A: This is a very important initiative, because there has been so little experience in developing trial registers. We are talking about experience that goes back only a decade and it is a great challenge to make sure it is done well. WHO, as the leading health organization in the world, has a leadership role to set standards. Quite rightly, WHO points out that greater transparency in clinical trials is a moral issue; and that it is a matter of moral concern that the trial process is not more transparent. After all, people are being invited to participate in clinical trials and it should be recognized that there is a duty of care to those people to ensure transparency.

All of WHO's activities depend on country support and it has the challenge of promoting progress at a rate that the major players can accept. It is obviously going to be a matter of judgement how best to do that. For example, a judgement was made recently that registers being developed in China and India should be accepted as primary registers in the WHO platform programme. The arguments in favour are that if you have two large economies like China and India signed up, as well as countries in Australasia, Europe and North America, you are encouraging recognition that this is a global issue that must be addressed at an international level. Others say it was premature to give such prominence to registers (in China and India) that are at very early stages of development.

Q: How do you regard the International Committee of Medical Journal Editors' bid to make trialists and sponsors more accountable by agreeing not to publish results of any trial unless it has been publicly registered before the first patient's enrolment?

A: This was very important, but the trouble is that it came about two decades late. It was precipitated not by the strong scientific and moral reasons for trial registration, but by a law case brought by the attorney general of New York State against a drug company for withholding data that should have been in the public domain. It is a great shame that a law case was needed to make the world's leading medical scientific journals take a stand that they could have made years before.

Surveys have shown repeatedly that a great deal of rubbish is published in medical journals. We need to acknowledge more openly that the much-vaunted ritual of peer review leaves substantial room for improvement. One very senior editor, Richard Smith (a former editor of the *BMJ*), has actually suggested in a recent article that journals should no longer be allowed to publish clinical trials because there are so many biases in the journal procedure itself. One of the ways in which medical journals make their money is by selling reprints of articles, and they know some studies are more likely than others to generate reprint income from commercial sponsors.

The most important thing is to ask the question: "Is the information that is being made available from clinical trial research the best that could be provided to promote the interests of patients and the public?" That should be the yardstick by which proposals are judged. Too often things get in the way – like academic credit, the profitability of journals or drug companies, or undeclared conflicts of interest among investigators. It is important to repeatedly remind oneself that the clinical trials business should be about trying to improve health care and the health of people. But as long as distortions exist in the research design and reporting processes, we won't have done as well as we could for the public interest.

Q: Can we ever expect full compliance and transparency from players involved in trials when so many interests are involved?

A: The Universal Declaration of Human Rights [adopted by the UN General Assembly in 1948] was a declaration of principles to which governments were invited to sign up. It is important that the declaration was issued because it provided benchmarks against which we think the behaviour of human beings to each other should be judged. More than any other actors in this arena, governments are responsible for trying to ensure those principles are observed. The same applies to the problems in current clinical trial enterprises. There are standards that should be set and everyone, particularly governments, should do what they can to ensure compliance.

But there will always be backsliding because the stakes are often very high, particularly the financial stakes for some players in this business. But something else is at stake too, and that is human health. It really does come down to a question on how you balance the interests of human beings who wish to improve and maintain their health, and what we can do about that, against other interests, such as financial, political and academic kudos. ■

Recent news from WHO

- WHO convened a conference in Damascus with the governments of Egypt, Iraq, Jordan and the Syrian Arab Republic on 29–30 July aimed at ensuring health care is provided to the more than 2 million displaced Iraqis living in neighbouring countries since the war in Iraq began in 2003.
- WHO, on 27 July, released the first ever report highlighting children's special susceptibility to harmful chemical exposures at different periods of growth. This new volume of the Environmental Health Criteria series, *Principles for evaluating health risks in children associated with exposure to chemicals*, is available at: http://whqlibdoc.who.int/publications/2006/924157237X_eng.pdf
- WHO announced on 25 July that it was expanding its clinical trial registry platform to include trial registers from China and India.
- The Food and Agriculture Organization (FAO) and WHO, on 19 July, urged all countries to strengthen their food safety systems, and to be far more vigilant with food producers and traders in light of recent food safety incidents.

For more about these and other WHO news items please see: http://www.who.int/mediacentre/events/2007/en/index.html