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REVIEW ARTICLE

# A MEDICAL ERROR: DOES LAW HELP OR HINDER

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## ABSTRACT

**Introduction:** Health systems and health policies across the European Union are becoming more and more interconnected and also more complex. This increased interconnection raises many health policy issues, including health care quality. Mistakes in medical care can occur anywhere in the health care system – at hospitals, doctor's offices, nursing homes, pharmacies, or patients' homes - and in any part of the treatment process involving wrong medication, improper treatment, or incorrect or delayed test results.

**The aim** of the article is to develop adequate theoretical and scientific-practical proposals for the modernization of the legal regulation to protect patients' rights aimed at observance of constitutional rights and freedoms.

**Materials and methods:** In order to obtain the results the analysis of medical, labor and civil law norms are investigated. The article uses analysis and synthesis methods, as well as a comparative legal method.

**Review:** A number of proposals are given for improving legislation in the area of eliminating obstacles to provision of qualitative primary care / medical-preventive care, prevention of formal attitude towards the patient, the implementation of preventive protection measures which should notify in advance about the violation of the law in the medical sphere.

**Conclusions:** Ukraine urgently needs a legal mechanism to protect the rights of patients; it will become a systemic phenomenon and will consist of legal means, forms, ways by which the restoration of violated patients' rights is provided, the support of protected interests by the law is maintained, legal disputes are resolved and other obstacles to realization of patients' rights are overcome.

**KEY WORDS:** patients' rights, responsibility, protection of patients' rights and interests, medical law

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## INTRODUCTION

Modern medicine has moved ahead. Particularly progressive is the change in patient's rights. One of the main achievements of modern medical legislation is to provide the patient with the right to freely choose a physician, methods of treatment, the right to receive reliable information about his/her health, the right to get qualified medical assistance, etc. Unfortunately, there are also numerous cases of medical errors, hospital malpractice that lead to serious and sometimes irreversible consequences. In Ukraine, there are no effective remedies available to patients. According to statistics, 70% of harmed patients do not even attempt to apply to court because they consider it meaningless. After all, it is almost impossible to win the process against the careless physician. Physicians also make a forensic examination of this medical error. And the honor of a white dressing gown is more important than the health of the patient [1, p. 308].

At the same time, it is a completely different situation in the EU countries. In particular, European countries often incriminate professional errors of physicians in the context of general crimes against the body and life – that is, wounding or causing grievous bodily harm, or causing the death of a person due to negligence – involuntary manslaughter. In this regard Slovenia is quite unique since the Slovenian Criminal Code contains a special offence of negligent treatment. A medical professional that violates the practices and rules of the medical science and profession, and whose conduct negligently causes a significant deterioration in health of a patient can be sentenced to imprisonment up to three years. If the patient dies, the sanction includes imprisonment from one to eight years. The offence is classified in Chapter 20 of Crimes against Human Health, where the central protected right is public health and public confidence in the health system.

From the point of view of the legal assessment of the medical assistance provided (in order to establish the grounds for bringing health professionals or the institution to responsibility), it was agreed to divide the adverse effects of treatment into: medical errors; medical accidents; medical malpractice (professional negligence).

It should be noted that today the well-balanced position regarding the concept of "medical error" has not been formulated yet. Despite the relevant questions were investigated by many scholars, including Bonetti M., Cirillo P., Komarov Yu.M., Leape L.L., Maidanyk N. I., Malein M. M., Martin M., Michael D., Raghuram R., Reason J., Ritchey F.J., Rykov V.A., Senders J.W., Seniuta I. Ya., Sonny B. Bal, Swaminath G., Stetsenko S.H. et al.

The official interpretation of the notion of a medical error in Ukraine is absent. However, the responsibility of a health worker depends on the interpretation of this notion. If the medical error is to take unintentional minor harm to the patient's health, then the physician's responsibility should be appropriate. However, if the result of a medical error was the provision of improper treatment (untimely medical care) which resulted in a significant deterioration in the patient's health, then this is not a physician's mistake but the infliction of emotional and material distress to the patient. This mistake should be compensated by the physician in a way stipulated by Article 16 of the Civil Code of Ukraine. However, traditionally a medical error can not be the result of a careless attitude towards their professional activities. A large number of subjective factors complicate the understanding of this issue, such as lack of experience of the physician, stressful situations and human factor.

## THE AIM

The aim of the article is to develop adequate theoretical and scientific-practical proposals for the modernization of the legal regulation to protect patients' rights aimed at observance of constitutional rights and freedoms.

## MATERIALS AND METHODS

Materials for investigating the patients' rights are: national legislation, the Constitution of Ukraine, the Law of Ukraine "Fundamentals of the Ukrainian legislation on protection Health", "On the Protection of Consumer Rights", the Convention for the Protection of Human Rights. Materials for investigating the medical error are: the Civil Code of Ukraine, Declaration of policies in the field of patient rights in Europe, the Copenhagen Declaration, the Declaration of Tokyo, the Declaration of Lisbon on rights of the patient, the World Medical Association documents, the Declaration on Euthanasia, the Declaration on Human Organ Donation and Transplantation, the Declaration of Helsinki. In order to obtain the results the analysis of medical, labor and civil law norms are investigated. The article uses analysis and synthesis methods, as well as a comparative legal method.

## REVIEW

For example, medical errors in the Republic of Kazakhstan will soon be investigated and combined in one registry. This step would distinguish the mistake from negligence. In addition, hospital ratings and patient reviews will be indicated here. Last year the physicians, by the way, paid for their mistakes more than 9 million tenges. Most patients complain about the physicians, such as anesthesiologists, obstetricians, gynecologists, resuscitators and surgeons. For example, in 2018 50% of complaints out of 3.5 thousand citizens were about the quality of medical care. As a result of consideration of these appeals 430 administrative protocols were drawn up, 299 individuals, 8 officials, 23 legal entities are brought to administrative responsibility [2].

In the world under the medical error scientists understand 1) an unintended act (either of omission or commission) or one that does not achieve its intended outcome [3], 2) the failure of a planned action to be completed as intended (an error of execution), the use of a wrong plan to achieve an aim (an error of planning) [4] or 3) a deviation from the process of care that may or may not cause harm to the patient [**5**].

Modern medical law operates also with the notion of a medical accident – this is an adverse result of medical intervention. This result can not be predicted and therefore it cannot be prevented through a set of objectively compiled random circumstances (although the physician acts correctly and in full accordance with medical rules and standard treatment methods).

In the EU, a medical accident is understood as 1) an unplanned, unexpected and undesired event, usually with adverse consequences [6]; 2) as a commission or an omission, with potentially negative consequences for the patient, which would have been judged wrongly by skilled and knowledgeable peers at the time it occurred, independent of whether there were any negative consequences [7].

So, if I compare the definitions in different countries of the European Union I can assume that there is no standard definition of a medical error which varies widely in the scientific literature. Usually scientists guide on recording, coding, reporting and assessment of medical errors. These definitions are quite similar but they are divided differently into certain categories.

As for the concept of medical malpractice (professional negligence) – these are negligent or intentional actions of a medical worker that has caused damage to the life and health of the patient. Medical malpractice is defined as any act or omission by a physician during treatment of a patient that deviates from accepted norms of practice in the medical community and causes an injury to the patient. Medical malpractice is a specific subset of tort law that deals with professional negligence [8]. Medical malpractice involves patient damage, injury or death attributed to negligent behavior by a medical practitioner or other health care professions [9; 10].

For example, a 24-year-old boy lost his life due to an incorrect diagnosis. An autopsy revealed that the cause of death was a stroke. As it turned out, after the next shift at the mine, Askar Khamzin began to complain of chest pain. Physicians' Ambulance Service diagnosed acute respiratory disease and prescribed treatment with injections. But this treatment did not help. After contacting a private clinic, he was diagnosed with pneumonia. And this time the treatment did not help. Physicians diagnosed a stroke only after the boy was unable to speak. Physicians decide to drive dying Askar 200 kilometers to the regional center. On the way to Aktobe the guy died. Then the physicians stated that the cause of death was the traumatic aortic rupture. But an autopsy proved that the young man died of a stroke. According to local newspapers, surveillance cameras are installed in the hospital reception. According to Askar's mother, the physicians had a record where Askar

complained of heart pain and was waiting for an hour to be examined. But by a strange coincidence, this video has already been deleted [11].

As it was mentioned above, the difference between a medical error and an offense is in the causes and conditions of their occurrence. Medical errors are usually allowed due to objective reasons and circumstances (lack of appropriate conditions for providing assistance, lack of time, insufficiently qualified staff). Therefore, the distinguishing feature of medical errors is the integrity of the medical staff. However, these errors were the result of an unreasonable attitude to the work of medical staff, the medical institution is obliged to compensate for the damage caused to the health of the patient due to the fault of its employees.

## DISCUSSION

Ukrainian legislation has a number of legal norms that must implement the patient's right to provide health care quality. The basic personal non-property rights of an individual are prescribed in the Constitution of Ukraine (the right to life, the right to health care, the right to medical care), the Civil Code of Ukraine (Articles 283, 284, 285), the Law of Ukraine "Fundamentals of the Ukrainian legislation on protection Health" (Articles 6, 38, 39, 40, 41, etc.). Every Ukrainian according to the Constitution of Ukraine has the right to health care quality but more and more often there can be seen medical errors that entail serious consequences for the patient. The right to life, the right to health care and the right to medical care are also provided by the Convention for the Protection of Human Rights and Fundamental Freedoms [12].

Typical causes of medical errors are: 1) the inconsistency of the actions of several physicians (if the patient undergoes treatment in several physicians); 2) the improper use of medical equipment (most often these are mistakes in dentistry); 3) the negligence and non-compliance with sanitary norms; 4) the improper prescription of medicines (inappropriate drugs or careless attitude to contraindications); 5) low qualification of physicians.

Examples of medical error are numerous. According to the current legislation civil liability is provided by the Civil Code of Ukraine, the Law of Ukraine "On the Protection of Consumer Rights" (health minor damage, for example, an incorrect diagnosis and accordingly the appointment of incorrect treatment that led to deterioration in the condition of patients) and criminal provided by the Criminal Code of Ukraine (illegal abortion which resulted in the death of the patient or serious harm to her health; introduction of infection which includes HIV as a result of noncompliance with sanitary standards, private medical activity without a corresponding license that caused the death of a patient or harm to health; failure to provide assistance to a patient that has resulted in a fatal outcome or causing moderate or severe harm to the health), negligence, improper or poor-quality (careless, negligent) performance by the physician of his/her duties that has led to serious irreversible consequences.

Medical errors can occur at any stage of the medication process (prescription, delivery, dispensing, administration and monitoring). In Europe, researchers refer to the most common medical errors: management errors, investigation errors, decision making errors, missed diagnosis, omission or delayed evaluation of important parameters, unnecessary treatment, unnecessary tests and deadly procedures, uncoordinated care, infections, from the hospital.

As a rule, lawyers treat medical error as unintentional harm to health resulting from improper provision of medical care or inactivity of the physician. In practice, proving the presence of a medical error is difficult enough. The main problem in proving the existence of a medical error is the collection of the necessary evidence by the victim. It is practically unreal to bring the physician's guilt to court, only if the physician prescribes forbidden medicines, accidentally injured the patient during the surgery and forgot tools or a napkin in the patient's body. At the same time, the most important stage in the process of gathering evidence is a written confirmation that the health problem arose from the fault of the physician. This will require all records from a medical card, examination data, etc. The best way to confirm the existence of a health disorder after providing unskilled help is to conduct an examination. But there are also nuances: the forensic examination is carried out according to the decision of the investigator/inspector and it is carried out by medical workers who do not want to prove the error of their colleagues.

Despite the presence of a large number of normative legal documents in Ukraine there is no real mechanism for protecting the patients' rights. It negatively affects at the image of Ukraine. After all, in all democratic states special attention is paid to the issue of human rights observance and freedoms. The development of the legal system for the protection of human rights is in the direction of differentiation of certain groups that need special treatment (depending on their age, gender, health, etc.) In this regard, the importance of the legal protection of the patient increases. The need for a special legal protection of the patient's interests is documented in a number of declarations and conventions adopted by international medical associations. These documents are the World Health Organization (A Declaration on the Promotion of Patients' Rights in Europe, dated 1994 [13]; the Copenhagen Declaration, dated 1994 [14], etc.), the World Medical Association documents (The Declaration of Tokyo, dated 1975 [15], the Declaration of Lisbon on rights of the patient, dated 1981 [16], the Declaration on Euthanasia, dated 1987 [17], the Declaration on Human Organ Donation and Transplantation, dated 1987 [18], the Declaration of Helsinki, dated 1989 [19], etc.

Ukraine urgently needs a legal mechanism to protect the patients' rights that will become a systemic phenomenon and will consist of legal means, forms, ways in which the restoration of patients' violated rights is ensured. The protection of humans' interests by the law, legal disputes are resolved and other obstacles to the realization of patients' rights are overcome. Essentially, this is a mechanism where the rights, duties, incentives and responsibility of the subjects of medical legal relations are combined. In order for the mechanism of protection to be effective, the synchronous actions of its components must be done. The qualitative legal norms are important but they are nothing when they can not be realized

in practice. Thus, the impossibility for the patient to gather evidence by legal means, the lack of adequate professional expertise undermines the provisions of the Constitution of Ukraine regarding the necessity to observe the constitutional rights and freedoms of citizens.

The right to protection can not be declarative. The right to protection includes, on the one hand, the possibility of an authorized person's own actions and on the other hand, the ability to demand appropriate behavior from the obligated person, as well as the possibility to apply to the competent state bodies for the protection of rights and interests.

Thus, it can be stated that the traditional mechanism of protection of patients' violated rights is ineffective. Accordingly, it is necessary to introduce measures that would prevent the commission of an offense (preventive protection) or in other words, measures to advance.

## CONCLUSIONS

The first is the implementation of measures for the development of legislation regulating relations in the medical sphere. In particular: the unification of legal regulation of medical workers, protocols of relations between a physician and a patient, treatment protocols, the creation of new model contracts for the provision of medical services by consulting the management of the Ministry of Healthcare with representative client groups in order to determine the conditions for the best provision of unified services, the creation in the structure state body of training centers, which will help to ensure the quality of services that will be provided in future by medical institutions of all levels [20, p. 14].

Secondly, to oblige the Ministry of Healthcare to monitor the multidirectional actions of normative legal acts, to prepare a generalization of enforcement practice and analytical work on eliminating gaps and conflicts in legislation and ways of harmonizing medical legislation.

Thirdly, it is appropriate to increase the level of personal responsibility of the chief medical officer for the response to the complaints of patients, excluding the cases of formal answers. At this stage the conflict between the physician and the patient can be resolved by mutual consent. In order for the application to protect the patient's rights had positive effects (timely and substantially considered) we should increase the personal interest of the chief medical officer. For example, it is necessary to formalize in legislation the duty of the medical centre administration to bring the person in charge (according to the results of the official investigation) to responsibility. It will increase the responsibility of the chief medical officer for taking concrete measures to eliminate the offense with the subsequent notification of the patient (the complainant) about the results. So, only the personal responsibility of physicians, medical centre administration and the prospect of being disqualified for some time (the inability to hold the corresponding posts) will promote the understandable result for the society. It will explain the mechanism for protecting patients' rights. This model will be perceived by patients as consolidating the real opportunities provided by the state. And inevitability of responsibility for the committed offenses will stimulate the representatives of the medical industry to legitimate actions.

Fourthly, in accordance with Article 22 of the Constitution of Ukraine: "human and citizen rights and freedoms affirmed by this Constitution shall not be exhaustive. The constitutional rights and freedoms shall be guaranteed and shall not be abolished. The content and scope of the existing rights and freedoms shall not be diminished by an adoption of new laws or by introducing amendments to the effective laws" it is necessary to introduce the notion of a primacy of the lawfulness of the patient. According to this the duty of the physician is to provide the evidence base on the merits of the conflict. As well as all the rules of law that are ambiguous should be treated in the best interests of the patient.

Fifthly, the preventive protection of the patients' rights can be realized through the participation of non-governmental organizations in making arrangements and implementation of medical services. At the same time, the list of such public organizations should be determined by a document at the level of the legislative act (the resolutions of the Cabinet of Ministers of Ukraine, Presidential Decree, etc.). This innovation will allow authorized non-governmental organizations to extend legislative safeguards for the observance of patients' rights by: 1) participating in the development of legal and regulatory framework of medical relations and standards for the provision of medical services; 2) harmonization of the standard terms of contracts that will be signed subsequently between the patient and the medical institution on provision of medical services (if they do not contravene the law); 3) public control over the actions of the administration of the medical institution and physicians on the application of the patient (victim) in case of violations of the requirements of the current legislation; 4) reverse control of the medical workers level of qualification, namely, participation in personnel attestation.

Sixthly, it would be advisable to introduce reformist principles in training physicians. Important and significant at the same time is the movement of the introduction of the principles of academic integrity, which is now gaining in popularity. The modern understanding of the concept of academic integrity is formulated in the document of the Centre for Academic Integrity in 1999. The basis of the definition is the phrase of fundamental virtues: honesty, trust, justice, respect, responsibility, courage. Thus, a conscious moral choice, care for reputation will become a solid basis for combating various abuses, corruption in the medical sector [21, p. 161].

The last and the most important issue that needs to be solved is increasing the competence of physicians and medical staff, encouraging and attracting health professionals to continuous professional growth. At the same time, it is important not only to acquire the necessary knowledge, skills, experience in professional occupation but also the ability to use them in practice for the benefit of patients. Modern medical education requires a systematic and conceptual approach to modernizing the learning process, taking into account new and advanced technologies, the latest innovations and borrowing the best foreign practices developed by the Accreditation Council for the Higher Medical School (USA), a toolkit for evaluation under the scheme called "Miller's Pyramid" etc. The general world tendencies in

postgraduate education of physicians are its continuity. That is, medical workers are constantly updating their knowledge and practical skills from compulsory education to the end of their professional activity. Such actions are carried out in order to improve the quality of medical services provision and patient's safety (there are qualitative indicators of safety and effectiveness of treatment). The moral responsibility for a patient's share is a physician's commitment which is realized through the mechanisms of licensing and certification of physicians and other medical workers. Public information is available about the quality of physician's work and the ratings of a health facility.

The introduction of such an experience will be beneficial for Ukraine because this is not a necessity for patients, but a modern necessity. Recently, there have been serious changes, in particular: the medical information update has been speeded up, the number of highly effective medicines and diagnostic technologies has increased, advanced health care practices have emerged that require highly qualified physicians and medical services have risen in price. Accordingly, the measures should be introduced in Ukraine that will promote the reform of the medical sector, first of all, by increasing the competence of medical staff. Therefore, it would be advisable to introduce a post-graduate accumulative system of educational credits (hours) for the training of physicians and nurses. It would be appropriate to create modern laboratories, centers for working out practical skills, technical means for distance learning in universities and medical institutions and provide access to modern high-quality information sources. They will later become the basis for the creation of a single Ukrainian medical-information space with the ability to exchange and share data.

So, in the field of health care in Ukraine there are many unresolved problems and these drawbacks affect both the quality of health service provision and the effectiveness of the mechanism of protecting patients' rights. It is clear that such issues are not solved in one day. However, the reform of the medical sector is urgently needed in Ukraine because health-care and well-being of all Ukrainian people depend on it.

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