

Research ethics—no easy fix ahead

Prospects for a swift end to what has seemed relentless controversy over the ethics of biomedical research on humans looked distant this fall after a high-level meeting to discuss revision of the Declaration of Helsinki ended without consensus. At issue is the need to protect individuals' rights while still permitting trials of new drugs and vaccines, particularly those that might benefit people in poorer countries. However, some experts believe neither need is being properly met.

Drawn up by the World Medical Association (WMA), an international body representing the national medical associations of 70 countries, the Declaration is the most widely cited code of ethics for biomedical research. Revised four times already in its 35-year history, it is under review again (*Nature Med.* 5, 6; 1999). But in London last month, at a meeting organized jointly by the Bulletin of Medical Ethics and the European Forum for Good Clinical Practice, ethicists, patients' representatives and researchers presented radically opposing views about the value of the Declaration and its future, effectively sending the revision process back to the drawing board.

Researchers have long criticized two key features of the existing Declaration. First, it makes a distinction between therapeutic research and "scientific," or non-therapeutic research, stipulating that the latter should use healthy volunteers. This, say critics, suggests that it is unethical for researchers to study the mechanisms of diseases that still lack treatments. Second, the Declaration requires that all subjects receive the best-proven therapy. This calls into question trials of drug treatments that may be less effective than the best but that are also much more affordable in poor countries, such as short-course treatment with the antiviral drug AZT to prevent mother-to-child transmission of HIV.

In an attempt to overcome these obstacles to research, Robert Levine, a cardiologist and ethics expert at Yale University, and others, were commissioned to propose changes to the Declaration earlier this year. One suggestion they made was that patients enrolled in trials of new drugs might be offered not the best-proven therapy but one no worse than the therapy they could expect to receive if they were not participating in the trial. Some critics said that these changes would create double stan-

dards between rich and poor countries, a claim Levine refutes. In fact, the WMA rejected the proposed changes, and instead set up a working group whose report is expected to take many months to complete.

The lack of consensus on how to go forward became obvious within the opening hours of the London meeting, according to Dan Wikler, staff ethicist at the World Health Organization (WHO; see below). In fact, some participants, including Secretary General of the WMA Delon Human, felt that the best way to protect patients was to leave the Declaration broadly alone: "I would say the general consensus was that [the Declaration] is very useful as it is, and so don't tinker with it," Human told *Nature Medicine*. However, he added that the consultation exercise on the Declaration would now be broadened to include groups outside the medical profession.

Vivienne Nathanson, of the British Medical Association, argues that the existing Declaration should be retained as a general statement of principles rather than an operational

document. But other participants claim it is being widely ignored and is becoming irrelevant. "Leaving it alone might leave patients unprotected," says Wikler.

Equally troublesome is the fact that researchers are already avoiding some areas of clinical research for fear of being accused of unethical behavior. Francis Crawley, a philosopher at the University of Brussels and one of the meeting's organizers, is convinced that the Declaration will have to be revised if both patients and researchers are to be protected. "We are in for a long ride on this," predicts Crawley.

Wikler stresses that there is also a need to bring together the half-dozen players that have drafted ethical guidelines for medical research. They include the WMA, the WHO and the Council of International Organizations of Medical Science (CIOMS), a non-governmental organization set up by the WHO and the United Nations, and the Joint UN Programme on HIV/AIDS (UNAIDS). Wikler is hoping to convene the players in Geneva in late 2001 to harmonize the various guidelines.

PHYLLIDA BROWN, LONDON

WHO appoints first staff ethicist

Only weeks into his role as the World Health Organization's (WHO) first staff ethicist, Dan Wikler has embarked on an ambitious project to draw on the expertise of a team of hand-picked philosophers and economists around the world to provide advice to the WHO on ethical issues.



Dan Wikler

The team of 10–12 consultant ethicists will include John Broome from the department of moral philosophy at St Andrews University, UK, Frances Kamm at New York University and Jiwei Ci from Hong Kong University. They will be briefed by WHO staff before participating in a series of meetings over the next 12 months that will culminate in the publication of an official WHO book on ethics. The work will be on display at the biannual World Conference in Bioethics, to be held in London next September.

Wikler is on sabbatical from the University of Wisconsin and was head-hunted to join the "Global Burden of Disease Project," led by Chris Murray and Alan Lopez, which aims "to expand the empirical basis for international public health." Wikler says the WHO is "dipping its toe" with his appointment, as the position of staff ethi-

cist did not exist previously. His recruitment is in line with the organization's efforts to hire specialists rather than rely on career WHO employees (*Nature Med.* 5, 249; 1998). Murray is on leave from Harvard University and Lopez from the World Bank.

WHO provides advice on healthcare issues to its member states and the type of ethical questions that Wikler must consider include the analysis of cost-effectiveness in healthcare. "For example, cost-effectiveness is often calculated in number of years of life gained per dollar spent. But is it right to measure this directly because this makes it biased towards the young rather than the old. Is every year of life equally worthwhile?" he asks.

Wikler will host a WHO meeting on cloning and related issues such as stem cell research later this year. Beyond that, he says that the area of commercial organ transplants must be re-examined: "Thinking around the world has not crystallized on this issue and there are roughly two perspectives: sale of organs should be banned outright, or it's too late to stop and should therefore be regulated." The WHO plans to update its guidelines on the sale of organs after a series of large-scale consultations.

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