

## LEGAL ASPECTS OF EVALUATING THE GENETIC CONSEQUENCES OF MEDICAL EXPOSURE

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**Key words:** *medical exposure, nuclear medicine, patient safety, genetic consequences, legal aspects*

Article received: 26.08.2019. Accepted for publication: 10.07.2019

### Introduction

Progress in the field of diagnostic exposure, the use of nuclear and radiation medicine methods in some cases raise questions of the legal order and regulation from the point of view of the possible deterministic and stochastic consequences of exposure to medical exposure. For example, for the treatment of malignant neoplasms, nuclear medicine methods have been successfully applied, including in patients of reproductive age. Of particular importance are the problems of using nuclear medicine methods in healthcare in the light of the federal project “Combating Oncological Diseases” being implemented by the Russian Ministry of Health. In this regard, it becomes urgent to assess the long-term genetic consequences of such treatment methods, including ethical and legal aspects.

In connection with equipping health facilities with modern equipment, a high level of coverage of the population with various types of medical procedures using sources of ionizing radiation is noted. The number of complex X-ray diagnostic studies is increasing annually. At the same time, studies using X-ray equipment make the main contribution to the patient dose.

Currently, 98 % of the total dose from artificial sources, i.e. 20 % of the total radiation dose from all sources in general. Interaction with sources of ionizing radiation can adversely affect the health status of workers and their offspring in the near and distant period. Compared to other categories of exposure, medical exposure is characterized by a number of features that can exacerbate its effect on health, including: a high dose rate; uneven irradiation of the body and its organs and tissues; exposure, as a rule, to a sick and weakened body; frequent exposure to persons with increased radiosensitivity (children and pregnant women), etc. These factors distinguish medical exposure from other types of human exposure and make protection against it a priority.

Article 19 of the Federal Law of November 21, 1995 No. 170-FZ “On the Use of Atomic Energy” enshrines the right of citizens-patients to both decide on the use of ionizing radiation and to provide, at the request of patients, full information about the size of the planned and actually received by them doses for examination and treatment. However, the application of this norm is practically impossible due to the low level of knowledge among the popu-

lation about the standard parameters of exposure and the possible consequences, the lack of accurate data obtained by instrumental methods of research, and the likely influence of widespread radiophobia. Also, the patient does not have the right to refuse the use of ionizing radiation in the case of medical procedures in order to identify diseases that are epidemiologically dangerous, for example, during fluorography.

### Legal aspects of the application of medical technologies related to the use of ionizing radiation sources

Of course, the legal aspects of the application of medical technologies related to the use of ionizing radiation sources require further research and study. It is necessary to create legal tools that allow the doctor to make an informed choice within the framework of the benefit-risk criteria, including taking into account the possible effect on the offspring. Today, every modern person believes that the state should guarantee him health protection, understanding him as one of the key constitutional rights.

### Constitutional aspects of genetic research

However, it is worth noting that such a law, despite its importance, importance, appeared in the basic laws of modern countries relatively recently, namely, after the Second World War. Thus, the Constitutional Acts of Great Britain, for example, do not contain a word about the need for the state to take care of the health of its people, as, indeed, the Constitution of the Kingdom of Denmark (1953), adopted already in the post-war period. But still, most modern European constitutions, such as the Constitution of France (1958), Italy (1947), the Federal Republic of Germany (1949), as well as the later fundamental laws of Russia (1993), Belgium (1994), Switzerland (1999), provide for such social law. Human right means the obligation of the state to guarantee the implementation of such a right. But here is how to do this, each state decides in its own way.

You should refer to the International Covenant on Economic, Social and Cultural Rights, adopted on December 16, 1966, which establishes in Article 15 the obligation of the States Parties to the Covenant to respect the freedom absolutely necessary for scientific research.

“Stressing the need for international cooperation for all of humanity to enjoy the benefits of biology and medicine” Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: The Convention on Human Rights and Biomedicine says that prognostic tests for the presence of a genetic disease or a genetic predisposition to a particular disease, including after applying medical exposure, can only be carried out for medical purposes or for medical science and provided with adequate advice of genetics.

The Universal Declaration on the Human Genome and Human Rights (11.11.1997) provides for the need for states to regulate work with the genome (Section D), and in its article 5 determines that research, treatment or diagnosis, including with the use of medical radiation related to the genome can only be carried out taking into account all the requirements established by national law. For example, the Federal Republic of Germany has adopted the following legislative acts on this issue: “On the Protection of Embryos” (1990), “On Genetic Research with the Participation of People” (or the Law “On Gene Diagnostics” (2009) in another way), “On the Regulation of Genetic Engineering” activities” (1990).

At the same time, the professor, lawyer Francis Sprecher, in his book “Medical research involving children and adolescents according to Swiss, German, European and international law”, criticizes the lack of union law, thus, medical research with subjects in Switzerland is primarily regulated by the law of the cantons, which supplemented by a special law of the Union.

### Problems of legal regulation of genetic risks

In recent years, a diagnosis of a genetic predisposition to the development of diseases during fetal development has been widely carried out. Genetic technologies make it possible to study a large number of genes and gene variations, evaluate the levels and variants of their expression, and reveal the biological foundations of polygenic diseases, in the development of which many genes are involved. At the same time, there is no clear understanding and no mechanisms of legal regulation in the event of a predisposition to genetically determined diseases. There are no clear mechanisms for state regulation of possible risks and damage if a fetus reveals genetic changes associated with exposure to ionizing radiation during medical procedures with its parents.

An equally difficult problem is the legal regulation of the rights of parents with respect to the choice of further medical interventions in case of any abnormalities in the fetus, including artificial termination of pregnancy, or in case of medical overexposure of a pregnant woman.

### Conclusion

Today, the issue of legal regulation of the possible consequences of medical procedures using sources of ionizing radiation, including with regard to offspring, is not properly regulated. Probably, it is necessary to adopt a separate law listing the main provisions that should be

contained in such a legal act. Of course, an appropriate regulatory framework should appear in order to avoid questions and disputes that cannot be resolved without causing harm to one of the disputing parties. Our team of authors sets the task to determine the legal regulation mechanism, the conditions that can help the development and development in the field of nuclear medicine, and the effective implementation of their medical practice.

In this regard, it is necessary to analyze international experience in the issue of the vertical of legislative regulation, the distribution of the law-making burden between the federation (confederation) and its subjects, in order to understand which model is most effective for Russian society. And also on the basis of judicial practice, identify those “sharp corners” of legal regulation that can be smoothed out. At the same time, it is vitally important to understand that any law can have errors that need to be corrected, and the damage from the restriction should be commensurably less than those goals that are planned to be achieved by such a restriction. The law should be built on logic and aim not to comply with formalities, but to protect human goods.

This work was supported by the Russian Foundation for Basic Research (project No. 18-29-14020).

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**For citation:** Samoylov AS, Goloborodko EV, Astrelina TA, Dedova EV, Chukovskaya IV, Gubaeva TV. Legal Aspects of Evaluating the Genetic Consequences of Medical Exposure. *Medical Radiology and Radiation Safety*. 2019;64(5):71-2. (English).

DOI: 10.12737/1024-6177-2019-64-5-71-72