

REPORT 2

Bebe Loff, Karen Hofman, Vasantha Muthuswamy

Over the past decade, funding for international research in low and middle-income countries has grown. As research activities have increased, so has the number of complex questions concerning the social and ethical dimensions of collaborative research. While the scientific and lay press have begun to take note of these concerns (1, 2, 3), until recently no platform existed for individuals from the developing world who are responsible for the ethical conduct of research in their countries, to engage in dialogue about how these issues might be approached in their own countries and in international collaborative research.

This report describes the activities of the Second Global Forum on Bioethics in Research (4), the most recent in a series of colloquia designed to examine conceptual and practical challenges arising from cross-cultural research and to provide guidance in improving institutional capabilities in bioethics in the developing world. Working with the US National Institutes of Health, the United Kingdom's Medical Research Council, the South African Medical Research Council and other international agencies, the meeting was hosted in Bangkok, Thailand, in October 2000 by the World Health Organization. At both the inaugural meeting held in 1999 (5) and the Bangkok meeting, the predominant representation was from the developing world.

The focus of the meeting in Bangkok was on;

- Capacity building for ethics review in developing countries
- The benefit of the process and products of research to the host country; and
- The impact of international and national intellectual property rights frameworks.

This report provides background on these issues and a sense of the discussion in Bangkok.

Capacity building for ethical review

If countries hosting collaborative research are to be full partners in the research process, it is crucial that they have their own capacity to conduct a thorough ethical review of research proposals. This may not be so simple, since the precise elements that constitute capacity are not clear. Some say that adequate capacity requires a properly constituted ethics review committee that follows fair and transparent procedures. For example, the WHO's *operational guidelines for ethics committees that review biomedical research* (6) states that "Ethics Committees should be multidisciplinary and multi-sectorial in composition, including relevant scientific expertise, balanced age and gender distribution, and laypersons representing the interests and concerns of the community." These guidelines go on to specify a series of requirements for review of applications including assessment of the nature of community involvement prior to and during research, and the extent to which the community will benefit as a consequence of the research.

A panel discussion at the Bangkok meeting highlighted some of the shortcomings of improving ethics review capacity alone. Even within the confines of an ethics committee, serious ethical debate could be problematic in social and cultural milieu lacking a tradition of egalitarianism or in an environment in which challenging authority is unusual. In settings in which unfounded but strongly held discriminatory presumptions operate with respect to gender, caste or race, it seems unrealistic to expect that ethical review will redress this. The self-interest of governments, of

researchers and the privileged few who may become members of these committees might influence the committees' deliberations and judgements, and without transparency could be difficult to regulate. Corruption or bias may be blatant or may be manifested in understandable loyalties to family, clan or region. Committees are not independent from economic and social pressures. These issues represent a significant challenge for capacity building in developing countries.

Benefiting the community

One common criticism of the conduct of medical research in developing countries is that those who ought to benefit as a result of research frequently do not. This is particularly true of participants in resource-poor settings. The indirect benefits of research may include provision of training, facilities, building capacity for independent scientific and ethical review, the creation of collaborative research opportunities and the recognition of community contribution in publications and research forums. Beyond the indirect benefits, however, the obligation to make successful interventions available to participants, and even more broadly to their communities and populations, is still hotly debated. However, the principle of reciprocity of benefit between those performing the studies and those volunteering as participants is increasingly being accepted as a requirement of ethical research, though there is no consensus on the appropriate scope of the obligation.

The Global Forum on Bioethics in Research in Bangkok contributed to the on-going debate on this issue by presenting three case studies that illustrated different approaches to negotiating and providing benefits to the community in three different settings at three stages in the research process. The cases were subsequently discussed in small breakout sessions during the meeting. The first case illustrated an elaborate process of negotiation between industry and the government of Thailand before initiating research on an AIDS vaccine. The second case illustrated lengthy negotiations about drug pricing, in this case medication for river blindness, a product that had been available for many years for veterinary purposes. A neutral body, in this instance the World Health Organization, acted as mediator. The final case illustrated the complexities of prior agreements. The Africa Centre for Population and Reproductive Health in South Africa presented a video documenting the difficulties and the detailed negotiations required after the research had begun because the perceptions and expectations of the community were changed during the process of participating.

Conclusion

Capacity building is a key first step in promoting ethical conduct and all efforts to do so should be encouraged to continue. These include efforts such as the Forum for Ethical Review Committees in the Asian and Western Pacific Region that could be used as a model for other regions, funding by donor governments such as the grant provided by the Government of Norway to promote collaborative ethics training between the University of Bergen and Thammasat and Mahidol Universities in Thailand, as well as the International Bioethics Education and Career Development Award funded by the Fogarty International Center and National Institutes of Health in the United States. There appeared to be some general agreement that while the value of a template for conceptualising and negotiating community benefits in advance of trials would be useful, this cannot be a 'one size fits all' arrangement. Extensive developing country input is required in the drafting of such a prototype.

Finally, the participants at the Forum hoped that the agenda for the next forum in the Gambia in 2001 and those that follow would continue to provide a platform where ongoing and unresolved issues can be openly discussed.

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Bebe Loff , Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Victoria, Australia;

Dr Karen Hofman , The John E. Fogarty International Center, National Institutes of Health, Bethesda, Maryland, USA;