REPORT 2

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The Global Forum for Bioethics in Research: Report of a Meeting, November 1999 (Journal of Law, Medicine and Ethics; Summer 2000; 28,2)

The first meeting of the Global Forum for Bioethics in Research was initiated by the Fogarty International Centre of the National Institutes of Health (NIH) and sponsored by the World Health Organisation (WHO), the Pan American Health Organisation (PAHO) and the NIH. Held in Bethesda on November 7-10, 1999, the intent was to bring together individuals involved in medical research in low- and middle-income nations to share views with each other and with organisations that support clinical research. Approximately 120 persons from 34 countries participated, including individuals from developing countries, pharmaceutical organisations, and communities where medical research is under way.

The participants addressed the partnerships required between research sponsors and investigators involved in clinical trials in developing countries and the long-term needs for international multicentred training programs.

In opening presentation, Professor Solomon Benatar (University of Cape Town) reminded the audience of the history of abuse during human research and the importance of protecting vulnerable research populations in the developing world. He suggested that the attractiveness of performing research in low- and middle-income countries was equivalent to a "sweatshop" developed to produce information for markets elsewhere. He noted the difficulty of performing research ethically in these countries. Acknowledging that seeking universal rules for research is laudable, he emphasised that health care delivery is significantly different in the developing world than in many of the countries funding research and that interaction of these two factors cannot be overlooked. Widening economic disparities and other effects of globalisation, including resurgence of armed conflict and profound disruption of social and family life, are having a dramatic impact on health, disease and human well-being globally. Professor Benatar suggested that the concept of intellectual property rights and the need for sustainable financing of health goals world-wide need to be re-examined in the context of new formulations of ethics and economics.

Dr. Robert Levine (Yale University) commented on the process of revising existing guidelines, including the Declaration of Helsinki, and the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS). Issues pertinent to revision of the Declaration of Helsinki include the concepts of "therapeutic research," "best proven therapeutic method," and placebo-controlled trials. CIOMS raises concerns about possible misinterpretations related to externally sponsored research and standards for ethical review in different countries.

Dr. Francis Crawley (European Forum for Good Clinical Practice (EFGCP) and UNAIDS) focused on guidelines formulated by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The goal of ICH is to develop common standards that bridge the regulation and practice of international research on pharmaceuticals. A newly formed Global Co-operation Group will work closely with WHO to facilitate dissemination of information in regions outside of Europe, Japan, and the United States.

Discussion.

The forum discussions centered on the issue of distributive justice internationally. The participants expressed diverse views on topics that ranged from the ethics of placebo-controlled trials to the standard of care required for study populations and the accrual of research benefits to these populations. The discussions frequently reverted to fundamental questions of resource allocation, inter-country disparities, decision making, and balance of power.

Ethical Concerns.

On the use of placebo-controlled trials, when a proven therapy becomes available, economic issues should not be the determining factor. The participants pitted this sentiment against concerns about ensuring scientific validity and reaching conclusions as rapidly as possible in order to act on the basis of evidence on behalf of all affected individuals.

Benefit Sharing.

The participants pleaded for broad consideration of the sharing of research benefits (e.g., the availability of the products of research) in host countries. They noted that improvement of health care accessibility for populations in studies and host countries is critical. Most participants concurred that sponsors, host governments, and researchers should strive toward arrangements that emphasise technology transfer and capacity strengthening, rather than simply supplying a product to a population.

Process.

The participants emphasised that research partners should adopt an explicit, transparent agreement on benefit sharing before initiating a study. Sponsors should be honest about their interests in, and motivation for, supporting the research, and host countries should clarify their intentions on completion of a study. The participants expressed concerns about the political and social contexts for research. They recognised that negotiations among stakeholders may reflect imbalances of power, but they did not agree on how to handle this issue. Mixed feelings were expressed with regard to public-private partnerships.

Communities as stakeholders.

The participants felt strongly that communities should be empowered to act effectively as major stakeholders in research studies. Defining who constitutes the community, who speaks for the community, and how best to achieve community involvement is a primary concern, especially with the current trend toward globalisation. The participants highlighted as exemplary the active role of communities in HIV/AIDS research and noted that community advisory boards have emerged as a useful model. Researchers, sponsors, and host governments may have to relinquish their primary roles in choosing research topics and structuring research projects. Inevitably, the ethics and paradigms of research will have to change to accommodate new stakeholders.

Training.

Few, if any, existing training programs are focused specifically on research ethics or on long-term bioethics training for investigators from developing countries. At the meeting, an international panel of individuals involved in bioethics training conveyed a sense of urgency about co-ordinating ethics and human rights programs, especially for developing countries. The participants agreed on the need for training and capacity building in human subjects' research, research methodology, and medical ethics.

Next steps.

In his closing remarks, Dr. Nelson Sewankambo (Makarere School of Medicine) stated that the forum could have a major role in changing the process for conducting research in developing countries, including the revision of guidelines. He called on developing countries to re-evaluate and take responsibility for implementing Western and internally sponsored research. These forums could continue to serve researchers and research sponsors from developing and developed countries by providing an opportunity to exchange views in an environment that fosters mutual learning and to open up the process of revising international guidelines. The participants enthusiastically supported the prospect of convening annual forums. They agreed that a consortium of sponsors is urgently needed to develop a long-term training initiative in the bioethics of research, which would be offered in various countries. This new paradigm of support for international activities would have positive transcultural implications and help establish linkages between research funded by various international organisations and capacity development in bioethics. The second forum on Bioethics in Research is scheduled for October 2000 in Bangkok, Thailand.