BMJ

BMJ 2013;346:f2837 doi: 10.1136/bmj.f2837 (Published 8 May 2013)

EDITORIALS

Revising the Declaration of Helsinki

Your chance to influence research governance

Vivienne Nathanson *director of professional activities*

BMA, London WC1H 9JP, UK,

In the middle of the 20th century, the Nuremberg trials laid bare the abuse of medical knowledge and techniques used in human experimentation, with perhaps the most famous offender being Joseph Mengele. The outcomes of the trials included the Nuremberg Code—a legal document intended to stop such abuses—and the establishment of the World Medical Association (WMA). Both were intended to ensure that doctors never again performed such inhuman experiments.

Over the next two decades the newly formed WMA began to put together a core set of policies, designed to reflect ethical thinking, to which doctors were expected to conform. The Declaration of Helsinki, published in 1964,[1] set out rules and limits for human experimentation based on the findings of the Nuremberg trials and an unshakeable conviction that human experimental subjects have fundamental rights that drive a series of duties for the experimenter. Key to its development and adoption was that it was essentially written by doctors for doctors.

Since then, the declaration has been incorporated into national laws in several countries and has been a touchstone for researchers. It has not remained static; changes have been made on eight occasions. Another revision is now under way, and a draft document is currently open for comments for the next month.[2]

The WMA committees, council, and member associations have often struggled to find clear, simple ways to express complex concepts, including the need for balancing rights and duties. An example is finding an ethical solution to what happens to a research subject who benefits from a new drug when a trial is over.

For the past two years a core group has worked with a large number of outside organisations to look carefully at the Helsinki Declaration and to restructure and rewrite it. The aim is to make it clearer, to remove elements seen as mutually contradictory, and to cover some areas previously left undiscussed.

Seven key elements have emerged from discussions. They are: the structure of the declaration, vulnerable groups, post-study arrangements for study participants, research ethics committees, compensation for research subjects, biobanks, and how often the declaration should be amended in the future.

Debate on a revised version of the declaration took place at the recent WMA council, and this has now been published for comments by interested parties. Comments will be taken into account and a revised version considered at an assembly meeting in October.

Most usefully, an annotated version of the draft revision is available for review on the WMA website.[2] It explains what the authors hope their changes have achieved. Some—such as the addition of the words "and wellbeing" to doctors' duties—are intended to reflect the broader emphasis of modern medicine and the essentially holistic nature of "doctoring." Throughout, the use of the words "must" and "should" has been carefully considered; the first is an absolute and the second a strong steer that recognises the existence of exceptions. The text is, for the first time, divided by a series of subheadings clarifying the focus of different sections.

The report's approach to vulnerable populations, a historically sensitive area, is worthy of mention. Specific groups are not mentioned as they were in previous documents. Instead, the current draft leaves readers to consider the circumstances that might make a group particularly vulnerable and the special protection that should apply. It goes on to emphasise that research on vulnerable people should be carried out only if the same answers cannot be obtained another way, and that the vulnerable group should stand to benefit from the research.

The working group has also suggested substantial changes to the section on research ethics committees, recognising that such committees vary in calibre. The group recommends that these committees must receive a report from the researchers containing a summary of the study's findings and conclusions. What should happen to that report? Should it become part of the transparency processes now seen as essential in medical research? And what should or must the committee do if such a report does not arrive?

Changes to a single paragraph on biobanks make it clear that research on materials or on routinely collected data also requires consent except in exceptional situations or when this would be impossible or impracticable. For some, who call for specific informed consent by all subjects in all cases, this will seem too weak. Others will think that consent is not needed in these circumstances and the placing of material or data in a research

VNathanson@bma.org.uk

repository or biobank is, in itself, sufficient to allow its use for ethical research.

The use of placebos has long been a contentious area. The revised draft tries to clarify when they may be used, while keeping as the central point the need to protect the health and wellbeing of the research subject.

Some items remain unchanged, such as a paragraph stating that doctors who both treat and carry out research on patients must have good reason to believe that participation in the research will not adversely affect their patients' health. But no researcher can know all the risks before doing the research. They cannot know if the research protocol will be beneficial or harmful—if they do, then the research is unnecessary and hence unethical. Some patients might benefit, whereas others may do less well than on a standard treatment. Some patients may be harmed, or even killed. Certainly, researchers must do everything possible to consider the likelihood of benefit and harm, but they cannot know for sure until the research is carried out.

The final version of the new revision of the Helsinki Declaration will depend on the final analysis of the committees, council, and assembly of the WMA. They will take into account all comments submitted by all interested parties—be they researchers, research subjects, lay groups, or healthcare practitioners. Comments should be submitted by 15 June 2013.

Competing interests: I have read and understood the BMJ Group policy on declaration of interests and declare the following interests: I have represented the BMA at the WMA. However, although I have accompanied the current BMA representative to WMA meetings on occasion, I have not been involved in the working group that has debated the revision of the Declaration of Helsinki.

Provenance and peer review: Commissioned; not externally peer reviewed.

1 World Medical Association. WMA Declaration of Helsinki—ethical principles for medical research involving human subjects. www.wma.net/en/30publications/10policies/b3/index.html.
2 World Medical Association. DoH public consultation 2013. www.wma.net/en/20activities/10ethics/10helsinki/15publicconsult/index.html.

Cite this as: *BMJ* 2013;346:f2837