

REVIEW ARTICLE  
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## VACCINATION AGAINST INFECTIOUS DISEASES: INTERNATIONAL STANDARDS OF PATIENT'S RIGHTS

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### ABSTRACT

**Introduction:** The spread of infectious diseases, the increasing number of people who refuse immunization, the study of international standards of patient's rights during immunization in modern conditions are relevant in modern medical law.

**The aim:** The aim of this research is clarification of patient's rights international standards for vaccination against infectious diseases and ways of their further implementation in Ukraine.

**Materials and methods:** The research is conducted using general and special scientific methods (philosophical-dogmatic, dialectical, logical-normative, system-functional and comparative-legal analysis, statistical and others). The analysis of documents and statistics of international institutions, in particular, the United Nations (UN), the Council of Europe (CE), the World Medical Association (WMA), legal acts of different countries, the judgments and decisions of the European Court of Human Rights (ECHR) and other courts on human (patient) rights and their compliance with immunization (86 court decisions), and questionnaires is conducted. The views of V. Pashkov [1–3], L. Udovyka [2], N. Gutorova [3] and other researchers are studied.

**Conclusions:** International standards of patient's rights for vaccination against infectious diseases and standards when compulsory of vaccination is not violation of international standards of patient's rights are identified in the study. Suggestions are made regarding the future implementation of such standards in health care system of Ukraine.

**KEY WORDS:** vaccination, infectious diseases, patient's rights, compulsory vaccination, international standards of patient's rights

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### INTRODUCTION

Infectious diseases continue to be a serious threat to the lives and health of many people, not only within a particular country or its regions, but globally. And in such circumstances, vaccines are the most important tool for preventing disease outbreaks and ensuring safety in the world [4]. According to the United Nations Children's Fund (UNICEF) cases of the measles disease more than doubled since 2017, to 350,000 in 2018. Many countries (Ukraine, Congo, Madagascar, Liberia, Somalia, Serbia, Georgia, Albania, Yemen, Romania) have the highest level of disease for this dangerous disease.

However, according to the findings of WMA and UNICEF in 2018, every tenth child of the world missed out on potentially life-saving vaccinations for not only measles but also diphtheria, tetanus (almost 20 million people) [4].

Ukraine is at the top of the list of countries with the highest rates of measles incidence, which, despite vaccination against this disease conducted in 2018 at 90% rate among infants, has created a threatening situation for the whole population. This is primarily the result of inadequate vaccination in recent years, which, for example, in 2010 and 2016 did not exceed 29% rate with an increase in the number of people refusing vaccinations [5], that reduced collective immunity to catastrophic levels [6, p. 258].

Based on recent trends, measles outbreaks and other vaccine-preventable illnesses may become more common

in the coming years. Even in countries where such illnesses are considered as eradicated or under control [7].

In the face of these real threats to people's lives regardless of their place of residence, the most important issue of medical law is to develop an international standard of patient's rights which will be common to many countries.

### MATERIALS AND METHODS

General and special scientific methods (philosophical-dogmatic, dialectical, logical-normative, system-functional and comparative-legal analysis, statistical and others) were used in this research, along with: (1) the international legal acts (the Universal Declaration of Human Rights (1948), the International Covenant on Civil and Political Rights (1966), the European Convention on Human Rights (1950), Declaration of Lisbon on The Rights of the Patient (1981, amendments to 1995), the Convention on the Rights of the Child (1989), the Statement on Patient Advocacy and Confidentiality adopted by the 45th World Medical Assembly (1993), the Declaration on the promotion of Patients' Rights in Europe (1994) (the Amsterdam Declaration), European Social Charter, Convention on Human Rights in Biomedicine, adopted by the Council of Europe (1997), European Charter of Patients' Rights (2002) (the European Charter) and others) on human (the patient's) rights; (2) the legal status of the patient's rights in differ-

ent countries (Australia, USA, Poland, Serbia, Slovenia, Ukraine, France); (3) WHO statistics; (4) judicial practice, in particular of the ECHR on the protection of patient and public interest of vaccination, and (5) the views, ideas of researchers about patient's rights and public health.

The empirical basis for the study is the results of the authors' questionnaire of 120 individuals conducted in 2019, Kharkiv (Ukraine), the respondents' group were: 60 parents of children aged 3 to 6 years; 60 young people between 18 and 25 years old higher education students. The purpose of the questionnaire is to find out the attitudes of parents of children and young people to vaccination and issues related to their immunization rights.

## REVIEW AND DISCUSSION

The standardization of health care services is a characteristic feature of health care reform in Ukraine and other countries. This approach also contributes to the introduction of general public health rules for the international community, in particular, regarding vaccination against infectious diseases with respect for human values. And that is the purpose of the UNICEF, WMA and other international organizations. The patient as a subject of medical relations on vaccination against infectious diseases (immunization) is endowed with certain rights proclaimed and recognized at international and national levels. At the same time, the standards of the international concept of human rights are the basis for the patient's relationship with healthcare institutions (doctor, other medical staff) [8, p. 1], enshrined in several international documents. The rights of the patient are implemented within the framework of medical relations concerning immunization from the moment of entry into force of a national law (legal act), that determines the procedure for organizing and carrying out this type of vaccination, and until its revocation.

International standards of the patient rights' in vaccination against infectious diseases are enshrined in: (1) the international agreements signed and ratified by signatory countries in accordance with national law; and (2) in other international legal acts, adopted by international institutions (UNICEF, WMA, etc.). They have different legal meanings: (a) obligatory (for implementation into national law and implementation into the health care system) if the patient's international standards are enshrined in an international treaty ratified by a signatory state, that is, the treaty is recognized as a constituent of national law, and (b) advisory (in all other cases). However, international standards of patient's rights are a model, a generally accepted rule in the medical field, a principle of medical activity in developed countries with an adequate level of human rights and freedoms and are independent of legal meaning. Such standards serve as a criterion for evaluating the quality of medical services and patient safety.

International standards of patient's rights are the rights proclaimed, in particular, in the Universal Declaration of Human Rights (1948): (a) «*everyone has the right to life, liberty and security of person*» (Art. 3), (b) «*no one shall*

*be subjected to torture or to cruel, inhuman or degrading treatment or punishment*» (Art. 5), (c) «*all are equal before the law and are entitled without any discrimination to equal protection of the law. All are entitled to equal protection against any discrimination in violation of this Declaration and against any incitement to such discrimination*» (Art. 7), (d) «*everyone has the right to an effective remedy by the competent national tribunals for acts violating the fundamental rights granted him by the constitution or by law*» (Art. 8), (e) «*no one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, nor to attacks upon his honor and reputation. Everyone has the right to the protection of the law against such interference or attacks*» (Art. 12), (f) «*everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including ... medical care*» (Art. 25), (g) «*in the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society*» (Art. 29) [9].

These international standards of patient's rights are fundamental (universal) for any type of medical activity, in particular in relation to the vaccination of a patient against infectious diseases. Other international human rights acts, adopted later than December 1948, mostly clarify or complement some of these international standards. For example, the International Covenant on Civil and Political Rights (1966) specified the human right to life, with the refinement in p. 1 of Art. 6: «*every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life*». In addition, Part 1 of Art. 24 the right of the child is stating that: «*every child shall have, without any discrimination as to race, color, sex, language, religion, national or social origin, property or birth, the right to such measures of protection as are required by his status as a minor, on the part of his family, society and the State*» [10].

Vaccination against infectious diseases is a medical intervention in the patient's personal life, therefore, the international standards of patient's rights are a guarantee that such intervention must be (a) solely in accordance with the procedures established by law, (b) with protection against illegal (baseless) interference, and (c) with effective restoration of violated rights by the national courts. The social aspect of the spread of infectious diseases and relationships between international healthcare instruments, human rights and the public interests are emphasized by a lot of scientists. V. Pashkov also specifies that «*in some cases the state may legitimately restrict certain rights and freedoms by carrying out mandatory immunoprophylaxis, but it is necessary to prove that such restriction of the human right to freedom of choice in healthcare is as follows: 1) provided by law and carried out in compliance with it; 2) consistent with such legitimate objectives as public health; 3) an absolutely necessary measure to achieve these goals (conformity); 4) necessary in view of lack of less rigid ways to achieve these goals (auxiliary character); 5) conducted not arbitrarily, but fairly and without discrimination*» [1].

It follows from these principle of the international acts: the personal rights of the patient shall be subject only to such limitations that are prescribed by law and are necessary for respect of the rights and freedoms of others and for protection of the public interest (general welfare) in a democratic society; medical staff cannot use the vaccine for vaccination against infectious diseases that leading to the most serious aftereffect as death of the patient; immunize children with life-threatening vaccines on any discriminatory basis, etc.

Specific (by region of action) international standards of patient's rights about medical intervention in the field of human health by vaccination are provided by Art. 4 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (adopted by Council of Europe in 1997): «*any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards*» [11]. This Convention has not been ratified in Ukraine yet and therefore it will take some time for implementation of the specified international standard of patient's rights, in particular, the realization of such standards of vaccination against infectious diseases.

In accordance with the Statement on Patient Advocacy and Confidentiality adopted by the 45th World Medical Assembly (1993) «*medical practitioners have an ethical duty and a professional responsibility to act in the best interests of their patients without regard to age, gender, sexual orientation, physical ability or disability, race, religion, culture, beliefs, political affiliation, financial means or nationality*» [12]. And one of the fundamental rights that medical practitioners must try to implement regardless of the position of governments is «*the right to informed consent to treatment or refusal of it*» (Declaration of Lisbon on the rights of the patient, adopted by the World Medical Assembly, 1993) [13].

Specific (by the territory of action) international (European) standards of patient's rights should include, in particular, the Declaration on the promotion of Patients' Rights in Europe, endorsed by the World Health Organization (Amsterdam, 1994), and European Charter of Patients' Rights, that was drafted by Active Citizenship Network in collaboration with 12 citizens' organizations from different EU countries (Rome, 2002). It was a significant step towards reforming the healthcare system of EU countries and other countries, in particular, Ukraine, that concluded and implemented the Association Agreement with the EU.

It is important that the Amsterdam Declaration consolidates principles of patients' rights, which are based on respect for human rights and human values in healthcare. Such principles are: *respect of person as a human being; self-determination; physical and mental integrity and security of person; respect for privacy and confidentiality; respect for mora, cultural and religious values; right to such protection of health as is afforded by appropriate measures for disease prevention and health care, and to the opportunity to pursue his or her own highest attainable level of health.* [14].

The Declaration provided fundamental patient's rights:

(1) *the right to information about health services and how to use them best;* (2) *the right to the informed consent of the patient as a prerequisite for any medical intervention;* (3) *the right to the confidentiality and privacy;* (4) *the right to receive such health care as appropriate to patients' health needs, including preventive care and activities aimed at health promotion.* It is also important that the Declaration provides for the definition of basic concepts related to patients' rights and, above all, the key concept of «*patient*» that become the official definition of WHO. [15].

The European Charter of Patients' Rights includes fourteen patients' rights: (1) *right of access to preventive health care;* (2) *right to information;* (3) *right to consent* (4) *right of access;* (5) *right to free choice;* (6) *right to privacy and confidentiality;* (7) *right to respect of patients' time;* (8) *right to the observance of quality standards;* (9) *right to safety;* (10) *right to innovation;* (11) *right to avoid unnecessary suffering and pain;* (12) *right to personalized treatment;* (13) *right to complain;* (14) *right to compensation.* The Charter also includes other patient rights, in particular, *the right to perform general interest activities* [16].

International standards of patients' rights are interconnecting with the patient's responsibilities and the rights and responsibilities of the medical staff. The ethical standards of International Code of Medical Ethics (General Assembly of the WMA, 1949) are essential among those standards.

International legal acts (Conventions, Charters, Declarations, Protocols, Recommendations, etc.) about vaccination against infectious diseases enter into force in the case of their general implementation in the national legislation (human rights, medical activity in general), for example, in the Constitutions of the States and/or specifically in relation to vaccination against infectious diseases.

In many countries specific legal acts that regulate the organization of vaccination against infectious diseases are adopted by the legislative body (government, judicial institutions). Slovenia has the Infectious Diseases Act and the United States has the Supreme Court's decision *Jacobson v. Massachusetts* (1905) that provide for the right of states to regulate vaccination issues [17] and vaccination state's law. These are the Laws «*Fundamentals of the legislation of Ukraine on healthcare*», «*On protection of the population from infectious diseases*», «*On providing of the sanitary and epidemic welfare of the population*», «*On stop tuberculosis disease*» and others in Ukraine.

Mandatory vaccination against infectious diseases from the view of international standards of patients' rights is subject of the discussion for many decades. Vaccination is a coercive measure of prevention of infectious disease in many countries (Australia, Belgium, Italy, Serbia, Slovenia, USA, France, Ukraine, Russia, etc.) and is supported by some countries in the world [18] while refusing by others [17, 21, 28, 29]. The main arguments of those who is against mandatory vaccination are violations of fundamental rights to the autonomy (inviolability) of the patient and the quality of medical services. Different approaches to vaccination in countries are the basis for the: number of measles immunizations, different periods of immunization of children,

the presence or absence of exceptions and the difference in their number, as well as different periods of immunization of children, the presence or absence of exceptions and the difference in their number, as well as the legal guarantees for the restoration of violated rights during vaccination in cases of adverse effects on the patient's health.

In this respect, in different countries governmental position with regard to immunization against infectious diseases differs.

For example, in Australia in 2015 the bill removed non-medical exemptions from existing vaccination requirements that had been linked to receipt of family assistance payments since 1998 (for those in the lowest tax bracket this was estimated to amount to \$15,000 AUS per year). In addition, three states also passed legislation that is tightening requirements for children of non-vaccinators [22].

In Italy new vaccines and other innovative measures have been introduced by the National Plan for Vaccine Prevention for 2017–2019 (the law was adopted in July 2017) [22]. According to the law, the list of mandatory immunization consists of 10 vaccinations against: diphtheria, tetanus, hepatitis B, poliomyelitis, measles, mumps, rubella (MMR), varicella, pertussis and *Haemophilus influenzae* type b (Hib). All unvaccinated children cannot attend preschool services until the age of 6 years and there are fines (from 100 to 500 Euros) provided for parents [23].

All states of the United States have a mandatory requirement that children cannot attend schools and preschools unless they have been vaccinated according to schedule and there are exceptions in some states (allowance to refuse vaccinations due to medical, religious or ideological reasons). The number of such limitations has been gradually reduced (for example, in California non-medical exclusions are eliminated, i.e., personal belief exclusions) [22].

Compensation payments according to the Court of Federal Claims («Vaccine Court») decision, which was established in 1980 to consider complaints in the case of vaccinations' negative consequences «in the absence of guilt» [23].

In Belgium 1 vaccination is mandatory, in France their numbers have recently increased (from May 2017) from 3 to 11. Vaccination is compulsory in Serbia [19] as well as in Slovenia, with significant severe measures for those who refuse vaccination [20]. In Poland such a situation gives rise to public protests [21]. In Ukraine 10 mandatory vaccinations should be made with the prohibition of non-vaccinated children to attend preschools and schools, but not all of the parents agree with this decision (According to the results of our questionnaire (Kharkiv, Ukraine, 2019) – 15% of respondents consider vaccinations as «negative» and «rather negative»). At the same time, for example, in Canada and in most EU countries vaccination is a recommendation.

Therefore, the mentioned information shows the different attitude of public institutions to vaccination against infectious diseases with different means of carrying out such an action.

The coerciveness of vaccination against infectious diseases is supported by the courts, for example, the ECHR

recognizes the priority of the public interest over personal (paragraph 36 in case *Solomakhin v. Ukraine*, March 15, 2012 [25]). The same position is observed in court decisions in different countries confirming the lawfulness of non-vaccinated child's admission to a preschool or school institution [17, 27–29].

Is the compulsory vaccination could be considered as a violation of the immunized people rights from the view of international patient rights' standards? The answer – it could be: yes, compulsory vaccination does not violate international patient rights standards if such immunization is (a) legal, (b) justified, (c) timely, (d) commensurate with the risks and (e) provided with quality medical services and quality vaccine; and (f) legal safeguards for the harm caused by immunization «in the absence of guilt» and «in the presence of guilt» are introduced in the country.

While the implementation of compulsory vaccination on the state level, the state actually has to ensure a balance between the public interest and the legal rights of the patient in the face of a serious threat of infectious disease. United States of America is an appropriate example of a comprehensive approach to population-based vaccination.

In today's realities in Ukraine there are problems in exercising a patient's right to receive medical care according to his or her health status, including the preventive and medical care proclaimed by the Amsterdam Declaration. This is confirmed by both the results of the questionnaire and the case law. Thus, 33.3% of respondents of the survey conducted in Kharkiv in 2019 indicated that there were no contraindications for vaccination before vaccination.

Significant violations of patients' vaccination rights, which must meet international standards, were established by the Vinnytsia Court of Appeal (Ukraine) (judgment of 12 February 2019, case no. 128/2994/15-c) [27]. The consequent link between tuberculin diagnostics on April 11, 2006 and the deterioration of the health status of underaged children.

The court found that the tuberculin diagnostics for the children of the Mizyakovo-Khutir secondary school were carried out by a series of medical ferments, which were not checked in accordance with the procedure established by law for compliance with the quality indicators by the state body entrusted with such duty – by the State Service for Medicinal Products. As stated in the resolution, there is no conclusion on compliance with the quality indicators for the 14/51 series of this medical ferments. In addition, no pre-medical examination of the children before medical vaccination was conducted by the medical staff and the consent of the parents of the minor children to the vaccination was not provided.

The aforementioned decision was left unchanged by the panel of judges of the First Cassation chamber of the Civil Supreme Court (Ukraine) (the law from 22 May 2019, case no. 128/2994/15-c) [28].

These two judgments confirm the violation of a number of international patient rights' standards, in particular the right to informed consent, the right to quality standards, and the right to information about the patient's health.

Vaccination is always a risk for the patient, and especially in Ukraine, where legal safeguards for patients' safety require substantial improvement. Despite the fact that patient safety is regulated by the Constitution of Ukraine and many other legal acts introducing civil, administrative and criminal liability, Ukrainian legislation only partially protects the abovementioned rights.

In order to realize the patient's right to safety in Ukraine there is no transparent process of functioning of the health care system at all levels, an independent procedure for quality control of the provision of medical services and rapid response to possible conflict situations have not been established and provided yet in Ukraine [8].

The patient's right to safety is defined in the European Charter, which recognizes that: «*Everyone has the right to protection from harm that may be caused to him by the poor functioning of the medical care system, criminal negligence or medical mistake, and entitled to receiving medical care that meets high standards of safety*». And this standard should be implemented in the Ukrainian healthcare system.

Ukraine is still on the first stages of the health care system reforming and a number of key measures need to be modified to achieve a level of compliance with international patient rights' standards.

First, researchers suggest that according to the European integration direction of Ukraine development it is necessary to proclaim and gradually secure the rights of the patient at the standards set out in the Amsterdam Declaration and the European Charter with the adoption of the Law on Patient Rights and the Medical Code [2]. Secondly, «the formation of a state policy on ensuring the rights to health and life, taking into account the various consequences of such a policy, cannot be narrowed down only to the proclamation of such rights, but also requires planning and development of relevant state programs» [3].

Therefore, state planning for immunoprophylaxis and ensuring the safety of the population should be implemented in Ukraine as soon as possible, with the adoption (as an options) of the National Infectious Disease Strategy and the National Infectious Disease Vaccination Program, in particular, with its mandatory components for quality of care and patient safety.

It is also advisable to consider development of specialized vaccination courts in Ukraine, for instance, using the US experience, and to consider patients' complaints about compensation for harm to their health.

## CONCLUSIONS

1. International standards for the rights of the patient for vaccination against infectious diseases shall be recognized as those rights enshrined in international treaties signed and ratified by the signatory countries in accordance with national law, as well as in other international legal instruments. Such standards are binding or advisory, depending on the relationship with international institutions and the particularities of national law.
2. Compulsory vaccination complies with international patients' rights standards if the state implements a set of

measures to eliminate or minimize the risks of immunization, in particular, to ensure the quality of medical services and the effectiveness of the judicial recovery of violated patient rights, first and foremost, with respect to compensation for the harm caused to the patient «In the absence of guilt».

3. In order to further implement international standards of patients' rights in Ukraine in the process of reforming the health care system, it is advisable to adopt the Law on Patient Rights, state legal acts on the strategy and program of vaccination against infectious diseases with further real steps to ensure the effectiveness and safety of vaccination.

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*The Authors declare no conflict of interest.*

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