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AEMH (AISBL N° 8510.776.04)-European Liaison Office – Rue Guimard 15 – B-1040 Brussels
Tel. +32 2 736 60 66, Fax +32 2 732 99 72
e-mail : secretariat@aemh.org, http://www.aemh.org

The art of medicine

Reconsidering the Declaration of Helsinki

See Online for appendix

Next year will mark the 50th anniversary of the Declaration of Helsinki. Consequently, the World Medical Association (WMA) is developing its eighth version of the Declaration. This anniversary presents an excellent opportunity to reconsider the problems of the Declaration and how they can be remedied to ensure the document retains its prominent status.

In 1964 when the Declaration of Helsinki was initially enacted, it contained 11 articles and 713 words. At that time, the Declaration was unique. Over the years, ethical guidance on research involving human participants has proliferated substantially to encompass the Belmont Report by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences; multiple laws and regulations, such as the US Federal Policy for the Protection of Human Subjects (known as the "Common Rule", 45 CFR part 46) and the European Union's Clinical Trials Directive; and the eight principles of *What Makes Research Ethical?*. Simultaneously, the Declaration of Helsinki has been revised six times and tripled in size with its 35 articles and 2045 words. The revisions have often been extensive. For instance, the distinction between "clinical research combined with professional care" and "non-therapeutic clinical research" was eliminated after much withering criticism. The article that relates to use of placebos was revised and scaled back multiple times between 2000 and 2008.

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Over the years problems with, and objections to, the document have accumulated. I propose that there are nine distinct problems with the current version of the Declaration of Helsinki: it has an incoherent structure; it confuses medical care and research; it addresses the wrong audience; it makes extraneous ethical provisions; it includes contradictions; it contains unnecessary repetitions; it uses multiple and poor phrasings; it includes excessive details; and it makes unjustified, unethical recommendations. For instance, the Declaration reads like a haphazard list of articles without an overall logical framework. The topics of articles 21 to 24 are literally a jumble: they cover the importance of the research outweighing research risks, the requirement for voluntary consent, the need to protect participants' privacy, and informed consent requirements for competent individuals, respectively.

The document also contains a number of contradictory recommendations. For instance, in article 4 the Declaration claims that it only "binds the physician", but then proceeds in article 30 to delineate ethical obligations of authors, editors, and publishers who are frequently not physicians. Similarly, the Declaration of Helsinki argues that physicians' primary consideration must be to promote the health of patients in article 3. However, article 11 states that physicians who take part in medical research need "to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects". Such protection—eg, self-determination and privacy—can conflict with promoting the health of patients. And, the consensus view is that self-determination should trump promoting health. In addition, the Declaration includes provisions that are ethically important, but have nothing to do with research that involves human participants, such as treating research animals with respect.

The frequency with which the Declaration of Helsinki has been revised—about every 6 years—is itself a problem. Frequent revisions foster sloppiness in drafting and also undermine the legitimacy of the Declaration. To put forward certain ethical requirements—eg, the use of placebos and post-trial access—and then revise and minimise their reach within a few years is an admission that the original claims were mistaken. This process of revision raises doubts about whether the Declaration's guidance is really well reasoned and authoritative; it encourages researchers not to take the Declaration seriously. Genuine ethical obligations do not change every few years.

The next revision must strive to reaffirm and re-establish the central importance of the Declaration and implicitly justify why it should be adhered to. A revision should also work within the Declaration's traditional format—a fairly

short statement of principle. This means the revision must aspire to be a statement of broad ethical principles that avoids details and extensive elaborations and justifications. Consequently, the language should be analogous to that of other enduring documents, much like the American "Declaration of Independence" or the Hippocratic Oath, which use broad ethical terms such as "fair" and "equal" that are subsequently elucidated through application to cases and in laws and regulations of nations.

The Declaration of Helsinki should establish universal, minimum standards without which research is unethical. Specification and application of these broad principles should be done by national laws and regulations and other guidelines, not the Declaration itself. The aspiration must be for a universal document that can be tailored to local circumstances by specification in the laws of individual countries. Similarly, to be authoritative, the Declaration must aspire to what might be considered "tentative immortality". Although revisions may be necessary, the text should be carefully crafted with the objective of enduring for decades rather than just 6-year intervals.

In the accompanying appendix I delineate a proposed revision of the Declaration of Helsinki that addresses the nine distinct problems I have identified, and contains fewer than 1800 words in 21 articles. There are four objections that might be raised to this revision. First, it could be argued that this proposed revision constitutes a revolution rather than an evolution. Critics may find it convenient to dismiss something they oppose as a revolution. Was it a revolution when the Declaration of Helsinki completely revised its subcategories by eliminating the faulty distinction between therapeutic and non-therapeutic research? Importantly, the proposed revision preserves the basic form of the Declaration and the ethical norms that have enduring value but reorganises them into a more coherent guiding document. The process of reorganising the articles into a more lucid, logical, and coherent structure should not be deemed revolutionary since editors frequently reorganise and restructure articles without changing their underlying meaning and significance.

Second, some might argue that this proposal weakens protections. In fact, this proposal clarifies and strengthens many protections, such as those related to risk, stored human samples, and unproven "last ditch" therapies. More importantly, it clearly delineates a floor that all research must exceed to be ethical.

Third, some might object to the way this revision addresses more than physicians. The WMA, it can be argued, represents physicians and only has standing to prescribe duties to physicians. Obviously, the existing Declaration of Helsinki fails to heed this claim: it prescribes obligations to many non-physicians, such as journal editors. More importantly, the authority of a document rests not with who its author or sponsor is, but with whether its provisions are universally ethically valid irrespective of authorship. Authors and organisations that do not contain researchers have proposed other authoritative documents that specify ethical duties for those engaged in research that involves human participants. For instance, the Nuremberg Code was written by lawyers for researchers. Similarly, the Belmont Report that aims for universal validity was written by a National Commission many of whose members and staff were neither researchers nor participants in research and all of whom were Americans. The validity of the Belmont Report inheres in articulating universal truths about research ethics, not in the characteristics of the organisation or its authors. The WMA has solicited the views of many non-physicians in revising the Declaration, including lawyers, bioethicists, nurses, and patients' advocates. If who issues the advice mattered, why should physicians adhere to a document produced from the recommendations of these non-physicians?

Finally, commentators might contend that this revision fails to acknowledge, as one of the WMA's Council writers put it, that the process of revising the Declaration and the final product will be "a political decision!". Stating that what is included in the Declaration constitutes a "political decision" seriously undermines the authority of the document. Ethics must rise above individual or group interests to present what is universally true and binding. Political decisions try to satisfy interests. The unique standing of the Declaration of Helsinki—its authority and legitimacy—inheres in the fact that it is a well-reasoned set of ethical principles binding on all who engage in research with human beings. If it is merely regarded as a political compromise that takes account of the interests of the various national medical associations, why should any researcher adhere to it since it lacks the force of law? Rejecting a revision of ethical guidance as not politically feasible is to make the wrong kind of argument. Either the Declaration of Helsinki is an ethical statement or there is no reason to adhere to its provisions.

The forthcoming 50th anniversary of the Declaration of Helsinki is a perfect moment to reassess this fundamentally important document and revise its provisions to address many long-standing criticisms. If done properly, a carefully crafted 50th anniversary revision would be a statement of general ethical principles that would be universally affirmed and endure for decades as a fundamental touchstone for guidance on research on human beings. Unfortunately, if the next revision results in a document that contains new provisions that will again be quickly clarified and revised, it will undermine the Declaration's important status because it could not "get it right" yet again.

Ezekiel J Emanuel
Department of Medical Ethics and Health Policy, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA 19104–3319, USA
vp-global@upenn.edu

Further reading

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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

Editorial: Fresh thinking about the Declaration of Helsinki (*BMJ* 2008;337:a2128)

Revising the Declaration of Helsinki

Your chance to influence research governance

Vivienne Nathanson director of professional activities, BMA, London WC1H 9JP, UK, VNathanson@bma.org.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 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.

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