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RESEARCH ARTICLE

DECLARATION OF HELSINKI AND ETHICAL ISSUES

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ABSTRACT

In this work we have done, in the Helsinki Declaration, which was recently published in Brazil by the World Medical Association (WMA), we aimed to reveal the issues that could create ethical problems especially for researchers. This declaration, which contains ethical principles related to medical research on humans, has provided considerable guidance to many investigators and researchers since 1964. Complicated advances relate to research involving human studies. When medical research is decided on human beings, the health and the protection of the rights of volunteers must be subject to ethical standards. Otherwise there is a possibility that ethical problems that will be talked about too much.

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INTRODUCTION

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and 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 52nd WMA General Assembly, Edinburgh, Scotland, October 2000 53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added) 55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added) 59th WMA General Assembly, Seoul, Republic of Korea, October 2008 64th WMA General Assembly, Fortaleza, Brazil, October 2013 (Declaration of Helsinki, 2013). The Helsinki Declaration, recently published in 2013, contains a total of 37 articles. When these materials are examined, it will be seen that human dignity, health, and the rights to protect their rights. For example article 9; "It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.

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The responsibility for the protection of research subjects must always rest with the physician or other health care professionals and never with the research subjects, even though they have given consent" (Declaration of Helsinki, 2013). In medical practice and in medical research, most interventions involve risks and burdens. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects (article 16). All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation. Measures to minimise the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher (article 17) Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed (article 18). In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study.

The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information (article 26). For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden (article 28).

Ethical dilemma may be the Helsinki Declaration Articles

Particularly in the Helsinki Declaration, which was published in 2013, there are articles (30,32,33,37) which could be ethically problematic. "Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorised representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorised representative" (article 30).

Article 30 is a matter of involving a group of patients whose informed consent is not possible. It seems that the recommended path here is based on the requirement that scientific studies should be performed on this group of patients. In cases where the patient does not have the capacity to make decisions on his / her own free will, a legal representative can take over. But if there is no legal representation of this scientific work and the willingness to participate in it, it can be considered as an interference with the autonomy of the investigating physician and the initiator of the ethics committee. "For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee" (article 32).The materials available in the bio-banks are regarded as the ownership of the patient. Because the right to save belongs to the patients, it can prevent the use of these materials with the leave from the patients. For example, the patient may be dead or there may be a problem that can not be reached. In this case, according to Article 32, it is possible to start working with a favorable decision to give ethical board. The state of property, which is a topic that is highly scrutinized by legal circles, can also lead to ethical debates.

"The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances: Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or Where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention. Extreme care must be taken to avoid abuse of this option" (article 33). In the absence of a proven trial, the use of placebo or no attempt at all is acceptable. However, if the scientifically sound methodological reasoning is to be applied to less effective intervention than the best proven method, or if patients who will be given placebo or never will not be able to undergo an additional serious or irreversible wound due to the failure of the best proven best practice, the Helsinki Declaration. It is an unbelievable fact that many new studies that are still in the research phase will be damaging or beneficial to the patients. The non-observance of the rights of the volunteers of the scientists involved in such studies may lead to crucial ethical problems. The attempt to include proven interventions, particularly those applied as standard treatments without the patients, is contrary to ethical principles of autonomy and justice. "In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorised representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy.

In all cases, new information must be recorded and, where appropriate, made publicly available" (article 37). There is a possibility that volunteers may be harmed in this item, which is related to the practice of an unproven attempt by a physician. The fact that there are researches that contradict the principle of non-maleficience the ethical principles cause us to think more about the content of this material. Ethics is about the behaviors that people make at the social scale and which have consequences that affect others and the thinking processes that shape them. As a subfield of philosophy, it deals with what ethics is, what goodness means in terms of behavior and what is good; aims to formulate the ideal behavior of the human being (Aydın, 2006; Kadıoglu, 2001; Yıldırım, 2007). Ethical values are the criteria for thinking processes that determine behavior in mind, and they provide a source of rules governing behavior at the community level. Ethical rules are those that are more concrete than ethical principles and are derived from ethical principles, which guide behavior such as ethical principles (Aydın, 2006; Kadıoglu, 2001; Yıldırım, 2007). The principles of beneficience, non-maleficience, justice and autonomy, which are accepted as international ethical principles. The greatest damage that may occur while providing health care is the death of the patient. Medical faculty students are trained to be benefit to their patients during medical education. In this process, it is also in the direction of "primum non nocere" (non-maleficience) principle which is included in Hippocratic teachings to provide health services without deteriorating the current situation of the patients. Especially beneficience and non-maleficience ethical

principles have complementary processes. Anyone who is willing to benefit from health services under the justice principle shall be entitled to any ethnic origin, material status, gender, nationality, country, religion, profession, it is necessary to ensure that all patients are available without any discrimination. Autonomy requires that patients be included in the decision-making process by adding them to their diagnosis and treatment processes (Beauchamp, 1999; Medical Ethics Rules of Medicine, 1999; International Medical Ethics Rules, 1949; Geneva Declaration, 1949; WMA, 2017).

DISCUSSION AND CONCLUSION

One of the basic conditions of scientific progress is experimentation. As a research subject, it is necessary for scientists to plan and apply their work very well. Because of the basic ethical principles, volunteers in the research should be autonomous, beneficience, non-maleficience and justice.

Researchers who act in the direction of ethical principles can carry out their work in many dilemmas. The Declaration of Helsinki has guided scientists on this issue since 1964. The Helsinki Declaration items 30,32,33,37, which may be ethical issues in the research of scientists. The WMA, which prepared the Declaration, aimed at facilitating the opening of scientific activities and the realization of their work. However, these materials in particular require the researchers to consider ethical considerations in order to avoid harm to the volunteers with great care.

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