of healthcare workers to serve under stressful and risky conditions	Provide priority-based protection to healthcare workers. Provide the healthcare workers with an assurance that they will receive incentives in the form of extra remuneration for additional hours of duty and special off days after the pandemic is over. State clearly the organisation's policy that healthcare workers are bound to discharge their moral duty unless there is a compelling reason not to.
Inadequate dissemination and communication of information	Clearly spell out and define the line of command for all communications. Make the public aware of the emergency numbers and the nodal officers they can contact. Conduct health education campaigns on influenza for the general public. The situation should be reassessed through time-bound meetings and periodic reviews of the contingency plans/decisions

workers are obliged to risk their lives to deliver clinical care is difficult to quantify, ethically, it must be made clear to them that they should discharge their duty unless it conflicts with one or more of their other moral duties, i.e. if they do not have a stronger, more compelling reason to absent themselves from duty, then they have an obligation to risk their lives and come to work.

*5. Adequate dissemination and communication of information*

The plan for dealing with an influenza pandemic should be communicated to the government authorities at various levels and to the related institutions. Attempts should be made to disseminate the provisions of the plan in a systematic manner.

Who defines and controls the protocol for communicating information on the pandemic?

How is the information disseminated? What measures are being taken to inform the population likely to be affected? Are any mechanisms in place for the redressal of complaints or grievances, and how are decisions on such matters taken and communicated?

The plan of the healthcare organisation should clearly specify the line of authority and define a single command which would serve as the channel for the communication of all information. This may entail identifying and appointing designated nodal officers for pandemic control and surveillance.

There should be mechanisms to ensure the proper collection and compilation of the necessary guidelines, as well as the systematic issuance of the guidelines to all the stakeholders concerned. No miscommunication, duplication or delay should be allowed in the percolation of the important information. Efforts should be made to promptly involve and notify the sections of the public likely to be affected by the pandemic. In this context, utilising the services of a dedicated team of the community health officials of the organisation or help from NGOs would be useful, as would be targeted public health education and awareness campaigns. Such campaigns would minimise the spread of panic, while the public's involvement and support would help in addressing many ethical issues in a more fair and transparent manner. A mechanism to ensure accountability must be put in place so that the process of decision-making is ethical throughout the crisis. Further, scope should be given for the elaboration and refinement of the contingency plans on the basis of inputs from the stakeholders, government guidelines, public complaints and suggestions.

## Conclusion

Influenza pandemics pose an ever-growing threat and in the near future, the morbidity and mortality associated with them

might greatly increase among all age groups. Our healthcare system needs to gear up for this challenge and plan strategic measures well in advance. Several ethical issues of a complex nature may crop up and hamper healthcare efforts or undermine public trust, but if we adopt an ethical framework for decision-making in our plans, our efforts to control the pandemic may well make a considerable impact. The aim of this article has been to highlight the importance of an ethical process while planning for the eventuality of a pandemic, and to outline and find ways of addressing the various ethical problems which may come up during the preparedness or response phase of an influenza pandemic.

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# Medical regulation in India: an outsider's perspective

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## Abstract

*This personal comment briefly describes the working of the General Medical Council, the medical regulator in the United Kingdom (UK), with the aim of informing the discussion on how to regulate medical education and doctors' practice in India. Given that the ministry of health and family welfare is still debating the final constitution of the Medical Council of India, this paper is timely.*

## Introduction

The issue of the regulation of medical education and doctors'

practice continues to attract attention in India due to the ongoing uncertainty about the future of the Medical Council of India (MCI), the media attention sparked by programmes such as "Satyamev Jayate" and the subsequent reaction of the Indian Medical Association (1). Since 2010, various boards of governors (BOGs) have been established for short terms, and the ministry of health and family welfare established yet another one with effect from May 2013, with a term of six months (<http://mciindia.org/>). The lack of a properly constituted BOG and the continuing uncertainty are not helping to take forward the

much-needed programme of reform or to build confidence in the minds of both doctors and the public. The training and professional standards of doctors are increasingly coming under scrutiny. The public wants to know when and how doctors will be regulated, and how patients can be assured that their doctors are trained properly and practising ethically. Patients want to be treated with respect and dignity, and not be overcharged or treated unnecessarily. While there is no denying the fact that the current discourse is doing a disservice to doctors who have high professional standards and practise in accord with the Hippocratic Oath, the absence of an objective, independent and validated mechanism for assessing medical education, training and practice means that it is impossible to defend them and to reassure the public. This lends urgency to the need to address the gap in medical regulation in India.

This paper is based on my recent experience as a member of the board of the UK's medical regulator, the General Medical Council (GMC). It is a personal account and builds on my previous paper, which commented on developments in India (2) as well as on attempts to promote collaboration between the MCI and GMC over the past few years. The paper starts with a description of the work of the GMC, and goes on to assess its successes and the challenges it faces, in the hope that such an analysis may be of use to my colleagues who are involved in medical regulation in India.

### **The General Medical Council**

In the UK, the fifteenth century saw the beginnings of an interest in medical regulation with the Royal College of Physicians finally starting the licensing of doctors in 1511. Driven by the need to separate qualified from unqualified practitioners to prevent "great harm and slaughter of many men." the discussions continued, until finally, the General Council of Medical Education and Registration of the United Kingdom (since shortened to the GMC) was established in 1858 through a Medical Act (3). Much work has been done since then and The Medical Act, 1983 provides the current statutory basis for the GMC's four main functions, which are to:

- keep the register of qualified doctors up to date,
- foster good medical practice,
- promote high standards of medical education and training, and
- deal firmly and fairly with doctors whose fitness to practise is in doubt.

The overall purpose of the GMC is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine. It reports directly to Parliament and is funded by the annual retention fees paid by all registered doctors and examination fees. It is a registered charity. It should be noted that the GMC is a regulator for the whole of the UK and that given the differences between England, Scotland, Wales and Northern Ireland in terms of how the National Health Service (NHS) and health services are organised and delivered, the GMC has to find the right balance

between UK-wide and country-specific areas of work.

The following is neither a historical, nor a detailed account and I strongly recommend that readers visit the GMC website ([www.gmc-uk.org](http://www.gmc-uk.org)) to learn more. Rather, the paper focuses on some key and recent developments to inform readers about the background and help them understand the implications for the Indian situation. Each of the developments discussed merits detailed papers in its own right.

Often, the most visible element of the work done by the GMC relates to the doctor's fitness to practise. Over the last two decades, there have been changes in how this function is discharged, and four main developments are worth highlighting. One, the procedures earlier considered the concerns arising out of doctors' fitness related to health, conduct and performance separately, but now a more holistic approach has been adopted since these three dimensions sometimes overlap. At the same time, there is recognition of the aspects of sensitivities and confidentiality, especially in the sphere of health concerns. Two, given the tensions caused by the GMC's dual role as prosecutor and judge, attempts were made to compartmentalise these functions. This finally led to the establishment of a separate organisation, the Medical Practitioners Tribunal Service (MPTS), in 2011, to adjudicate the cases brought to it by the GMC. It should also be noted that patients can still pursue their complaints in the courts, and that the MPTS's final decisions can, and do, get challenged. Thus, there are safeguards in the system. Three, recognising that the GMC is part of a whole system which looks into issues related to doctors' fitness to practise (the other main bodies being the employers of established doctors and the deaneries for trainees), the GMC established the position of liaison advisors. These people were posted in discrete geographical areas and entrusted with the job of engaging all relevant stakeholders in dealing with problems promptly and speedily. Four, although purists would argue that revalidation (the GMC is the first regulatory body in the world to require all doctors to demonstrate that they are fit to practise and hence can hold the licence, every five years) is not about fitness to practise, which is invoked when things have gone wrong; the very fact of introducing revalidation means that there is now a much more proactive, rather than reactive, way of dealing with concerns regarding a doctor's practice.

The last point links up with another major area of work, ie maintaining an updated register of doctors. Over the years, the register has been repeatedly refined, both in terms of its content as well as online access to it, to make it more meaningful to employers, the public, policy-makers and the doctors themselves. Anyone can look up the register to find out whether his/her doctors are qualified or whether there are any matters of concern regarding them (although details regarding the latter are not available in the public domain). The register is proving to be a valuable resource for the purpose of manpower planning also. Like most other areas of work, it remains under regular review so that its utility and utilisation for various purposes can be improved.



Education is obviously a very important function of the regulator. The GMC has ultimate oversight of all education, from the Professional and Linguistic Assessment Board (PLAB) test for “foreign” doctors, to under- and postgraduate medical education, to continuing professional development for trained doctors. The GMC works closely with the Royal Colleges and Faculties, which provide the specialist input, and the medical schools and deaneries, which deliver or arrange for under- and postgraduate education. There are both proactive reviews and assessments of all stages of medical education, as well as reactive assessments based on reports of concerns identified either through surveys of training, for example, or by other regulators, colleges, employers and doctors. For example, the PLAB test is undergoing a review currently and there are plans to develop “credentialing,” which is the “formal accreditation of capabilities at defined points within the medical career pathway that takes into account knowledge, capabilities, behaviour, attitudes and experience.”

Of course, as a regulator, the GMC is involved in influencing health policy and developing guidance on medical practice. The most recent example of the GMC’s influence on policy was its initiative to introduce English language testing for doctors from the European Union (EU) (the GMC is also bound by the EU rules). This step was taken in the wake of a tragic case (4), apart from other concerns. Of course, the GMC periodically reviews the Good Medical Practice (the “Bible” for doctors) to take stock of changes in health policy and the delivery of healthcare. It also provides guidance on major issues affecting doctors, such as around the care of patients at the end of life, or for doctors involved in management.

The GMC’s work involves a great deal more, but for the purposes of this paper, I will mention just another area, which is the nature of its board (surprisingly called the council). The board has undergone major changes in recent years. The main changes are the reduction in the number of members from 104 to 35 to 24 to 12 starting in 2013; the equal numbers of lay and medical members now; the “appointment” of all members by an external body and not by “election” by medical members; and the appointment of the chairman by the external body rather than by election from among the appointed members. The latter is the most recent change. These appointments are for fixed terms.

### **A critique of the work of the GMC**

The GMC is a much envied and valued regulatory body, both within the UK and abroad, and its perseverance in the matter of introducing revalidation has catapulted the organisation into the spotlight internationally.

As with many other aspects of regulation, the GMC has also been through major changes over recent years. Clinical quality, patient safety and regulation are relatively new concepts in the grand scheme of things, at least as far as explicit and formal approaches to such issues are concerned, and the GMC has had to change radically to fulfil its mission and generally keep up with the needs and demands of the whole host

of stakeholders, including the government, the public and healthcare professionals. A few years ago, when the case of Dr Harold Shipman (the general physician who murdered over 200 patients) came up, there were serious concerns about the survival of the GMC. The confidence of the government, media and public had been shaken, and the GMC became a target for the “anger” engendered by the case. The failure of the GMC led to calls for its dissolution. This, in turn, acted as a stimulus for the GMC to become much more proactive and responsive. The introduction of revalidation and the move to introduce parity in the number of lay and medical members in the council are just two examples of the changes thus introduced.

In critiquing the work of the GMC, it would be worthwhile to focus on two dimensions: the work it does on its own and the work it does in its capacity as a part of an overarching healthcare system. The GMC has a specific remit in the sphere of doctors’ education, training and practice, but increasingly, doctors are not working in isolation from other professions and, in any case, all professionals are part of the wider healthcare system.

Judging the GMC’s effectiveness is, therefore, not an easy task. One has to decide on whose perspective one is viewing the matter from and which function one is judging. At the risk of oversimplification, one could say that there are two types of “independent” regulators in the NHS apart from the policy-makers and funders/commissioners who also look at how well (or poorly) the services perform. These are the professional regulators and the system regulators. There are nine professional regulators, including the GMC; the others being the General Chiropractic Council, the General Dental Council, the General Optical Council, the General Osteopathic Council, the Health Professions Council, the Nursing and Midwifery Council (NMC), the Pharmaceutical Society of Northern Ireland and the General Pharmaceutical Council. These are overseen by the Commission for Healthcare Regulatory Excellence (CHRE, now renamed the Professionals Standards Authority for Health and Social Care). The system regulators, which oversee the performance of healthcare organisations in terms of clinical quality and financial performance, include the Care Quality Commission and the Monitor in England. It is to be noted that systems regulation is very country-specific, and there are different arrangements in Scotland, Wales and Northern Ireland, whereas most professional regulators are UK-wide.

It would be no exaggeration to say that among the professional regulators, the GMC is seen as the leader in terms of the manner in which it works and constantly adapts to the changing landscape of healthcare. Moreover, it has provided leadership in professional regulation, something which the CHRE reports attest to (5). As for my assessment of the GMC’s work, some of its very valuable functions, which it has fulfilled in an exemplary manner, are maintaining the register, setting standards for medical practice through the Good Medical Practice and providing policy guidance on important issues.

More work is needed in the areas of doctors’ fitness to practise and of education. There has been a yearly increase in the

number of cases of “poorly performing doctors” being referred to the GMC and this is neither sustainable nor desirable. There is a need to examine how this whole issue is managed from the local level up to the national level. It could be argued that due to the easy access to the GMC, cases of “relatively minor” severity also end up before this body. Of course, all cases should be dealt with proportionately and speedily to maintain the public’s confidence, but this would be better achieved if there were a seamless system of medical regulation from the local to the national levels. The introduction of the liaison advisors may prove to be useful over time, but there is a long way to go yet. In addition, there are continuing concerns about the inconsistencies in the sanctions awarded in cases of poor performance. These are most notable when it comes to the treatment of cases involving international medical graduates (IMG) who tend to receive harsher sanctions. The GMC could also be criticised for not being tough enough on figures in the establishment. This includes failing to take proactive action against medical directors or other senior doctors whose management performance has been found wanting. It is too early to comment on the possible (hopefully positive) effect of revalidation on the issue of poor performance of doctors. Finally, this may sound strange but there is also the issue of whether the bar is too high, ie whether the standards expected of doctors are unrealistic. The “zero-tolerance” mentality that has pervaded the NHS does not help anyone. Maybe there is a need for a discussion of what constitutes poor practice, but this is a thorny issue and it is hard to see how to promote the necessary debate, which is, after all, a societal issue.

Challenges will also be faced in the sphere of education – both under- and postgraduate – for various reasons. These include the changing health systems in general and the recent reorganisation of the NHS in England; the difficulties being faced in planning of the workforce; and the rapid changes in medical practice. Education/training is not keeping pace with the breathtaking speed at which medical and technological advances are being made. New challenges await the UK, with the possibility of the establishment of private medical schools, the established UK schools opening campuses overseas, and the royal colleges starting to offer their diploma examinations internationally. The GMC has not always been seen as being tough on medical schools. For example, until recently, there was hardly any example of a medical school being handed down serious sanctions, or of the GMC being able to comprehensively and systematically ascertain the fairness and quality of postgraduate qualifying examinations. Concerns have also been voiced over the possibility that colleges view postgraduate examinations as a source of income, with doctors in training having to pay high fees. There is no mechanism yet to try to determine the appropriate fees, an amount which would not place too much of a financial burden on doctors.

In my view, the problems facing the GMC are not necessarily related to how it goes about its own work, although there is scope for further improvement. The problems also arise from a lack of coordination between the professional and systems regulators. The recent publication of the enquiry into the care of patients at Mid Staffordshire Hospital shows how this

lack of coordination is compromising the safety of patients (6). All the parties concerned – the GMC, NMC and systems regulators – were partially aware of the problem, but failed to come together in a timely fashion to tackle the situation. It will be interesting to see what happens in the next few years. My assessment is that a fundamental rethink on regulation is required in the NHS, which has swung from a “light” touch favouring self-regulation to a “heavy” touch leaning towards external regulation over the last two decades. A new model is necessary to keep patients safe; to ensure that doctors continue to be committed and do not retreat into defensive medicine or shy away from “challenging specialities”; and to see to it that healthcare remains affordable.

Generally speaking, the GMC must be credited with having played its part well so far, but it needs to find a balance between protecting patients and supporting doctors. It has yet to get the “right” touch – neither light, nor heavy – as far as regulation is concerned. Further, it needs to be seen as one part of the entire regulatory system, and not as the provider of solutions to all the problems facing the healthcare system.

### Lessons for medical regulation in India

So what does the above mean for India? I do not know enough about what is happening with the MCI and in the sphere of medical regulation to be able to make detailed comments. However, I would like to offer the following in the spirit of sharing and helping. The reader may also wish to go through a report commissioned by the GMC that examined medical regulation in the 10 countries from which doctors come to the UK to work (7).

The most important lesson is that things do take time – the GMC did not achieve success overnight. It is over 150 years old and has had rough times during its journey. Also, the GMC sits within a national health system which is part of British society, and reflects the values and aspirations of that society including the medical profession. At the risk of being controversial and judgmental, the medical profession in India is neither ready, nor organised enough, to either provide leadership or be seen as sufficiently trustworthy to provide leadership yet. The debacle following the “*Satyamev Jayate*” programme, with the Indian Medical Association asking the actor, Aamir Khan, for an apology, shows how far behind the times the organised profession is. The reason I emphasise the organised profession is that I am well aware of the existence of many good doctors who are equally concerned about the issue as Aamir Khan and others. The article by the Medico Friends Circle is just one example (8). This lack of leadership by the organised profession is not helped by the apathy and inability of the policy-makers to take control and mandate a properly constituted and resourced medical regulator.

So, the most urgent task facing the country is the establishment of such a body. It is not necessary, or possible, to get everything right from the beginning, but it is absolutely essential to get some principles and values right. The new body should be independent, with properly appointed (not elected) members, including lay members. It should start with a modest yet

achievable programme of work. No one with a criminal record or who is not in good standing should be appointed. Independent evaluation and external scrutiny should be carried out by an internationally selected group, the members of which can act as critical friends.

With regard to the programme of work, I have four suggestions, as follows.

1. An up-to-date and ongoing system of registration of doctors should be established so that people can check the status of their doctors. Unqualified doctors should be separated from qualified ones, so as to create the right conditions for cleaning up the system. It would be useful to follow the GMC's model of charging an annual retention fee from all doctors (although I do believe that the GMC should moderate its costs).
2. A federal system should be established to deal with the issue of doctors' fitness to practise, with the states having operational responsibilities within a national framework. Given the rampant corruption in India, all efforts should be made to involve "clean" and well-trained people in such a system.
3. An equivalent of the Good Medical Practice should be developed to provide the national framework. A programme of ongoing national policy guidance on issues of importance to the medical profession can be based on this.
4. There is a need for a review of the current arrangements for monitoring medical colleges, given the scandals related to high fees, the absence of or limited faculty, and almost bogus degrees. The much-needed and planned expansion of medical colleges is a recipe for disaster, unless we sort out the current problems.

I am aware that these suggestions are not new, that there is no shortage of policies, and that the usual problem of implementation – a problem which has perennially plagued India – is what is holding things back. I could also be accused of ignoring other issues such as review of the medical curriculum or post-graduate education and training. However, there is a trade-off between trying to get a few things right, which might help one gain experience and confidence, and trying to do everything. I personally do not believe that India is ready for a comprehensive system of medical regulation yet and the suggestions made above should be seen as the first steps in a long journey.

In conclusion, being an Indian doctor in the twenty-first century is both a responsibility and a privilege. With almost one in six persons in the world being an Indian and the vast scale of health inequalities in India, Indian doctors have a huge responsibility. Equally, with almost 1.2 million doctors of Indian origin working worldwide and given the interconnectedness in the global village, it is a privilege to be able to share and work with like-minded colleagues (of whom there are many), and to try to make a difference in India and globally. The current situation in India is a lose-lose proposition; both doctors and the public are losing out. The bad doctors and vested interests are getting in the way of the good doctors who wish to reform the system to ensure

affordable and quality care to the public. Putting our house in order, therefore, is a pressing issue and we urgently need to establish an effective system of medical regulation.

### Note

*This paper was commissioned following the publication of my reflections on working as a GMC council member (9). Among other things, I was a member of the UK Revalidation Board. The British Association of Physicians of Indian Origin had invited Dr Ketan Desai to visit the GMC in 2009 and subsequently, I took part in hosting the (then) MCI's visit to the GMC in 2010. I am often asked how I can be so positive about the GMC, given its track record in dealing with international medical graduates (10) and my answer is that just because it has failed in that regard (although attempts are being made to address racial discrimination), we should not dismiss its successes in many other areas. In any case, I also cannot see how the stark inequalities arising from the factors of caste, religion and financial status in India are any different, not that I condone either. It is important to try to change the system, but not destroy it. The views expressed here are personal. Any shortcomings are my own. Further details of my work are available at [www.leadershipforhealth.com](http://www.leadershipforhealth.com).*

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# Clinical trials in Sri Lanka: new Act at the behest of the pharmaceutical industry?

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Clinical trials are defined as studies involving human participants, with the intervention being selected by the investigator (1). The intervention can be related to a new drug or device, or a new indication for an already approved drug or device. The intervention can also relate to different healthcare options, eg the trial may be aimed at comparing the management of a particular illness in the hospital to its management in the community.

The state regulatory body for drugs in Sri Lanka is the Cosmetics Drugs and Devices Regulatory Authority (CDDRA). The CDDRA's permission is required for the registration and import of new drugs. In January 2009, the ministry of health appointed a subcommittee on clinical trials (SCOCT) under the CDDRA. The SCOCT's regulatory approval is necessary for clinical trials. The SCOCT requires ethical approval by a recognised ethics review committee (ERC). Further, according to the regulations, registration in the primary World Health Organization clinical trial registry network is mandatory. The clinical trial registry, which is in the premises of the Sri Lanka Medical Association, is the only such registry in the country.

Recently, bureaucrats in the health and the finance ministries, as well as a few academics, have been pushing for a new Act on clinical trials (2). This paper highlights the various loopholes in this draft Act and describes how it may give the pharmaceutical companies opportunities to circumvent its provisions and exploit patients. The clinical trial industry has been perceived by these Faustian treasury economists as a magnet for foreign currency. The draft Act reflects an insouciant attitude to the patient's welfare and the free health system, which is unique to Sri Lanka. There were no consultations with the public or the stakeholders when this Act was drafted, and its provisions have still not been made known to academics, ERCs and the public.

The supposed aim of the Act is to regulate clinical trials in Sri Lanka, since the country lacks a legal framework to regularise clinical research. It is expected to cover the legal loopholes that arise during all phases of the conduct of clinical trials in drugs and devices. As in the USA, this Act will protect contract research organisations (CROs) and clinicians from law suits in case of an injury to a participant (3). Injuries such as multi-organ failure when injected with a biological agent (anti-CD28 antibody) in a highly publicised phase one randomised clinical trial (RCT) make it imperative to discuss mechanisms of compensating and treating research injury (4). Although the draft Act claims to follow the International Conference on Harmonisation Good Clinical Practice (ICH-GCP) guidelines, there is ample evidence to show that even the ICH-GCP was

formulated to safeguard the pharmaceutical industry (5).

The authors managed to get a copy of this draft Act forwarded by the attorney general's department to the secretary of the ministry of health. A copy was also sent to the attorney general for the issuance of a certificate of constitutionality. This is a common practice to verify whether an act is in harmony with the law of the land or constitution. The draft Act has a Preamble and 38 Articles. Its main objective is to establish the regulatory framework for randomised controlled trials (RCTs) and to facilitate the process of obtaining the licence and approvals required to conduct them. The other objectives are to ensure the implementation of the WHO's good clinical practice (GCP) guidelines, register all RCTs, support and protect study participants, provide accreditation and register CROs. Articles 3–6 relate to the policy and regulatory framework, while Articles 7–9 deal with ERCs. Articles 10–20 pertain to the licence for conducting clinical trials. Article 21 deals with the conduct of clinical trials and the payment of compensation. Informed consent is described in detail in Article 22. Articles 23, 25 and 26 discuss the responsibilities of the licence-holder and Article 27 is about adverse events. Article 24 discusses the conduct of clinical trials in emergency situations. Article 28 relates to amendments to the protocol, and Articles 29, 31 and 32 give details of responsibilities of sponsors and investigators. Article 33 describes offences and sets forth the pecuniary penalties, specifying the minimum and maximum limits. Article 34 describes the powers of the health minister, while Article 35 mentions regulations that should be included in the gazette. Articles 36, 37, and 38 deal with procedural aspects of the Act.

After the new Act is passed, the national policy on clinical trials will be drafted and reviewed every three years. The Act will be enforced mainly by the Clinical Trials Regulatory Division (CTRD), a new entity to be established under the CDDRA in the ministry of health (Article 4). The CDDRA has a history of scandals (6), the most recent one being related to an irregularity in a tender for surgical gloves (7). There is a belief that the CDDRA is under the influence of or being pressurised by Big Pharma (<http://lankacnews.com/sinhala/main-news/45178/>). Thus, it is likely that the CTRD will also be influenced by the pharmaceutical companies.

Paragraph 7 of Article 4 of the draft Act specifies that the CTRD will receive independent funding. However, there is no explanation regarding who will authorise payment from that fund and who or what organisations can give donations and grants to the fund. There is not a single sentence about the management of the fund. This gives an opportunity to various



foundations that represent the corporate social responsibility face of Big Pharma to manipulate the CTRD.

The draft Act requires the establishment of a regulatory review committee (RRC), which will include three pharmacologists and three clinicians, among others. The chairman of the RRC, who will be elected during the first meeting, need not be from the ministry of health or CTRD (Article 5, paragraph 3). If an influential clinician is elected as chairman, he/she will be able to manipulate the proceedings because of the enormous power that clinicians wield in developing countries such as Sri Lanka. Also, four clinicians have been co-opted as non-voting members to advise the committee. All of them are required to declare any conflicts of interest on a case-by-case basis (Article 5, paragraph 6). This may lead to further abuse as clinicians who have earlier been subtly involved with pharmaceutical companies can influence decisions. Sri Lanka has no law regulating the physician-industry relationship and no law on the transparency of such interactions. In a recent newspaper article, it was alleged that a medical consultant is paid as much as Rs 150,000 for recruiting a patient for a clinical trial.

The same medical consultants do their "rounds" in ethics committees, clinical trials registries and hospitals conducting RCTs, and are sometimes handsomely paid according to the number of patients they recruit for RCTs. Their collusion enables the conduct of RCTs at cheaper cost, in less demanding legal settings, and with less resistance from a less informed public (8).

A 12-member panel of experts has been appointed on the recommendation of the CDDRA to review applications for clinical trials (Article 6). If necessary, an expert may be consulted for his opinion (Article 6, paragraph 2). The expert has to give his feedback within 14 days of the receipt of the application. In the case of major disagreements, another expert has to review the application. The provisions are unsatisfactory, considering the review standards maintained by journals, funding agencies and ERCs, which deem that a minimum of two experts is mandatory. Also, the 14-day time limit is too short.

Article 7 of the draft Act discusses the accreditation of the ERCs. However, there is no mechanism for appeal if accreditation is denied. Currently, the ERCs of the major universities and professional organisations have a central body – the Forum of Ethics Review Committees, Sri Lanka (FERCSL) – which is under the patronage of the Sri Lanka Medical Association. Two ERCs in the FERCSL have received recognition from the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) through the Forum for Ethics Review Committees in Asia Pacific (FERCAP). Although the draft Act discusses the accreditation of ERCs and their standards, such as those related to ongoing monitoring of clinical trials, it does not mention the issue of increasing the capacity of the ERCs. ERCs do not have separate funding, secretarial or support staff, office equipment or stationery. They depend on the goodwill of the heads of the academic departments of universities to carry out their work. They are unable to monitor approved research due to lack of resources. Article 8 discusses the responsibilities of the

ERCs, including site visits, if necessary (Article 8, paragraph 4). Presently, no site visits are being undertaken by ERCs in Sri Lanka due to lack of funding. Also, the Act devolves the responsibility of safeguarding the rights and ensuring the safety and well-being of trial subjects on investigators. In Article 21, the onus of dealing with research-related injury is placed on the investigator and the institution conducting the trial. The Article specifically requests the investigator to enter into an agreement with the sponsor of the trial about insurance and indemnity. Instances when compensation should not be paid are specified here. For example, the clause relating to the natural progression of the disease provides the sponsors of trials with an escape mechanism, helping them to avoid paying compensation (Article 21, paragraph 11). The draft Act proposes the establishment of an arbitration committee under the CDDRA to resolve disputes between the sponsor and the investigator about the compensation for trial-related injury.

The draft Act has other serious drawbacks as well. All the drug trials are not covered by it or by the CTRD. Non-commercial drug trials conducted by academic or healthcare institutions, collaborative groups and individuals, and cooperative establishments are not under its purview. This would make it possible for pharmaceutical companies to use proxy organisations to conduct research. Investigator initiated clinical trials, academic multicentre trials investigating non-drug therapies, exploration of drug therapies for neglected tropical diseases, and investigation of already established complementary and alternative medicines need to be encouraged. Increased paperwork and a complex procedure of regulatory review, together with additional administrative hurdles, are likely to further discourage local academic researchers (9). The wealthier foreign trial sponsors have the capacity and resources to produce the necessary paperwork that can clear the bureaucratic hurdles.

Another drawback is that pharmaceutical companies can apply to the CTRD and ERC simultaneously. If this draft Act is serious about protecting patients' rights, approval from the ERC should be a prerequisite for applying to the CTRD. The applicant can influence the ERC on the strength of the fact that he has obtained approval from the CTRD.

The draft Act is full of clauses and exclusions that can be used by multinational pharmaceuticals companies which have abundant resources, including their teams of lawyers, ethicists and researchers, to circumvent the Act's provisions and exploit patients. As in the case of India, "mere guidelines will not suffice" and the need for stronger legal oversight cannot be overemphasised (1). The fact that the provisions of the draft Act have not been made known to everyone, lobbying by the economists who are regulating the monetary policy in Sri Lanka and the lack of transparency, which is reflected in the absence of debate and discussion in open forums, have caused concern. The draft should be available in the public domain and a mechanism of transparency should be put in place to solicit the views of all stakeholders, encourage debate and aid the process of reaching a consensus. A sufficient amount of

time should be devoted to the implementation of these steps as there is no urgent need to rush the legislation. Meanwhile, the ERCs can be strengthened by injecting more resources into them and enhancing the capacity of their members. The FERCSL should be encouraged to expand its role of providing guidance and increase its efforts in the sphere of capacity-building. It is important to distinguish between clinical trials initiated by local investigators, those initiated by Big Pharma and those by foreign academics and institutions, and the same set of guidelines should not be used to regulate all of them (10). There are other intricacies, too, that need to be taken care of. These include local investigator-initiated trials that test new food products, complementary and alternative medicine therapies and biotechnological products, which need to be evaluated separately. The approval of some such trials may need to be expedited, considering their importance to the national economy.

Meanwhile, the absence of any law is the preferable option till the ERCs have the capacity to stand alone confidently. As the new Act seems to have assigned the ERCs a pivotal role in the regulation of RCTs, it is essential to enhance the capacity of their members and expand the infrastructural support available to them before the draft Act sees the light of day. In the short to medium term, it seems that RCTs can be monitored well enough by the existing channels, such as the ERCs, Sri Lanka Clinical Trials Registry, the approval process of the CDDRA, the country's vigilant media and the outspoken, whistle-blowing academics. In the long term, ensuring transparency and full consultations with the public might reduce exploitation, but this is not a foolproof option. Increasing the science, health and research literacy of ordinary people, in addition to improving their living standards and reducing poverty would be the best method of preventing the exploitation of poor patients by the "clinical trials industry".

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## SELECTED SUMMARY

## Advancing physicians' skills versus safeguarding individual patient interests: an ethical dilemma

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### **Kendler S, Kodner IJ, Keune JD. The role of the poor in medical research and the physician's duty to protect. *Surgery*. 2013 Feb;153(2):287-91a**

The divide between medical innovation and routine clinical practice is a grey zone. Clinicians are often torn between their dual roles as healers and investigators, between the need to cure and the desire to improve existing practice. While medical research involves "experimentation" on human subjects to identify novel treatments, one is often tempted to use newer techniques to improve the outcomes of treatment in routine clinical practice. There is no controversy surrounding the adoption of a new therapy which has been proven to be superior to the existing methods of treatment and which can be delivered as well, if not better. However, a moral and ethical dilemma arises when the new therapy has not yet been proven to be superior and the treating physician is not certain that administering this treatment would be at least as good as providing standard care. This is especially so when dealing with potentially vulnerable patients. In procedure-related fields, such as surgery, endoscopy and interventional radiology or cardiology, this problem is compounded because the physician not only has to decide if the "new" treatment is truly experimental or just an adaptation of an established method, but also whether he/she possesses the skills and expertise required for the new procedure.

This paper uses a hypothetical clinical scenario to examine two very important ethical aspects of clinical practice, ie, the application of the principles of research ethics to routine clinical care and the challenges of using vulnerable populations as subjects for the training of clinicians. The case described is that of a semi-literate, uninsured patient who needs to undergo a standard surgical procedure (cholecystectomy). The surgeon wants to use this opportunity to improve his proficiency in an innovative technique – robotic surgery – which he wishes to master to perform robotic liver transplants subsequently. The complexity of the problem is enhanced because the subject is semi-literate and is therefore, not considered capable of giving truly "informed" consent for a procedure that is not standard-of-care. Also, since she will be getting the surgery done for free, she may feel inhibited about refusing to undergo the robotic cholecystectomy. The paper discusses the ways in which this situation can be handled and the ethical issues raised by each of the alternatives mentioned.

One option is to perform the experimental (robotic) technique and consider it justified for the following reasons. First, the patient is receiving free treatment from society and, therefore, should contribute to the progress of medical science. Second, using this patient for enhancing the surgeon's skills will be advantageous for many future patients. While this seems acceptable in the larger perspective of scientific advancement, it is a gross violation of the patient's personal right to autonomy, the physician's obligation to primarily provide benefit, and a breach of the principle of social justice. The second option is to offer the patient both treatment choices and attempt to obtain informed consent for robotic surgery. This involves several issues, such as the difficulty of explaining the technicalities of an experimental procedure to a semi-educated patient and the question of whether the consent would be truly "informed," which again defeats the principle of autonomy. The last alternative involves creating an independent committee to standardise and supervise the use of experimental procedures in vulnerable populations on a case-by-case basis to ensure that patients' rights are protected, while at the same time allowing medical science to progress. A practical difficulty could be the feasibility of getting prompt responses to such situations on a day to day basis to ensure that treatment is not delayed. However, this might be an ideal long-term solution, though it would need careful planning and investment of resources.

After careful consideration of the pros and cons of these options, the authors conclude that the ideal and safest option is to perform the surgery using the default technique (laparoscopy). In this way, the patient receives "standard" care, there is no experimentation and the dilemma of obtaining consent from a vulnerable patient for an experimental procedure is avoided. Though there is no long-term benefit to society, the patient's autonomy is protected and the principles of beneficence and justice are upheld.

We feel that the solution offered by the authors is conveniently safe, but overly simplistic. In this context, two issues must be considered. First, is a semi-literate patient incapable of understanding the difference between standard-of-care and experimental therapy, even if she cannot understand the actual technicalities of the procedure? Surely, a person who can give "informed" consent for a surgery as complex as a laparoscopic cholecystectomy should be able to decide if she wants to

undergo a novel procedure. Is it not being paternalistic and violating the patient's autonomy, to assume that she will not be able to comprehend the nuances of robotic surgery and, on this basis, deprive her of the opportunity to contribute to medical progress? The authors have briefly alluded to this, but have concluded that non-maleficence should parallel patient autonomy. The second issue relates to the training of doctors. Academic hospitals train people to become competent doctors and this is a necessary process to ensure that future generations get the same, if not better standards of medical care than we have today. This will not be possible if less-experienced doctors are not allowed to treat and carry out established procedures on patients, albeit with supervision, and also (as in this hypothetical scenario) unless experienced doctors are allowed to offer novel treatment and perform new procedures after obtaining informed consent. Every new technique has a learning curve and if doctors do not constantly practise and upgrade their skills, they will never achieve proficiency in the latest procedures. It would be naïve and unrealistic to expect that all physicians should perform new procedures only after they have been mentored by an expert till this learning curve is completed.

To sum it up, though in this particular case, performing a laparoscopic surgery on the patient would be more expedient, the other option, ie, explaining both procedures to the patient and allowing her the freedom to choose, would be communally advantageous and ethically appropriate, even if more complex. If during the counselling process, the surgeon genuinely feels that the patient does not understand what the new procedure is all about, he can resort to the default option of performing a standard surgery. If such situations are frequent, an experimental treatment research protocol could be developed to supervise such procedures – but this process should be applied to all patients potentially suitable for such procedures, irrespective of their level of education or paying capacity. The assumption that semi-educated or uneducated patients are incapable of understanding or that the poor have no altruism is both paternalistic and presumptuous. Socioeconomically backward patients depend on society to meet their healthcare needs and they should not be exploited and made guinea pigs for experimentation by virtue of this dependence; at the same time, they have the right to contribute to the progress of medical science and they should not be denied the opportunity to make this choice.

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## FILM REVIEW

# Do our bodies belong to us? Exploring ethics, power, and choice

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***Ship of Theseus*, Producer: Sohum Shah, Director: Anand Gandhi. English with Hindi, Arabic, Swedish. 143 minutes, 2012.**

Anand Gandhi's *Ship of Theseus* is a visual and intellectual feat, one that is able to ask fundamental questions about our relationship with our bodies in the modern world. The film reveals how the maintenance and management – under fast-paced scientific innovation – of the able body that sees, resists internal degeneration and replaces defunct organs to live for as long as possible is more under medical control, and under the control of capital, than we think. This is a world in which organs are a part of global traffic and circulate within a system of capital flow. Gandhi raises deeply philosophical questions against the background of this material context, exploring issues related to ethics, political action and choice.

Each of the three stories that make up this film asks us some very difficult questions, thankfully without offering simplistic solutions. The central dilemma presented at the start of the movie is: if all the old wooden planks of the ship of Theseus were replaced by new ones, and the old ones re-assembled to form another ship, which then, if either, is the real ship of Theseus? The film goes on to add layer upon layer to this, and pushes us to think about the relationship between a part and the whole, and how we perceive and position ourselves in a larger system of social relations.

In the first story, the blind photographer, Aaliya (Aida Al-Kashef), navigates the city, directing her camera at sounds that arrest her. Her aim is to capture, document and archive moments as they occur around her. Despite her disability, she is able to retain remarkable control over her images. However, once she is able to see again (a cornea replacement operation restores her vision), the sudden onrush of visual stimuli in the city confuses her and she seems incapable of taking good photographs any more. It is only when she goes to the mountains for inspiration that she is able to understand what it means to stop and take stock of her surroundings with new eyes. As her lens cap accidentally falls into a stream, we understand that her eyes have been symbolically opened forever.

The second story begins with a monk, Maitreya (Neeraj Kabi), walking barefoot through the city in the pouring rain. The monk, gentle yet formidable, is on his way to a court hearing for a case against pharmaceutical companies that perform tests on animals for non-essential and cosmetic research. Through

conversations between the erudite Maitreya and Charvaka, a zippy young lawyer-apprentice also on the case, we learn that Maitreya believes that all existence – and not just all humanity – has a life force. He also believes in taking responsibility for his every action (and inaction). As we view a scene that makes us cringe – a shampoo is being tested on a rabbit which is writhing desperately – we are confronted with the possibility of accepting Maitreya's argument on fundamental ethical grounds, rather than on religious grounds (at one point, he expresses his desire to hold a dialogue with the medical community). Yet, once he realises he has liver cirrhosis, Maitreya is faced with a choice between the very principles he stands for and his life.

The third story gives us a powerful overview of the global flow of body parts today, and deserves a special mention from a bio-ethics perspective. Navin (Sohum Shah) is an unsophisticated stockbroker, the grandson of an earnest woman who runs an NGO. The tension between the two is palpable. While she thinks he is obsessed with money and does nothing to reach out to people who "need his compassion," he thinks her "revolutionary" ways are stifling and useless. (The two argue in a well-executed scene right after he helps her urinate into a bedpan in a hospital.) Things change for Navin when he comes face-to-face with Shankar, a labourer who has had one of his kidneys stolen in the course of an appendix operation. Navin, who has just had a kidney replacement operation, is deeply shaken by this. Even after his doubts about whether his own surgery was the result of a donation have been laid to rest, he launches a search for Shankar's buyer-recipient. This takes him halfway across the globe to Stockholm. The buyer-recipient is a white man who, when confronted by Navin, first evades the subject, then becomes defensive and eventually breaks down. He offers to pay Shankar more money, but Navin wants a kidney for Shankar. We realise that today, capital disperses body parts in an economy that literally steals a poor man's kidney and puts it in the body of a hapless foreigner, who has the power but not the ability to see the context in which he is placed.

This circulation, in which we rent or sell parts of ourselves that could not earlier be rented or sold (think surrogacy, clinical trials, organ and blood donation/sale, stem cell research, etc), reflects the vulnerability of our bodies to the power of capital. Such transactions are taking place in newer and newer ways every day. This trend raises a plethora of questions regarding medical ethics, the marriage of capital and science (especially

biotechnologies), regulation and the role of the State, and the larger issues relating to poverty, rights and livelihoods. Together with the second, this last story seeks to understand individual choices within the varied contexts in which they are made.

The three stories come together seamlessly at the end of the film. The movie leaves us contemplating questions related to identity, as well as the costs at which scientific advances that give us an opportunity to lead a better/longer life are made possible.

**WORKSHOP TO PROMOTE PROFESSIONALISM AND ETHICAL  
PRACTICES IN MEDICINE IN INDIA:  
Taking stock and setting an agenda  
KOLKATA, INDIA  
January 10, 2014**

Serious concerns have arisen on all aspects of medical practice: from entry to medical colleges, and post-graduation, to the quality of education and training; and issues like self-referrals and commissions paid. The questions being asked are: Have doctors lost their way in India? Why are they failing to provide the necessary leadership to address these problems and the steadily deteriorating health indices?

The Forum for Medical Ethics and the *Indian Journal of Medical Ethics* have already been raising awareness on ethical issues and on the need for professionalism for many years. More recently, the Global Association of Physicians of Indian Origin ([www.gapio.in](http://www.gapio.in)) has been formed to mobilise Indian doctors worldwide to enable them to achieve professional excellence and to support health developments in India.

A few of us (Drs Nobhojit Roy, Amar Jesani and Rajan Madhok, supported by many others) have explored the synergy between these two initiatives and proposed a one day workshop in Kolkata on January 10, 2014 (venue to be notified) to:

- a. Learn about the state of professionalism and ethical practices in medicine in India: where we are heading, and what is being done to address problems
- b. Share the experiences of Indian doctors overseas and explore their relevance to India
- c. Discuss the values and behaviours (the professional framework) required to address the challenges in India – and what the *global Indian doctor* should be like
- d. Discuss and develop a potential programme of work to recognise, support, and develop health leaders who can help promote these values and behaviours, and effect change

The workshop will be an informal get together of like-minded colleagues, and, subject to discussion, formal arrangements for subsequent work will be put in place. Attendance at the workshop will be limited, especially as there are no funds to support travel/subsistence. Expressions of interests from willing participants – both for the workshop, and to be a part of the network -- are invited and should be submitted to Rajan Madhok ([rajan.madhok@btinternet.com](mailto:rajan.madhok@btinternet.com)) who is coordinating this. Further details will appear on [www.leadershipforhealth.com](http://www.leadershipforhealth.com).

## FROM OTHER JOURNALS

### **Studying designs of an HPV vaccine trial**

Defining the minimum standard of care in clinical trials is an ethical concern, and this informs the way researchers design a trial to test a new drug/molecule. The authors of this paper point out that given the various counts on which a study is expected to perform successfully, designing an ethically sound study has become a challenge in itself. This paper describes the possible study designs of an HPV vaccine trial enrolling HIV-infected adolescent girls in low-income settings. The designs are as follows:

- Superiority placebo-controlled crossover design: This uses random sampling for half the study population and at the end of the three-year period, unblinds the participants and offers the vaccine to the placebo group.
- Designs without untreated controls: Since the vaccine is likely to be at least somewhat efficacious in HIV-infected adolescents, it is offered to all participants.
- Designs without untreated controls, including cohorts of HIV-infected and HIV-uninfected girls: Here, the previous design is modified by studying individuals in all the study arms from a similar background with the same study endpoint.
- Open-label uncontrolled trial administering three doses of vaccine to HIV-infected girls: A cohort of HIV-infected adolescent girls is enrolled, three doses of the vaccine are administered, information is collected on its safety and immunogenicity, and the patients are followed up long enough to estimate the proportion of those developing persistent HPV infection. This proportion is then compared with published estimates from trials in older women with the same endpoint.
- Superiority design randomising HIV-infected girls to four versus three doses of vaccine: In this design, randomly selected HIV-infected girls are given either three or four doses of the vaccine to determine if the rate of infection in the four-dose regimen is lower.
- Non-inferiority design randomising HIV-infected girls to two versus three doses of vaccine: A randomly selected sample of HIV-infected girls is given either two or three doses of the vaccine, on the basis of observational data from trials showing that the efficacy of one or two doses was similar to that of the full three-dose series.

After considering the merits and limitations of each of these study designs, the authors suggest that for the purpose of assessing the efficacy of an HPV vaccine in a low-income

setting, the sixth design performs the best across most criteria. This design has the maximum scientific validity, has no untreated controls, has specific returns for the study population, is feasible, and provides a minimum degree of protection to all participants. However, the first design is the most potent as far as maximum scientific validity is concerned, though it fails to provide the minimum care to all participants. The authors end by stressing on the moral need to design trials that aim to achieve the best balance between scientific validity, social values, feasibility, and protection of participants.

**Lindsey JC, Shah SK, Siberry GK, Jean-Philippe P, Levin MJ. Ethical trade-offs in trial design: case study of an HPV vaccine trial in HIV-infected adolescent girls in lower income settings. *Dev World Bioeth.* 2013;13(2):95-104.**

### **Mapping the non-medical causes of maternal deaths**

When it comes to maternal deaths, the focus remains primarily on the medical causes and lapses. This study was designed to understand the social/non-medical causes in two districts of Jharkhand. The "Delay Framework" (Thaddeus and Maine) was used to map the social causes of the deaths. An average of two deaths per month was recorded in the area during the one-year period of the study. It emerged that none of the women had received antenatal care, while only 10 had received the tetanus toxoid injections. A majority of them had developed mild to severe complications during the antenatal period, but most had sought no form of care. In some cases, the local traditional practitioner had held on to the case till it was too late. Referral had been made to the district hospital, which is the first referral unit (FRU) in the area. As per the National Rural Health Mission guidelines, an FRU should have blood transfusion facilities and be able to provide surgical and emergency obstetric care. However, the FRUs in the area were too ill-equipped to offer any of these and, as a consequence, routinely referred the women to the tertiary hospital, which is in the adjoining state, 70 km away. The communities knew that the tertiary hospital had the facilities, but could not directly seek admission there, without being routed through the FRU; a significant number of deaths occurred on the way from the FRU to the tertiary hospital. Also, the transport system in place – the state-sponsored ambulance – was known to demand exorbitant amounts to transfer patients, and families lost precious time while trying to arrange for the money. This also meant massive out-of-pocket expenditure, which most families in these districts could ill afford.

India has one of the highest maternal mortality rates in the world and is struggling to lower it significantly by 2015 as part of its commitment to the Millennium Development Goals. This study becomes all the more important in the light of these facts. It is an ethical imperative for the stakeholders, especially those responsible for policy-making and monitoring of the public healthcare system, to understand the causes of maternal deaths from all standpoints, and not see it just as a medical issue. It is only after these social causes have been dealt with that maternal mortality can be better addressed.

**Banerjee S, John P, Singh S. Stairway to death: maternal mortality beyond numbers. *Econ Pol Wkly.* 2013 Aug 3;48(31):123-36.**

### **Integrating “tobacco control” with the medical curriculum**

Close to 70% of deaths owing to tobacco consumption occur in low- and middle-income countries. The authors of this paper argue that making tobacco cessation a normative part of all clinical practice is the only way to reduce tobacco-related deaths and counter tobacco-related morbidity in the long-run. The contact between patients and doctors is considered the point of entry for this. It is important that doctors inform their patients about the immediate and long-term health-related problems that tobacco users are likely to face and, as the authors point out, the precondition for this is that the doctors should be aware of these problems.

However, the medical curriculum in India at present does not contain detailed information on the dangers of tobacco use.

A cross-sectional survey was conducted among all undergraduate medical students and faculty members in five medical colleges to assess the levels of tobacco use, receptivity to and practice with respect to tobacco cessation, and their readiness to adopt a more comprehensive education programme. One of the findings was that around 60% of the students (from a universe of 2585) had started smoking after joining medical college, and the percentage had increased over the four years. Only 20% of the medical faculty (from a universe of 713) reported having sufficient training or experience to help patients quit the use of tobacco. Eighty-nine per cent of the students felt that doctors should mandatorily advise patients to quit using tobacco. Close to 96% of the students felt that, as future doctors, it was important for them to receive education on tobacco control, as well as training on how to counsel patients.

The study is timely, considering the exponentially growing rate of tobacco-related deaths in India. Its novelty lies in the fact that it advocates the integration of the subject of tobacco-use with the medical curriculum. Until now, it has been the Indian state that has been concerned with tobacco-related morbidities and has mandated statutory warnings and graphic labels on tobacco products. If the medical fraternity is also sensitised on this issue in depth and if doctors adopt counselling as part of

their routine interaction with patients, the problem of tobacco-related morbidity/death would be more effectively addressed.

**Thankappan KR, Yamini TR, Mini GK, Arthur C, Sairu P, Leelamoni K, Sani M, Unnikrishnan B, Basha SR, Nichter M, for the Project Quit Tobacco International. Assessing the readiness to integrate tobacco control in medical curriculum: experiences from five medical colleges in southern India. *Natl Med J India.* 2013;26(1):18-23.**

### **ARV drugs: prioritising prevention over treatment**

The allocation of medical resources, especially in resource-poor settings has generated much ethical debate. This debate has assumed greater urgency in the context of HIV and the antiretrovirals (ARVs), especially in low-income countries such as those in sub-Saharan Africa. Several studies have argued that what is needed to end the epidemic is the adoption of a preventive strategy rather than only a curative one. In July 2012, the US Food and Drug Administration approved the use of Truvada (an ARV) as a preventive. However, those on the other side of the divide argued that the diversion of resources towards prevention rather than using them to treat the already affected population is unfair, especially when the drug is in limited supply. Against this background, the author asks: why should treating urgent cases be ethically superior to preventing urgent cases in the future? The author argues that unless effective preventive mechanisms are put in place, treatment will always seem to require priority, simply because the size of the affected population will never shrink enough unless prevention is prioritised. However, the author refuses to take sides and instead, insists that it is important to focus on the *context* before deciding to use ARVs for prevention or cure. Here, the context would include the efficacy and resourcefulness of the existing health system and other socio-economic conditions. The need to generate more supporting evidence of the efficacy of ARVs as prophylaxis in the context of different social settings is also reiterated.

The author concludes by saying that while much research is still needed to establish the likely impact and cost-effectiveness of the strategies for reducing the transmission of HIV, responsible implementation would involve dedicating substantial resources to careful monitoring and evaluation, HIV testing and counselling, raising awareness among communities, and structural interventions to reduce vulnerability to HIV infection.

**Rennie S. Ethical use of antiretroviral resources for HIV prevention in resource-poor settings. *Dev World Bioeth.* 2013;13(2):79-86.**

### **Ethics of embryo donation**

A decade ago, it was estimated that the number of unused frozen embryos in the USA was 47,000 and on an average, 45,000 embryos are cryopreserved in the UK every year. This article supports the proposal that embryo donors can impose specific conditions in the choice of who the recipients of their embryos should be. The authors start from the assumption



that the embryo does not have the status of a “person” and the practice of conditional donation does not have to be as complex and onerous to organise legally as the practice of formal adoption. They go on to argue that conditional donation would encourage non-anonymity and healthy contact between donors and recipients, thus making donation a vehicle for the creation of new family relationships (“relational model”) rather than a one-off event in the clinic.

However, the authors oppose the view that donors should be allowed to impose blanket conditions on the choice of recipients (denying donation to certain races, ethnicities and people of specific sexual orientations), and admit that in practice, it is impossible to ensure that even people who require specific conditions always make a fair, unbiased choice.

**Frith L, Blyth E. They can't have my embryo: the ethics of conditional embryo donation. *Bioethics*. 2013 Jul;27(6):317-24. doi: 10.1111/bioe.12034. Epub 2013 May 30.**

### Models of contract motherhood

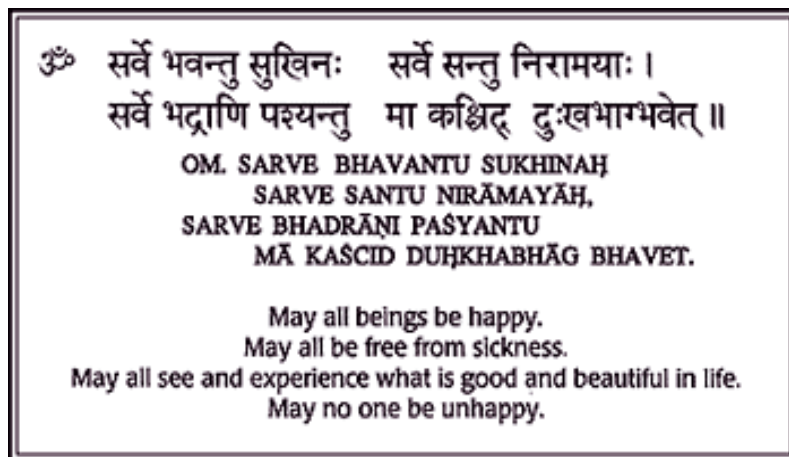
In this article, the authors argue in favour of a professional model for contract motherhood or surrogacy as a third alternative to the commercial and altruistic models, which are the subject of much debate. In the commercial model, both

parties enter into a legal agreement for personal gain and the woman receives a fixed fee in exchange for her services. The altruistic model is based on the gift relationship, which is not legally enforceable. The terms of exchange are not fixed and surrogacy is motivated by altruism. Both models appear to have their disadvantages. In the commercial model, the woman, being motivated by monetary gain, may put the foetus at risk if she is not satisfied. In the altruistic model, the woman is vulnerable to exploitation by the potential parents. The authors state that since contract motherhood satisfies the conditions required for professionalism, ie it requires certain levels of skills and training and has a strong ethical dimension, the professional model should be adopted. Adopting this model would also make it possible to pay a fixed remuneration to the mothers, whose collective interests could be safeguarded by the formation of a professional body.

**Van Zyl L, Walker R. Beyond altruistic and commercial contract motherhood: the professional model. *Bioethics*. 2013 Sep;27(7):373-81. doi: 10.1111/j.1467-8519.2012.01962.x. Epub 2012 Apr 16.**

*Contributions from Rakhi Ghoshal, Anuradha Panchmatia*

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## *International Symposium on Spirituality and Ethics in Medicine*

Friday, November 15, 2013

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Dr. Subrata Chattopadhyay, MD, PhD, Erasmus Mundus Master of Bioethics

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## LETTERS

### The medical trade

It is disturbing to hear the numerous revelations of malpractice and ethical lapses committed by members of the medical profession. Technology is often misused, with patients being made to undergo unnecessary examinations, hospitalisation and even surgery. In many small nursing homes, doctors have their own medical store and laboratory. Unnecessary prescriptions are issued and no explanation is given to patients or relatives. Large multinational pharma companies regularly supply ECG material and cardiac monitors to some leading physicians who prescribe only their products. This unethical approach has also infected medical colleges. Some professors convey to their students that unethical practice is the right way to conduct oneself as a doctor.

Recently, I received a cheque for Rs 1200 (no. 52185525, dated March 14, 2013) from an MRI centre with many branches in Mumbai and Pune. On enquiry, I discovered that the cheque was by way of a "professional fee for referring a patient to the centre" for an MRI. The patient had already paid my professional fee when I had examined him at my hospital in Mahad. I returned the cheque, which was reimbursed by the MRI centre to the patient at my request by a cheque dated March 31, 2013 in the name of the patient. On April 30, 2013, I lodged a detailed complaint against this practice with the Medical Council of India. Until today, I have heard nothing more from the Council. This is reminiscent of the experience of MK Mani as far back as 1995 (1).

In another case, a 26-year-old married woman had been ill with fever, cough, anorexia; and noticeable weight loss over a period of two months. Her sputum tested positive for acid-fast bacilli, and a chest x-ray showed miliary tuberculosis. She revealed that her mother had pulmonary Koch's disease. In spite of sufficient evidence for a confirmed diagnosis, her physician advised a chest CT scan which cost her Rs 4000 but did not alter the diagnosis. All this only for a commission of Rs 1000 from the radiologist!

There are no free lunches in this world (3). The conference of a physicians' association was held at a five-star hotel at a hill station by a pharmaceutical company to introduce a new molecule acting simultaneously on blood sugar and lipids. Of the 120 doctors who registered as participants, 88 were provided funds for their hotel stay and transport by the company. I refused the offer of sponsorship and attended the conference at my own expense. At the end of the conference, the president warmly felicitated the pharma company boss.

As I have been well acquainted with the practices of such companies for the last 25 years, their medical representatives and managers are not permitted to see me.

An authority and legal adviser of my medical association told me that a company may pay a "cut" or appoint agents and pay a commission to promote business; and nothing is wrong with such a policy. He further advised me not to discuss this. A wise social advocate advised me to collect a few more cases, after which he would file a public interest litigation in a court of law.

We spoke personally with the manager of a nearby centre, who had sent us a Rs 500 note in an envelope for referring a patient for a CT scan. He said he did agree with our viewpoint, but was helpless as the majority of referring doctors wanted a "cut". Such unethical conduct has driven those doctors who believe in practising ethically to close down their nursing homes. The cost of modern medical treatments is beyond the capacity of the middle class partly because of the huge expenses incurred by the healthcare industry in sponsoring gifts, honorariums, conferences, symposia and research grants which are eventually paid by the consumer. In today's scenario, it is almost impossible to be a good doctor (2,3).

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### Breaking bad news in the paediatric ICU: need for ethical practice

Communicating with the parents of children who are extremely sick or dying in the intensive care unit (ICU) is an extremely challenging task. The physician in charge of intensive care, apart from administering the routine medical treatment, has other vital roles to play, such as communicating the poor prognosis, advising the guardians on decisions regarding the withdrawal of life support, requesting permission for an autopsy and initiating the process of organ donation (1). Intensivists play the unique role of helping parents prepare for the child's death and ushering in the grief process which will help the family remain functional and intact. Allowing parents to play an active

role in management decisions and informing them about the patient's condition at every stage of treatment can build their trust and help them prepare to face worse situations.

The manner in which the bad news is discussed is extremely important to most parents and a casual approach can seriously add to their mental agony (2). Unlike in the West, the parents' emotions and bereavement following their child's death are often overlooked in India, the more so in government hospitals. Lack of empathy, crowded hospitals, overworked doctors and understaffed ICUs could be responsible for this, but these factors are certainly not justifiable.

Informing parents about their child's death is probably the most difficult job even for an experienced paediatrician. This delicate matter is dealt with mostly by residents and junior faculty members (rather than consultants in charge of the child), who spend more time with the patients, especially "out of hours." It is often assumed that residents are good at communication, though studies have shown that most physicians are not good at communicating bad news to parents (3). The problem becomes more acute if they do not know the language spoken by the parents. The common errors committed are making a brief, rapid declaration, not answering the parents' queries and not spending enough time with the parents. Such approaches can send out wrong signals, such as leading the parents to suspect that there has been a "cover up." They can worsen the parents' anxiety, make it difficult for them to accept the news, complicate the subsequent bereavement process and even result in litigation (4). Parents want empathetic, honest and complete information, communicated in lay language and at a pace that is easy to comprehend. Hiding true facts regarding the disease or prognosis from the parents can lead to false hopes and feelings of fury, betrayal and distrust (2).

Discussing donation of the child's organs has been found to have a positive effect on bereaved parents and can help them cope with the bad news (4). On the other hand, it can also be a double-edged sword as parents sometimes perceive it as an opportunistic act and a sign of complete lack of sensitivity on the part of the doctor. However, if the subject is handled with sensitivity, the parents may derive solace from the prospect that their child's organs will continue to live and this can help them cope with the traumatic event. The personal belongings of the dead child, however trivial they may be, are extremely important to the parents. Be it a dress, hair clip or toy, the staff should take care to return it to the parents. A study on bereaved parents showed that nearly all of them wished to spend some time with their dead child, even if the body was mutilated (4).

The junior doctors should be sensitised to this serious issue and must be trained adequately to deal with the bereavement of parents. The assessment of communication skills in simulated encounters with parents and feedback from senior faculty members can improve the doctors' ability to counsel and break bad news to parents. Such an exercise has been found to improve the parents' level of trust and make junior doctors feel more confident (5). Training of a similar nature should be incorporated into the postgraduate curriculum.

Being empathetic, using the right words, speaking in a clear and unhurried manner, making sure that one's look and body language convey concern, choosing a private area for discussion and giving the parents enough time are all factors that are vital to the task of breaking the bad news with sensitivity.

If the doctor handles the subject of a child's death in an ethical manner, it makes a huge difference to the parents. Even from the doctors' perspective, this approach is associated with personal satisfaction and a sense of fulfilment, once one goes beyond the blow of losing the patient. The content of our medical textbooks and curriculum is inadequate with respect to the skills needed for the ethical management of death (6). Due to the lack of formal training in this area, it is up to the physicians to develop their own skills and this largely comes with experience. It is worth remembering the two important prerequisites of the successful management of death – empathy for the parents and sensitivity to their feelings.

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## Satpal Dang – a personal memoir

In the early 1990s when this journal was in its infancy and struggling to establish itself, I used to enthusiastically show it to all those who I thought would be even remotely interested. I always carried copies and passed them on to colleagues, friends and family members. I then requested them to read it, spread the word among their doctor contacts and of course, solicit subscriptions. Many of them would look at the journal and say the usual nice things, and it often ended there.

Satpal Dang was my wife's maternal uncle. I had heard of him as he was a prominent political activist of the Communist Party of India in Amritsar, Punjab. During one of our earliest interactions, I presented him with a copy of the journal. He promised he would read it and get back to me. Within a week, I received a three-page-long handwritten letter containing his views on the journal. It dwelt mainly on the importance of the subject and how he could help spread the word. There was also a cheque for his personal subscription. Within the next few weeks, we started receiving subscriptions from doctors in Punjab, some collected by him and others directly. He soon requested more copies of the journal and I promptly arranged to have them sent to him. I discovered later that he had personally written to more than 100 doctors from all over India, urging them to subscribe.

Later on, he was to write for the journal. He also sent us newspaper clippings about various scams involving the medical fraternity in Punjab. He wrote articles on the deterioration in ethics among doctors for the newspapers of Punjab, especially *The Tribune*. In the late 1990s, he led a campaign to punish those involved in a kidney transplant racket in Amritsar. Ironically, he got a lot of flak from the local medical professionals for being "anti-doctor". When I visited him and his wife, Vimla, in 2002, he spoke about the campaign and how very few doctors supported his stance. He also expressed his happiness with the fact that the journal had grown in its sweep and reach.

The Dangs were a family which, like many others in that tragic juncture in history, had fled from Lahore to India in the aftermath of the Partition. Satpal had been playing an active role in the student movement in Lahore. He met Vimla Bakaya, who belonged to a Kashmiri family and was also a student activist, in Bombay and the two got married. After a stint in Bombay as secretary of the Students Federation, Satpal became a full-time activist of the Communist Party of India, as did Vimla. They volunteered to go to Cheharta, a suburb of Amritsar, to organise trade unions in this new industrial belt. Due to his commitment to the cause, which entailed living and working among the working class and the poor of Cheharta, Satpal (and later Vimla) was elected

a member of the Punjab Assembly on three consecutive occasions, and even became a minister for a brief period. During the period of Khalistani terror, the Dangs were in the forefront of those organising ground-level resistance, as well as helping innocent victims of terrorism. In fact, it was well known that Cheharta was one of the few areas where the Khalistanis were unable to make any inroads and Jarnail Singh Bhindranwale had announced a reward for killing the Dangs (many activists of the communist parties were killed by the Khalistanis during this time). While at this point, the communists fought for the victims of terrorism, they later also fought for the victims of police excesses and fake encounters. When he received the Padma Shri, Satpal returned it, saying that he had no interest in such titles. Later in his life, Satpal became a prolific writer, dealing especially with issues related to terrorism. He has three books, two of them focused on terrorism in Punjab, and numerous articles to his credit.

Since his death, a lot has been written about the amazingly simple life of the Dangs. Although I was well aware of this aspect of his life, I was still surprised and felt humbled when during my only visit to him in Cheharta, I saw that he and Vimla were staying in an anteroom of the party office. They had almost no possessions, except two cupboards full of books. When they took us sightseeing, almost everyone in the city seemed to know them.

Satpal Dang continued to be interested in this journal till very recently. When I met him in 2007, he enquired in detail about the progress of the journal and was keen to know whether the subscribers he had got us from Punjab had renewed their subscriptions. For the last two years of his life, he developed severe dementia, and a party worker and his family looked after him. Vimla passed away in 2010 and Satpal in June 2013. They bore no children, which was apparently a conscious decision since they felt that given their lifestyle, they would not be able to look after them. They did not leave behind any property or money, but left behind the huge legacy of lives spent with ordinary working people, lives spent fighting for these people's right to a decent existence.

Satpal Dang was no doctor, ethicist, academic or scientist, but he enthusiastically supported this journal's struggle for existence in its early days. More importantly, he led an exemplary life marked by high ethical standards as a grassroots political activist. I suspect that like many others of that time whose thinking was similar, he knew no other way.

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