

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

References

1. Shetty Y, Marathe P, Kamat S, Thatte U. Continuing oversight through site monitoring: experiences of an institutional ethics committee in an Indian tertiary-care hospital. *Indian J Med Ethics*. 2012 Jan-Mar;9(1):22-6.
2. Pandiya A. Quality of independent review board/ethics committee oversight in clinical trials in India. *Perspect Clin Res*. 2011 Apr;2(2):45-7.
3. Thatte U, Bavdekar S. Clinical research in India: great expectations? *J Postgrad Med*. 2008 Oct;54(4):318-23.
4. DeMets DL, Fost N, Powers M. An institutional review board dilemma: responsible for safety monitoring but not in control. *Clin Trials*. 2006;3(2):142-8.

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