

## The Declaration of Helsinki – its history and its future

Urban Wiesing

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Fifty years ago, in June 1964, the delegates of the national medical associations came from all over the world to Helsinki to attend the 18<sup>th</sup> General Assembly of the World Medical Association. The Finnish president of the WMA, Dr. Urpo Siirala, invited the delegates. The Finnish medical association was responsible for organizing the assembly. The delegates might have thought to attend one of numerous meetings, as many others before. They might have thought to be involved in business as usual. Those who thought this were wrong. But the delegates could have hardly imagined the historical significance that would later be gained by this general assembly and by their decision to adopt a certain document. The document they adopted without a dissentient vote would serve for generations of researchers as a point of reference. The document on “Recommendations guiding doctors in clinical research” came to be known as the “Declaration of Helsinki”. It was the first international set of ethical principles for research involving human subjects. In the following years this guideline became the most influential one and still is. One tiny step had been taken by the delegates that would later turn out to be a giant leap. As I said: This happened 50 years ago.

“But the road to the Helsinki declaration was neither straight nor smooth.”<sup>1</sup> The work took more than a decade. The discussion started shortly after the founding of the World Medical Association in 1947, two years after the war, and still in the wake of the crimes committed by German doctors in the concentration camps. In the same year, the Nuremberg Code as a guideline for medical research on human subjects resulted from the “Doctors’ Trial” at the Nuremberg Trials.

What was the Nuremberg Code? And what was its role in history? The Nuremberg code was meant to prevent crimes like those committed by Nazi doctors in the concentration camps. Therefore it demanded to obtain participants’ voluntary consent without any exception. In addition, the code set a limit on reasonable risks and demanded that subjects have the right to leave the experiment at any time. However, the code attracted little interest at first. How could it? It served to justify the judgment of an American military court. It was a secret document in some countries. What authority could such a Code claim to have? This was a difficult question to answer. The Nuremberg Code was an important document, but it did not serve as an influential answer to the demanding situation in medical research. Another answer was needed.

In 1953 a first proposal for a position paper was submitted to the Medical Ethics Committee of the WMA. It was published a year later as the “Resolution on Human Experimentation”. In contrast to the Nuremberg Code, participants’ informed consent was not an absolute condition. It gives researchers a little leeway when it comes to

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<sup>1</sup> Susanne Lederer (2007): Research without Borders: The Origin of the Declaration of Helsinki. In: Schmidt/Frewer: A History and Theory of Human Experimentation. Stuttgart, Franz Steiner Verlag, p. 145-167, p. 145.

research on those incapable of giving informed consent. These patients could be included in experiments if their legally authorized representatives provided consent on their behalf. Even though this first document was vague, very short and somewhat poorly phrased, it shows important characteristics of the subsequent declaration: first of all the resolution stresses the respect for the individual. Furthermore, it differentiates between research on healthy volunteers and research performed on patients for whom medical treatments are considered. This is not mentioned in the Nuremberg Code. And the declaration makes research possible on those incapable of giving informed consent under strict regulations.

Seven years later, in 1961, the Medical Ethics Committee presented the first draft of the declaration. Three additional years of intense and controversial debates had to pass until it was adopted. Many suggestions have been made and discussed - among them the suggestion to implement an article on astronauts, which has not been done. Highly controversial were the questions on research with prisoners and with children. The discussion continued up to the General assembly in Helsinki, and corrections were made until the day before. Finally the declaration was adopted in a version that represents the character of the further versions: A compromise, balanced, far away from unrealistic demands, but clear in central norms for the protection of participants. Research with children was not totally prohibited, but regulated, and the same goes for prisoners. Realism is one of the characteristics that makes and has made the declaration acceptable for 50 years.

### **Medicine and human subject research: a dilemma**

The declaration is the most imported document of ethical principles for the regulation of research involving human subjects. But why did it gain such an importance? The declaration is what it is because it gives an answer: an answer to a question that is desperately needed to be answered in modern medicine; an answer to the fundamental ethical question of research involving human subjects, an answer to a dilemma.

What is the dilemma modern medicine is confronted with? On the one hand, modern medicine knows that precise knowledge concerning the efficacy and safety of interventions can only be gained from research involving human subjects. Animal or laboratory experimentation is necessary and a prerequisite to clinical research. But they cannot provide the knowledge relevant for medical practice. On the other hand, research involving human subjects is fraught with ethical conflicts that cannot be completely prevented. If one conducts research on human subjects, there will always be the risk of harming them. Exposing the patients to such risks is inconsistent with the medical professional's obligations, especially with the old Hippocratic principle *primum nil nocere*, do no harm. However, harmful effects are inevitable in research. If the researcher knows beforehand that the patient will not be exposed to any risks because the intervention is effective and does not inflict any harm, then no further research is needed.

Research involving human subjects is controversial because of the risks. Therefore one might think that it is morally preferable to abstain from research involving human subjects. But this idea is fundamentally wrong. Abstaining from conducting this research to avoid ethical conflicts would mean treating future patients with previously untested drugs. This would significantly lessen the quality of medical practice. And now we are arriving at one of the central dilemmas of modern medicine: The

unsolvable problem lies in the fact that physicians are *not* permitted to use empirically untested interventions but are simultaneously not supposed to empirically test them. The ethical principle “do no harm” cannot be realized in therapy without clinical research. But clinical research is ethically critical because it violates the principle “do no harm”.

This ethical dilemma is much older than the Declaration of Helsinki. The ethical dilemma arose when medicine wanted to become a science based discipline. And the declaration is by no means the first regulatory response to this conflict. Some national institutions had been aware of this problem since the end of the 19<sup>th</sup> century. They adopted regulations and continued to do so in 20<sup>th</sup> century. These national regulations emphasized, among other things, the patient’s informed consent as a requirement for research. But they had little influence. They failed to prevent the unspeakably cruel experiments performed on inmates of the Nazi concentration camps. That means: The fundamental problems of research involving human subjects were known, but the response thereto was insufficient.

These ethical problems grew larger with the increase in complexity and power of medicine. It grew larger with scientific progress. In addition the problem grew larger with the altered self-conception of the people. They did not want put themselves at the disposal of medical science without being asked. They simply did not want to become guinea pigs. An increased awareness of the ethical issues called for new solutions. Moreover, the Nazi crimes and other scandals in medical research threatened to undermine the public’s faith in the entire medical community. The Nuremberg Code was one answer but more or less unknown. The Declaration of Helsinki gave the most important answer to the dilemma associated with research involving human subjects.

This is the historical achievement of the declaration. It gives an answer to an unavoidable dilemma of modern medicine, to an unavoidable conflict between the role of a physician and the role of a researcher. The declaration regulates an unavoidable tension between exposing current patients to risks for the benefit of future patients. Therefore the declaration stresses the protection of the participants on the one hand and medicine’s need for research on the other.

## **Final part**

After the adoption of the declaration the inevitable happened: the declaration was debated. It was classified from the very beginning as too permissive by some commentators and as too restrictive by others. The debate on whether the Declaration of Helsinki is too “research-friendly” or too restrictive persists up to the present day. But if a document is criticized to be too liberal and also criticized to be too restrictive it may very well be a balanced compromise.

In an open society, in the modern world the Declaration of Helsinki is the object of controversial discussions. This is unavoidable; it is a sign of an open society. It has to be welcomed; it is nothing but necessary. It can only serve to improve the document. There is no doubt: The international literature on the declaration was extremely helpful for the last revision process and I am sure for the others as well. And – I assure you by my own experience – the WMA is willing to lead such a discussion. The WMA – the proud owner of the declaration, as they call themselves – does not

shy away from any debate. The declaration is a living document that is adapted to a changing environment and improved.

However, regardless of the debate on certain revisions and paragraphs, the declaration as a historical document is uncontroversial. For with the adoption, much more has been accomplished in terms of implicit judgments than visible at first glance. What does this mean? Allow me to explain.

First of all the Declaration of Helsinki embodies the acceptance that research involving human subjects not only has scientific and technical but also ethical dimensions. It underlines that the ethical aspects can by no means be answered by science alone. More than science is needed, what is needed is ethics. In this respect, the declaration is also based on the acknowledgment of the limits of science. It is a document of scientific prudence. Science can say how the world is, yes, and better than ever before. But science cannot say how the world should be. Science can say how one is supposed to go about researching something, but not whether it should be researched at all. The declaration is based on the acceptance of these fundamental theoretical distinctions and argumentative integrity. Therefore it is a document of argumentative transparency. In this sense the declaration is simply modern.

The declaration also secures trust. Thanks to the declaration and others this research no longer has an exclusively negative image. The declaration not only limits research on human beings, but it also legitimizes it. The declaration not only protects the participants but the researchers as well. This not only stabilizes the medical profession but gives the system of research hope that the people will accept it. The acceptance and trust in research is essential in modern, open societies.

The declaration expresses a profession's will and capability of self-control. I have to remind you that other institutions, organizations etc. could have adopted a comparable regulation. But that is not what happened. The declaration was created and adopted by an organization of physicians for physicians, thus creating a close relationship to the profession and the professionals. The declaration remains an expression of professional self-reflection. It is living proof that a profession can regulate not only scientific but also ethical aspects responsibly.

The adoption and the successful efforts of the World Medical Association for self-imposed regulations confirm the fundamental willingness and ability to learn as a professional self-organization. Thus, the declaration is an expression of responsibility: The medical profession and its world organization are aware of the ethical challenges in conducting research on human subjects. They feel responsible for responding appropriately. The profession has not been forced to do so. The Declaration is an expression of a *voluntary* assumption of responsibility. It is an expression of the free will of the profession and of practical reason.

If the declaration didn't exist it would have to be invented. There is no substitute for the declaration. And there is no declaration 2.0. No, there is only one. And today we are celebrating its 50<sup>th</sup> birthday.

What will happen in the future with declaration? Some things are for sure: The scientific and technological development of modern medicine will go on. They will confront us with new challenges. I only have to remind you of some of the latest

medical projects like individualized medicine, system medicine, new developments in genetics or biobanks. And I am sure there are more to come and are already coming. I am speaking in particular of the Ebola crisis.

In the case of Ebola, we can see how adequate the ethical principles of the Declaration are. We do not need a new ethics in the case of Ebola. However, we *do* need to make new decisions in the face of such a global crisis, but these decisions must be made on the basis of existing ethical principles. The ethical principles laid down in the declaration remain valid. They are applicable to the current situation and indeed helpful.

The Declaration stresses the importance of protecting participants on the one hand and medicine's need for research on the other. Both must be balanced. This holds true when it comes to Ebola as well. A balance between exposing current patients to potential risks for their own benefit as well as the benefit of future patients is absolutely crucial in order to prevent a pandemic. This is precisely what needs to be done in the case of Ebola.

Furthermore, the declaration allows the "treatment of an individual patient, where proven interventions do not exist" under certain conditions and demands that these cases "should subsequently be made the object of research, designed to evaluate its safety and efficacy". This is exactly what needs to be done now. All of these norms are valid and applicable to the global crisis of Ebola. Allow me to reiterate: The case of Ebola illustrates just how appropriate the ethical principles of the Declaration are. We do not need a new ethics but ethically well founded and courageous decisions.

Ebola won't be the last crisis the medical world is confronted with. It would not be realistic to assume that research ethics will not be demanding in the future. But there are good reasons as well that the declaration will meet the challenge. In the past 50 years it was well maintained, and the proud owner – the WMA – is willing to continue to maintain the document. It has always been a document that is up to date – and I am optimistic it will be in the future.

The frequency of the revisions has been questioned. And of course; this is a discussable topic. However, the main question is not how often the declaration should be revised. This is a second order question. The primary question to be answered is: How does it keep providing the ethical principles for research involving human subjects in the face of rapid developments in science and society? And after answering this question the frequency of revisions can be determined. On the one hand the frequency should be low; on the other hand it must be an appropriate frequency to keep up with scientific and ethical progress.

As long as the declaration remains the most important answer to one of the fundamental challenges of modern medicine I have no doubt that there will be good reasons to meet again in 10, 25, in 50 years for the next anniversaries. And where should a meeting take place? There is no doubt: In the city, where it started, where the original version was adopted. James Bond, the famous British secret agent would answer the question very briefly: "In Helsinki, where else?"