

Ethic Principles against Medical Experiments on Humans after 1945

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The atrocities committed by the Nazis were widely discussed after WW II. Attempts to punish perpetrators were made, however due to imperfections of positive law, many turned out to be unsuccessful. However, a process against doctors responsible for unlawful medical experiments took place in Nuremberg (in front of the International Military Tribunal), along with proceedings against other infamous Nazi perpetrators, like Herman Reinecke, head of the General Office of the Armed Forces at OKW (*Oberkommando der Wehrmacht*).

A turning point: The Nuremberg Doctor's Trial

Although prosecution convicted only 16 out of 23 accused doctors, the process was a symbol of condemnation of eugenic theories. Simultaneously, it became clear that a field of cognitive (including medical) experiments has to be regulated by international law. The necessity to grant protection for minors was even more obvious. A few years passed before proper regulations (though in 1947 the Nuremberg Code was passed) were drafted, signed and ratified. The basic assumption behind the idea of securing freedom was expressed in art. 6 of the Declaration of Helsinki:

“In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.”

An analogous regulation is to be found in art. 2 of the Convention on Human Rights and Biomedicine (Oviedo Convention):

“The interests and welfare of the human being shall prevail over the sole interest of society or science.”

World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects

Declaration of Helsinki

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Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964; amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975; 35th WMA General Assembly, Venice, Italy, October 1983; 41st WMA General Assembly, Hong Kong, September 1989; 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996, and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000

A. Introduction

1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.

2. It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.

subjects in their own countries as well as applicable international requirements. No national, ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

B. Basic principles for all medical research

10. It is the duty of the physician in medical research to

The Declaration of Helsinki was passed in 1964 and is a milestone of ethical principles regarding medical experiments on humans. Source: World Medical Association, public domain.

Medical-ethic principles against the abuse of children

The main aim of the above provisions is to ensure that nobody will become subject of experiment against his will. According to art. 6.1 of the Oviedo Convention and rule 28 of the Declaration of Helsinki, an experiment on a child can be conducted exclusively when having permission (in writings) of its representative (parent or custodian). The decision of the representative however has to be accepted by a competent ethic commission. The subject (or his representative) has to be fully aware of rules and conditions. Regardless of internal regulations (civil contracts etc) the subject is also entitled to withdraw his consent during the whole experiment (art. 5 of Oviedo Convention).

Particular protection of children?

Among the most significant regulations it is necessary to mention art. 6.1 of the Oviedo Convention which forbids to conduct any kind of exclusively cognitive experiments (i.e. that do not result in direct benefit for health) on children. It is a commitment that minors cannot be put at risk if they are not expected to benefit from the medical action. Art. 17 lists additional conditions to keep in case of experiment on a child. It can be conducted only if there is no possibility to conduct it on a person capable of giving consent. It is also obligatory to obtain consent of the minor.¹

It must be noted that nearly all regulations dealing with issues concerning minors are included in the Oviedo Convention, which, regrettably, was ratified by only 29 countries. This means that in significant parts of today's world, minors sadly have the same status as adults in the field of medical interventions. Hopefully, the situation will change and regulations granting additional protection will be enforced.

The case of the *nasciturus*

Even though international law is not perfect², generally minors do not have to worry. Only in a few countries (like North Korea) their rights are neglected and it is unlikely that any change of international law could prevent that. There is, however, a group of children, which is either protected very poorly or is a subject of legal exclusion. Art. 18 of Oviedo Convention explicitly allows research on so called *nasciturus* (status of embryo). It later states that law *shall ensure adequate protection of the embryo* but the

1 It is a significant restriction in comparison to medical intervention of another kind, in which case the opinion of a minor should only be taken into account (art. 6 Oviedo Convention). See also rules 28-30 of WMA Declaration of Helsinki.

2 It is not only lack of ratification of Oviedo Convention but also some internal regulations, e.g. until 1995 in state of Mississippi eugenic sterilization was allowed by law.

expression is so unclear and imprecise, that practically every state can decide itself about the rights of an embryo. Another example is a eugenic abortion. In the vast majority of countries, it is legal to kill a *nasciturus* in case of its alleged illness or disability. In my opinion, as there is no relevant difference, that could justify treating the life of an unborn differently than the life of a born child, such legal regulations must be recognized as discriminating.

Conclusion

At the end of the day, it seems reasonable to state that there are two answers on the question whether law provides sufficient protection for children. If it relates to born children, the answer is: in most states definitely yes. But when considering unborn children, the answer is exactly the opposite.

Sources:

Declaration of Helsinki (1964): <http://www.wma.net/en/30publications/10policies/b3/>

Nuremberg Code (1947): <http://www.hhs.gov/ohrp/archive/nurcode.html>

Oviedo Convention (1997): <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm>