LETTERS

Proactive role for ethics committees

The study conducted by Shetty et al (1) on the experiences of an ethics committee (EC) in developing an oversight mechanism is indeed an eye opener (1). The study has identified some crucial areas where good clinical practice (GCP) guidelines have been violated at investigator sites. These would probably have gone unnoticed had the EC not intervened. The authors have rightly argued that the current procedure followed by ECs to maintain oversight through passive monitoring needs to be changed.

In the current scenario, where India is looked upon as a potential hub for global clinical trials of increasing complexity, it is necessary for all ECs, institutional and otherwise, to review their roles and responsibilities as regulators of clinical research (2), introspect on their operating procedures, and consider innovative measures to discharge their duties efficiently.

In the current study, the IEC of the concerned tertiary care hospital proactively graduated from passive monitoring to active oversight of its investigator sites. This role of active monitoring is especially important for investigator-initiated clinical trials where sponsor monitoring is limited. Also in sponsor-initiated clinical trials, this procedure would help to maintain ethical oversight of trial procedures.

However, undertaking routine monitoring for investigator sites may yet be a challenging task for ECs facing problems such as inadequate space for their operations, lack of trained manpower, and lack of funds (3). To incorporate routine monitoring as undertaken in this study, ECs need to have GCP-trained individuals on board with adequate experience and expertise in on-site monitoring and audit. This calls for training the existing EC members or having additional members with monitoring experience. Funding the monitoring exercise may require building the cost for on-site monitoring into the review fees charged by ECs. It would also be essential to maintain effective follow-up with the investigator sites to ensure that issues raised during monitoring are resolved promptly. In addition, it is essential for ECs to also develop a system for safety monitoring to assess adverse drug reactions and serious adverse events reported at the investigator sites (4).

Having an oversight mechanism in place for ECs is the need of the hour, and its vital role in enhancing the ethical standards of conducting research cannot be overemphasised.

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Privatisation of healthcare and the Left

The editorial by Dr Sanjay Nagral on the AMRI fire (1) does not, amongst other things, point out the complicity of politics (in this case of the CPI(M) party and the Left Front government) with the private sector (in this case, the private health sector). It also does not point out the neglect of the health sector ('retreat of public health institutions') during the three decades of CPI(M) rule. Both issues have been widely reported by the media. There is an underlying assumption in the current Left discourse that the privatisation of the health sector and the withdrawal of the public sector in health in India is a result of the LPG (liberalization-privatization-globalization) policy. Here is the example of both happening under the blessings of a Left government. This has got implications for social analysis.

Secondly it *has* taken mostly philosophical analysis to bring to the fore the power of images. In contemporary times the work of Jean Baudrillard, amongst others, comes to mind. The powerful use of images and simulations in late capitalism has been highlighted by his work. Hence it takes philosophical analysis and not commonsensical understanding to unearth the complexity of the enchantment of modernity.

Moreover, many of the questions raised by the author regarding safety issues and Indian society resonate in existing analyses (both from the Left and the Right) of the continued failure of the 'welfare state' in India and the developing world. The questions raised by the author are very familiar - they become pertinent only when they indicate the need for a hard-nosed class-based analysis and (behind that) a civilisational analysis of the situation. It is only a complex of rigorous Marxist analysis and a comprehension of the socio-cultural and moral trajectory of a society or civilization which can give sensibility to the questions raised.

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Public health in India: unethical neglect

The vital importance of public healthcare in our country has long been neglected.

In most developed nations, public health systems play a crucial role in maintaining the health status of the populace. While the private sector focuses on curative medicine and is oriented to the individual, the government is responsible for public health services, which are concerned with preventive medicine and disease control and treatment for the population as a whole. However, public healthcare can be effectively implemented only when the government is sincerely committed to providing such healthcare facilities to its people.

When it comes to providing world class quality medical treatment, we are at par with most developed nations and can provide high quality treatment at a far lower cost than most of them. But we lag far behind when it comes to providing public health services, many of which are particularly important for the common man, for 80% of India's population. While we boast about our booming economy marching at a fast pace, we still have numerous segments of our population suffering from disease and hunger.

Time and again, experts have voiced the need for trained public health personnel. After much deliberation and delay, the Public Health Foundation of India came into being on March 28, 2006 (1). Yet, till date, it is not fully functional as an independent body and its presence is hardly registered in Indian medical circles. There is only one institute in India whose master's degrees in public health and applied epidemiology (National Institute of Epidemiology, Thiruvananthapuram, Kerala) are recognised by the Medical Council of India (2). A few other universities and deemed universities offer degrees or diplomas in public health. But it is not clear if all of them follow a common course relevant in the Indian context because there is, as yet, no governing body for public health training regulations in India. So, if we have admitted to the importance of public health in India, why does the state fail to provide for its development? The lack of experts and funding has forced us to modify the results of studies and measures undertaken in other places to fit our needs, and this has often had disastrous results (3,4).

There are not many public health specialists in India excluding those doctors employed in international health agencies like the WHO, UNICEF, and NGOs providing healthcare to the community. Meanwhile, all the evidence indicates that India desperately requires such experts to boost its community and primary healthcare. Admittedly, we have made much progress in the control of malaria, tuberculosis, HIV/AIDS, blindness, leprosy etc. But much more can be achieved. For this, we require qualified and trained public health experts, trained by competent institutes, to replace the 'experts' who do more harm than good to the offices of public health they head. Then only would we be practising true medical ethics in the care of the community as a whole.

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Analysis of physicians' strikes and their impact

Resident doctors often resort to strikes for reasons concerning safety at the workplace, better working conditions, better remuneration, and policy issues such as caste-based reservations and appointments to institute positions (1). Although many articles have discussed whether or not physicians should resort to strikes, few have analysed the prevalence of strikes, their direct impact on healthcare delivery, and beneficial outcomes, if any, for physicians (2-5). We conducted a single centre retrospective study for analysing the same.

In March 2011, an application was filed, on behalf of Rahul Yadav, one of the authors, at the Office of Public Information of Guru Teg Bahadur Hospital, New Delhi, under the Right to Information (RTI) Act, 2005, asking for information on all strikes called by the Resident Doctors' Association (RDA) of the hospital over the previous five years. Information was obtained on the frequency and duration of strikes and their consequences; demands of the residents and remedial measures taken by the authorities; any punitive measures imposed by the authorities; and the number of times the provisions of the Emergency Services Maintenance Act (ESMA) had been invoked. The impact of strikes on healthcare services in the hospital was assessed by analysing the number of patients seen during working days, averaged over a month, preceding the strike period, and the number of patients seen during strike days.

The reply to the application under the RTI Act revealed that during the preceding five years from April 1, 2006 to March 31, 2011, work was struck on five different occasions, amounting to a total 22 days (eight days in August 2007, two days in April 2008, six days in September 2008, three days in October 2008 and three days in February 2011) in five years, an average of 4.4 days per year. The common factor mentioned for all the strikes was "misbehaviour by attendants with residents". The April 2008 strike concerned misbehaviour of attendants with nurses.

The RDA's demands were related to improvements in security. There were no incidents of violence. ESMA was invoked twice in October 2008, and in February 2011.

There was a significant decrease in the number of patients attended to in the outpatient department (OPD) during strike periods, compared to the number of patients seen preceding each strike. The number seen in OPDs each day, averaged over a month, preceding the five strike periods, were 4,866, 4,719, 4,920, 4,878 and 4,550 respectively, and the average number seen in OPDs during the corresponding strike periods were 1,680, 2,377, 3,668, 1,389 and 3,093 respectively. The cumulative average of the number of patients seen during the strike period is 2,441.4 which is only 51% of the cumulative average of 4,786.6 patients seen during the month preceding the strike period.

Information on remedial measures by the management revealed that during the August 2007 strike, the management promised that "the present security will be scrapped and a better agency will be employed" and "regular surveillance will be done in the security services and patient care facilities". A written assurance was given in reply to our RTI application, for time-bound implementation of these measures and also that no action would be taken against striking doctors. During the April 2008 strike, the management issued directions for regular rounds by security officers. A file was moved for 95 extra security guards. During the September 2008 strike, the management deployed additional security, installed close circuit televisions at intensive care units. Also a "one patient-one attendant" norm and the display of a gate pass by one attendant at a time were made mandatory.

No record was available of whether any RDA member's services were terminated or suspended, or whether there was a cut in the salary of any RDA member due to the strike.

Our analysis of the strikes revealed that there is a significant decrease in the average number of patients seen in OPDs during strikes. Though striking residents often start parallel OPDs during strikes, it is clear that the health services are seriously compromised during strikes (5). Some studies have shown that strikes have led to decreased mortality though the reasons suggested for this were scarcity of emergency services and lack of emergency surgeries (4).

Repeated strikes for the same demands suggest that despite announcing appropriate measures every time, the management has failed to address the grievances of the residents adequately.

Tight regulation of security personnel and a serious assessment of the quality of security services are needed. Inclusion of RDA members in the decision making team may help formulate effective policies for ensuring the safety of residents at the workplace.

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Human embryonic stem cells: cells without end?

Recently, human embryonic stem cells (HESC) have been in the public discourse for a number of reasons. Prominent critiques have been about the ethical issues related to killing human embryos, adverse reactions, immune-rejections, malignancy, phenotypic/genetic anomalies in transplanted cells and futuristic notions of eternal life. Key stake holders in our social and health system need to provide sustainable solutions for an under-mentioned issue that concerns not only medicine and science; but also humanity as a whole.

HESC policy models vary between countries, from being restrictive to permissive and flexible. Countries like India, China and the United Kingdom have a flexible policy. In India, HESC treatment is allowed for incurable conditions. All countries except the USA have legally banned reproductive cloning. In the present scenario of varied legal frameworks, resource-limited nations like India still need an open platform for evidence-based HESC application and a responsible discussion on the HESC concept.

Should stem cell research be encouraged in India just because it is easier to produce embryonic cell lines owing to greater legal flexibility and lower costs? A significant chunk of the Indian population still exists below the poverty line and donors are willing to 'sell' eggs for meagre incentives without ever questioning their own rights or the medico-legal aspect. This certainly raises concerns about inducement or coercion of vulnerable groups. The issue is not just 'whether to pay' but also 'when and how much to pay'. Who must set these boundaries, and how does society conduct an informed debate on this subject? The promise of stem cells is too alluring to be undermined just because these concerns are not posed and addressed adequately.

The common Indian is perplexed by extreme claims and confusing terminology. There is a clash between religion and science in this spiritual nation. But we don't need a biology or philosophy degree to understand what the real issue is. The fundamental ethics is easy enough to understand when it involves large scale production and instrumental killing of viable embryos. Destruction of human life cannot be justified, even in the name of saving another life.

It must be remembered that benefits may still be a long way off as cures for complex diseases are never simple. We require many more years of intensified research to know what we are trading in. Till then, India and the rest of the world will remain in precarious speculation. No serious researcher is engaged in producing a 'whole human being' from stem cells; rather, the efforts revolve around standardising HESC usage and production methods. Still, it cannot be ruled out that human cloning is possible. As of now, there is a general consensus that human cloning is a boundary that should not be crossed (2).

India needs a stem cell debate that is coloured neither by religious and utilitarian fanatics nor by the 'big science with big funding' profit driven agenda of biotech corporate giants.

Uncontroversial progenitors like adult cells, marrow, placenta, cord blood and induced pleuripotent cell lines should be increasingly explored as a standard therapy medium that will be both useful and ethical. Using surplus embryos from IVF clinics with dignity and 'multiple re-use' of source embryo could further alleviate our moral burden. The medical benefits of HESC in the treatment of dilapidating diseases are quite promising and it certainly is a worthwhile direction to explore in India. However, ethical discussions must be advanced judiciously to avoid untimely political truncation of the true potential of stem-cell research in India.

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Ethics of bedside clinics

Teaching at the bedside is a time-tested and traditional method of instilling the basics of medical practice in students. In fact every medical student looks forward to "clinics at the bedside." The students see clinical signs, hear murmurs and palpate organs with excitement and enthusiasm. The teachers in turn demonstrate disease manifestations with zing and zeal. It is here that basic clinical skills as well as "bedside manners" are acquired by the students. Each patient is a chapter of a medical text book to be written in the grey matter of the student.

Let us imagine ourselves in a typical case discussion at a teaching hospital. The day before the class there is a frantic search for "good cases". Once the "case" is identified, the presenter moves to the "case" and starts asking for details of his or her illness. Then he or she is examined, exposing parts of the chest or abdomen. The patient is asked to twist, turn and obey various commands to make the physical examination complete. More often than not, the willingness of the patient to be part of the class the next day is not requested. Once history taking and examination are accomplished, the batch mates come in twos and threes and repeat this procedure, despite protests and signs of non-cooperation from the afflicted individual. This kind of prior preparation for the class happens in the general ward, with no screen or curtain to maintain some privacy. The class follows the next day, where the entire process is repeated. Full length discussions on the different diagnoses, treatment options and prognosis are heard by the patient who is obviously anxious to gather any detail of his illness. Ardent discussions and conversations about complications and causes of death go on. Everyone, including the presenter and the teacher enjoys the class, ignoring the fact that some patients may be well versed in the English language.

While respecting the basic rights of all human beings, "autonomy" affirms the right of every individual to determine what shall be done to his/her body. The word autonomy originates from the Greek word for self rule. Autonomy is one of the four basic principles of medical ethics, affirming that the choice of a patient with regard to his/her therapy should be respected by the treating physician. Confidentiality in a doctor patient relationship also stems from the patient's right to autonomy. This has been emphasised equally in the ancient medical codes of Hippocrates and Charaka as well as in the modern day ethical codes of the World and Indian Medical Councils.

Textbooks of medicine and clinical methods in medicine acknowledge and honour the above rights of patients as human beings. History taking and physical examination together is considered the beginning of a doctor-patient relationship. *Hutchison's clinical methods* states that clinical skills are grasped during a lifetime of practice (1). The authors demand that students treat patients with sensitivity and gentleness, causing only minimal disturbance. Self introduction and statement of purpose should be done at the beginning of examination (2). It is also recommended that permission be sought to conduct physical examination (1). Adequate privacy should be maintained by means of a screen and conversation should be in low tones to prevent others from hearing the interview. When a male doctor examines a female patient, and vice versa, a chaperone is recommended. It is stated that presentations may be embarrassing for the patient and so the students are asked to be "kind, thoughtful and brief". Subsequent discussions which cause unwanted anxiety to the patient should be avoided in his/her presence (3). Widely accepted textbooks of medicine like those of Harrison and Davidson also reiterate the importance of good communication and respect for the patient's dignity all through a doctor's interaction with a patient (4, 5). The Latin word *patiens,* from which "patient" has originated means "sufferance" or "forbearance". It is the duty of the physician not to cause any further distress or discomfort to the patient.

Let us extend the principles of autonomy and confidentiality to these classes so that ethics begins at the patient's bedside.

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Are doctors soft targets for government?

Every medical graduate is aware of the fact that getting a post-graduate seat in a good medical college in India is not child's play. The numbers of post-graduate seats, especially in medical colleges run by state governments, are dwindling every year. One has to spend a good 10 years up to post-graduation in intense study and get out of medical college as aged, unmarried, balding doctors. To add to our woes, a few states in the country have made compulsory a bond service period of three years after post-graduation.

Recently, the state of Maharashtra, in an unprecedented move, had decided to execute the said bond services for medical graduates from colleges run by the state government or by municipal corporations. The Director of Medical Education and Major Hospitals, Municipal Corporation of Greater Mumbai, issued a notification regarding the execution of the said bond services for candidates passing out from three corporation medical colleges viz. Seth GS Medical College, Lokmanya Tilak Medical College and Topiwala National Medical College located in the region of urban Mumbai. To our utter surprise, candidates with a super speciality degree i.e. Doctorate of Medicine (DM) and Master of Chirurgical (MCh) qualifications were, after 13 years of toil, allotted posts of assistant medical officers which could have been allotted to an MBBS graduate, rather than posts of Assistant Professors in the respective specialty, with unrealistic duty schedules and work hours. These 66 candidates decided not to accept their postings and filed a writ petition in the Honourable High Court of Bombay demanding posts at par with their qualification.

On the directives of the Honorable High Court of Bombay, in a writ petition 1440 of 2011 (Dr Maqsood Khan & others vs. State of Maharashtra), the Directorate of Medical Education and Research was given the responsibility of allotting such bond services (1). In a shocking and incomprehensible move, the Director of Medical Education and Research undertook a massive drive to allot the so-called bond services to around 900 candidates (PG Diploma – 235, MS – 189, MD – 420, DM – 30, MCh – 33) who passed out from government and corporation-run medical colleges in an overnight procedure from the morning of September 6, 2011, to the next morning. The allotment procedure was chaotic, with the authorities being oblivious to the candidates' queries regarding the nature of duty, work profile, and duty hours.

Many of the DM and MCh candidates were allotted the post of medical officer in a speciality (a post created on paper), but in reality these doctors were assigned the duties of an MBBS doctor. Thus, the expertise and talent of well-qualified doctors was under utilised by the state authorities (2). The government machinery grossly misinterpreted the health needs of society by pushing over-qualified doctors into the rural sector which lacks basic infrastructure. Even more shocking was the government action of removing ad-hoc medical officers (already serving for a period of five to seven years) to accommodate the bonded candidates. When the Honorable High Court was apprised of the tactics employed by government machinery, the state received a sharp rap on the knuckles for making super-speciality and broad speciality doctors serve as general duty medical officers. Some of the MD/MS doctors were allotted posts that had either been discontinued or were already occupied. One of my dermatology colleagues got an allotment as a medical officer in a leprosy unit of Pune district. To her utter surprise, the said post had been discontinued much earlier, and she was asked to serve under the tuberculosis control programme, taking instructions from the medical superintendent, attending polio vaccination camps and doing work which was in no way related to her speciality. If such misapplication of mind continues, our medical colleges will be lacking in full-time teachers and none would get timely promotion.

Since 2006, the Maharashtra Public Service Commission has not filled the regular posts of Assistant Professor, and Associate Professor and government is trying to fill those vacancies with such bonded candidates who cannot be permanently commissioned. Thus there is an acute shortage of medical teachers, to the extent that some medical colleges are on the verge of losing the mandatory Medical Council of India recognition of their post-graduate courses.

It is high time that the government applied its mind to tackling this issue with common sense and sincerity. If the government does not have enough vacancies to accommodate bonded doctors, shouldn't one question the validity of such bonds?

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