The ethics of international biomedical research

 Needs a commitment to high values in an open discussion with a variety of partners

The combination of the increased burden of AIDS in the developing world and the absence of affordable therapies and vaccines has raised the sensitivity of health professionals to issues of ethics and equity in international biomedical research. Foremost among the concerns is whether new treatments should be compared against Western standards of care or against existing local standards. Other thorny issues include whether communities can benefit from research they have taken part in when they may not be able to afford the new interventions that they have helped prove efficacious and how researchers and their institutions in developing countries can be strengthened through international collaboration. Strong emotional responses and increased entrenchment have begun to characterise the discussion on how to design and conduct international biomedical research.

The importance of these issues for the international research community is reflected in the current debates on revising the World Medical Association’s Declaration of Helsinki and the Council for International Organisations of Medical Sciences' International Ethical Guidelines for Biomedical Research Involving Human Subjects, as well as in some of the considerations in the WHO's Operational Guidelines for Ethics Committees That Review Biomedical Research and the Joint United Nations Programme on HIV/AIDS (UNAIDS)' guidance document, Ethical Considerations in HIV Vaccine Research. These discussions bring out the concerns of the international community of researchers, ethics committee members, sponsors, and others regarding research in developing countries. The importance of these issues to society as a whole is further reflected by the recent public inquiries into the ethics of biomedical research in developing countries by the Nuffield Council on Bioethics in the United Kingdom and the National Bioethics Advisory Commission in the United States. The draft reports of these groups examine complicated and difficult issues, such as differences in cultural values and levels of healthcare, informed consent, post-study benefits, appropriateness and implementation of ethical guidelines, and the various roles of ethics committees.

Those who venture into the discussion on international research have an obligation to begin with fairness as the principal rule of engagement, concerned that each party will have an equal share in what is brought to the table, and each will leave feeling equally satisfied. In reality, there is the overwhelming power of assertion among some participants and the temptation of expediency urging deference on the part of others.

The economic, social, technological, and political situations of disparity that weigh so heavily on this discussion should, however, not be used as reasons to disparage it. Parties affected by proposed health research projects need to become increasingly involved in designing and carrying out the research. In support of this, the role of local and national ethics committees in developing countries is becoming increasingly important. Similarly, local research institutions and scientists are gaining stronger roles in international research projects. There is also broader recognition of the need and value of consulting local communities and involving potential participants in research early on in the process of designing research protocols.

However, more effort needs to be made to provide an opportunity for all to participate in the discussions on ethical issues in international research, particularly the patients and communities of developing countries. Electronic discussion groups and individual responses to questionnaires do not constitute full participation in decision making. Local and intercountry forums should be set up to include, not only researchers, but also members of ethics committees and representatives of communities and patient groups. These forums will enable all of us to develop a better understanding and appreciation of the ethical issues.

Given the enormous disparity between the parties involved in international research, it may not always be possible to achieve unity.
or even consensus. On the other hand, to allow any one voice (or group of voices) to dominate the conversation would be irresponsible. By fostering fairness and demanding a strong commitment to the highest values, we contribute to the power of health research to more fully address the urgencies of disease and the inequities of healthcare.

M A Lansang, professor of clinical epidemiology and medicine.

University of the Philippines, Ermita, Manila 1000, Philippines (mlansang@mail.upm.edu.ph)

F P Crawley, chairman.

Ethics Working Party, European Forum for Good Clinical Practice, 3010 Kessel-Lo, Belgium


© BMJ 2000

This article has been cited by other articles:

(Search Google Scholar for Other Citing Articles)

Declaration of Helsinki? Fair partnerships support ethical research Gains and losses for rights of consumer and research participants. Research will be impeded. Some clauses will hinder development of new drugs and vaccines. BMJ 323: 1417-1423 [Full text]


Rapid Responses:

Read all Rapid Responses

Ethics of Healthcare-related Research in Developing Countries
Yvonne Melia
bmj.com, 24 Oct 2000 [Full text]

Ethics in international health research: the role of transnational organizations
Fernando Lolas
bmj.com, 3 Jan 2001 [Full text]