Ethical issues in international health research

The programme for this five-day meeting on the ethical dimensions of international health research, in Durban, South Africa, described it as a forum to address various ethical controversies arising from the growth in collaborative health research in developing countries.

"As more and more health research is being conducted in developing countries, practitioners, funders, and overseers are increasingly forced to deal with ethical controversies and conflicts arising from the differences in cultures, politics, wealth, standards of care, individual and group rights, and priorities."

Sixty-five participants (from medicine, research, community health organisations, journalism, ethical review boards, and the pharmaceutical industry) and 12 faculty members gathered at a resort near Durban for the period of the seminar. The participants from India came from the All India Institute for Medical Sciences in Delhi, the National AIDS Research Institute in Pune, and Mumbai.

Solomon Benatar, director of the Bioethics Centre at the Faculty of Health Sciences, University of Cape Town, South Africa, spoke on the general principles of health research ethics.

The recent interest in ethics stems partly from controversies in AIDS research. Also, the quantum of medical research has gone up sharply, as have reports of violations of existing ethical guidelines for health research. There is the question of access to research, and to the products of research. At present, 90 per cent of the world's research is done on 10 per cent of the world's problems.

The principle-based approach to bioethics — using the principles of beneficence, non-malfeicence, autonomy and justice — was presented as providing a framework within which these problems could be addressed.

A discussion on professional ethics was led by Kenneth Winston of the Kennedy School of Government. The purpose was to explore the conflict between one's moral responsibilities as a member of the human community, and one's professional obligations.

Robert Levine, Chair, Human Investigation Committee Yale-New Haven Medical Centre, outlined the history of research ethics, from the protectionism of the 1960s, to viewing the benefits of participating in research. He argued that the Helsinki document's distinction between therapeutic and non-therapeutic research is illogical, out of touch with current ethical thinking, and widely disregarded. He proposed two changes to existing international ethical guidelines: that the distinction between therapy and research be removed, and that the standard of care for participants be based on the "highest attainable and sustainable care available in the host country".

The proposals sparked off extended debate with strong views expressed against and for the proposed revisions.

H. M. Coovadia, investigator in childhood HIV in Africa and member of the Institutional Review Board at the University of Natal, presented the history of the standard-of-care controversy.

This debate dates back to 1995 when the *New England Journal of Medicine* challenged on-going research on short courses of antiretroviral drugs to reduce vertical transmission of HIV. A longer course, known as the 076 regimen, had already been proved effective, but was felt to be too expensive and logistically unsuitable for developing countries. These trials, conducted on over 15,000 women in Asia and Africa, were called unethical because the control group received a placebo, even though an effective treatment existed. The *NEJM* argued that the trials violated the researchers' primary responsibility to the study population (asserted in international ethics guidelines) as health provider.

Professor Coovadia mentioned ethical, logistical and economic arguments to support placebo-control trials in specific situations. The longer course was neither affordable nor implementable. Its efficacy was unproven in a breast-feeding population. Finally, local institutional review boards could make autonomous decisions. Finally, this research eventually led to the development of successively cheaper alternatives to the 076 regimen. This presentation, too, provoked a good deal of discussion.

To the suggestion that economics was used to drive science and the ethics of scientific research, Professor Coovadia responded that the placebo-control trials concerned both scientific and economic issues. He did concede that decision-making had sometimes been blurred in what had become an emotion-charged debate.

Other sessions discussed issues in policy setting on health research, researchers' obligations to the community, ethical review processes and the functioning of institutional review boards, international research and the law, informed consent in the cross-cultural context, ethical issues in randomised clinical trials, conflict of interest, scientific misconduct and the regulatory process.

Many of the issues discussed at the workshop concern Indians greatly. Collaborative research is increasing in India. There is a need for greater awareness of and discussion on medical research ethics, translating into better, more ethical research in India.

Sandhya Srinivasan

The meeting was sponsored by the Africa Centre for Population Studies and Reproductive Health, the South African Medical Research Council, and the University of Natal (in South Africa); the Harvard School of Public Health, the Kennedy School of Government, the Tufts University School of Medicine, and the United States National Institutes of Health (US); and the Wellcome Trust, UK.

Ms Srinivasan's participation was sponsored by the organisers. Travel and related costs were funded by the Institute for International Education, USA (through the Ford Foundation, India), and the Adenwalla Trust, Mumbai.

Sandhya Srinivasan, *8 Seadoll, 54 Chimbai Road, Bandra (W), Mumbai 400 050.*