

## INSTITUTIONALIZATION OF PATIENTS' ORGANIZATIONS IN RUSSIA

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### Abstract

The aim of the study, the results of which are presented in the article, is to study the processes of institutionalization of foreign and Russian patient organizations. The authors of the article assess the role of patient organizations in the health policies of different countries. Evaluate compliance with legal and ethical standards governing the relations of patient organizations with public authorities and health care institutions. Classify problems of patient organizations based on the results of analysis of theoretical literature, comparative analysis, in-depth interviews with representatives of patient organizations with diseases associated with primary immunodeficiency. According to the results of the study, the authors of the article developed recommendations for improving institutional processes, including solving the identified legal and ethical problems, and the forms of interaction of these public organizations with healthcare institutions. The theoretical significance of the study, the results of which are presented in the article, is a contribution to the theory of public administration in terms of studying the institutionalization process of a specific type of public organizations as an element of civil society, as well as identifying conditions for the development of these organizations.

**Key words:** institutionalization, patient organizations, legal, ethical, norms

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### Introduction

Currently, civil society actors are actively involved in various activities previously implemented only by public administration authorities. Among them are socially-oriented non-profit organizations, which are created in response to actual requests from civil society. One of the results of the institutionalization of interaction between civil society and public authorities is the formation of interest groups, on the basis of which various organizational structures emerge that protect the rights of patients or patient organizations. The institutionalization of this type of organization lasts more than 50 years, respectively, there are

significant results. Patient organizations are most effective in the United States, New Zealand, Australia, and France (Brouard-Lapointe, Moutel, & Gimenes, 2015). The European Patient Forum (EPF) was created, representing the interests of 50 European patient organizations, including those with chronic diseases. An even larger association is represented by the International Alliance of Patient Organizations, which unites patients of all nationalities and all diseases. In Russia, the process of institutionalization of non-profit organizations created to protect the rights of patients began much later than in Europe, only in 2010-2011. Currently, 314 non-profit organizations represent the interests of their patients (Vlasov, 2018) in public councils under the health administration in 46 regions.

## **1 Methodology**

Various aspects of the formation, development, recognition of patient organizations are actively studied by foreign researchers. According to the authors of the article, an institutional approach is most applicable for the analysis of processes related to patient organizations. This approach makes it possible to assess the significance of the role of patients and patient organizations, identify the criteria these organizations must meet for successful interaction with public authorities, assess the degree of compliance with legal and ethical standards of interaction, and also analyze the best institutional practices. Along with the institutional approach and relevant scientific methods for the analysis of theoretical literature it is advisable to use comparativistic analysis. Thus, K. Landzelius rightly notes that in modern times, the importance of the individual and the role of the patient increased in all countries, which influenced the revitalization of the activities of patient organizations that are now involved in medical research, health restructuring, etc. (Landzelius, 2006). Along with the strengthening of the role of the patient, the importance of patient organizations and their families has increased. According to K. Beier, I. Jordan, C. Wiesemann, and S. Schicktanz (2016), patient organizations and their families can now be considered as collective actors that are of great importance for bioethical practice. Also, the positive processes of institutionalization are facilitated by the creation of self-help organizations uniting patients with rare diseases. G. Pogány analyzes the problems that people with rare diseases have in Hungary, respectively, reveals the circumstances that led to the creation of the Hungarian Federation of People with Rare and Congenital Diseases, which has the status of a non-governmental organization (Pogány, 2014). The recognition by civil society, the state and representatives of the scientific community of the role of patients, patient organizations and

their families is a clear confirmation of the development of the institutionalization process, which is accompanied by a clarification of concepts, the development of criteria for the performance of patient organizations. The researchers, along with the concept of “patient organizations,” began to use the concept of “self-help organizations,” substantiating the criteria that self-help organizations must meet in order to be accepted by governments and represent patients (Rojatz, Fischer & Van de Bovenkamp, 2018). Researchers evaluate the positive experience of the governments of Austria and Germany, which not only formulate criteria for interacting with patient organizations, but also help to unite their efforts. As part of an institutional approach, researchers study the extent to which patient organizations influence this type of policy. For example, K. Souliotis, E. Agapidaki and other researchers (Souliotis, Agapidaki, Peppou, Hasurdjiev. & Sarkozy, 2018), comparing the participation of patient organizations in Italy and France, come to the conclusion that in these countries the low degree of influence of such organizations on health policy, so in this situation it is advisable to coordinate their efforts. Also, researchers are actively exploring the causes that hinder the satisfaction of patients' needs and, above all, their safety. E. Renkema, M. Broekhuis and K. Ahaus rightly believe that patient safety is hampered by doctors violating ethical and professional standards and norms of behavior: doctors, often protecting their personal interests, do not inform patients about medical incidents (Renkema, Broekhuis, & Ahaus, 2014).

In Russia, the process of institutionalization of patient organizations compared to European countries began later on 35 years, so they are currently at the stage of formation and are solving the corresponding tasks. Russian organizations for the protection of patients' rights act in accordance with the federal law “On the basis of the protection of public health in the Russian Federation”. Patient organizations are members of public councils established created by public administration authorities, which is consistent with international practice. At this stage of institutionalization, as a result of the interaction of public councils, patient organizations and authorities, changes in regulatory legal acts that simplify the availability of painkillers can be considered. The result of the interaction is developed procedures for rendering palliative medical care to adults and children, creating conditions for parents to stay with their children in intensive care units, as well as partnering at joint conferences and seminars on the development of palliative medical care. But, despite some results, there are problems in the process of institutionalization of patient organizations. They are especially evident in the Russian regions: a small number of patient organizations and difficulties in the interaction of these organizations with public authorities and health care institutions.

There are especially many problems in organizations that unite patients and parents of minor children with hereditary diseases against the background of primary immunodeficiency states. Primary immunodeficiency (PID) – genetically determined violations of one or more elements of the immune system. As a result, these children develop severe, genetically determined diseases, which are characterized by severe infectious processes, autoimmune, autoinflammatory manifestations and a tendency to develop malignant neoplasms. The most serious group of diseases is severe combined immune deficiency, which manifests itself in the first months of a child's life. The frequency of occurrence of this pathology is 1: 20,000 – 1: 100,000 newborns (Deryabina, Tuzankina, Vlasova, Bolkov & Shershnev, 2017). According to the authors of the article, to develop recommendations for the development of institutionalization of patient organizations with health care institutions, it is necessary to assess which legal and ethical standards actually regulate the interaction of patient organizations and health care institutions, and also to identify what standards contribute to the development of partnerships or impede. Special attention, according to the researchers, is necessary note to the problems that arise in the interaction of the parties in the conduct of genetic diagnostics and the provision of subsequent medical services. Further, it is necessary to classify the identified legal and ethical problems, as well as the subsequent development of recommendations for their solution. For research, it is advisable to apply such methods as analyzing theoretical literature, regulatory legal acts, comparative, sociological analysis, namely, conducting in-depth interviews with members of patient organizations (parents of patients – children with congenital errors of immunity). The application of this method is explained as follows. The amount and number of analyzed patient organizations is small, which does not allow for a survey using the quota sample. Also, almost all patients and parents of sick children do not want to advertise diagnoses. Accordingly, problems can be identified only when establishing the personal contact of the interviewer with the interviewee, when confidence arises. In the study using this method, 15 in-depth interviews were conducted with members of a patient organization registered in the Sverdlovsk Region, one of the largest regions of the Russian Federation.

## **2 Results and discussion**

The analysis of empirical material on the interaction of patients with innate errors of immunity with health care institutions, allows us to draw the following conclusions. During the consultation, doctors are required to issue a referral to a genetic examination of a newborn

child in order to identify or exclude hereditary and congenital diseases. But since today in the Russian Federation there is no established procedure for conducting a genetic examination, doctors do not see the need to register a referral for a genetic examination of a child or an adult patient. At the same time, this type of diagnostics, conducted on the initiative of the patients themselves or the parents of minor patients, is expensive. Accordingly, when doctors do nothing, there are systematic risks: this is a time delay in making accurate diagnoses of diseases of patients, which leads to ineffective treatment. As a result, after 5–10 years, patients are registered for a disability, and in some cases they die. The wrong decision or inaction of doctors affects both the health of citizens and in the future on the health of family members, because diseases with congenital immunity errors are inherited. In the future, risks are accumulating affecting to the deterioration of the country's gene pool.

Theoretical conclusions are confirmed by in-depth interview results. Here is a fragment from an interview with Julia, a member of the patient organization and the mother of a child with innate immunity errors: *“Children get the correct diagnosis very late. For example, a child has been ill since the first year, and he is diagnosed only at 9-10 years old. Accordingly, during this period the child was in intensive care several times, on the verge of life and death. Or another extreme: parents receive an accurate diagnosis of the child’s illness completely by accident: the mother of a sick child knows a good doctor and turns to him for a clarification of diagnosis. But by this time the child had already accumulated organic diseases, which, of course, destroyed the organism. And these destructions could be stopped if replacement therapy prescribed in time.”* There is no doubt that the pooling of efforts by patient organizations should influence the introduction of changes to the existing federal law and the establishment of procedures for conducting genetic diagnostics. Also, the constant interaction of patient organizations and health care institutions can contribute to the development of the training of health professionals who should conduct genetic counseling and provide medical services based on the results of genetic diagnosis. Let us give an interview with a member of a patient organization, Irina, the mother of a sick child who has a hereditary disease based on primary immunodeficiency: *“At local clinics at the place of residence, doctors should immediately identify such children (with FID symptoms) and refer them to immunologists. I understand that in this situation they will have a tremendous burden. But so much time will be saved when making the correct diagnosis! And now our children are sent to different medical specialists, but not to those who need! Doctors conduct various examinations of sick children, but the root cause of diseases often cannot be established! In general, the consultation of an immunologist should be added to the list of medical specialists*

*whose consultation is obligatory. After all, today the consultations of a neurologist and an ophthalmologist are held as mandatory.”* Another interview of a member of the patient organization, Natalia, which confirms the conclusions about the needs of Russian society in the training of specialists carrying out genetic counseling and related medical services: *“There are no competent immunologists. My child and I have been registered with the immunologist since the age of two. But the child was diagnosed by an immunologist in another hospital, not where we were examined. In 90 percent of cases, doctors from local clinics do not even have an idea of what PID is. They also do not assume that it is possible to make such a diagnosis! But even if the diagnosis is made, many doctors do not know how to treat such children. Moreover, I have many times encountered a situation where doctors read the conclusion about the presence of a child's PID and comment on it as follows: “What have these diagnosticians invented?!”*”.

The efforts of patient organizations together with physicians can contribute to the adoption of such an important ethical standard as the training of specialists in the field of genetic counseling, which is reflected in the Valencia Declaration<sup>1</sup>. Often, members of patient organizations representing the rights of patients with hereditary diseases based on FID, when interviewed, note a violation of this ethical standard, such as the doctors' unwillingness to explain the diagnosis to patients and relatives (most often the parents of sick children), as well as prescribe treatment taking into account individual characteristics diseases. Here is a fragment from an interview with a member of the patient organization, the mother of a sick child, Natalia: *“I am starting to consider myself a bad mother. My third child is still not diagnosed. This is taking into account that the story about the older child is known (from the authors - the PID patient). And all the doctors said that there is no and can't be any interrelation in the family between the illness of an older child and the health of other children!”* Another problem has been identified that has both a legal and ethical nature, namely: patients have the opportunity to receive drugs purchased at the expense of budget funds exclusively for the treatment of the main disease. But there is no opportunity to purchase drugs at the expense of budget funds for the treatment of other diseases, but associated with the main disease. While it is necessary for the patient to take medication, regardless of the cost. Often, doctors refuse to patients in the appointment and discharge of drugs under a false pretext. This situation is evidenced by the in-depth interview participants. *“All the medicines that you have to buy yourself (besides the appointment of a doctor) are*

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<sup>1</sup> Valencia Declaration on the Ethical Issues of the Human Genome Project. (1991). June. *International journal of bioethics*, 2(2), P. 94-95. Retrieved from <https://repository.library.georgetown.edu>

*very expensive. Suppose my children, whose primary diagnosis of the disease is “primary immunodeficiency,” constantly suffer from: snout, otitis, bronchitis, laryngitis, diarrhea, and so on. And the drugs that doctors prescribe to us are not included in the list of so-called “life-saving medication.” The drug, which we open and use for the treatment of a child, has a expire date of only one month. Accordingly, I buy the necessary medicines every month. The approximate cost of each drug is 300 rubles (about 4 euros from the authors). Thus, our family spends up to 10–11 thousand rubles a month to buy drugs (approximately 135 euros from the authors). Besides, in order to prescribe the correct therapeutic treatment of a child, it is necessary to pass tests, pay for them, as well as carrying out procedures, and staying in toll chambers during replacement therapy, the cost can reach up to 30 thousand rubles (about 400 euros from the authors)”(Natalia).*

But at the same time there are certain results obtained from combining the efforts of patients, patient organizations and medicians. The concept of predictive, preventive and personalized medicine has been approved in Russia<sup>2</sup>. Expectations from the implementation of the goals and objectives of the Concept are associated with the development of new methods of prevention, diagnosis, treatment and rehabilitation based on an individualized approach to the patient (Order of the Ministry of Health of the Russian Federation, 2018, April). Another problem characteristic of the interaction of patients with a diagnosis of “primary immunodeficiency” with representatives of health care institutions has been identified: this is a significant loss of time during repeated studies, often mandatory, as well as in cases where patients are forced to go to other medical institutions. The solution to this problem may be the study and adaptation of international experience in the adoption of standards that protect the rights of patients, including those with diseases caused by primary immunodeficiency. For example, the Czech Republic’s Law on Medical Care establishes a norm, the use of which allows the patient to make a choice in the provision of medical services (Litovka, Litovka & Chebonenko, 2008).

## **Conclusion**

Undoubtedly, the process of institutionalization of patient organizations in Russia is developing. Proof is a gradual increase in organizations, their participation in community councils, international alliances, their interaction with both public authorities and health

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<sup>2</sup> On approval of the Concept of predictive, preventive and personalized medicine. (2018). April. Order of the Ministry of Health of the Russian Federation. Retrieved from= <https://www.garant.ru/products/ipo/prime/doc/71847662/>.

institutions. The results of institutionalization are presented in partnerships of the All-Russian Union of Patients and its managers with the Ministry of Health of the Russian Federation. But such relationships are formed with difficulty in the Russian regions, which is explained by several problems. These are legal restrictions affecting the actions of doctors when prescribing a diagnostic examination and subsequent treatment of patients with diseases caused by primary immune deficiency. The most reliable way to solve the identified problem is to expand the possibilities for diagnosis based on the accepted concept of personalized medicine, to adopt regulatory documents that should establish the procedure for conducting diagnostics and subsequent treatment of patients. Violation of such ethical norms as the unwillingness of many doctors to explain the diagnosis to patients and features of its treatment, absence the right to choose another medical institution, impede the process of institutionalization. Consolidation of the efforts of patient organizations with medicians and representatives of public authorities, the study of existing problems and the joint search for their solution, the adaptation of the best international experience is the key to the development of social practices aimed at protecting the rights of patients.

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