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.

***Rashmi Kadam**, Quality Assurance Manager, Chest Research Foundation, Marigold Premises, Kalyani Nagar, Pune 411 014 INDIA email: rashmipatkar@gmail.com*

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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.

***Parthasarathi Mondal,** Assistant Professor, Centre for the Study of Developing Societies, Tata Institute of Social Sciences, VN*

Purav Marg, Deonar, Mumbai 400 088 INDIA e-mail : pmondal@tiss.edu

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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.

Pankaj Thomas, *MPH student, School of Health System Studies, Tata Institute of Social Sciences, Deonar, Mumbai 400 088, INDIA e-mail: pankajthomas@gmail.com*

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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.