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PRACTICAL BIOETHICS

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VALUE OF GENDER'S RATIO FOR INTEGRITY ETHICAL AND SCIENTIFIC STANDARDS IN CLINICAL TRIALS

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This article has stressed on actual problem to take into consideration the gender's ratio in clinical trials for following the ethical principles and maintain data quality. It is shown that the essential different in medications activity are depended from gender factors. Bioethical and gender indexes have been companied at the different phases of planning the study, selecting the participants and conducting clinical trials. In article is presented that the data of gender's ratio in R&D of medications dose should be available and the evaluation of pharmacological features of drug necessary to make in clinical trials where gender balance of participants take place. All potential problems of gender balance connected with cultural, religion and social-economic factors. There are the specific of gender's behavior for different groups of participants what influence on following ethical standards in the process of obtaining and documenting informed consent. Subject protection and the collecting of relative data requires the transparency of gender's ratio concerning with trial's participants.

Key words: gender's ratio, bioethics, human rights, relative data, scientific efficacy of clinical trials.

ЗНАЧЕНИЕ ГЕНДЕРНОГО БАЛАНСА ДЛЯ СОБЛЮДЕНИЯ ЭТИЧЕСКОЙ И НАУЧНОЙ ЦЕЛОСТНОСТИ КЛИНИЧЕСКИХ ИССЛЕДОВАНИЙ

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Представлены материалы, посвященные актуальной проблеме необходимости учета гендерной составляющей проведения клинических исследований, с целью соблюдения этического компонента и получения объективных данных о действии фармакологических средств. Показаны различия в действии лекарственных препаратов в зависимости от гендерного признака. Проведено сопоставление биоэтических и гендерных показателей на различных этапах планирования, организации и проведения клинического исследования. Продемонстрировано значение культурных, религиозных и социально–экономических характеристик гендерных групп для соблюдения этических стандартов и получения объективных результатов исследования.

Ключевые слова: гендерные различия, этика, права человека, объективность результатов, научная эффективность биомедицинских исследований.

General advances in biomedical science and its correct application in practice of medicine are faced with new ethical problems provoking by the influence of gender's ratio on the data's quality in clinical trials (CT). For the solving this particular problem it is necessary to indicate ethical view on gender's aspect, describe the specific value of gender's criteria in medicine and notify the different periods in process of the conducting CT where the balance of gender's elements and bioethics could be critical. The fundamental understanding of the gender's aspects should be guided by the spirit and the text of «Universal Declaration of Human Rights» (UDHR), 1948 [1,2,6.12]. In the preamble of this document has been strictly mentioned that «*…the peoples of the United Nations have in the Charter reaffirmed their faith in fundamental human rights, in the dignity and worth of the human person and in the equal rights of men and women…».*

Article 2 of the UDHR directly focused «*…everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status..».*

Sharing the principle of gender equality as an important element of observance the ethics in the scientific progress, in the frame of this article, the specific role of the gender's ratio and ethics in clinical trials will be considered. Scientific value of this observation is based on the results of 4th year's analysis that confirmed the essential different in the influence of the medications on

duration and outcomes of diseases on men and women [7]. It was shown the reasonable dependence between sex of the patient and its predisposition to various diseases, as well as different effect of the same medication on clinical features and the forecast what objectively takes place. There is an incontestable statistics of significant gender differences at various physiological and pathological states that fills evidential base of special sections of gender medicine.

In this regard the view on the disease with the understanding of the difference on men and women on the base biological (anatomical, physiological and etc) and psychological difference in behavior based on social - economical norms, cultural diversity (gender' roles).

From scientific point of view, there should be done the special focus on essential distinctions in pharmacokinetics/pharmacodynamics of drugs at men and women that doesn't allow transfer the data obtained without gender's specifics or otherwise doing them nonobjective i.e. unethical. Widely known the different indexes of efficacy and safety acetylsalicylic acid (Aspirin) used for the prophylaxis of cardio-vascular diseases on men and women, could be a good example of this phenomenon [3].

Despite an irrefutability of medical value of gender's distinctions, the data of gender's ratio in research and development (R&D) of medications are available neither in the corresponding literature, nor on the sites. Authority does not record the number of patients required by gender per protocol and the sponsors who notify their CTs to database EUDRACT do not enter the number of patients required by gender. Unfortunately, the publicly accessible database only inform whether the trial is accessible to males, females or both and the proportions are not revealed.Similar approaches don't give the grounds for correct interpretation of these studies because the real influence of gender's distinctions is certainly great. In this point, it is interesting to keep in mind that phase I of CT's usually calls for healthy men (volunteers), so in this case it is the problem for application the data of bioequivalence/dose's regime on women without essential distinctions in pharmacokinetics/pharmacodynamics at persons of a different sex [4]. Not only physiological features of gender's distinctions define specifics assessment of the CT's data, there are psychological characteristics capable to cause various psychosomatic reactions depending on gender's accessory. First of all, it is necessary to specify the gender's aspects of personal adaptation on healthy men and women in the situation of isolation which is often applied when carrying out the phase I of CT's. In special supervision it was demonstrated that owing to gender's specifics of the person, the woman transfer temporary isolation which is followed by development in them of a certain psycho-physiological complex capable to have impact on the correct interpretation of the data obtained at the study more often worse [5]. Thereby, it is obvious that without adequate correction direct transfer, the data with the purpose obtained on men for their using at women, as well as the return process – transfer of data from women on men isn't possible. For understanding the interrelation between gender and ethical aspects in clinical trials, the special attention has to be paid to the corresponding calls arising during various stages of CT's design and the different periods of conducting the study. So, according to design of clinical trial, there are certain conditions of access to CTs, selection of research subjects, entering in CT, inclusion/exclusion criteria, decision making and informed consent (IC) process, risk/benefits balance and the study medication good treatment compliance.

According to the consideration of the contradictions and ethical conflicts arise because of gender's aspects during the listed above CT's periods, the following foreshortening can be presented. First of all, there could be some reasons that women can be discriminated from selection and entering in CT's existed both in developing and in developed countries.

In those countries where social, economic, cultural and religious dependence of women takes place, is absent not only the possibility of equal participation of women in clinical trials caused by their conditions. It is reality, that investigators in such countries do not fully "trust" women with respect to the difficulties of modern clinical trials (self-administered questionnaires where women are often illiterate, recording devices with complex instructions, frequent visits to the site not compatible with the time-consuming duties of women at home, and the traditional dependence from men's or families solution). Frequency the situation is not better in developed countries with a high proportion of immigrant/clandestine populations from developing countries who are mostly motivated to take part in clinical trials because sometimes it could be only one way they can gain access even to general medical care. The investigators in economically advanced

countries/cities where the sites for conducting CT's are usually located, may discriminate against women from immigrant/clandestine populations because they have limitation to equitable understanding of study's essential information: do not speak the local language, or they can only participate in a trial accompanied by one of their children who goes to school and can translate, but in this case the investigator finds this unreliable, because a minor would have to be informed and questioned about sexual or mental disorders of their mother.

Due to the need the following to inclusion/exclusion criteria as well as risk/ benefits balance reasons, there is an obvious inequality concerning for men and women. As a general it concerns indispensable rule in all CTs carrying out the pregnancy test and requirements for prevention and an exception of pregnancy throughout all terms of participation in the study. This requirement, in fact, violates the reproductive rights of women and represents direct intervention in policy of the family's planning. Concerning equal conditions of observance risk/benefits balance it is also necessary to state objective restrictions for women on this sign in connection with existing extra risk for future children, because of limited data of chronic and specifically toxicity particularly embryo toxicity.

With special evidence the ethical conflict and contradictions in respect of gender accessory are shown at decision making and informed consent process. There are serious doubts in basic opportunity for women to make the free/ voluntary/individual IC, especially, in those communities and the countries where there is an obvious religious and social dependence of women and the principle of the decision of men/family dominates. Equally the similar situation belongs and to the fact of a free/voluntary withdrawal from the study that can be also caused by will of the man (the husband, the father) and need of submission to this will. It is necessary to emphasize that the similar situation not always contradicts the ethical canons accepted in society, and, on the contrary, can correspond to the last completely. So, according to the principles of Islamic bioethics, the model of decision making and giving the informed consent is based not on autonomous/individual opinion, and relies on the principle of the family decision [5]. Taking into account this circumstance concerning the doctor and the patient, the form of the coordinated process of decision making and the consent approved by a family is taken. In case of gender distribution, it is important that in these situations the taking priority right remains for men. It is also necessary to add often the unequal opportunities to receive the good education for men and women. As a result of such situation, it could be the different level of their knowledge existing in the certain countries which can also provoke impossibility for females to have adequate and comprehensible understanding the CT's information what could be critical for correct decision making to participate/or not participate in the study.The most sharply gender specifics are shown in CT's which are specially focused for investigation the medicines/methods at pregnant/or nursing (breast feeding) women. For such situation the special consideration should be given by investigators and ethics committees to conduct CT's on pregnant, laboring, newly delivered and feeding women as on vulnerable population..Recognizing and considering high value of cultural diversity as basis and a source of identification of the person and a historical link of generations, it is necessary to make the maximum efforts in order that these basic characteristics didn't become a pretext for infringement of the rights and freedoms of separate categories of people. Great moral force for execution of the ethical concept of biomedical research is fully presented in the «Universal Declaration on Bioethics and Human Rights» approved by the 33rd session of General Assembly of UNESCO on October 19, 2005 [8]. Within scope of the UNESCO declaration, in decisions or practical actions, the principles, following which have to be observed provides general respect and observance of human rights and fundamental freedoms and inadmissibility of gender inequality. These postulates are fixed and in the list of main documents on the basis of which a formation of the UNESCO Declaration was prepaid. In this regard, first of all, it should be noted the «Convention on the Elimination of All Forms of Discrimination against Women» adopted by United Nations. [9]. According to the moral assessment to the existing provision on a ratio gender and ethics in clinical trials, it is expedient to rely on accurate treatment of the leading articles of the UNESCO Declaration, because of the reasonable association between the moral ideals and realities stated in this document. Thus, is extremely important recognition that ethical decisions in one concrete research are significant not only for this particularly research and concern not only its certain participants, but are capable to make global and

harmonious impact on various public groups and all mankind in general. With the idea of the main expectations connecting with biomedical research and taking in consideration the elements of an imbalance of ethical bases and gender's policy in CT are given above, it is necessary to define a correct list of consecutive innovations. So, taking for evidence that the purpose of clinical trials to maximize data quality, adhere to the ethical principles, new knowledge and progress in prevention, treatment and diagnostic diseases, it is necessary to ensure gender influence on scientific and ethical parts of research. For this purpose quantitative gender information should be available in the databases about the gender ratio at the beginning of the trial and achieved when the trial was completed. Any major discrepancies would have to be discussed in the CT's report. Publications of CT's data should have details about the number of patients recruited by site, and the gender information as well. This would allow readers to assess where the clinical data come from in the world, and whether sites have plausible gender ratios.

In conclusion it could be summarized that for improvement the basic approaches of carrying out biomedical research, the moral responsibility and the analysis of the ethical problems arising in connection with objective existence of a gender's variety and its influence have to be an integral part of planning, implementation, assessment and presentation results of clinical trials.

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REALIZATION OF INFORMED CONSENT AS ONE OF PATIENT RIGHTS: CURRENT SITUATION IN AZERBAIJAN

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Azerbaijan is a country in which the law is based on democratic principles. The mentioned principles are lying in the basis of the national healthcare law. Democratic values, such as respect for human rights and freedoms, human dignity, as well as universal bioethical principles that are widely implemented in national law, create conditions for implementation of patient's rights. The basic law governing the doctor-patient relationship - "Law on Protection of health of population in Azerbaijan" reflects the basic patients' rights and obligations of doctors and medical institutions. Informed consent, which is a key component of patient rights, is also reflected, however, to date, a significant drawback of the Azerbaijan medical legislation is described in the article in this field. For example, at the moment there is no single standardized informed consent form in the different country's medical institutions. In the absence of such legally approved standards for informed consent form, public and private health care institutions provide such forms individually, which sometimes can differ significantly. At the moment, one of the important directions in the field of healthcare is its improvement in accordance with international standards. The authors also analyzed the main provisions of medical law of Azerbaijan and identified the main trends of its further development.

Key words: *patient rights, informed consent, legislation of Azerbaijan Republic*

РЕАЛИЗАЦИЯ ИНФОРМИРОВАННОГО СОГЛАСИЯ КАК ОДНОГО ИЗ ПРАВ ПАЦИЕНТОВ: АКТУАЛЬНАЯ СИТУАЦИЯ В АЗЕРБАЙДЖАН

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