Evolving roles of ethics committees in India

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A national conference on the evolving roles of ethics committees in India was held on May 31 and June 1, 2013.The conference was organised by the Apollo Hospitals Education and Research Forum, and supported by the Indian Council of Medical Research, Apollo Hospitals, Sanofi, and Quintiles.

The stated objectives of the conference were to provide an overview of the workings of research ethics committees and practical training on the review and oversight process of clinical trials. It was also to discuss the development of guidelines and laws pertaining to ethics committees. It was designed for ethics committee members, investigators, members of regulatory bodies and non-governmental organisations, project managers and directors, and others in the field of contract research.

While India has had a vigorous clinical trial industry, recent ethical controversies have led to a downward trend in the clinical trial field. This has also been accompanied by a "restrictive and sometimes not so facilitatory environment". The role of the ethics committees is seen as extremely important in re-establishing credibility and trust in the clinical trial system for regulators and the public at large.

As the title implied, the conference focused on the role of ethics committees (ECs) in India, especially in the light of the above. It was acknowledged that the pharmaceutical industry itself could not go forward without well functioning ECs at all levels in the system. Most sessions dealt with how to structure and operate an EC, including the need to train members of the committee. Developing a quality culture for ethics review including standards, best practices, self assessment, flexibility, and independence is also essential. A question was addressed to the group as to how many ECs had a policy on exposing fraud and plagiarism. One EC reported having a clear policy on not tolerating plagiarism; none had a clear policy on exposing fraud.

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. It has a website and produces an on-line journal which is available to those who pay a fee to join the organisation.

There are studies that indicate that in institutions where clinical trials were conducted, there is better patient care. There is a need to educate the public on this and other potential benefits—a need to engage these stakeholders. Those responsible for ethical research are not just the investigators but also the sponsors.

Questions were raised by Rule 122DAB-1 of the Drugs and Cosmetics Rules, especially in terms of compensation to subjects for injury and death. What is the definition of trial- related injury? Should those who receive placebo be covered for injury or death unrelated to the trial? How should compensation be calculated for injury or death? Who decides if an injury or death is study related? How long should the sponsor be liable after the study has been completed? If everyone who dies in a study is to be compensated, how will studies be done on any terminal disease, especially where the treatment may intentionally put the patient in harm's way? Why should there be compensation for a failure of intended benefit since that is often unknown when the trial begins—ie how can the intended affect be guaranteed? Connected to this question is the concept of equipoise. The compensation policies of the United Kingdom, the European Union, Australia, and Peru were reviewed.

The 10-day turn-around period for reporting an injury or death was seen as inadequate, and suggestions were made for this requirement to be changed to two weeks to a month. The Drugs Controller General of India was asked to define what is meant by a 'clinical trial' and a 'trial sponsor' and to issue a written statement on this, as the answer to these questions was not clear to all in attendance. As one speaker observed, in times of conflict and public agitation there is a great opportunity for positive change.