

## Ethic criticism of clinical trials

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*Modern medicine has achieved enormous results in the treatment of many diseases and trauma which terrified the humanity for ages. On the other hand the longevity and the quality of life of each person as an individual becomes the problem of modern medicine. The medicine of twenty-first century must be not the medicine of strictly divided diseases but the prevention and treatment of every ill individual, not the disease. Such personalized treatment will achieve the better quality of life after medical treatment, not only the longevity under any conditions. In this paper the authors are discussing the problems of modern medical investigation and research with human beings and the ethic collisions made by many of very important but mostly nonethical types of investigations.*

**Key words:** Medical ethics, Specific treatment, Bioethics

### 1. INTRODUCTION

The study of ethical and moral implications of the new biomedical investigations as in fields in bioengineering, transplantation, euthanasia and drug research has been actualized at the beginning of the twenty-first century. The only one little branch from the great philosophical tree, called ethics, which is occupying the specific problems arising from medical and biological practice, as the treatment, the experiments on the live experimental animals, the experimental investigation of the drug and specific procedures with the human beings is called bioethics. During the decades and centuries galloping rise of medical practice have gathered enormous stock of ethical and bioethical problems concerning the relation patient-physician, the limits of acceptable intervention with every unique individual, not the disease, but the human being. Every human is one specific disease and has a proper specific treatment of him and his own disease. In the history of medical ethics the first mile stone was Hippocrates Oath: *primum non nocere* (translated in Latin) which means, „first do not harm“. Later scientific investigations with the humans led to the first „informed consent“ from the human beings involved in research. The cultural emphasis of individual human rights confronted with

growing concerns over medical advances provoked the government intervention: the so called „brain death“ of the potential transplant organ donors on one hand and on the other, prenatal genetic examinations and discriminations, must be studied and incorporate into the civil codex which will give the borders of medical research and „power“ by the law and the „red line“ which could not be passed. Many religious communities all over the world (especially in the USA but not in Serbia) stood as the statement that the genetic screening might increase abortions of „problematic“ babies. In the year 1974 US Congress established the National Commission for the Protection of Human Subjects of biomedical and Behavioral Research [1,2]. This Commission relied on three principles, of beneficence, justice and autonomy as secular bioethical guidelines. In the doctor-patient relationship the basic place has the relationship of Christian theology and liberal philosophy. This relation is the key word in the processing the political and governmental order of every state's law by which is ruled and controlled the transplantation, genetic operations and clone treatment [3].

### 2. OUR MATERIAL AND METHODS

During the last decade every clinical, regional health centre and the Republic health centers have organized the ethic committees. There two levels of ethic committees, just like in the law institutions. The first level is the ethic committees which exist in every clinical, regional health care organization and there they control the whole health care activity of all

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medical procedures which are performed on the patients in the treatment of all health problems. The second level for whole republic of Serbia is the Ethic committee of the Serbian medical association and this Committee is controlling the function of primary ethic committees and is obliged to control the studies and research of institutions of National or State level [4]. The clinical research trials are performed in the stationary health institutions and are mostly of III and IV level of clinical investigation, that means that the experimental phase or drug introducing in animals or special laboratory, biochemical investigations have been finished successfully. In Serbia we have organized control of all research studies by different Associations (Serbian Medical Association, Animal Health Protection, Human Rights Watchers) [5]. The clinical trials could be divided in three groups according to funding [6]: (1) industry organizations; (2) charity organizations; (3) national health organizations.

The trial can modify the drug treatment but also a medical device of psychical procedures, a therapy or an intervention such as health promotion. Of course the drugs, types of operations surgical procedures or other medical therapies must be before the phase III and IV and extensively investigated in the laboratory and after that testing on animals. If the results of these studies are positive the principal investigator could get the approval to begin the trial in humans. Here have the local or regional ethic committee the enormous power but also the responsibility to see, to predict to correct or reject the proposal. Most of the investigations of the so called „double blind randomized study“ where the institutions which are performing the stage III or IV study makes two parallel groups of patients (a sick people) and than one group becomes the tested drug and the other placebo. So the patients suffering of acute or chronic disease had to be treated for the problems they suffer „are led to the occasionally or lotto treatment“. Such types of studies must be avoided by ethic committee although they provide sometimes excellent drugs which they get gratis and there for they accept such a contract and participate in the investigation. This is typically for undeveloped or countries in transition where are always shortages in drug appliance. The better type of clinical study is to divide patients in two groups so that first group get the conventional or classic treatment either surgical or medical and the prospective group where the patients underwent the new sort of operative or medical treatment. Of course the results would be compared and analyzed. Many chemical industries, a little bit smaller the machine and device producers and the fewest the health institutions are not agreed with such type of study

because statistically significant difference between two groups does not exist. The investigations which never collide with ethic norms are those where we exclude some harm substances from the patients' life like alcohol tobacco, fatty meals, harmful drugs. They are the best for the patients but also for the doctors, because they could not provoke any important health problem.

### 3. CONCLUSIONS

Clinical trials must be performed in phases. This type of clinical research is derived in four (like Food Drug Administration – FDA) or in five as in Europe. Each phase designed to answer certain questions about the drug or treatment and each phase of investigation must be completed before the next phase can began [7]. Phase one considers the studying the safety of the operation of medical or surgical device [8]. In this phase must be enrolled only a small number of participants. Phase two of the trial study consists of short term effects of treatment [9]. Here could be enrolled slightly larger number of patients. This phase shows us whether the drug or operation or device works as initially expected. Phase three presents the long term effect of the treatment on a very large numbers of patients looking for any unsuspected side effects, allergy, intolerance, resistance [10]. Phase four consists of studying the minor problems which might be marked. In this phase the treatment is tested with thousand and more participants. Those phases can take a long time, sometimes more than two three years. For some diseases such as AIDS and cancer we can perform or tolerate the so called „fast track“ a very rapid drug development.

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## REZIME

### ETIČKA KRITIKA KLINIČKIH OPITA

*Savremena medicina je ostvarila velike rezultate u lečenju mnogih bolesti i trauma koje su zastrašivale čovečanstvo dugi niz godine. S druge strane dugovečnost i kvalitet života svake osobe kao individue postaju problemi kojima se bavi savremena medicina. Medicina dvadesetprvog veka ne sme da bude medicina strogo podeljenih bolesti nego medicina prevencije i lečenja bilo koje neusaglašenosti u pogledu zdravlja ( ne obavezno bolesti) svake osobe. Ovakvo personalizovano lečenje ostvariće bolji kvalitet života nakon medicinskog lečenja, ne samo dugovečnost pod bilo kojim uslovima. U ovom radu autori diskutuju probleme savremenih medicinskih ispitivanja i istraživanja u koja su uključena ljudska bića i etičke sukobe prouzrokovane mnogim veoma važnim ali uglavnom neetičkim tipovima ispitivanja.*

**Ključne reči:** *medicinska etika, specifično lečenje, bioetika*