

## Ethical aspects of clinical research in developing countries

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**The University of Malawi College of Medicine hosted an international meeting on ethical aspects of conducting clinical research in developing countries (26-28 March 2001, Mt. Soche Hotel, Blantyre). The meeting was jointly organized by the two groups within the U.S. National Institutes of Health, the Department of Clinical Bioethics and the Parasitology and International Programs Branch (Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases). The 24 participants came from eight African countries (Malawi, Kenya, Uganda, Ghana, Egypt, Nigeria, Mali, and Tanzania) and included investigators as well as members of local ethical committees. Representatives from the College of Medicine attended many of the sessions and participated in the discussions that followed each presentation.**

Professor Robin L. Broadhead's thoughtful and articulate comments opened the conference and set the tone for the rest of the sessions. He introduced Dr. Joseph Mfutso-Bengu, a medical ethicist who has recently joined the College of Medicine as a senior lecturer in the Department of Community Health (see below), commenting that Dr. Mfutso-Bengu's appointment is tangible evidence of the College's commitment to bioethics, and reaffirms its intention "to infuse clinical research with the best moral and ethical considerations in order to maintain the integrity of the research and to safeguard the well being of the populations in which it takes place."

Professor Broadhead highlighted the challenges inherent in conducting research in different cultures and societies. We can "break new ground in our appreciation of common aims and objectives", but we must "listen to each other with care, attention and respect". The most basic aim is to conduct clinical research that will benefit humankind now and in the future. In the process, we "seek to cause no harm directly or indirectly to anyone, nor to exploit any person as a means toward this goal." However, the means by which this aim is pursued may differ from country to country, from setting to setting. Sustained discussions, such as those sparked by the presentations in this conference, will help to illuminate the issues involved in developing the appropriate means to conduct relevant and important clinical research. Professor Broadhead noted four areas that create challenges for investigators working in developing countries:

\* *Poverty*: "Poverty essentially takes away choice. It imposes an awesome asymmetry in the ethical equations between resource-rich countries and poor ones."

\* *Autonomy vs community*: "The principle of giving the primacy to 'autonomy of the individual'...has been emphasized by many rich countries, especially those which have embraced

the capitalist free market philosophy. In many parts of Africa, a greater emphasis is given to the community in which an individual exists."

\* *Placebo-controlled trials*: Is it ethical to use placebo treatments for control groups in clinical trials, if 'placebo' is the only locally available treatment, or should control groups be offered the best available therapy, even if it is not locally available, affordable or sustainable?

\* *Informed consent*: There is a consensus that informed consent is a *sine qua non* for participation in a clinical trial - but what does it mean to be informed if one is semi-literate or illiterate? What degree of comprehension is desirable, and is that degree attainable?

Professor Broadhead concluded his remarks by cautioning the participants to "beware those voices who seem to have all the answers to hard questions. This conference will be a success if it can clarify questions, define the dilemmas, and admit that there are some ethical paradoxes that do not admit to easy solutions."

Faculty for the course included members of the Department of Clinical Bioethics (Drs. Ezekiel Emanuel, Christine Grady, and David Wendler), Dr. Reidar Lie (University of Bergen, Norway), Dr. Jeremy Sugarman (Duke University, USA), and Dr. Segun Gbadegesin (Howard University, USA). Their presentations covered the following topics:

- \* Ethical Guidelines and IRB Review
- \* Current Guidelines and Declarations for Clinical Research
- \* Function and Performance of Ethical Review Committees
- \* Informed Consent of Communities
- \* Informed Consent of Individuals
- \* Randomized Controlled Trials and Determining the Standard of Care
- \* Placebo Controlled Trials
- \* Recruitment and Incentives
- \* Stored Tissue
- \* Research with Traditional Medicine
- \* Conflicts of Interest
- \* Evaluating Risks and Benefits of Research
- \* Community Benefits, Intellectual Property Rights, and Making Treatments Available

A companion book, containing background material in all of these areas was provided for each participant, and a copy of this book is available in the College of Medicine library. In addition, electronic versions of the slides that illustrated each oral presentation have been sent by e-mail to each of the participants; these too are available for viewing in the College of Medicine computer lab.

Several of the talks were followed by presentations given by representatives of various research groups in Malawi. Dr. Desiree Witte, working on a measles study in Ndirande, described the experience of informed consent of individuals. Dr. Chris Plowe (University of Maryland) presented a proposed

trial of cotrimoxazole prophylaxis in HIV-positive adults in Ndirande to a "mock IRB" for its consideration and Dr. Kondwani Kayira discussed the use of incentives in an autopsy-based study in the Department of Paediatrics. Each of these presentations sparked a lively discussion involving participants and faculty. Many of the participants used case studies from their own sites to illuminate the discussions. The group found the cases particularly useful, and decided to work to develop a book of case studies, each followed by a discussion of the ethical issues involved. The group also decided to sustain the dialogue engendered during the meeting by establishing an electronic list-serve. The conference was an ideal way to welcome Dr. J M Mfutso-Bengu back to Malawi, and all of the Malawi-based participants look forward to fruitful and useful ethical discussions now and in the future.

The conference came at right time, when the College of Medicine is in the process of launching the Malawi Bioethics Research Unit (MABIRU) in the Department of Community Health. MABIRU is dedicated to nationally and internationally recognized innovation and excellence in:

\* **Teaching**

Educating healthcare professionals, researchers, and students in biomedical ethics in the Malawian context. The ethical principles are universal but their application is local and contextual. In order to accomplish this, MABIRU will survey several of the major philosophical approaches to ethics within and outside the African context such as: deontology, teleology, utilitarianism, casuistry, African-moral philosophy on goodness, evil, justice, health (*umoyo*), humanism (*umunthu*), communalism (*umodzi*) and African taboos.

\* **Research & scholarship**

Enhancing knowledge through research in bioethics and health policy and by offering postgraduate certificates & masters degrees in bioethics.

1. *Program objectives*: The MA programs will provide advanced training for professionals who wish to become prepared for teaching, research, policy development, and clinical work related to bioethics.

The program will include didactic, clinical, and research components; each student will be expected to write and present a Master's Thesis project.

2. *The conditions of admission*: The targeted students for this program are mid-career, high-level, professionals who are seeking to enhance their research, teaching and consulting skills.

\* **Bioethical consultancy**

Assisting ethics committees and health care providers in identifying information, addressing issues, and advising policy and lawmakers in bioethical decision-making and prudence.

MABIRU does not want to be a national medical ethics answering machine, but rather will strive to equip our students and collaborators with the skills for decision making in complex medical ethical dilemmas, where right and wrong are not easily distinguished.

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