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Medical Illegality and Errors in the Leading Legal Practice

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Abstract The lack of a unified approach to understanding and tackling medical errors is a factor in the failure of the established leading legal practices of national courts. Under the Article 140 of the Criminal Code of Ukraine there exists a responsibility for improper performance of professional duties by a medical or pharmaceutical worker. Ukrainian law does not actually distinguish between a medical error and a criminal offense.
Our results allow us to distinguish three approaches to understanding of the medical error. Under the first approach, a medical error is seen as objectively unlawful action with a negative social consequence inherent in it, a defect in professional activity. According to the second approach, a medical error is understood both as a result of good faith deceit and as a result of the committed negligence. In accordance with the third one – under the error is recognized any departure from medical standards, including clinical protocols. The relationship between concepts "doctor's error", "medical error", "healthcare mistake" is determined. In the practice of the European Court of Human Rights, a medical error, medical negligence and deliberate failure or improper performance of professional duties are distinguished. The European Court of Human Rights sets out two aspects of dealing with cases of death due to failure of provision or inadequate provision of medical care: effective legal regulation of healthcare; efficient means of control, investigation and prosecution of perpetrators.

Keywords: *leadership, legal practice, law, medical illegality, medical error*

1 Introduction

National jurisprudence under Art. 140 of the Criminal Code of Ukraine (hereinafter referred to as the CC of Ukraine) which provides for liability for the improper performance of professional duties by a medical or pharmaceutical worker is not established and is at the stage of becoming and needs to be solved a number of tasks, including the delineation of medical errors and medical negligence. In addition, it is worth noting that ambiguous understanding of the meaning of the term "medical error" among healthcare workers does not contribute to the normalization of relations "doctor-patient" and negatively affects the designated domestic jurisprudence under Article 140 of the CC of Ukraine. According to an analysis of court decisions in Ukraine, a significant number of job instructions in the field of health care contains the order on liability for error. However, the legal regulation in Ukraine of this phenomenon does not fully meet the requirements of legal certainty, because in accordance with paragraph 22 of Part 1 of Article 92 of the Constitution of Ukraine, it is by law, and not by other normative legal acts, that the principles of legal responsibility are fixed and various types of offenses are established, which is fully in line with the legal principle "*nulla poena sine lege*". At the same time, as the case law of the European Court of Human Rights (hereinafter referred to as the ECHR) points out, the problem of the provision of quality medical services as well as the prevention of medical errors is constantly being raised even in other European states.

The analysis of the research literature related to the subject of our study suggests that lawyers tend to uphold the thesis about the need for liability for a medical error, and healthcare professionals usually argue for the inappropriateness of such liability.

In 2018, the Medical News of Georgia published the results of a study of a team of authors (see Buletsa et al. 2018), however, in this paper, as in "Medical Error in Ukraine" (Buletsa 2011), the social nature of the medical error is not appropriately taken into account therefore, the analysis of the national jurisprudence and of the practice of the ECHR is not being conducted. Another paper by Opanasenko et al. (2017) highlights only the medical aspect of the phenomenon under study.

The attention of many researchers is also focused on certain types of medical errors in order to evaluate the prescription writing errors in different community pharmacies and tertiary care hospitals also to assess the knowledge of patients regarding their disease and treatment. Some of these issues are considered, for example, in the paper by Khan et al. (2019).

A team of Iranian scientists while studying the problems of medical errors has set a goal to "design a valid and reliable questionnaire to investigate the status of medical error disclosure by physicians" (see Mohammadi 2019). Systemic changes in the health care system aimed at improvement of health care delivery, including the prevention of medical errors, have become the subject of cognition by Linville and Bates (2017). In addition, the results of a systematic study of health risks and related medical errors are outlined among others by Jimenez-Rodriguez et al. (2018). However, the specificity of the activities within the health care necessitates the need for comprehensive cognition of the phenomenon of medical error and the issue of provision of appropriate quality medical services, which requires both legal and medical knowledge.

The purpose of our paper is to determine, based on the results of the analysis of the practice of national courts and the practice of ECHR, the criteria for distinguishing between medical errors and medical negligence, and to identify areas for improvement of the existing legislation in this field.

2. Materials and methods

The systematic methods were put into the basis of the research which allowed to comprehensively cover the issues of medical errors, determine their correlation with similar phenomena and analyze the decisions of courts within the studied category of cases. Generalization of judicial practice was made with the help of statistical methods. Generalizations by the results of the judicial practice analysis have become possible due to the use of modeling method.

Achieving the goal of the study led to the need to work out 32 sentences of national judicial authorities adopted in criminal cases under Article 140 of the CC of Ukraine, within the period from 2014 to 2018 inclusively, which was carried out using logical methods of analysis and synthesis. Study of ECHR practice, in particular, of 27 decisions against Azerbaijan, Belgium, Bulgaria, Italy, Latvia, Lithuania, Germany, Poland, Portugal, Russia, Romania, Slovakia, Slovenia, the United Kingdom, Turkey, Ukraine, France, and the Czech Republic was carried out using a comparative method, in addition to methods of analysis and synthesis.

3. Results and discussion

In Article 6 of the Fundamentals of the Ukrainian legislation on health care enshrine the right of citizens to health care, which includes, in particular, qualified medical care; indemnification of damage caused to health; appeal against misconduct and decisions of bodies and individual workers of health care institutions. However, medical care should be provided by professionally trained health care professionals who are required to follow the system standards within the field of health care, the constituent part of which are the clinical protocols. Similar regulations are found in other European states. However, this does not exclude the presence of medical errors and of inadequate provision of medical services.

The appearance of the term "doctor's error" in the territory of Ukraine is associated with the name of the prominent surgeon Pirogov, who pointed out the necessity to realize the intrinsic need of every conscientious person to disclose his/her mistakes in order to prevent them by others, less informed (Petrovskij 1976).

The Great Medical Encyclopedia interprets the concept of medical errors as "*errors of the physician in the performance of his professional duties, which are the result of conscientious deception and which do not contain essential elements of offence or features of a misdemeanor*" (Petrovskij 1976). As Tweedy (2017) points out, the United States National Patient Safety Fund (NPSF) avoids the use of the term "medical error" using instead the term "healthcare error", interpreting the latter as an "unintended consequence of a medical help caused by a defect while helping the patient. Mistakes in health care can be errors of action (performance of wrong actions), inaction (failure to perform the right actions) or completion of the necessary formalities (performance of the right actions incorrectly (wrongly)" (Tweedy 2014). The same term is used within the Canadian health care industry (Baker and Norton 2006).

In our opinion, this approach does not correspond to the legal traditions of the system of continental

law, within which the established requirements for legal technology in the field of lawmaking are elaborated. The use of a fixed term in the national system of law over-extends the scope of the phenomenon under study and will contribute to the unification of approaches to its understanding and, accordingly, legal certainty. Thus, a mistake in the field of health care may include purely technical mistakes made by employees of the central body of executive power in the field of health care.

At the same time, the use of the term "medical error", on the contrary, unduly narrows the phenomenon under study. Indicative in this context is the case against a doctor of Shevchenko Central District Hospital of Kharkiv region, as well as a nurse of the same medical institution in connection with causing by the latter to patient serious injuries due to intravenous administration of a medicine "Ferrum Lek". The nurse, following the doctor's prescription, made an intravenous injection of the medicine, which is only administered intramuscularly according to the inscription on the package and the ampoules (2014).

Given the above mentioned it is most appropriate to use the established term "medical error". In general, the analysis of scientific medical and legal literature allows us to distinguish three main approaches to understanding the concept of "medical error".

Within the first approach, a medical mistake is considered as an objectively unlawful action with inherent negative social consequences, a defect in professional activities, innocence of an action (act or omission), failure to achieve a positive result of medical care. It is within this approach that the medical error and the improper performance of professional duties by a medical or pharmaceutical worker (Article 140 of the CC of Ukraine) are distinguished, the main criterion of which being the subjective side of the action. An offense (criminal, administrative or disciplinary) is always characterized by the presence of guilt (for the phenomenon under study a person possesses guilt in the form of negligence – unlawful overconfidence or unlawful negligence). Medical error, however, is an innocent act committed through the faithful deception of a medical professional.

Making a mistake, the health care worker is not aware of the social harm of his or her actions and does not anticipate (and cannot predict) the occurrence of negative consequences.

According to the second approach, medical error is understood both because of a deliberate deception and as a result of negligence. This approach allows distinguishing between excusable and inappropriate medical errors. The first of these is interpreted as such one that could not be avoided by a conscientious and thorough analysis of the situation. Accordingly, the fault of the healthcare worker is absent. The second is regarded as such that could have been avoided on condition that of careful analysis of the situation. The criterion for distinguishing between these types of medical error is the subjective side of the action, namely: absence / presence of guilt.

We can note that the analysis of national jurisprudence under Art. 140 of the CC of Ukraine indicates that national law enforcement does not actually distinguish between medical error and criminal offense. Thus only 10 defendants have pleaded guilty, with one of them pleading guilty to the criminal offense in part, requesting that the amnesty law be applied to them.

In addition, the analysis of 32 judgments of national judicial authorities allows to assert about high probability of that that in a significant number of cases a person has pleaded guilty, based on motives for dismissal from criminal liability through the application of the provisions of the amnesty law or in connection with the expiry of the limitation period (Article 49 of the CC of Ukraine), exemption from serving a sentence of probation (Article 75 of the CC of Ukraine).

It should be noted that the analysis of the sentences of the Ukrainian courts indicates that most of the accused (defendants) under Art. 140 of the Criminal Code of Ukraine are anesthesiologists and maternity wards workers. Thus, according to 2018 data, the designated category of persons was about 4 out of 6.

The third, - broad, - approach to understanding medical error involves recognizing as such any deviation from medical standards, including clinical protocols. Under such an interpretation of a medical error, it also includes intentional acts. The analysis of national legislation suggests that this approach is not applicable in the national legal system. This is directly indicated by the existence of criminal liability for failure to provide assistance to a sick by a medical worker (Article 139 of the CC of Ukraine).

The basics on legal framework as to prevention of improper performance of professional duties by a medical worker and medical errors in the member states of the Council of Europe is reflected in the ECHR's practice. According to paragraph 1 of Article 46 of the Convention for the Protection of Human Rights and Fundamental Freedoms (hereinafter referred to as the Convention), the parties to the Convention undertake to comply with the decisions of the ECHR to which they are parties. And given the immanence of precedent to the practice of this Court, decisions against other States parties to the Convention are important in preventing complaints against an individual State. In doing so, the jurisdiction of the ECHR extends to all matters of application of the Convention. Although the Convention does not enshrine the right to health care or the provision of medical assistance, a large proportion of cases relating to health care system shortcomings are considered in the context of Article 2 of the Convention (the right to life) and Art. 8 of the Convention (the right to respect for privacy and family life). Considering that the ECHR practice under Art. 8 of the Health

Convention goes beyond the scope of our study (for example, surrogacy, childbirth home without doctors, frozen embryos issues, etc.), we focus on the Court's decisions under Article 2 of the Convention.

The right to life implies both negative and positive obligations of the state. The latter, in particular, require anticipating adequate measures to "ensure the high professional standards of healthcare professionals and protection of patients' lives" (European Court 2006). The state is obliged to adopt legislation that, in its turn, obliges healthcare institutions (not only public or communal, but also private) to take the necessary measures to ensure the protection of patients' lives. In addition, an effective and independent judicial system must be established to identify the causes of death of the persons who were being provided medical assistance to and to hold to account those responsible (ECHR 2013). The ECHR's position on medical error and carelessness of healthcare workers is as follows:

1. error of judgment of a health care worker, negligence in coordinating the actions of such workers during the treatment of a patient are not sufficient to hold the state liable for the fulfillment of positive obligations under Art. 2 of the Convention (ECHR 2006);
2. in order to prevent medical negligence, the national system of law should provide for remedies for victims: a) in criminal courts; b) in civil courts, either individually or in conjunction with remedies in criminal courts;
3. in disciplinary bodies (Calvelli and Ciglio vs Italy) (ECHR 2002).

In general, each of the States Parties to the Convention criminalizes medical negligence (homicide by negligence, unintentional bodily harm, etc.), with Bosnia and Herzegovina, Armenia, Slovenia, Ukraine, Croatia, Macedonia committing medical negligence is qualified as a separate crime. It is the state itself that is responsible for the damage caused by its representatives, and liability for the harm caused to the health or life of the patient by the actions of health care workers is a component of that responsibility of the state;

3) the state should create conditions for immediate consideration of the case concerning the death of a person in hospital. Information about the facts and possible mistakes made in the care process is set out to be disseminated to health care staff to prevent the recurrence of such mistakes, which will contribute to the safety of health care recipients (Byrzykowski vs Poland) (ECHR 2006);

4) the deficiencies in the provision of medical care do not make the Contracting State responsible for the breach of Art. 2 of the Convention (Lopes de Sousa Fernandes vs Portugal) (ECHR 2017);

5) breach of obligations under Art. 2 of the Convention may occur if the actions and omission of health care workers go beyond mere error or medical negligence, when health professionals who violate their professional responsibilities refuse the patient immediate treatment, fully recognizing that failure to provide treatment threatens a person's life (Mehmet Şentürk and Bekir Şentürk vs Turkey) (ECHR 2013).

Thus, the ECHR distinguishes two aspects of the handling of death cases through the failure to provide or improperly provide medical assistance. The first is related to the effective legal regulation of health care sphere, which obliges medical institutions to take appropriate measures to protect patients' lives. Usually the ECHR does not find such a violation. As an exception, let's call the case Arskaya vs Ukraine, by the result of examination of which it is stated that the Ukrainian national legislation in the field of providing medical care and abdication of a patient did not explain in sufficient detail the conditions under which refusal to receive treatment was valid and obligatory for medical staff. The legal framework did not adequately ensure ability to make decisions by the patient promptly and objectively in the course of due and fair process. In addition, the legislation did not adequately regulate the admission of patients to (ECHR 2013) intensive care units.

The second aspect analyzed by the ECHR is the procedural one – how effective are the means of control, investigation and prosecution of perpetrators. At the same time, deliberate failure to perform or improper performance of duties by medical professionals, medical negligence and medical error are distinguished.

The difficulty of distinction between medical negligence and medical error is stipulated by the very nature of the latter. The individual characteristics of the patient's body, the state of development of medical science, the personal professional experience of a medical professional are the factors that, in the aggregate, may influence the diagnosis of the patient, the choice of treatment tactics and, accordingly, may not always be fully regulated. Much of the situation is unique. Thus, in the case on charges of a doctor of the Military Medical Clinical Center of the Central region of insufficient examination of the patient before surgery, underestimation of his health status, not performed during the surgery of the ECG monitoring that led to the death of the latter, experts were interviewed in court and it was found that a fracture of the neck of the thigh is a threat to the lives of patients, 80% of whom die without surgery. At the same time, if a patient is put on an endoprosthesis with the use of cement (licensed in Ukraine), then according to statistics 3% of patients die from the toxic effect of cement, which is poisonous, one of the complications specified in the instructions before its use is cardiac arrest, stroke, heart attack, thromboembolism. One expert claimed that "*it is impossible to distinguish whether a fracture of the femoral neck or direct surgery led to the death of the PERSON_6. ... It could have been*

anticipated the occurrence of fat embolism in the PERSON_6 by the doctor the PERSON_2, but he did not know what to do to prevent the death of the patient " (Unified State Register of Judgments 2015a).

In another case, the panel noted the fact that "the problem of acute deep vein thrombosis and pulmonary artery thromboembolism remains one of the most difficult problems in medicine. This is evidenced by the high mortality rate among patients, including the traumatic profile, which ranges from 20% to 64% in leading clinics in the world" (Unified State Register of Judgments 2015b).

In one case in 2016, an expert testified that the patient had a disease that did not manifest itself, however, affecting all organs, and during the surgery, blocked breathing. Doctors objectively could not have known about the patient's presence of this disease (Unified State Register of Judgments 2014a; Unified State Register of Judgments 2014b).

In this context, it should be noted that in the case on the charge of the head of the urological department of the regional clinical hospital it was stated that the incident, which could be seen as a special case, could not be prevented "even with the most conscientious attitude to his professional duties and which may be caused by the particular complexity of the diagnosis of the disease, the anatomical, physiological properties of the organism of a particular person, the atypical development of the disease" (Unified State Register of Judgments 2015c).

That is why all the cases analyzed (except for a few, where a plea agreement was concluded between the prosecutor's office and the accused), involved the involvement of experts. Without specialists with specialist medical knowledge, it is virtually impossible to determine the adequacy of medical care. In doing so, experts need not address the issue of the presence / absence of guilt of the healthcare worker whose resolution is the responsibility of the prosecution party and is finally established by the court.

4. Conclusions

Overall, one can see that medical negligence and medical error are different in kind and content phenomena, so that in order to improve the practice of national courts, it is necessary to amend the Fundamentals of Ukrainian legislation on health care by supplementing Part 1 of Article 3 with the following definitions of "medical negligence" and "medical error": medical error – the innocent action (act or omission) of a healthcare professional that has caused (or could cause) potential harm to a patient's health and which results from a deliberate deception; medical negligence – failure to perform or improper performance professional duties by a healthcare professional as a result of a negligent or dishonest attitude towards them that has caused / could cause harm to a patient's health.

Due to the social nature of the medical error and medical negligence, a compulsory procedural action (both of criminal and of civil proceedings) must be accompanied by appropriate medical expertise (the responsibility of which is not to establish the guilt of the medical professional), even if the guilt is admitted by a medical professional in the incident.

Our analysis of the national courts' judgments conducted in this paper makes it possible to conclude about the ability of improvement of the educational process in medical schools for training anesthesiologists and maternity wards workers. These findings received by result of analysis of judicial practice form the basis for further investigation of the identified issue.

As a final remark, we can state that everyone has the right to be treated by medical professionals in accordance with a reasonably expected standard. An important means of securing this right is civil and law liability. The results obtained form the basis for further study of the issue of civil and law liability for a patient's health harm caused by a medical error.

References

Baker GR, Norton P (2006) Patient Safety and Healthcare Error in the Canadian Healthcare System. A Systematic Review and Analysis of Leading Practices in Canada with Reference to Key Initiatives Elsewhere. https://www.canada.ca/en/health-canada/services/health-care-system/reports-publications/quality-care/patient-safety-healthcare-error-canadian-healthcare-system-systematic-review-analysis-leading-practices-canada-reference-key-initiatives.html Accessed 29 Mar 2020

Buletsa S (2011) Medical Error in Ukraine. Medicine and Law 1(30):39-53

Buletsa S, Drozd O, Yunin O, Mohilevskyi L (2018) Medical Error: Civil and Legal Aspect. Georgian Medical News 3(276):156-162

ECHR (2002) Case of Calvelli and Ciglio vs Italy, Application no. 32967/96. http://hudoc.echr.coe.int/eng?i=001-60329. Accessed 29 Mar 2020

ECHR (2006) Case of Byrzykowski vs Poland, Application no. 11562/05. http://hudoc.echr.coe.int/eng?i=001-76066. Accessed 29 Mar 2020

ECHR (2013) Case of Arskaya vs Ukraine, Application no. 45076/05. http://hudoc.echr.coe.int/eng?i=001-138590. Accessed 29 Mar 2020

ECHR (2013) Case of Csoma vs Romania, Application no. 8759/05. http://hudoc.echr.coe.int/eng?i=001-115862. Accessed 27 Mar 2020

ECHR (2013) Case of Mehmet Şentürk and Bekir Şentürk vs Turkey, Application no. 13423/09. http://hudoc.echr.coe.int/eng?i=001-118722. Accessed 27 Mar 2020

ECHR (2017) Case of Lopes de Sousa Fernandes vs Portugal, Application no. 56080/13. http://hudoc.echr.coe.int/eng?i=001-179556. Accessed 29 Mar 2020

Jimenez-Rodriguez E, Feria-Dominguez JM, Sebastian-Lacave A (2018) Assessing the Health-Care Risk: The Clinical-VaR, a Key Indicator for Sound Management. International Journal of Environmental Research and Public Health 15(4):639. doi: 10.3390/ijerph15040639

Khan, MF, Ali Salman M, Khan NH, Masood T (2019) Evaluation of Errors in Prescription Writing: A Cross-Sectional Study at Community Pharmacies and Tertiary Care Hospitals of Lahore, Pakistan. Bangladesh Journal of Medical Science 2(18):260-266. doi: 10.3329/bjms.v18i2.40695

Linville Jr. MD, Bates JE (2017) Graduate Medical Education-Accelerated Change. The American Journal of the Medical Sciences 2(353):126-131. doi: 10.1016/j.amjms.2016.12.001

Mohammadi, M., Larijani, B., Tabatabaei, S.M., Nedjat, S., et al. (2019). A study of the validity and reliability of the questionnaire entitled "physicians" approach to and disclosure of medical errors and the related ethical issues". Medical Ethics and History of Medicine 2(12):1-15. doi: 10.18502/jmehm.v12i2.765

Opanasenko MS, Konik BM, Tereshkovych OV, Levanda LI (2017) Medical Error: the Essence of the Problem and the Clinical Case of Videothoracoscopic Removal of the Foreign Body of the Pleural Cavity. Ukrainian Pulmonary Journal 2:18-21

Petrovskij BV, Big Medical Encyclopedia, Volume 4, 1st edn. (Moscow: Soviet Encyclopedia, Medical Errors, 1976), 557 p.

Tweedy JT, Healthcare Safety for Nursing Personnel: An Organizational Guide to Achieving Results, 1st edn. (UC: Taylor and Francis, 2006), 366 p.

Unified State Register of Judgments (2014a) The judgment of the Shevchenko district court of Kharkiv region in the case No. 637/586/14-к dated 17.06.2014. Kyiv: State. Enterprise "Information Judicial Systems". http://re8. yestr.co9. urt.gov.ua/Review/40619218 Accessed 24 Mar 2020

Unified State Register of Judgments (2014b) The judgment of the Vinnytsia district court of Vinnytsia region in the case No. 127/18037/14-к dated 22.07.2015. Kyiv: State. Enterprise "Information Judicial Systems". http://reyestr.court.gov.ua/Review/47178535 Accessed 23 Mar 2020

Unified State Register of Judgments (2015a) The judgment of the Kitsman District Court of Chernivtsi Region in Case No.718/2479/15-k dated 19.02.2016. Kyiv: State. Enterprise "Information Judicial Systems". http://reyestr.court.gov.ua/Review/55966282 Accessed 25 Mar 2020

Unified State Register of Judgments (2015b) The judgment of the Pereyaslav-Khmelnytsky City Court of Kyiv Region in Case No. 373/693/14-k dated 15.01.2015. Kyiv: State. Enterprise "Information Judicial Systems". http://reyestr.court.gov.ua/Review/42298036 Accessed 27 Mar 2020

Unified State Register of Judgments (2015c) The judgment of the Uzhgorod city district court of Transcarpathian region in case No.712 / 18839/12 of 25.02.2015. Kyiv: State. Enterprise "Information Judicial Systems". http://reyestr.court.gov.ua/Review/42896009 Accessed 25 Mar 2020