Tort Liability of Medical Workers in the Patient Safety System in Ukraine and the World

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Abstract: Health 2020: European health and well-being policy. It focuses on supporting the actions of governments and society in the direction of significantly improving the health and well-being of the population; reducing the level of inequality in receiving medical services; promoting the health of everyone; ensuring that the health care system is "human-centred". The position of the World Health Organization is unequivocal – "the most important general health issue internationally" is patient safety (an integral component of service quality). It was proven that the reduction in the number of medical errors and similar health-related situations is the result of the integration and coordination of services through the participation of patients and consumers of medical services. The purpose of the paper is to investigate and compare the features of tort liability of medical workers under the legislation of Ukraine and the standards of the World Health Organisation. Our research is based on such methods as comparative legal method, method of analysis, formal legal method, as well as bibliographic method. Semasiology of the concept of "tort liability" for health professionals in Ukraine has differences in comparison with the WHO standards. Accordingly, the level of patient safety in Ukraine is such that needs to be improved to meet international standards.

Keywords: Tort liability, medical workers, patient safety system.

INTRODUCTION

The Constitution of Ukraine defines human life and health as the highest social value and guarantees everyone the right to health care and medical assistance, and the state creates conditions for effective and accessible medical care for all citizens (Article 49) (Constitution of Ukraine 1996). However, in practice, patients often remain quite vulnerable, and their main benefit – life and health – is at stake due to imperfect legislation, medical errors, and objective circumstances – as is the case for internally displaced persons within Ukraine. As of September 2, 2019, according to the Unified Information Database on Internally Displaced Persons, 1,405,184 migrants from the temporarily occupied territories of Donetska and Luhanska Oblasts and the Autonomous Republic of Crimea have been registered (Internally displaced persons 2019).

Proper legal regulation of tort liability and compensation for medical malpractice to protect the violated rights of the patient is an appropriate guarantee of the patient's confidence that in case of harm to their life and health, they will either be restored (because such benefits as life and health cannot be restored in kind), or the damages will be reimbursed and the perpetrators will be brought to justice. At the current stage of development of Ukrainian society and medical and legal science, tort liability comes to the fore concerning the responsibility of medical workers. According to the Civil Code of Ukraine (hereinafter referred to as the CC of Ukraine) there is a possibility to bring the medical worker to responsibility without the proved fact of commission of a crime, in particular these are Articles 1166-1168, 1172 of the CC of Ukraine (The Civil Code of Ukraine 2003).

The main feature of the liability of medical workers in Ukraine lies in the lack of legislative definition of the concept of medical error (malpractice). The international medical and legal community is working to create the safest healthcare systems so as to reduce the likelihood of medical errors and to reduce their impact on both patients and healthcare professionals (Kohn, Corrigan and Donaldson 2000, Cook and Woods 1994, Grober and Bohnen 2005).

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The purpose of the study is to investigate the features of tort liability of medical workers in Ukraine by analysing the regulations of medical legislation, judicial practice, positions of leading scientists in the medical and legal field on the category of "medical error (malpractice)", "carelessness", "casus fortuitus", including medical statistics of Ukraine. To analyse the possibilities and ways to unify the provisions of national legislation with the relevant standards of the World Health Organisation, in particular through work on the international classification of basic concepts in patient safety, which is designed to define and harmonise concepts in patient safety and their grouping.

MATERIALS AND METHODS

The main materials of the study are the provisions of national legislation: the Constitution of Ukraine, the Civil Code of Ukraine, the Fundamentals of the legislation of Ukraine on healthcare, materials of judicial practice in cases of compensation for damage inflicted as the result of medical intervention.

The legislation was studied with consideration of hierarchical and temporal criteria. According to the hierarchical criterion, a regulation with higher legal force is studied first, after which regulations of lower legal force are studied, contradictions between them are taken into consideration and conflict situations are interpreted at the scientific and theoretical level. Next is the investigation of how regulations are used in the process of law enforcement by courts and how legal conflicts are resolved. At the same time, when applying the temporal criterion, the current version of the regulation and the nearest court practice at the time of publication are taken as the starting point. In the following, earlier versions of regulations and court decisions, which resolved cases that were subsequently interpreted differently, are analysed in retrospect.

The specific feature of the methodology of this study is to take into consideration the differences in the understanding of legal and medical terms by representatives of the legal and medical professions, caused by different patterns of perception of theoretical material. This caveat is inherent in the entire text of the study and without being mentioned each time separately, applies to all the results obtained, which should ensure the most unified perception of scientific opinions by lawyers and medical workers. The study was also based on international regulations: Principles of European Tort Law (Principles of European Tort Law 2005), Global Strategy on Human Resources for Health: Workforce 2030 (Global strategy on human resources … 2014), EUR/RC67/R5 Resolution Towards a sustainable health workforce in the WHO European Region: framework for action) (EUR/RC67/R5 … 2017). Statistical indicators of the Unified Information Database on Internally Displaced Persons, the Centre for Medical Statistics of the Ministry of Health of Ukraine, the Food and Drug Administration (FDA), the European Medicines Agency (EMA).

Research methods are selected with consideration of the purpose and objectives of the study. Philosophical, general scientific and special legal methods of scientific cognition were used in the course of the study. The use of the logical method provided a sequence of formulated conclusions, allowed to define such concepts as "medical error", "carelessness", "case". The formal legal method formed the framework for a comprehensive analysis of medical legislation of Ukraine and the standards of the World Health Organisation to ensure patient safety at various levels of medical care, the procedure for bringing medical workers to justice for violations of the law and grounds for excluding its application. The content of provisions and standards that define the concept and procedure for the application of tort liability of medical workers were identified based on the formal legal method. The comparative legal method was used during the review and study of the relevant legal literature, the main scientific approaches to solving the tasks of research, upon the analysis of national and international medical legislation. The hermeneutic method allowed to analyse the content of international law in the medical field and the provisions enshrined in current legislation, which reflect the procedure for determining the grounds for tort liability of health workers, as well as the content of provisions that ensure adequate patient safety. The praxeological method, the modelling method and the prognostic method were used in determining the prospects for increasing the level of patient care in Ukraine, factoring in the existing global challenges. The method of generalisation was used in formulating conclusions and proposals. The bibliographic method helped in identifying and compiling a bibliographic description of regulations of medical legislation.

RESULTS AND DISCUSSION

The level of exercise and protection of rights and freedoms and interests is the criterion that determines the state of civil society. The protection of patients'

rights, as a kind of civil rights and obligations, is carried out through the use of means of protection, in particular, compensation for damage caused by wrongful acts. In Ukraine, the fact of causing non-contractual (tort) damage by medical workers creates tort relations, which are described by the focus on restoring the balance of interests of the parties, which existed within the regulatory relationship before the moment of inflicting the damage (Spasibo-Fateeva 2014). In accordance with US civil legislation, torts are considered civil offenses, which allows victims to reimburse their damages. Affected parties may file a claim for damages in the form of monetary compensation or an injunction that compels the other party to cease operations. In some cases, courts award punitive damages in addition to compensatory damages to prevent further offences. In the vast majority of tort cases, the court establishes compensatory damages to the injured party, who has successfully substantiated its claims. Compensatory losses are usually equal to the monetary value of the loss of the injured party, loss of future wages, pain and suffering, as well as reasonable medical expenses. Thus, courts can award compensation both for incurred and expected damages (Legal Information Institute) (Tort Definition … 2020, Karnaukh 2012). According to the Principles of European Tort Law, "a person who is legally found to have inflicted damage on another person shall be obliged to compensate that damage" (Principles of European Tort Law 2005).

"Carelessness" or "negligence" is the most common and perhaps the most important area of tort law, as it governs most of modern society. The tort of negligence has three elements that must be proved to the plaintiff: a) the defendant has a duty of care; b) breach of duty by the defendant; c) the existence of damage caused by breach of duty of care (resulting damage) (Spasibo-Fateeva 2014). However, there are broader "approaches" to understanding the category of tort of negligence. In particular, "duty of care" includes the concept of the standard of care and "a reasonable person as an ethereal concept of the average person and its behaviour, against which the actions of another are being weighed" (Lloy 2015). In national legal science, tort liability of medical workers is defined as a variant of legal liability arising from the violation of property or personal intangible assets of citizens in healthcare, which lies mainly in the need to compensate for the damage. A necessary condition for the occurrence of such liability is the presence of the following components: illegal behaviour, i.e. actions or inaction of medical workers, damage, causal link between illegal behaviour and the occurrence of harmful consequences, including the guilt of medical workers (Senyuta 2018). The legal science is based on the fact that the tort legal relations provide for the obligation of the plaintiff to prove the existence of damage, its size, the wrongful conduct of the perpetrator, and the causal link of such behaviour with the damage. For example, the decision in case no. 128/2994/15-ц on July 18, 2016, which was considered by the Vinnytsia District Court of the Vinnytska Oblast, the joint plaintiffs were denied compensation for the damage caused by the medical worker during the tuberculin test. The reference of the plaintiffs and their representatives to the presence of the diagnosis included in the medical records of children as an atypical reaction to the introduction of tuberculin constitutes the basis for meeting the full requirements, the court "called" false as not based on the law, because in themselves these medical documents do not prove the existence of damage before the court, its stated amount, the illegality of the conduct of the defendants and the causal link of such behaviour with the damage, therefore the claim was rejected (Decision of the Vinnytsia District … 2016).

Of particular theoretical and practical importance is the issue of establishing the guilt of medical workers in court, in particular the types of "negligence", as well as the distinction from the category of "accident or casus fortuitus". The presence of a medical error or casus fortuitus excludes the possibility of liability of medical professionals. Doctors define their mistakes in professional activity as a result of good faith in the absence of negligence, negligence or ignorance, that is, due to the lack of corpus delicti, or improper action (or inaction) of a doctor, the basis of which lies in the imperfection of modern medical science, lack of knowledge, or inability to use available knowledge in practice (Dialogue 2014). Lawyers have different approaches to determining a medical error (Hertz 2015, Mykhaylov 2010, Korobtsova 2016, Mykhaylov 2008), its relationship to an accident, but its presence excludes the liability of the medical worker. The issue of carrying out medical activity and rendering medical services is associated with risk. It should be noted that the Anglo-American system of torts has a "wider scope " of possibilities to establish the category of guilt of a medical worker, due to the presence of guilt (intent, negligence, and carelessness) in all elements of the tort of negligence: duty of care; breach of duty, and resulting damage. The term "medical negligence" is

often used as a synonym for "illegal medical activity" and is defined as the action or inaction of a healthcare professional that deviates from the accepted medical standard of care (Goguen 2019). We can state that medical negligence, as a form of guilt in tort legal relations, does not constitute a "sole" basis for the application of such liability to a medical worker. And the presence of harm with the patient (deterioration of health, death) is also not always a fact that allows to refer to "medical negligence". Since the patient's response to medications or procedures, or the course of the disease may not depend on the quality of medical care or the "quality" of the health care provider. Obviously, this is why there is no legislation on the imperfection of medical services.

And although, in particular, surgeon Martin Macari, a researcher at Hopkins University (USA), says that in most countries there is no accounting system for statistical research, as the cause of death is determined by the International Classification of Diseases (ICD), which does not have a code called "human factor" or "medical staff error" (Relentless statistics … 2020), in our opinion – the expansion of the ICD and the creation of appropriate economic, legal, social conditions in society are not interrelated. The other side of the issue is the application of the principle of continuous training of health professionals, which has long been common practice in Europe, America, and Asia, including the United Kingdom, the United States, Poland, the Czech Republic, Sweden, Singapore, etc. For Ukrainian doctors, such a component started operating only in 2019. Another factor influencing the level of medical services in Ukraine is the number of doctors of basic specialties and the provision of the population with them in 2018. Total number of doctors is 156,863.00, which is 37.36 doctors per 10,000 population; therapists – 10,675.00, which is 2.54; endocrinologists – 1,419.00, which is 0.34; pediatric endocrinologists – 195.00, which is only 0.05; nutritionists – 72.00, which is 0.02 (per 10,000 population). A comparative analysis of statistical data of the Centre for Medical Statistics of the Ministry of Health of Ukraine gives grounds to claim that in recent years the tendency of increasing number of doctors is not observed (Centre for Medical Statistics … 2020).

The European Community faces no less difficult challenges. Population growth, an aging society, and changing disease patterns are expected to increase the demand for skilled health workers over the next 15 years. By 2030, the global economy is projected to create about 40 million new jobs in health care, mostly in middle- and high-income countries. There is a projected shortage of 18 million health workers required to achieve the UN Sustainable Development Goals (SDGs). More specifically, the Global Strategy on Human Resources for Health: Workforce 2030 aims to improve health, social, and economic development by ensuring availability, accessibility, acceptability, coverage, and quality of health workforce through appropriate investment in strengthening health systems and implementing effective policies at the national, regional, and global levels (Data and statistics 2019). The solution of this issue has been prolonged in accordance with EUR/RC67/R5 Resolution "Towards a sustainable health workforce in the WHO European Region: framework for action", which is designed to accelerate progress towards the values and objectives of European health and well-being policy through the sustainable provision of professional health resources within strengthened health systems.

A medical error is a preventable side effect. A systematic approach to medical errors and other healthcare problems is proposed, which identifies problems in rendering medical services, and not just the isolation of incompetent health workers. According to sources such as the Oxford University Press and the Columbia Encyclopaedia, the causes of medical errors (malpractice) include communication errors, specialisation and fragmentation of the healthcare system, "occupational burnout", diagnostic and equipment errors, and even improperly designed buildings of medical institutions (Guidance for Industry … 2014). For example, according to the Food and Drug Administration (FDA) and the European Medicines Agency (EMA), at least 600 pairs of similar names have been identified since early 1992, and the U.S. Institute of Medicine has released about 7,000 patients since 1999. (Guidance for Industry … 2014); European Medicines Agency (EMA) developed and implemented reference terminology for unique names of substances and identifiers – the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD) (EMA Substance … 2018).

In accordance with the Fundamentals of the Legislation of Ukraine on Healthcare, a medical worker bears responsibility for the following activities: engaging in medical and pharmaceutical activities without a license (Article 17 of the Fundamentals); untimely and low-quality provision of medical care (in this case, the authorities and treatment and prevention facilities bear responsibility, and not medical workers as individuals); failure to provide medical care (Article

39 of the Fundamentals); violation of medical privacy (Article 40 of the Fundamentals); violation of the conditions of medical intervention (Articles 42-43 of the Fundamentals); coercion to donate blood (Article 46 of the Fundamentals) (Law of Ukraine … 2020).

Medical legal systems tend to condemn foreseeable errors of negligence or medical carelessness much more often than any other risk, thereby encouraging an ever-increasing and excessive number of diagnostic tests as a strategy to reduce legal risk (Vento, Cainelli and Vallone 2018). This phenomenon is called "defensive medicine", the main features of which include: the assignment of an excessive amount of methods of examination and treatment; refusal of surgical intervention in patients with chronic disease and the use of complex invasive diagnostic methods; predominant use of methods more sophisticated, but safer for the doctor in legal terms (excessive use of caesarean section in obstetric practice. According to the WHO, the "leader" among the number of operations is Brazil – 56% of all births are by caesarean section, followed by Egypt (51.8%), Turkey (47.5%), and Italy (38.1%) – a record holder in terms of births by caesarean section in Europe (Perasso 2015)); choice of the least complex orthodox methods of intervention; organisation of unreasonable consultations and multidisciplinary team meetings; unreasonable referral to other medical institutions, etc. (Morozov, Stepanenko and Kucherenko 2004). On the other hand, according to study carried out by the Centre for Evidence-Based Research, the Faculty of Health and Medical Sciences, Bond University, Gold Coast, Queensland, Australia – clinicians did not often have accurate expectations of benefit or harm, with errors in both directions. However, doctors are more likely to underestimate rather than overestimate the harm, and overestimate rather than underestimate the benefits. Inaccurate ideas about the benefits and harms of medical procedures can lead to suboptimal choice of clinical treatment (Hoffmann and Del Mar 2017).

According to the experience of foreign countries, "protective medicine" is a negative phenomenon, as it not only contradicts the basic principles of medical ethics, but also takes extremely large funds from national budgets. For example, the US medical liability system costs over 55.6 billion dollars annually, and the contribution of defensive medicine is over 82% (45 billion) (Pate 2019), and in Italy the cost of defensive medicine is estimated at around 10-12 billion euros a year (Gelmetti 2016). The search for ways to solve these problems in the civilised world has almost a century of history. In England, 100 years ago, the Doctors and Dentists Protection Union (DDPU) was established, whose lawyers and doctors provide comprehensive legal aid to health professionals not only in matters of tort liability, but also on issues regarding employment or unjustified refusal, and many others (What is DDPU?).

CONCLUSIONS

Patient safety is a global issue affecting countries at all levels of development. Tort liability of healthcare professionals is an integral, important part and mechanism for achieving a higher level of patient safety in healthcare. Having investigated the national legislation and the legislation of individual countries that are members of the WHO, including international "safety" standards, we can sum up the results. Legislative consolidation of the category "medical error" is a complicated and ambiguous task. Therefore, WHO is on the path of developing a new policy (Health 2020) to increase the level of medical services, the introduction of high standards of patient safety at all levels of rendering such services.

One of the main tasks is to inform patients about their rights and ways to protect their violated interests in healthcare matters. To develop appropriate solutions, it is necessary to understand the scale of this issue and the main factors that exacerbate it. The WHO Patient Safety Programme has developed a list of global research priorities that reflect areas where there are significant knowledge gaps and where their expansion is expected to significantly improve patient safety and harm reduction. The national situation regarding the tort liability of medical workers is influenced by socio-economic factors and systemic problems that exist in the judicial branch. Ukraine's path to unification of medical legislation with the WHO standards is not so fast, but participation in joint international projects should help to introduce new high standards of patient safety.

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