Bioethics and public health research, including ethical guidelines related to post-trial access to drugs.

REPORT 1

The ethics of conducting clinical research in developing countries have lately aroused heated debate, largely among those in the developed world. It is hardly surprising that passions are running high when the ethical principles guiding clinical trials have been predominantly created in developed countries. But where are the voices of the developing countries themselves in all this? What are their views on the best ways to protect research participants?

The Global Forum on Bioethics in Research - an informal partnership of several organizations with a shared interest in this area - enables developing-country perspectives to take centre stage. At its annual gatherings, developed and developing country participants come together for frank and wide-ranging discussions centered on practical issues. At the recent Forum in Cape Town, which was organised by the UK Medical Research Council, the problems of pursuing ethical purism were readily apparent. Or as one participant put it: "We can't simply give principles as if shining light down from above; we have to start from the practical and then move to the principle".

The Forum drew the participants - 120 individuals from some 40 nations including 20 African countries - into a process of thinking about very complex ethical issues. This helped them discover where their own values lay and how these values could translate into a new approach for handling ethical challenges. In conducting research, the questions on the science alone are difficult, and when the layer of ethics is added to that, it is often very difficult for the researcher to know which is the best way to proceed.

It was also important for researchers to prepare the community and to carefully think through all the consequences of their study - even of an unexpected harmful outcome - before the research began. This also meant that well-thought out stopping rules and arrangements for what would happen when the trial ends should be set before the study began. An important message for funding bodies was that they should place far more emphasis on infrastructure and on pilot studies.

The issue of consent was highlighted as the cornerstone of ethical practice. There was a need to recognise the legitimacy of different levels of "permission" - which may be needed from communities or families - to access trial participants. However, most participants felt that "community consent" could not replace individual consent. Individual consent also had to be genuine and based on real understanding, and there had to be processes which supported that. There was a lot of discussion on oral versus written consent, with recent research showing that recorded oral consent could in many ways be stronger that a signature or a cross.

Particularly in the case of HIV vaccine trials, there is a real concern about whether rural women in developing countries have enough information about the process and enough autonomy to be able to give informed and voluntary consent. Current ethical codes regarding vulnerable populations, though well conceived, are often simply articles of faith and are sometimes more concerned with legal indemnity. What is needed is a process supporting informed voluntary decision making.

The principle that the benefits and risks of a new therapeutic model should be tested against the best current therapeutic methods - as outlined in the Helsinki Declaration - also came under

scrutiny. Sometimes the best current therapeutic methods were out of reach for a developing country's health care system and, if applied, this principle would make the trial meaningless to the host nation. The relevant question then may be whether the new intervention is better than the currently used and affordable standard therapy.

The ethical principles guiding new interventions had to be judged in the context where research was being carried out, otherwise the research was irrelevant - and therefore unethical.

The forum also brought out areas for further discussion and deeper understanding. The first was the field of traditional medicine - would different standards of science and ethics be applied here? Experiences in South Africa and in India showed that research on traditional medicine may be an area where the developed world might learn from developing countries - particularly as it faces new questions with the growth of alternative medicine in the developed world.

The second subject that took ethics in a new direction was the challenge posed by genomics. The thesis was that inequities in global health were among the greatest ethical challenges in the world today, and genomics had the potential to increase these inequities. However, with timely and decisive action, the unfolding revolution in genome-related biotechnology could be harnessed to improve equity in global health.

Genomics provided the opportunity to take forward scientific thinking, bioethical thinking and regulatory frameworks in a more constructive and interactive way.

"Do we want 'ethics as usual' or should we in fact be defining a new bioethic that promises real world solutions to real world problems?" was the question that summed up this approach.

During the Forum it became increasingly clear that there are seldom right and wrong answers, particularly in such a rapidly changing world. What was more important was to build partnerships where researchers could learn from each other and exchange their views on the infinite complexity of ethics and its interpretation. The Forum was valuable in enabling participants to contribute to this exchange of views on equal terms.

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