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Review Article

Ethical aspects of biomedical research in the context of progress in medicine

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ABSTRACT

Introduction: Among numerous branches of science, advances in biomedical research are perceived to be the most controversial. This relates to biomedical experiments which involve human and animal trials. This article attempts to outline both historical and current dilemmas in the field of biomedical sciences.
Aim: The aim of this study was to discuss ethical and moral issues connected with experiments involving animals and human beings. The authors aimed at presenting directions of development for new branches of medicine.
Materials and methods: This study presents a review of contemporary medical literature and legal regulations concerning experiments on animals and human beings.
Discussion: The issue and definition of bioethics, its historical evolution, as well as specificity of medical sciences, experimental control methods, current implementation of a new operative technique – fetal surgery – and legal regulations concerning the protection of animals used for experimental purposes are presented.
Conclusions: Experiments have always been a part of medical developments and it is unlikely that such would ever be abandoned. Over the years, not only the advancement of medical procedures, but also the efficacy of treatment has changed. Along with developments in medicine, the approach to medical experimentation on humans and animals has changed as well. Currently, medical experimentation has entered a new age which may be termed "humanitarian," "planned" or "aimed," which are all connected with devising well-accepted standards and appropriate legal regulations.

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1. Introduction

In the first part of this article the authors presented bioethics in the context of scientific experimentation and research, its history and the complexity of its financing. In the present article this discussion is continued, with special interest placed on the ethical aspects associated with the cloning of a human being, methods of controlling biomedical research, specificity of psychiatry in medical research and threats and benefits connected with the new branch of medicine – prenatal surgery.

2. Aim

The aim of this work is to present the ethical and moral aspects of biomedical research and progress in medicine.

3. Materials and methods

Authors performed a review of scientific literature and contemporary legal regulations concerning biomedical experiments.

4. Discussion

A special kind of control should be established with respect to biomedical research. The committee responsible for such a task should be fully independent of researchers and guarantee a multidirectional perspective concerning a given problem, in consequence of the multidisciplinary character of that team of experts – scientists and moral authorities – involved. Such a board would verify the bases of medical experimentation, its compatibility with the Declaration of Helsinki and national regulations. Members of the board would also verify in detail a patient's consent to the medical procedure that is to be undertaken, not only examining its authenticity, but also ensuring that the patient fully understands its content.

Control over research conducted on humans is exercised by Local Bioethics Boards elected in each Regional Medical Chamber or Medical University. These boards observe the regulations for accepting each research project according to the Declaration of Helsinki (1964), detailed at the Tokyo Conference in 1975. They act in compliance with national regulations. In Poland such regulations include, among others, the Medical Profession Act and the Ministry of Health ordinance on detailed regulations concerning the establishment, financing and functioning of bioethics committees. Standards of biomedical experiments are established in compliance with all legal regulations addressing this issue.[7,9,12,19,20,21,22,23,24,27,30,32]

Experiments on animals have always been and still are a driving force for progress in medicine as best exemplified by the first attempts concerning organ transplantation. Dehoux et al. mention the utilization of large animals, including the primates, in biomedical research in order to obtain data reproducible in humans.[5] Knight questions the benefits of including the primates in experimental research because of the neglectable impact of such data on the citation rate. Moreover, he states that conducting experimental work of questionable scientific value, burdened with high rate of moral doubts, proves a decline of science.[13]

Looking back, as in experimentation on humans, the first attempts involving animals were conducted in the absence of regulations which could prevent those animals from suffering. In 1978, during the UNESCO meeting in Paris, the Universal Declaration of Animal Rights was conceived. It is a set of regulations that oblige scientists, among others, to respect the dignity of animals; these regulations forbid killing animals for no justifiable reason, maltreating and subjecting them to acts of violence. When an animal must be killed, an appropriate method causing neither pain nor fear should be undertaken. No experiments connected with physical or mental suffering are allowed under the provisions of the European Council Directive 86/609/EEC. This Directive defines the types of animals which may be regarded as experimental (laboratory, bred animals), defines methods of humanitarian treatment, minimizes suffering by allowing a certain number of anesthetic drugs to be used, and establishes a proper control system over the experiments, protection of endangered species, decent conditions in breeding institutions placed in an official register.[31] Moreover, it allows only those killing methods regarded as humanitarian.[17,18] An unjustified act of killing an animal is regarded as a crime against life. In the light of Polish law, according to the Animal Protection Act[29] and the Act on experiments on animals,[28] experiments on animals are restricted only to those cases in which potential results are not obtainable by means of any other methods.

Local Ethics Committees, controlled by the National Ethics Committee, are responsible for controlling experiments conducted on animals.[31] They devise a list of institutions allowed to conduct experiments on animals, breed animals for the sake of experiments, and determine the register of animal species defined as "experimental." Moreover, they establish the rules of conducting research on animals. According to the experimental animals' register in Poland, the experimental species are mice, rats, guinea pigs, cats, Japanese quails, gerbils, field voles, red voles, and lab opossums.[14] The "scale of invasiveness of experiments on animals" defines the degree of invasiveness and thus constitutes one of the basic tools in the assessment of an experimental project by local ethics boards.[33] It is a five-point scale assessing not only the kind of procedure utilized, but also the involved species, the consequences of implementing a chosen procedure, the possibility of enforcing humanitarian methods of killing the animals and of minimizing their suffering. It begins with level 1 procedures (non-invasive), used mostly in behavioral studies, while level 3 procedures involve moderate suffering and stress – they cover most surgical procedures. Level X involves forbidden procedures, causing extreme stress or suffering, allowed only in extraordinary circumstances, having first obtained a positive opinion from the local ethics board.[2]

In Germany a specially designed, double control model was established in order to maximize the degree of transparency and ethics clearance of experiments on animals. This model