

ETHICS IN MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

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ABSTRACT

That we can not assign to the "force majeure". Medicine experience their progress in all its areas contributed to the continuation of the life of man. Advances in medicine due to the research, especially those research involving human subjects, although there is a small number of findings obtained in experiments on animals by means of computer simulations or other not living systems. Research on people nephodni in scientific and research work. In overall medical research which included a man, it is necessary to respect ethical rules and principles. There must be ethical limits to where you can go in research work. For this purpose there are international documents that govern the ethical issues in medical research on humans.

Keywords: *ethical rules, the Hippocratic Oath, the Nuremberg Code*

Introduction

Today's advanced medicine is the result of long work of scientists. That we can not assign to the "force majeure". Medicine experience their progress in all its areas contributed to the continuation of the life of man. Advances in medicine due to the research, especially those research involving human subjects, although there is a small number of findings obtained in experiments on animals by means of computer simulations or other not living systems. Research on people nephodni in scientific and research work. The reasons for such medical research: to understand the causes of disease, to understand the course of the disease, to improve prevention, improve diagnostics, to improve therapeutic approach and to evaluate the safety, effectiveness, efficiency, availability and quality interventions. These include tests of side effects from the use of some medications and other treatments to improve the health and medicine. In overall medical research which included a man, it is necessary to respect ethical rules and principles. There must be ethical limits to where you can go in research work. For this purpose there are international documents that govern the ethical issues in medical research on humans. The inception of the instruments that emphasize ethics in medicine are seen in the Hippocratic oath, which provides the basic ethical principles. It is emphasized the patient's health as the most important concern of the doctor, and the absence of prejudice of national, racial, political, religious, class. Hippocratic oath refers to the ethical principles in the relationship between doctor and patient, but it was necessary to determine the ethical principles for medical research involving human subjects. In Nuremberg Code defined as a result of the Nuremberg trials of the Second World War, presented ten directives concerning ethics in experimentation on humans.

The emphasis here is on the free will of man who undergoes medical research for free pristanok in research. Emphasized that research must be carried out by force, to avoid any unnecessary injuries and pain. The research must be performed only in specialized institutions and qualified scientific researchers. But at the Nuremberg Code is governed only basic ethical principles, therefore, it was expanding with the addition of special provisions for the protection of vulnerable populations, the protocol in research ethics committee overseeing the research, forecasting the risks and publication of results. These issues are regulated by the Helsinki Declaration¹ refers to the ethical principles for medical research involving human subjects, including research on identified human material and data. When it comes to ethics in medical research involving human subjects should be noted bad experiences the world has to Nazi research

¹ Paragraph 7, WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.

on prisoners in concentration camps. In this case the men were forced experiments felt tremendous pain in this life ends.

With these extremely unethical research dozen doctors doing satisfied their curiosity and desire for profit. They performed long unregulated and behind closed doors. Here the question is whether to use the data obtained from these and similar unethical research. In theory meet various views on this dilemma. Some believe that if the obtained results why not be used in medicine, if they can save lives. Others consider that crime victims to be further increased. There are views that such research have no scientific value, because no one will contribution of these results, this research did not reveal anything that modern medicine can not use, and because it had not been officially published, it becomes a question mark their accuracy.

However, it is believed that some papers containing the results obtained from the Nazi doctors, without explaining how they arrived at these results, especially in papers published during the Second World War.

This contributed to create various tools that protect the health of the respondents in the survey, the first Nuremberg Code, now supplemented with the Helsinki Declaration. Helsinki Declaration finds its application in precisely in research involving humans. It was adopted in 1964 by the General Assembly of the World Medical Association in Helsinki, Finland. Experiencing changes in October 1975, October 1983, September 1989, October 1996, October 2000, the 2002 is an explanatory note to paragraph 29, and in 2004, explanations of paragraph 30, and October 2008 suffers last amended by the 59th Amendment to the General Assembly of the World Medical Association in Seoul, Korea. It is mandatory for all medical researchers, but are recommended by other participants in medical research involving people to adopt these principles.

Declaration of Helsinki is an international document fundamental in biomedical research. It established ethical standards and limits in research involving people. It is emphasized that in all research welfare of each researched must dominate over any other interest. Special emphasis is placed on certain populations that require special protection. These are people who can not give or refuse pristanok in research or strongly influenced, such as children, the mentally disabled, prisoners and psychiatric sick. Medical research according to the declaration must conform to generally accepted scientific principles. The ethical principles which must be respected in research involving humans, which are presented in the Helsinki Declaration: the welfare of research subjects; protection of the life of the subject; protection of the health, dignity, integrity of research subjects, right at the discretion of pristanok in medical research, the subject of privacy and confidentiality of information obtained in the survey. In addition, the design and performance of each research study on humans must be clearly shown in the research protocol. The protocol should include a statement of the ethical issues involved and be submitted for review, comments and guidance and approval of the ethics committee for research before you start studying. This committee must be independent of the investigator, sponsor and other improper influence.²

The research must be performed only by qualified individuals, and it is necessary to predict the risks. It takes awareness of the potential researched subject to all relevant aspects of the study. These and many other ethical issues are governed by the Declaration of Helsinki.

Apart from the activities in performing research ethics must find its own application and keeping the study data. What what is important here is confidentiality. Scientist or researcher in no circumstances in their papers to leave the name of its respondent. So there are a few rules of storage and anonymising personal data provided in Personal Information in Medical Research, Ethics Series. They settled general ethical principles for the use of personal information in medical research. Highlighted is the confidentiality of the data from the entity that participates in medical research as one of the ethical principles. Moreover, determined and unified general principles of good scientific practice Good Research Practice, Ethics series where regulated key elements of

² ²Medical Research Council, Good research Practice, Ethics Series, December 2000, 2.

good scientific practice. They altruism, integrity, objectivity, moderate, openness, honesty and leadership. While the key principles in taking human tissues and biological samples for research are set out in Human tissue and biological samples for use in research, Ethics series.

Now medical research on humans must be carried out in conditions like those of Nazi doctors. Now the matter is regulated by the legal system in each country, as with general laws and the rules and guidelines adopted and enacted by government departments, professional bodies, employers or funds. Doctors must respect the ethical, legal and regulatory norms in their country, as well as international norms and standards. In addition they must not reduce or eliminate the protection of the subjects of the research that is provided with the Helsinki Declaration.

The fact is that medicine has very long to use human subjects in their research. Because it is necessary to develop bioethics at the highest level in each of the scientists. Ethical boundaries must be respected. Otherwise, what we see in science fiction movies where a man turns into inhuman creature of artificial viruses in the future will start to worry and reality. In studies involving the man it is necessary to observe the rules of bioethics. When it should and increased regulation of state mechanisms. Need adopting general and secondary laws and regulations for biomedical research. Also, it is the introduction of uniform rules for specific areas of research involving human subjects. Such research must be guided by genuine and top professionals. It takes constant emphasis on ethical principles in medical research. The man must be the subject of experimentation in special conditions and with a written consent in advance, while respecting all ethical values. The massacre of the Holocaust must never be repeated. Ethics should be constantly present in medical research. Its task is to develop awareness of the highest level among scientists about the ethical rules. So, you get the trust of human subjects involved in research that will ensure that their lives would be endangered.

REFERENCES

1. Baruch C. Cohen. The Ethics of using medical data from Nazi Experiments. www.jewishvirtuallibrary.org/jsource/Judaism/naziexp.html#1
2. Medical Research Council. Good Research Practice, Ethics Series, December 2000th
3. Medical Research Council. Human tissue and biological samples for use in research, Ethics Series, April 2,001th
4. Medical Research Council. Personal Information in Medical Research, Ethics Series, October 2009th
5. The Nuremberg Code. Directives for Human Experimentation. Reprinted from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol.2, pp.181-182. Washington, DC: US Government printing Office, 1949th www.hhs.gov/ohrp/archive/nurcode.html.
6. World Medical Association. Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects.