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ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECT

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Abstract:
The authors discussed about Declaration of Helsinki for research and pointed out that Ethical Committee should made its statement for those cases when physician decided to investigate anything involving human subjects. Medical research involving human subjects must conform to generally accepted scientific principles, be based on thorough knowledge of the scientific literature, other relevant sources of information an adequate laboratory and animal experimentation. They pointed out that in Sarajevo are functioning three Ethical Committee's. First, and the oldest, in the Clinical Center of University, and two on the Medical Faculty and Faculty for Dentistry, University of Sarajevo. They also pointed out that every cantonal center should have had its Ethical Committee, especially in University centers, and the useful model could be the Ethical Committee of Clinical Center of Sarajevo University.
Key words: Medical ethics – medical research involving humans

In June 1964. Eighteenth General Assembly of World Medical Association proposed the Declaration of Helsinki, ant it obliged all investigators. We are talking about behavior of all investigators concerning their ethical principles during the investigation. This declaration was amended by 29th World Medical Association General Assembly in Tokyo, 1975. , 35th meeting the same organization in Venice, 1983. 41st in Hong Kong, 1989., 48th in Somerset West, South Africa, 1996. , and the 52nd in Edinburgh Scotland in October 2000. The latest amend was in Washington, on 52nd meeting 2002.

Introduction

World Medical Associatin has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to the psysicians and other participants in medical research involving human subjects, because on this field were a lot of misunderstanding and because of situation that some physicains did not pay attention to behavior according the ethical principles. Medical research involving human subjects includes research on identifiable human material or identifiable data. It is the duty of physician, and those who work with him in the same team, to promote and safequard the healht of

the people. The physician's knowledge and conscience should be dedicated to the fulfillment of this duty.

The Declaration of Geneva of the World Medical Association binds te physician with the words: "The health of my patient will be my first consideration", and the Internation Code od Medical Ethics declares that, " a physician shall act only in patient's interest when providing the medical care which might have the effect of weakening the physical and mental condtion of the patient".

But, medical progress is based on research which ultimately must rest in part on experimentation involving the human subjects. In medical research on human subjects, considerations related to the well-being of the human subjects should take precedence over the interests of science and society. The primary purpose of medical research involving the human subjects is to improve profilactic, diagnostic and therapeutic procedures, and understanding of aetiology and pathogenesis of disease. Even the best proven profilactic, diagnostic and therapeutic methods must continously be challenged through research for their effectivness, efficiency, accessibility and quality.

One must admit that in current medical practice and in medical research, most profilactic, diagnostic and therapeutics procedures involve risk and burdens. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vurnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognised. Special attention is also requied:

1. for those who cannot give or refuse consent for themselves,
2. for those who may be subject to giving consent under duress,
3. for those who will not benefit personally from the research,

and those for whom the research is combined with care.

Investigators in medical research should be aware of the ethical, legal and regulary requiremenets for research on human subjects in their own countries as well as applicable international requirements. No national, ethical, legal or regulary requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration of Helsinki.

Basic principles for all medical research

It is the duty of physician in medical research to protect the life, health, privacy, and dignity of the human subject. It must be the main goal in the medical research. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientic literature, other relevant sources of information, on adequte laboratory tests and on the animal experimentation, where it was appropriate. Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be resepected.

Design and performance of each experimnetal procedure involving human subjects should be clearly formulated in the experimental prtocol. It should be submitted for consideration, comment, guidance, and where it was appropriate, approval to specially appointed ethical review committee, which must be independent of the investigator, or a sponsor. Because sponsor also might put some undue influence. This independent committee should be in conformity with the laws and regulations of the country in which research experiment is performed. The committee has the right to monitor ongoing trials, and researcher has the obligation to provide monitoring information to the committee, specially any serious adverse events. He should also submit to the committee, for review, information regarding funding, sponsors, institutional affiliations, other potential conflits of interest and incentives for subject in research.

Medical research involving human subjects should be conducted only by scientificaly qualified persons and under the supervision of clinically competent medical person. It must be accordig the principles of Helsinki Declaration. Responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.

Every medical research project involving human subjects should be preceded by careful assessment of predicable risks and burdens in comparison with foreseeable banefits to the subject or to others. This does not preclude the partipiation of healthy volunteers in medical research. The design of all studies should be publicly available.

Physicaisn should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assesed and ca be satisfactorily managed. Psysicians should cease any investigation

if the risks are found to outweight the potential benefits or if there is conclusive proof of positive and beneficial results.

Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research. The subjects must be voluteers and informed participants in the research project.

The right of research subjects to safequard their integrity must always be resepected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize impact of the study on subject's physical and mental integrity and on personality of the subject.

In any research on human beings, each potential must be adequtely informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the resercher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After the ensuring that he subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed. When obtaining informed consent for the research project, the physician should be particularly cautious if the subject is in a depenedent relationship with the physician, or may consent under durress. In that case the informed consent should be obtained by well informed physician who is not engaged in the investigation and who is completely independent of this relationship.

The subject who is legally incompetent, physicaly or mentally incapable of giving consent, or legally incompetent minor for medical research, the investigator must obtain informed consent from legally authorised representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be peformed on legally competent persons.

When a subject deemed legally incompetent, such a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addtion to the consent of the legally authorised resresentative. Research on individuals from whom it is not possible to obtain consent, includind proxy or advanca cob+nsent, should be done only if the the physical or mental condition that prevents obtaining informed consent is necessary characteristic of the research population. The specific reasons for involving research subjects with a condition

that renders them unable to give informed consent should be stated in the experimental protcol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from an individual or a legally autorised person who will replace that subject.

Both autors and publishers have ethical obligations. In publicaion of the results of research, the investigators are obliged to preserve accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of fundung , instututional affiliations and any possible conflict of interest should be declared in this publication. Reports of experimentation not in accordance with the principles laid down in Helsinki Declaration should not be accepted for publication. .

Aditional principles for medical research combined with medical care

The physicain may combine medical research with medical care of the patient, only to the extent that the research is justified by its potential prophylactic, diagnostic and therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects. The benefits, risks, burdens and effectivness of a new method should be tested against those of the best current profilactic, diagostic. and therapeutics methods. This does not exclude use of placebo, or no treatment, in studies where no proven profilactic, diagnostic, and therpetic method exists. The World Medical Association hereby reafirms its position that extreme care must be taken in making use of a placebo - controlled trial and that, in general, this methodology should only be used in the absense if existing proven therapy. However, the placebo - controlled trial may be ethically ecceptable under following circumstances

1. Where for compelling and scientifically sound methodological reasons its use is necessary to determine efficacy or safety of a profilactic, diagnostic or terapetutic method, and
2. Where a prophylactic, diagnostic or therepeutic method is being investigated for a minor condition and the patients receiving palcebo will not be subject to any additional risk of serious or irreversibile harm.

The physicians should fully inform patient which aspects of the care are related to the research. The refusal od the patient to parcipate in the study must never ineterfere with the patient – physician reationship.

Situation in Bosnia

There are three Ehical Committees to day in Bosnia (2oo3. 05. 03). The oldest one is in Clinical Center of Sarajevo University, and it is formed exactly according to regulations of Helsinki Declaration. There are three fellows representatives of three religious groups, lawyer and social worker, and representative od Ministery of Health, psychiatrist (president), chief of the Center, manager of Clinical Pharmacy and secretary of Medical Department of Academy of Sciences and Art of Bosnia and Hercegovina. All of those are active participants of the decisions and every physicain who likes to be researcher including humans must present his project in front of the this Committee, and behaviour according to the rule they are proposed. This Comittee lasted for more than ten yaers and it could be model for formating the Ethical Comittees all over the conutry, because every Cantonal Hospital, specially university centers, must have its own one. The remaining two Committees are one at Medical and one at Department of Dentistry of Sarajevo University

Apstrakt:

ETIČKI PRINCIPI U MEDICINSKIM ISTRAŽIVANJIMA KOJA OBUHVAĆAJU LJUDE

Autori diskutuju o Helsinškoj konvencji za istraživanje, naglašavajući da je potrebna saglasnost Etičkoga komiteta, za one slučajeve kada se ljekar odluči za istraživanje koje uključuje žive ljude. Svako istraživanje koje uključuje ljude mora biti oslonjeno na općenito prihvaćene naučne principe, biti bazirano na reviji medicinske literature drugih relevantnih izvora istraživanja i informiranja, te adekvatnome eksperimentu na životinjama. Naglašavaju da samo u Sarajevu funkcioniraju tri Etička komiteta, jedan, i to najstariji, u Kliničkome centru Univerziteta, a druga dva na Medicinskome i Stomatološkome fakultetu.. Također ističu da je potrebno da svaki Kantonalni centar ima svoj Etički komitet, a pogotovu Univerziteski centri. Za to koristan model može biti Etički komitet Kliničkoga centra Univeriteta u Sarajevu.

Ključne riječi: medicnska etika – mediniska istraživanja koja obuhvaćaju ljude

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