Helsinki Declaration revisions

In October 2000 the General Assembly of the World Medical Association (WMA) met in the UK. This highest decision-making body of the WMA discussed, among other issues, the wording of the latest revised version of the Declaration of Helsinki (1), the pivotal international ethics document guiding medical research. Nearly two years of international controversy over the document's wording and content came to a conclusion. During this process, the Secretary General reported, the WMA was flooded with hundreds of comments, resolutions and discussion documents from individuals, national medical associations and non-governmental organisations the world over.

At the heart of the controversy were two questions: Is it conceptually feasible to uphold the distinction between therapeutic and non-therapeutic research? Should there be a universal prescribed standard of clinical care or should a local standard of care apply? This report focuses on the second question.

A US-based agenda was the driving force behind the initial changes to the Declaration. The pre-October 2000 version read: *In any medical study, every patient – including those of any control group, if any – should be assured of the best proven diagnostic and therapeutic method.* A draft with revisions to the Declaration, circulated in March 1999, read: *In any biomedical research protocol every patient-subject, including those of a control group, if any, should be assured that he or she will not be denied access to the best proven diagnostic, prophylactic or therapeutic method that would otherwise be available to him or her.*

Obviously an attempt was made to change the parameters of what level of clinical care should be provided to trial participants from a scientific to an economic standard.

A debate ensued internationally over the ethics of this (2). The dividing lines between the debating camps were not clear-cut, but it became obvious that, for instance, of the WMA national member associations, the American Medical Association and the British Medical Association supported differential standards of care, while continental European, Japanese, Latin American and the South African Medical Associations rejected this strategy.(3) The initial proposal to revise the Declaration was made by the American Medical Association. Arguably the AMA and the BMA were more prepared than most other medical associations to accept as a given the economic disparities we see between developed and developing countries. They tried to design a research ethics guideline which allows economic factors to impinge on clinical standards of care, while the other organisations refused to accept this. The German medical association was driven by an absolutist, universalist principle based approach that would not countenance differential standards of care. These different responses are not necessarily an indication of less or greater concern for research subjects in these different countries and cultures; they are indicative of different approaches to and understanding of the Declaration of Helsinki.

The idea of differential standards of care was retained in the draft proposal discussed by the WMA in May 2000: *In any medical study, every patient – including those of any control group, if any – should be assured of proven effective prophylactic, diagnostic, and therapeutic methods.*

Using the example of AIDS treatments, it is possible to follow this guideline to the letter by providing effective treatment that is so substantially below the best proven treatment that it does not ensure the patient's survival.

In October 2000 the General Assembly of the WMA met in Edinburgh. It adopted this version in the revised Declaration: *The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods.*

In trials other than for preventive vaccines this requirement, if adhered to by investigators, would eliminate the possibility of poor research subjects in developing countries being exploited by western researchers.

The revised version of the Declaration includes a note on post-trial availability of drugs to the trial subjects: *At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.* If implemented by trial sponsors, it means that those who made the development and testing of a new drug possible, because they volunteered as research subjects, will be provided any drug successfully tested.

Unfortunately, this will not help prevent deaths in preventive vaccine trials. For example, people infected during HIV vaccine trials will not be provided post-trial with the best proven AIDS treatments. Ongoing UNAIDS-backed trials accept HIV infections of trial participants (for instance those resulting from a research subject's therapeutic misconception) as inevitable, but refuse to provide to these HIV-infected trial subjects essential AIDS medication. The revised version of the Declaration is silent on this matter. Since trial subjects need only be provided with drugs "identified by the study", and preventive vaccine trials will not identify treatments, the Declaration does not require that subjects infected during a vaccine trial be provided essential medication. The consequences will be particularly disastrous for research subjects affected by AIDS.

The standards of current research ethics, as set by the Declaration of Helsinki, are better than what was expected when the first drafts were circulated. It is reassuring that the organisation did not allow itself to be pressured into lowering standards of clinical care *during* clinical trials. However, the WMA ignores the problems preventive vaccine trials will cause.

References:

1. http://www.wits.ac.za/bioethics/helsinki.htm.

2. Schuklenk U, Ashcroft R. International research ethics. *Bioethics* 2000; 14: 158-172.

3. WMA. Memorandum to National Medical Associations July 1, 2000.

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