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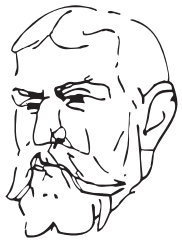

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CONTENS / SPIS TREŚCI

ORIGINAL ARTICLES / PRACE ORYGINALNE

REVIEW ARTICLES / PRACE POGLĄDOWE

ORIGINAL ARTICLE
PRACA ORYGINALNA

LEGAL MECHANISMS OF PATIENT'S RIGHTS PROTECTION

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ABSTRACT

Introduction: Human life and health are considered to be of the highest social value, with particular emphasis on health care. However, the patient's rights are pretty often violated by medical professionals. According to statistics, a medical error is recognized as one of the most common causes of patient's rights violations in Europe and the United States. That's why the research of jurisdictional mechanisms of patients' rights protection in the context of medical error, seems particularly relevant.

The aim: To propose the effective jurisdictional mechanisms of the patients' rights affected by medical error protection and to summarize scientific approaches for understanding the essence of medical error.

Materials and methods: The research used a set of general scientific and special methods of scientific cognition, in particular, dialectical; comparative legal; analysis and synthesis; formal-logical (dogmatic); statistical and generalization. The empirical base of the study is the statistics of the Prosecutor General's Office of Ukraine and the State Judicial Administration of Ukraine within 2014-2018, generalization of the practice of the Constitutional Court of Ukraine, as well as statistics in the field of protection of patients' rights of some countries of Europe, USA and Japan, as well as the authors' own experience who serve as a judge and a judge assistant of the Supreme Court, a judge of the Constitutional Court of Ukraine.

Results: It is argued that the most effective jurisdictional mechanisms for protecting the patients' rights affected by a medical error include: criminal, civil and constitutional ones. Summarizing national and foreign positions of scholars and practitioners, four main approaches to the interpretation of the "medical error" concept are highlighted.

Conclusions: In order to protect the patients' rights adequately, including those affected by a medical error, the state must guarantee the right of access to jurisdictional protection mechanisms, as well as establish a system of non-jurisdictional mechanisms for the protection of health rights.

KEY WORDS: criminal-legal jurisdictional mechanism of protection, civil-legal jurisdictional mechanism of protection, constitutional jurisdictional mechanism of protection, medical error, patient's rights

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INTRODUCTION

Protecting the person's rights in the field of health care is an important element of the state's activities. At the same time, the person's rights to health care, in particular a patient's right, may be violated by medical professionals. One of the most common causes of patient's rights violation is a medical error. For example, a study commissioned by the Directorate-General for Health and Consumers found that 8–12% of patients admitted to a hospital in the European Union had adverse events while receiving health care; most of the events could have been prevented. The main events were health care-associated infections, medication errors, surgical errors, medical devices failures, errors in diagnosis and failure to act on the results of a test. A Danish study on adverse events in 2018 found that 9% of patients suffered harm, while a recent unpublished Polish study (2015) reported that 7.2% had adverse events [1]. In the U.S. medical errors account for 9.5% percent of all deaths in the country, which is making errors the third leading cause of death after heart disease and cancer [2]. There are no statistics available in Ukraine to assess the real situation of patients' rights violations due to medical errors, but there is little reason to believe that the problem is significantly different from that of other countries. Taking into account the above, we believe that the study of jurisdictional mechanisms of patients' rights' protection affected by a medical error appears to be particularly relevant.

THE AIM

Solving the scientific problem of identifying the most effective jurisdictional mechanisms for protecting the patients' rights affected by medical errors and generalizing scientific approaches to understanding the essence of medical error.

MATERIALS AND METHODS

To achieve this aim and to provide scientific substantiation of the research results, such methods of scientific knowledge as dialectical, comparative legal method; methods of analysis and synthesis; formal-logical (dogmatic) method; statistical method and generalization method were used. The empirical basis of the research is the statistics of the Prosecutor General's Office of Ukraine within 2014-2018 on the quantity of reported criminal offenses; statistics provided by the State Judicial Administration of Ukraine within 2014-2018 regarding the number of convicted persons for crimes in which the medical subject is a special subject, statistics

within 2016-2018 regarding the amount of compensation to victims of criminal offense; results of generalization of the practice of the Constitutional Court of Ukraine in the field of health; statistics on protection of patients' rights in some countries in Europe, US and Japan, as well as the authors' own experience who serve as a judge and a judge assistant of the Supreme Court, a judge of the Constitutional Court of Ukraine. In addition, the authors used their own previous experience in advocacy, including the protection of patients' rights affected by medical error, and as practicing lawyers whose combined experience is over 20 years.

RESULTS

According to Article 13 of the European Charter of Patients' Rights, every person has the right to complain of suffering and damage and to receive a response or other appropriate reaction. According to Article 80 of the Basics of the Healthcare Legislation, persons who are guilty of violations of health care legislation are subject to civil, administrative or criminal liability under the legislation. Thus, in the event of a patient's rights being violated, the patient may have recourse to various jurisdictional mechanisms to protect his/her rights. Depending on the type of violation, the case may be heard by a court in criminal proceedings, administrative or civil proceedings, as well as in an administrative offense case. In addition, if all domestic remedies are exhausted, the person may also apply to international courts or judicial authorities, in particular the European Court of Human Rights. Let's review the most effective, in our opinion, jurisdictional mechanisms for patient's rights protection in Ukraine.

Criminal-legal jurisdictional mechanism of protection of the patient's rights. The Criminal Code of Ukraine (hereinafter – the Criminal Code of Ukraine) establishes criminal liability for a number of crimes with special subject, such as medical professionals.

Thus, according to the statistics of the General Prosecutor Office of Ukraine [3] under Art. 131 of the Criminal Code of Ukraine – a misconduct that caused infection with human immunodeficiency virus or other incurable infectious disease - pre-trial investigation was initiated in 2014 in 19 criminal proceedings; in 2015 there were also 19 such proceedings; in 2016 - 4; in 2017 - 19; in 2018 - 2. However, according to the State Judicial Administration, from 2014 till 2018, no person was convicted under this article.

Under Art. 137 of the Criminal Code of Ukraine – a misconduct in the field of protection of life and health of children - in 2014, 380 criminal offences were registered, 6 persons of them were convicted; in 2015 – there were 485, 1 convicted; 529 criminal offences were in 2016, 2 convicted; 546 were in 2017, 5 convicted; 352 were in 2018; 3 convicted.

According to Art. 139 of the Criminal Code of Ukraine - failure to assist sick person by medical professional - 226 criminal offenses were recorded in 2014; in 2015 - 257; in 2016 - 318; in 2017 - 22; in 2018 - 222. According to the State Judicial Administration, from 2014 till 2018, no person was convicted under this article.

From 2014 till 2018, pre-trial investigation was conducted in 20620 criminal proceedings under Art. 140 of the Criminal Code of Ukraine – a misconduct of medical or pharmaceutical professionals. At the same time, only 35 persons were convicted of committing this crime, which is less than one percent of the total number of conducted investigations. From 2014 till 2018, no criminal offense was reported under Art. 141 of the Criminal Code of Ukraine - violation of the patient's rights.

Thus, by analyzing the statistics, the authors can conclude that this category of crimes is small enough. The main reason for such a situation is that theorists and practitioners consider the lack of an effective methodology for investigating health crimes, difficulties in establishing the evidence base and establishing a causal link between the medical professionals' actions and a harm caused to a patient, etc. After all, the fact of referring patients to law enforcement agencies with the corresponding statements is not yet sufficient reason to believe that actions of medical professionals have indeed an available composition of concrete crime.

At the same time, despite a few of medical professionals who have been convicted of violating patient's rights, we still believe that criminal-legal jurisdictional mechanism for protecting health rights should be applicable. Although, according to the experience of Japan [4], excessive criminalization of medical professionals' actions does not solve existing problems, but creates additional ones. Therefore, along with criminal law, there must be other jurisdictional mechanisms of patients' rights' protection.

Special mention should be made of patient's inalienable right to bring a civil action in criminal proceedings, which is the only way of compensation for the damage caused by the crime (property and / or moral) in the criminal process.

However, according to the prescriptions of part 7 of Art. 128 of the Criminal Procedure Code of Ukraine, if the patient has not filed a civil claim in criminal case, or his/her civil claim is left without consideration, he/she has the right to bring this claim in civil procedure.

Civil-legal jurisdictional mechanism of protection of the patient's rights. The main mechanism for protecting patient's rights in civil proceedings is to bring a lawsuit. A key requirement of a claim is the ability to indemnify property and non-pecuniary damage caused to a patient by actions or omissions of medical professionals and / or healthcare facility.

Questions about indemnification to a patient in civil proceedings may arise from both contractual and tort relationships. For example, if the failure to provide or improperly provide medical care does not cause harm to patient's health or life, at the same time the contractual terms for provision of health care services are not fulfilled properly and / or not fully implemented, then contractual civil liability arises. In the case of failure to submit health services delivery that has harmed the patient's health or life (provided that medical services contract was concluded), contractual and tort liability are combined. If, however, the failure to submit health services delivery has harmed

the patient's health or life (but no health care contract has been concluded), tort will arise under Art. 1195, 1166, 1167 of the Civil Code of Ukraine (hereinafter - the Civil Code of Ukraine).

However, if a medical professional has been prosecuted, a patient as a victim of a criminal offense may also file a lawsuit under Art. 1177 of the Civil Code of Ukraine. This provision establishes the obligation to indemnify (compensate) the harm to an individual who is a victim of a criminal offense. In this case, both property and non-pecuniary damage are liable to compensation. However, it is a prerequisite for a patient to seek legal enforcement of a court order to prosecute a medical professional.

The general conditions of liability, including medical professionals and health care institutions, for causing property and non-pecuniary damage are defined in Art. 1166 and 1167 of the Central Committee of Ukraine. Thus, in order to bring medical professionals to civil liability, the following conditions must be combined at the same time: unlawful decisions, actions or omissions of a medical professional; causing harm (property and / or moral) to a patient with adverse effects on life or health; causal link between decisions, actions (omissions) and such harm; fault of a medical professional.

It should be noted that in the legal relations for the compensation of harm, including, in the provision of medical care, there is a presumption of guilt of an offender. That is, a patient does not prove the guilt of a medical professional and / or health care institution, and the medical professional and / or health care institution prove the lack of guilt. An example is the decision of the Civil Court of Cassation within the Supreme Court in Case No. 537/4429/15-c of 14 March 2018 [5], which granted a cassation appeal and received non-pecuniary damage from a maternity ward caused by a physician's misconduct of this medical institution.

According to court statistics, in 2016, victims of criminal offenses, including crimes committed by medical professionals, were fined to 63 258 308 UAH, including 17 059 606 UAH for moral harm; in 2017 - 67 306 352 UAH, of which 15 541 203 UAH for moral harm; in 2018 - 85 206 547 UAH, including 16 640 387 UAH for moral harm. Therefore, we believe that analysis of statistics shows that compensation for harm to a patient as a victim of a criminal offense is an effective jurisdictional mechanism for protection of his/her non-property rights and ensures the restoration of property rights.

Foreign experience on this issue appears to be interesting in the study context of criminal-legal and civil-legal jurisdictional mechanisms of protection of patients' rights affected by a medical error.

For instance, in the United States aggrieved patients that sustain injuries and damages due to doctor error have legal recourse under civil tort law, which allows the patient (the plaintiff) to initiate a lawsuit in court against the doctor and/or the hospital (the defendants) where the negligent treatment was provided, in order to recover monetary damages [6]. Also, the nurses and physicians involved may face some sort of administrative sanctions, however, and medical professionals in the US rarely have to be concerned about the risk of criminal proceedings. On the other hand, a case of death due to an error can be considered a crime, but it would have to be a major, gross or reckless one. If a medical accident is to become a criminal case, it would be limited to a case such as murder or when a drunken or drug-addicted physician was involved in an operation [4].

In Sweden victims of medical accidents have full access to traditional litigation, yet practically all cases are settled out of court, often with (full) support of their physician(s) [7].

The continental legal system is characterized by the use of criminal-legal mechanisms of protection of patients' rights, which constitute the criminal offense of negligent or careless acts of medical professionals who have harmed the patient's health or caused his/her death. For example, the Criminal Code of the Republic of Slovenia contains Article 179, which establishes liability for negligent treatment. Under this Article, a medical professional that violates the practices and rules of 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. Paragraph 3 of Article 179 stipulates that 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 health system [8].

A similar approach can be seen in the Criminal Code of the Republic of Croatia, which provides for special offence of negligent medical treatment by Article 181.

The criminal law of Japan contains the composition of the crime named "professional negligence". At the same time, according to scientists, criminal penalties for professional negligence resulting in damage to health or death of patient is widely interpreted by courts and covers medical error [4].

Based on the above, as well as summarizing the provisions of the laws of certain foreign countries, we can state that in the English-American (in particular, in the US) legal system and in the Scandinavian jurisdictions there are civil-legal mechanisms that are able to protect the rights in civil litigation and extrajudicial mechanisms, including those related to insurance and alternative ways of conflict resolution applied. At the same time, both in continental legal system and in some other countries (Japan in particular), along with civil jurisdictional mechanisms of protection there are also criminal laws that provide for the possibility of criminal prosecution of medical professionals due to their negligence or carelessness that caused harm to patient's health or life.

Constitutional jurisdictional mechanism of patient' rights' protection. The Constitutional Court of Ukraine has a special role in the protection mechanism of patient's rights in the field of health care in Ukraine. This judicial authority is empowered to exercise constitutional control over the observance of individual rights, including healthcare scope.

An appeal form to the Constitutional Court, within which a person (patient) can defend his/her rights, is a constitutional complaint. In a constitutional complaint, a patient asks the Constitutional Court about unconstitu-

tionality of the law of Ukraine (its provisions), which was applied by the court in a final judicial decision in a case (criminal, civil, administrative) affecting the rights and interests of such patient, and which in his/her opinion violates their constitutional rights in the field of healthcare.

Constitutional representation is another appeal form to the Constitutional Court which, although it may not be personally implemented by a patient as a physical person, is equally important to a person and a state legal system.

Analyzing the case law of the Constitutional Court of Ukraine, it is possible to outline the following key decisions made in cases on constitutional representations that were of importance for the protection of patients' rights, they are:

– Decision of October 30, 1997, № 5- зп., where the Constitutional Court interpreted the meaning of medical information concept and determined the revealing specifics of such information;
– Decision of November 25, 1998, No. 15-рп., where the Constitutional Court declared unconstitutional the provisions for approving the list of paid services that can be provided in public health care institutions and for allowing medical institutions to accept payment from patients for other medical services provided as voluntary compensation;
– Decision of May 29, 2002, No. 10-rp /2002, where the Constitutional Court concluded that the provisions of part three of Article 49 of the Constitution of Ukraine should be understood so that medical care in state and communal health care institutions is provided to all citizens regardless of its volume and without their previous, current or subsequent calculation for providing such help.

The above decisions of the Constitutional Court have played an important role in establishment and protection of person's rights in the field of health care, including patient's rights, since these decisions have resulted in changes of existing legislation that have significantly improved legal regulation in this area.

Thus, the role of the Constitutional Court of Ukraine among jurisdictional mechanisms for the protection of patients' rights is to ensure the supreme legal force of the Constitution of Ukraine and to prevent amendments and additions to the Constitution of Ukraine, which result in a narrowing of scope or content of the relevant right.

DISCUSSION

Due to the lack of a clear definition of the term "medical error" in the national legislation of Ukraine and foreign countries, scientific discussions on the content and essence of this concept in the legal doctrine are ongoing. At the same time, having examined the positions in domestic and foreign literature and practice, we consider it possible to distinguish the main scientific approaches to interpretation of the "medical error" concept, according to which this concept meaning is: legitimate and justified actions (inactivity) of medical professionals, due to circumstances objective and / or subjective in nature that have led to adverse health or life effects of a patient [9; 10; 11; 12; 13; 14; 15]; iatrogeny, that is, any adverse effects of various medical effects on a patient, resulting from both erroneous and correct actions of a doctor [16; 17; 18]; a kind of defect in the provision of medical care [19; 20]; negligence and / or dishonesty of medical professionals [21; 22; 23].

CONCLUSIONS

In democratic countries, human life and health are recognized as the highest social value. That is why it is the direct responsibility of every state, including Ukraine, to ensure that effective jurisdictional mechanisms are in place to protect patients' rights, including those who have suffered from a medical error. In our opinion, the most effective jurisdictional mechanisms for protecting the patients' rights affected by a medical error are: criminal law, civil law and constitutional law mechanisms. At the same time, as international experience shows, there is also a need to create an effective system of non-jurisdictional mechanisms for protection of patients' rights, which must include different insurance systems and alternative means of dispute settlement, in particular mediation.

REFERENCES

1. Technical assistance for establishing a patient safety system in Estonia: Mission report. World health Organization Regional Office for Europe. 2017, 32 p.
2. Anderson J.G, Abrahamson K., Your Health Care May Kill You: Medical Errors. Studies in Health Technology and Informatics. 2017; 234:13-17.
3. Statystychni dani Heneralnoi prokuratury shchodo zareiestrovanykh kryminalnykhpravoporushen ta rezultaty yikh dosudovoho rozsliduvannia za 2014-2018 roky [Statistics of the Prosecutor General's Office on Registered Criminal Offenses and Results of Their Pre-trial Investigation for 2014-2018]. Available from: https://www.gp.gov.ua/ua/stst2011.html?dir_id =113653&libid=100820#. [reviewed 2019.09.04] (Ua)
4. Higuchi N., Should Medical Errors Be Judged by the Criminal Court? Towards the creation of a new system for patient safety in Japan. Japan Medical Association – Journal. 2012;55(2):128-138.
5. Postanova Kasatsiynoho tsyvilnoho sudu u skladi Verkhovnoho Sudu [Judgment of Civil Cassation Court in Supreme Court] vid 14.03.2018 u spravi № 537/4429/15-ц. Available from: http://www.reyestr.court.gov.ua/Review/72909007 [reviewed 2019.09.04] (Ua)
6. Flis V., No Fault Compensation for Medical Injuries. Medicine, Law & Society. 2016;9(2):73-84. doi: 10.18690/24637955.9.2.73-84(2016)
7. Watson K, Kottenhagen R., Patients' Rights, Medical Error and Harmonisation of Compensation Mechanisms in Europe. European Journal of health law. 2018;25:1-23. doi: 10.1163/15718093-12460348
8. Šepec M., Medical Error – Should it be a Criminal Offence? Medicine, Law & Society. 2018;11(1):47-66. doi: https://doi.org/10.18690/2463-7955.11.1.47-66.(2018)
9. Antonov S.V. Tsyvilno-pravova vidpovidalnist za zapodiyannya shkody zdorovyu pry nadanni platnykh medychnykh posluh [Civil liability for causing harm to health when providing paid medical services] thesis abstract for obtaining the degree of candidate of law. Kyiv 2006, 20 p. (Ua)

10. Rishennya Prymorskoho rayonnoho sudu m. Odesy [Judjment of the Primorsky District Court of Odessa] vid 28.04.2015 r. y spravi 522/21210/13-ц; Available from: http://www.reyestr.court.gov.ua/Review/43838596. [reviewed 2019.09.04] (Ua)
11. Avdriyevska T. I. Tsyvilno-pravova kvalifikatsiya medychnoyi (likarskoyi) pomylky [Civil qualification of medical (doctor) error]. University research notes 2009;1(29):107-111. (Ua)
12. Liang B. A., A system of medical error disclosure. Quality & Safety in Health Care. 2002;1:64-68. doi: 10.1136/qhc.11.1.64
13. Kohn L.T, Corrigan J.M, Donaldson M.S., To Err Is Human: Building a Safer Health System. Committee on Quality of Health Care in America. Institute of medicine. Washington, D.C.: National Academy Press, 2000,312 p.
14. Bal S.B., An Introduction to Medical Malpractice in the United States, Clinical Orthopaedics and Related Research. 2009;467(2):339-347. doi: 10.1007/s11999-008-0636-2
15. Grober E.D., Defining medical error. Canadian Journal of Surgery. 2005;48(1):39-44.
16. Sedov V.M, Bibikov V.U., Issledovaniye definitsii yatrogeniy [Iatrogenic definition study]. Uchonyye zapiski Sankt-Peterburgskogo gosudarstvennogo meditsinskogo universiteta im. akad. I.P. Pavlova. 2009; XVI(1):8-12. (In Russian)
17. Kozlov S.V., Avdeyev A.I., Ekspertnaya otsenka yatrogennoy patologii [Expert assessment of iatrogenic pathology] Dal'nevostochnyy medetsinskiy zhurnal. 2009;3:81-83. (Ru)
18. Ayzenshteyn F.A., Analiz letal'nykh iskhodov (zadachi i metody) [Death analysis (tasks and methods)]. Moskva: CheRO.1995, 132 p. (Ru)
19. Senyuta I. YA. Defekty nadannya medychnoyi dopomohy: ponyattya i vydy [Defects in health care delivery: concepts and types]. Medical Law. 2017;1(19):55-66. (Ua)
20. Stetsenko S.G., Meditsinskoye pravo: Uchebnik [Medical law: textbook]. SPb.: Yurid. tsentr Press. 2004, 570 p. (Ru)
21. Dzhuma K.A, Shulzhyk I.I., Likarska pomylka v medychnomu ta pravovomu aspektakh [Medical error in medical and legal aspects]. Ukrainian scientific-medical youth journal. 2011;1:66-68. (Ua)
22. Leybovich YA. L. Otvetstvennost' vracha [Doctors' responsibility]. Moskva: INFRA. 1989, 122 p. (Ru)
23. Radysh YA, Bedryk I., Radysh L., Kuzminskyy P., Medychna pomylka: sutnist, klasyfikatsiya ta pravovyy vymir [Medical error: nature, classification and legal dimension]. Medical Law..2008;1:51-60. (Ua)

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IMPROPER HEALTHCARE MARKETING: GERMAN AND UKRAINIAN EXPERIENCE IN PREVENTION

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ABSTRACT

Introduction: Improper healthcare marketing is a part of institutional corruption in the pharmaceutical markets, which causes significant harm to public health. Legal measures are an important component of the mechanism for preventing this phenomenon.

The aim: The purpose of the article is to raise awareness and stimulate serious discussion about the necessity to improve the preventative role of law in the field of healthcare marketing by adjusting liability for offenses in this area.

Materials and methods: This study is based on the analysis of international law, medical and criminal legislation, juridical practice, criminal and medical law legal doctrine, physicians survey results and expert interviews. Dialectical, comparative, analytic, synthetic and system analyses research methods were used, also for interpretation purposes.

Results: The study showed the effectiveness of the US fight against improper healthcare marketing by applying millions and billions of fines to the largest pharmaceutical companies in the world, which led to a reduction in corruption in this sphere. Legal restrictions on the activities of medical sales representatives of pharmaceutical companies are justified by the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as well as in the German legislation (Medicinal Products Act).

An analysis of Articles 299a and 299b of the German Criminal Code (StGB), as well as the practice of their application, showed their effectiveness. Still, there are problems in delimiting these offenses from the legal provision of drug information. The lack of anti-corruption regulation of drug promotion in Ukraine negatively affects the situation in this area.

Conclusions: The legal mechanism for the prevention of improper healthcare marketing at the national level should include the following measures: a) strict legal regulation of the rules for the promotion of medicines; b) anti-corruption restrictions on the activities of medical sales representatives of pharmaceutical companies; b) the criminal liability of pharmaceutical companies for corruption in the implementation of healthcare marketing; c) the criminal liability of representatives of pharmaceutical companies and Healthcare professionals (HCPs) for active and passive briberies; d) legal support for professional self-regulation aimed at creating ethical standards of conduct in the pharmaceutical markets.

KEY WORDS: healthcare marketing, pharmacy crimes, corruption and medical sales representative

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INTRODUCTION

The pharmaceutical sector is one of the fastest growing and most profitable segments of the global economy. At the same time, the promotion of drugs on the market from producer to consumer has a significant specificity that distinguishes pharmaceutical products from the vast majority of other goods and services. This specificity lies in the fact that the consumer, as a rule, due to the lack of specialized knowledge, does not have the opportunity to choose the necessary product independently, and physicians make this choice for him.

In countries where the health care system is at a sufficiently high level, the decision to purchase a particular medicine is made by the doctor, primarily paid by the state, insurance companies, or other entities, while the patient is the final consumer. Ed Schoonveld, in his book "*The Price of Global Health: Drug Pricing Strategies to Balance Patient Access and the Funding of Innovation*" *(2015)* draws an analogy with as an unusual "dinner for three". This author proposes to imagine three people going to a restaurant, where the first makes a meal choice from the menu, the second is consuming the meal and the third is paying the bill. In drug terms, the doctor prescribes the drug, the patient takes the drug and the insurance agent pays the bill [1, p. 21]. In countries where patients bear the bulk of the financial cost of buying medicines (for example, Ukraine), such a "dinner" will be "for two". In this situation, the doctor decides to prescribe the medicine (choosing the product), but the patient or his or her family makes the payment. But the essence does not change – the product is not chosen by the one who pays for it. This feature determines a high level of corruption risks in the relationship between pharmaceutical manufacturers and HCPs.

Studies show that there are cases of pharmaceutical companies using improper drug marketing, putting their financial interests above the interests of patients. With such marketing, direct and indirect bribing of doctors is used to maximize the promotion of drugs on the market.

These problems exist both in low-income countries (for example, Pakistan [2], India [3]), and in countries with high levels of economic development (for example, the USA, Canada [4]).

Thus, in the research Transparency International "*Corruption in the Pharmaceutical Sector. Diagnosing the Challenges*" (2016) states that the marketing of medicines, which is primarily an interaction between the pharmaceutical industry and (HCPs), constitutes a large part of pharmaceutical company expenditure [5]. MA. Gagnon, in his research "*Corruption of pharmaceutical markets: addressing the misalignment of financial incentives and public health*" (2013) notes that "in the United States, the pharmaceutical industry spends up to $42 billion in promotion towards physicians every year, which is, on average, $61,000 per physician to influence their prescribing habits and generate profits." [4] In many cases, payments made by pharmaceutical companies to HCPs in the guise of paying for drug information are corrupted and built to increase sales unjustifiably through improper advertising. This activity leads to an unjustified increase in the cost of medical services, which reduces the availability of treatment. As a result, the level of trust in physicians decreases, the number of people self-medicating increases, as well as the risk of harming the life or health of patients due to excessive use of drugs.

At the same time, the line between the legitimate informing of medical professionals about drugs and indirect bribery is not clear enough. The legal regulation of these relations in different countries is significantly not the same. Moreover, it ranges from fairly loyal legislation (Ukraine) to severe restrictions with the establishment of criminal punishment for receiving and giving illegal remuneration (Germany).

Thus, the study of German and Ukrainian experience in preventing improper healthcare marketing is relevant.

THE AIM

The purpose of the article is to raise awareness and stimulate serious discussion about the necessity to improve the preventative role of law in the field of healthcare marketing by adjusting liability for offenses in this area.

MATERIALS AND METHODS

This study is based on the empirical and analytical data of the WHO, European Commission, NGO "Transparency International", Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, legislation of Ukraine and Germany, legal practice of the USA, Germany and Ukraine, physicians survey results, expert interviews, criminal and medical law legal doctrine. Totally 26 laws and papers were analyzed, 75 physicians were surveyed, and 8 experts were interviews. Dialectical, comparative, analytic, synthetic and system analyses research methods were used, also for interpretation purposes.

RESULTS

THE USA LEGAL PRACTICE

Over the past ten years, the United States has taken decisive steps to combat pharmaceutical corruption, including through the promotion of drugs. Such actions have significantly affected the situation in the world as a whole. Thus, in 2009, American pharmaceutical giant Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. have agreed to pay $2.3 billion to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products. The company illegally promoted four drugs – Bextra, an anti-inflammatory drug that Pfizer pulled from the market in 2005; Geodon, an anti-psychotic drug; Zyvox, an antibiotic; and Lyrica, an anti-epileptic drug – and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs. The civil settlement also resolves allegations that Pfizer paid kickbacks to health care providers to induce them to prescribe these drugs [6]. In 2012 Pfizer H.C.P. Corporation, an indirect wholly owned subsidiary of Pfizer Inc., has agreed to pay a $15 million penalty and more than $26.3 million in disgorgement of profits to resolve an investigation of Foreign Corrupt Practices Act violations in connection with improper payments made to government officials, including publicly-employed regulators and health care professionals in Bulgaria, Croatia, Kazakhstan and Russia. In these countries, Pfizer H.C.P. Corporation has developed and implemented special corruption programs, such as "Incentive Trips" (Bulgaria), "Consulting Agreement" (Croatia), and "Hospital Program" (Russia). Thus, Pfizer Russia employees were allowed to provide incentives that were calculated as 5% of the value of certain Pfizer products purchased by the hospitals. Pfizer Russia used the Hospital Program to make cash payments to individual government healthcare professionals to corruptly reward past purchases and prescriptions of Pfizer products, and to corruptly induce future purchases and prescriptions [7].

In 2011 The U.S. Securities and Exchange Commission (SEC) charged Johnson and Johnson (J&J) with violating the Foreign Corrupt Practices Act. The SEC alleges that subsidiaries of the New Brunswick, N.J.-based pharmaceutical, consumer product, and medical device company paid bribes to public doctors in Greece who selected J&J surgical implants, public doctors and hospital administrators in Poland who awarded contracts to J&J, and public doctors in Romania to prescribe J&J pharmaceutical products. J&J subsidiaries also paid kickbacks to Iraq to obtain 19 contracts under the United Nations Oil for Food Program. J&J agreed to settle Cases Brought by SEC and Criminal Authorities by paying $ 70 million [8]. In 2012 Global health care giant GlaxoSmithKline LLC (GSK) pleaded guilty and paid $3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices. GSK paid millions of dollars

to doctors to speak at and attend meetings, sometimes at lavish resorts, at which such drugs as Wellbutrin and Paxil were routinely promoted [9]. James M. Cole, Deputy U.S. Attorney General, emphasizing the importance of this multi-billion dollar settlement, said: "At every level, we are determined to stop practices that jeopardize patients' health, harm taxpayers, and violate the public trust – and this historic action is a clear warning to any company that chooses to break the law." [9]

EUROPEAN UNION LEGISLATION

The Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use contains provisions on how to inform HCPs about drugs. Recognizing the need for such information, paragraph 47 of the Preamble states that the advertising of medicinal products to persons qualified to prescribe or supply should be subject to strict conditions and effective monitoring, referring in particular to the work carried out within the framework of the Council of Europe. The requirements that must be met by informing HCPs about medicines, including by medical sales representatives, as well as general approaches to establishing sanctions for violations of these requirements, are recorded in Art. 91-99 Directive. So, in particular, Art. 94 contains the following prohibitions: Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy (p. 1). Hospitality at sales promotion shall always be reasonable in level and secondary to the main purpose of the meeting and must not be extended to other than health professionals (p. 2). Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2 (p. 3). [10] In 2017 *Updated Study on Corruption in the Healthcare Sector. Final Report* was published by European Commission. [11] In this report, improper marketing, the facts of which were revealed in Lithuania [11, p. 61] and Poland [11, p. 81-82], are indicated as types of corruption in healthcare sector.

GERMANY LEGISLATION AND LEGAL PRACTICE

StGB criminalizes public health corruption, such as taking bribes (§299 a) and giving bribes in the healthcare sector (§299 b). Thus, according to Section 299a whosoever as a member of a healthcare profession for which a state-regulated professional education in order to practice his profession or use his professional title is established requests, allows himself to be promised or accepts an advantage for himself or for a third party while practicing that profession, in order to

1. when prescribing pharmaceuticals, remedies, aids or medical devices or
2. at the purchase of pharmaceuticals, remedies, aids or medical devices which are intended for direct application by the member of the healthcare profession or its professional assistant or
3. when assigning patients or test materials

unfairly give preference to another in the national or foreign competition shall be liable to imprisonment of no more than three years or a fine.

Section 299b of the StGB is actually a mirror image of section 299a of the StGB, which establishes liability for active corruption, i.e. an act of offering, promising or granting a benefit under circumstanced which were described in §299a. According to Section 300 StGB aggravated cases of taking and giving bribes in the healthcare sector an offender under sections 299a and 299b shall be liable to imprisonment from three months to five years. [12]

It should be noted that the StGB was added by sections 299a and 299b based on the German Act on Fighting Corruption in the Healthcare Sector (Gesetz zur Bekämpfung der Korruption im Gesundheitswesen) [13], which entered into force on June 4, 2016.

The decision to develop such a document was taken in response to a gap in the criminal law established by the German Federal Court of Justice (Bundesgerichtshof). Thus, for several years, a practice called "prescription management" was carried out in Germany, according to which physicians received a percentage of the selling price of the respective manufacturer as a bonus for prescribing certain drugs of the manufacturer. These payments were each reported as fees for fictitious scientific lectures. The Regional Court of Hamburg found that the pharmaceutical consultant handed over to the physicians, under such circumstances, 16 checks for a total of about 18,000 euros. One of the physicians was charged and found guilty under section 1 §299 StGB, and a pharmaceutical consultant under section 2 §299 StGB for taking and giving bribery in commercial practice [14]. This sentence was appealed to the 5th Senate of the Federal Court of Justice, which on July 20, 2011 sent the case to the Supreme Senate to decide whether the health practitioners are officials in the sense of §11 StGB or persons authorized by hospital insurance companies in the sense of §299 StGB [15]. On March 29, 2012 the Federal Court of Justice in its decision declared that in dependent health practitioners could not be held criminally liable as perpetrators of the corruption offences in force at that time since they are neither public officials nor employees or agents of a business [16]. Based on this decision, the 5th Senate of the Federal Court of Justice overturned the sentence of the Regional Court of Hamburg [17].

This gap in criminal law was eliminated by adding Articles 299a and 299b to the StGB. After that, the provisions of these norms began to apply to all corruption actions in the health sector committed by both private physicians and physicians working in medical institutions. Criminal liability has been established for any benefit that HCPs receive from pharmaceutical companies, and pharmaceutical companies give it to unfairly favor others in national or foreign competition.

Based on the § 30 Administrative Offenses Act (Ordnungswidrigkeitengesetz) [18], as well as the Medicinal Products Act (Arzneimittelgesetz) [19], a pharmaceutical company may be fined for bribing HCPs.

PROFESSIONAL SELF-REGULATION

Professional self-regulation is a significant component of the prevention of improper healthcare marketing. So, from January 1, 2017, the MedTech Europe Code of Business Ethics has become mandatory for corporate members of MedTech Europe. The organization's website says that it regulates all aspects of the industry's relationship with HCPs and Healthcare Organizations, to ensure that all interactions are ethical and professional at all times and to maintain the trust of regulators, and – most importantly – patients. [20]

In Germany on February 16, 2004 Voluntary Self-Control Association for the Pharmaceutical Industry (FSA) was founded by the members of the Association of Research-based Pharmaceutical Manufacturers. There are no fewer than 56 well-known pharmaceutical companies in FSA, which cover at least 75% of the pharmaceutical market in Germany. The association has developed and adopted three codes: 1) FSA Transparency Code – member companies commit themselves to publish all monetary benefits to health professionals and medical institutions; 2) FSA-Codex Expert Groups – for the benefit of the patient, it regulates the ethical cooperation of drug manufacturers with doctors, pharmacists and other medical professionals; 3) FSA Code Patient Organizations – establishes binding rules for a trusting, transparent and ethical cooperation of patient self-help organizations and pharmaceutical companies. The provisions of these codes in Germany are corporate rules, for violation of which the FSA may imposes a fine on a legal entity. [21].

In Ukraine, on September 15-17, 2010, the VII National Congress of Pharmacists of Ukraine adopted the Code of Ethics for a pharmaceutical worker, an integral part of which is the Rules for the proper promotion by pharmaceutical companies of medicines to healthcare professionals. [22] However, these rules are declarative, there are no sanctions for their violation, and therefore they should be considered instead as wishes.

UKRAINIAN LEGISLATION AND LEGAL PRACTICE

In Ukrainian legislation, the relationship between pharmaceutical companies and healthcare providers regarding drug information is not regulated. The Law "On Medicines" [23], adopted back in 1996, does not even address this problem, in no way regulating the activities in Ukraine of the army of thousands of sales representatives of pharmaceutical companies.

The Ministry of Health of Ukraine tried to fill this legal vacuum on October 9, 2013 by approving the regulation "Medicines. Good Promotion Practices." [24] It was based on the provisions of the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [10]. This regulation established the rules for the promotion of medicines, including rules on the interaction of pharmaceutical companies and their medical sales representatives with HCPs in such activities. However, it lasted less than two months and was canceled on November 18, 2013, so far, the legal vacuum remains.

Bribery of an employee of an enterprise, institution, or organization (both active and passive) in Ukraine is a crime under Article 354 of the Criminal Code of Ukraine (CCU). [25]. Theoretically, bribing a doctor by a representative of a pharmaceutical company to unfairly give preference to another in the national or foreign competition should be punished under this rule. However, an analysis of the judicial practice of Ukraine (it was carried out by studying the Unified State Register of Judicial Decisions) showed that there is no practice of applying this article in cases of improper marketing in healthcare.

THE RESULTS OF UKRAINIAN EXPERT INTERVIEWS AND PHYSICIAN SURVEYS

As part of this research in September 2019, eight experts with more than 20 years of experience in healthcare were interviewed based on anonymity. Interviews were given by three heads of municipal hospitals, three heads of pharmaceutical companies, one employee of the central office of The State Service of Ukraine on Medicines and Drugs Control, and one medical lawyer in the field of pharmaceutical law.

All interviewed experts drew attention to the fact that the activities of medical sales representatives of pharmaceutical companies in Ukraine are widespread. Their communication with HCPs occurs regularly, but it is carried out in a legal vacuum, without any law regulation. Experts note that, as a rule, medical sales representatives are not perceived by doctors as high-level professionals, carriers of new knowledge about medicines. Physicians generally consider them unhappy medical professionals who quit their profession due to a lack of skills or desire to get higher wages.

The main task of medical sales representatives is to increase sales of pharmaceutical products manufactured by their company. To this end, they need to convince HCPs of the quality and effectiveness of these products and, where possible, encourage them to prescribe such products to patients more frequently.

There are various ways of influencing HCPs, but these have changed significantly over the past ten years. All experts noted that 10-15 years ago, direct bribery of physicians was widespread, where they received a cash reward of about 5% of the cost of medicines they prescribed to patients. In some clinics, doctors were even offered medicines at wholesale prices, which they sold to patients with their interests. None of the experts remembered a single case in which a physician and a sales representative were liable for taking or giving illegal remuneration.

Over the past ten years, the situation in Ukraine has begun to change, because medical representatives of large American and European pharmaceutical companies, as a rule, refuse such practice. Representatives of Ukrainian pharmaceutical companies are more focused on working with large pharmacy chains, which, receiving products at lower prices, take on obligations in terms of sales.

In the area of relations with HCP, pharmaceutical companies make extensive use of sponsorship of scientific events that advertise their products, pay for the lectures of doctors who share positive experiences with the use of such products, and pay for the travel of doctors to scientific events, including abroad. Medical representatives also provide doctors with free samples of medicines, as well as souvenirs and some other products with a company logo that they can use at the workplace.

Experts pointed to serious corruption risks for pharmacies located in hospitals and other medical institutions. Since patients buy more than 90% of medicines in Ukraine, most of the medications prescribed for patients with inpatient treatment are purchased in such pharmacies. This situation makes it possible to quickly determine the number of prescriptions of a particular medicine made by a doctor and, accordingly, provide material incentives for doctors.

The next stage of this research was a physician survey to determine their attitude to the activities of medical sales representatives of pharmaceutical companies. In October 2019, 75 doctors from the Poltava and Sumy regions were interviewed. The results of the survey of physicians show that the majority of respondents (97.3%) had experience of direct communication with medical sales representatives of pharmaceutical companies. Only two physicians from the Sumy region with work experience from 1 to 3 years made an exception. Most of the interviewed physicians (69.3%) consider such experience useful for themselves. However, direct communication with medical representatives was named as the most productive way to obtain information only by eight physicians (10.7%), while others prefer to receive information from highly qualified doctors and pharmacists, both in personal communication and at conferences, seminars, and advanced training courses.

DISCUSSION

Marc-André Gagnon (*Corruption of Pharmaceutical Markets: Addressing the Misalignment of Financial Incentives and Public Health, 2013*) concludes that institutional corruption in the pharmaceutical sector is caused by the misalignment of private profit-maximizing objectives with public health needs. Based on the analysis of a business model promoting harmful practices, this author recommends such means of realigning financial incentives in order to foster therapeutic innovation and promote the rational use of medicines: 1) fines and criminal penalties for illegal conduct; 2) tax policy to promote specific corporate activities; 3) new forms of prescription drug pricing, such as reference-based pricing and value-based pricing [4].

At the same time, German researchers B. Bahner (2017) [26] and H. Diener (2018) [27] assess the new criminal laws on corruption in healthcare (sections 299a and 299b of StGB) as contradictory. In their opinion, these laws are not clear enough. Therefore, today, in Germany, there is no decision on which types of cooperation between HCPs and the pharmaceutical industry are legal and which are a crime. Such a situation does not contribute to the protection of patients for whom these laws were created.

Researchers at drug promotion practices Nilan T. Jacob (2018) [28] and V. Sasirekha (2018) [29] emphasize that the pharmaceutical sector is suffering from a poor reputation. These authors believe that greater transparency and accountability must be ensured in all aspects of HCPs and industry relationships. The key to sustainable growth is ethical business practice.

CONCLUSIONS

The high level of corruption risks in healthcare marketing, due to the specific consumption of pharmaceutical products, requires adequate legal measures to prevent offenses.

Incorrect healthcare marketing is a corruption crime, for which a penalty has been established for both individuals and legal entities. Not only HCPs and sale representatives but also heads of pharmaceutical companies should be punished for the commission of such crimes.

It is necessary that the criminal law on the punishment for such crimes will be clear and make it possible to distinguish offenses from the legitimate informing of HCPs by representatives of pharmaceutical companies. At the same time, the activities of medical sales representatives of pharmaceutical companies should be regulated in such a way as to ensure transparency of the costs of informing about medicines, as well as minimize personal communication of such representatives with HCPs.

Reputable professional organizations, realizing the dangers of improper pharmaceutical marketing, are taking steps to create ethical standards in this area, as well as to monitor their implementation by drug manufacturers. Such measures are, in many cases, effective, especially where such professional organizations have government support (for example, in Germany).

Given the high level of globalization of the pharmaceutical business, effective measures to prevent unfair marketing used in countries with a high level of economic development (USA, Germany, etc.) have a positive impact on the situation in the pharmaceutical markets in other countries, including Ukraine.

REFERENCES

1. Schoonveld Ed. The Price of Global Health : Drug Pricing Strategies to Balance Patient Access and the Funding of Innovation. 2nd Edition (2015). doi.org/10.4324/9781315553993
2. Ahmed, Rizwan & Saeed, Ahmad. Ethical and Non-Ethical Pharmaceutical Marketing Practices: Case Study of Karachi City. Interdisciplinary Journal of Contemporary Research in Business. 2012 3. 456-475.
3. Lexchin J., Kohler J., Gagnon MA. et al. Combating Corruption in the Pharmaceutical Arena. Indian Journal of Medical Ethics. DOI: https://doi.org/10.20529/IJME.2018.022
4. Gagnon MA. Corruption of pharmaceutical markets: addressing the misalignment of financial incentives and public health. J Law Med Ethics. 2013 Fall;41(3):571-80. doi: 10.1111/jlme.12066.
5. Corruption in the Pharmaceutical Sector. Diagnosing the Challenges. Transparency International, 2016. Available at: https://apps.who.int/medicinedocs/documents/s22500en/s22500en.pdf

6. Justice Department Announces Largest Health Care Fraud Settlement in Its History. Pfizer to Pay $2.3 Billion for Fraudulent Marketing. Available at: https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history
7. United States v. Pfizer H.C.P. Corporation Court Docket Number: 12-Cr-169. Available at: https://www.justice.gov/criminal-fraud/case/united-states-v-pfizer-hcp-corporation-court-docket-number-12-cr-169
8. SEC Charges Johnson & Johnson With Foreign Bribery. Available at: https://www.sec.gov/news/press/2011/2011-87.htm
9. GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data. Available at: https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report
10. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. OJ L 311, 28.11.2001, p. 67–128 (ES, DA, DE, EL, EN, FR, IT, NL, PT, FI, SV). Available at: http://data.europa.eu/eli/dir/2001/83/oj
11. European Commission. Updated Study on Corruption in the Healthcare Sector. Final Report. 2017. doi: 10.2837/68580
12. Strafgesetzbuch. Available at: https://www.gesetze-im-internet.de/stgb/
13. Deutscher Bundestag: Basisinformationen über den Vorgang. In: Dokumentations- und Informationssystem für Parlamentarische Vorgänge. Available at: http://dipbt.bundestag.de/extrakt/ba/WP18/685/68571.html
14. LG Hamburg, Urteil vom 09.12.2010 - 618 KLs 10/09 (5701 Js 47/09). BeckRS 2011, 23487
15. 5. Strafsenat für Strafsachen des BGH Beschluss vom 20.07.2011, Aktenzeichen 5 StR 115/11 Available at: http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&sid=d704cebcfcf3fa46c7a52ef4f7343096&nr=57204&pos=1&anz=2
16. BGH, Beschl. v. 29. 3. 2012 – GSSt 2/11, NJW 2012, 2530.
17. Strafsenat für Strafsachen des BGH Beschluss vom 11.10.2012, Aktenzeichen 5 StR 115/11 Available at: http://juris.bundesgerichtshof.de/cgi-bin/rechtsprechung/document.py?Gericht=bgh&Art=en&sid=d704cebcfcf3fa46c7a52ef4f7343096&nr=62012&pos=0&anz=2
18. Gesetz über Ordnungswidrigkeiten vom 19.02.1987 (BGBl. I S. 602) Available at: https://dejure.org/gesetze/OWiG
19. Gesetz über den Verkehr mit Arzneimitteln (Arzneimittelgesetz) vom 12.12.2005 (BGBl. I 2005 S. 3394). Available at: https://dejure.org/gesetze/AMG
20. MedTech Europe Code of Ethical Business Practice. Available at: https://www.medtecheurope.org/resource-library/medtech-europe-code-of-ethical-business-practice/
21. FSA. Kodizes. Available at: https://www.fsa-pharma.de/de/kodizes/
22. Pravyla nalezhnoi promotsii farmatsevtychnymy kompaniiamy likarskykh zasobiv profesionalam okhorony zdorovia. [Rules for the proper promotion of pharmaceuticals by pharmaceutical companies to healthcare professionals]. Available at: https://www.apteka.ua/article/65892 (In Ukrainian)
23. Zakon Ukrainy "Pro likarski zasoby" vid 04.04.1996 № 123/96-VR [Law of Ukraine "On Medicines" of 04.04.1996 № 123/96-BP]Available at: https://zakon.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80 (In Ukrainian)
24. Ministerstvo okhoony zdorovia. Nakaz № 870 vid 09.10.2013 Pro zatverdzhennia nastanovy „Likarski zasoby. Nalezhna praktyka promotsii" [Ministry of Health. Regulation No. 870 of 09/10/2013 On Approval of the Instruction "Medicines. Good Promotion Practice"] Available at: https://zakon.rada.gov.ua/rada/show/v0870282-13 (In Ukrainian)
25. Kryminalnyi kodeks Ukrainy [Criminal Code of Ukraine]. Available at: https://zakon.rada.gov.ua/laws/show/2341-14 (In Ukrainian)
26. Bahner B. Die Zusammenarbeit zwischen Krankenhäusern, niedergelassenen Ärzten und sonstigen Leistungserbringern, RDG 2017, 290
27. Diener H. Zwei Jahre Antikorruptionsgesetz – ein erstes Resümee aus Sicht der Freiwilligen Selbstkontrolle für die Arzneimittelindustrie e.V. (FSA), PharmR 2018, 334
28. Jacob NT. Drug promotion practices: A review. Br J Clin Pharmacol. 2018 Aug;84(8):1659-1667. doi: 10.1111/bcp.13513. Epub 2018 Feb 20.
29. Sasirekha V. Ethically Practiced Unethical Strategies in Pharma Industry - Whom to be Blamed. International Journal of Research - Granthaalayah, 2018 6(2), 32-45. doi:nhttps://doi.org/10.5281/zenodo.1186096.

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RISK IN THE PERFORMANCE OF MEDICAL ACTIVITIES: MEDICO-LEGAL OVERVIEW

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ABSTRACT

Introduction: The article analyzes the medical and legal analysis of the professional right to justified medical risk and the grounds for exclusion of their responsibility for the occurrence of negative consequences as a result.

The aim:of the article is to review the legal regulation of medical risk at the international level and, based on that analysis, to define the concept of justified medical risk and to analyze its main features.

Materials and methods: International acts, legislation of European states, scientific developments, jurisprudence were analyzed, building on dialectical, comparative, analytical, formally logical, statistical, complex methods of scientific research and sociological method (questionnaire).

Results: The survey found that most physicians understand some of the actions that a doctor takes to improve a patient's health, and believe that the risk begins with the identification of circumstances that may endanger the patient's life and health. The results made it possible to confirm that the medical risk is present in the practical activity of each of the doctors, and the main purpose is to save the life and health of the patient.

The analysis of court convictions shows that due to insufficient regulation of risk, its onset and basic features, most of the concepts are evaluative, which leads to a lack of uniformity of jurisprudence on medical risk issues and the unlawful prosecution of doctors.

Conclusions: Based on the analysis of key signs of medical risk, it has been formulated that justified medical risk is the risky action of a doctor within the framework of normative acts on treatment, which are performed in order to protect the life and health of the patient, if the stated goal cannot be achieved by risk-free actions. The study also revealed trends in the use of justifiable risk by physicians in practice.

KEY WORDS: right to life and health, treatment, medical risk, justified medical risk

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INTRODUCTION

Turning to health providers for patient's diagnosis, prevention and treatment, there's always the possibility for serious unexpected effects. Although the standards of modern treatment allow us to choose such methods that will be beneficial for the patient's recovery, but individual specific features of a patient's organism and other factors might have an impact on the usual course of treatment and compel a doctor to risky methods. Being allowed to take risks, physicians should be aware of the state's obligation to exclude their liability in case of the adverse effects of risky treatment. In order to protect the fundamental rights and freedoms of the patient from medical errors during the treatment process, as well as to guarantee the professional right of the physician to take risks, it is necessary to be aware of the reasons for its justification in each particular situation, the commencement of the risky action, its motivation and objectives, with an assessment of which often arise difficulties. Therefore, it is important to regulate medical risks in the treatment properly, while taking into account the interests of both patients and physicians at taking risks. Clarification of the outlined issues is possible on the basis of international experience.

THE AIM

To find out the state of regulation of medical risk at the international level and in the legislation of the individual European countries, to formulate the concept of justified medical risk, to analyze the basic signs of medical risk as a basis for effective protection of the doctors' rights in their practical activity.

MATERIALS AND METHODS

International Acts of the World Medical Association (hereinafter - WMA), legislation of certain European countries (Poland, Germany, France Italy), scientific works, judgments of the European Court of Human Rights (hereinafter - ECHR), 96 sentences of national courts of Ukraine under art. 140 of the Criminal Code (hereinafter referred to as the Criminal Code) of Ukraine for the «Inadequate delivery of professional duties by a medical or pharmaceutical worker», the results of a survey among 92 medical specialist.

This article is based on dialectical, comparative, analytical, formal-logical, statistical and complex methods of scientific research and sociological method (questionnaire).

RESULTS AND DISCUSSION

According to researcher Z. Gladun, the basis for regulating the relationship between the patient and the doctor or other medical workers is the norms of morality and ethics, which over time have developed into a separate area of knowledge, called medical ethics. From his point of view, the relations between the patient and the doctor or other health care workers are regulated by both legal and moral and ethical standards, which in this sphere of relations acquire the character of medical-ethical, deontological norms [1, p. 9-10].

Practical application of Art. 2 of the Convention on Human Rights and Fundamental Freedoms (hereinafter referred to as the Convention), which establishes, in essence, the negative and positive obligations of the State to ensure the right to life. And if a negative obligation means to abstain from the unlawful deprivation of a person's life, then a positive one is to protect a person's right to life through the statutory provisions regarding criminal liability for the unlawful deprivation of a person's life. Besides, as the ECHR notes in the case of «W v. the United Kingdom»1987, the responsibility for the deprivation of life should extend to the actions of individuals as well as those acting on behalf of the state [2, p. 166]. This means that any negligence or carelessness in providing health care services, which leads to negative consequences and violates the human right to life is a ground for liability of the health care provider for violation of Art. 2 of the Convention.

The private life of a person is also under the protection of art. 8 of the Convention which is filled not only with the individual's personal space but also, in the interpretation of the ECHR (Niemitz v. Germany decision 1992), is much broader than the traditional Anglo-American concept of «privacy» and includes both the moral and the physical integrity [2, p. 294-295]. For example, in the case of Csoma v. Romania in 2013, the ECHR held that the violation complainant's right to privacy occurred because she was not included in the choice of medical treatment and the absence of notification of a possible risk during the medical procedure [3].

In order to protect the patient's right to life and health, medical reform has been undertaken in most European countries, the main focus of which is standardization and protocolization of patients' treatments and it allows the doctor to choose the most appropriate treatment option. In practice, there are cases where a physician chooses more risky method of patient's treatment than the others prescribed by appropriate protocols to improve the patient's condition [4, p. 1839]. Therefore, the cornerstone of the issue under consideration is the attitude of the legislator towards physicians who, when applying risky therapies, there is a risk of being prosecuted for the harm caused to the patient's health whose protected rights and freedoms may be violated at risk. Therefore, the study will look one-sided if it focuses only on patients and their right to life and health, without taking into account the professional rights of doctors.

In order to protect the rights of physicians in their medical activities, more attention should be paid to cases in which the physician harms a patient, but it is not related to a medical negligence. One such case is a medical risk. Doctors who exercise the right to risk need additional safeguards and protection in the event of a negative consequences if the risk is justified.

The WMA has adopted a number of acts that regulate general health care issues and, to some extent, regulate medical risk issues. The analysis of international instruments makes it possible to conclude that medical risk is considered in the context of: 1) the patient's right to information about treatment; 2) implementation of medical activities; 3) conducting medical research. This article discusses international instruments that regulate medical risk when performing medical activities.

The right of a doctor to medical risk is enshrined in the International Code of Medical Ethics of the WMA: «A doctor should act only in the best interests of the patient when he or she uses such types of care that may impair the patient's physical or mental state» [5]. This leads to the conclusion that a doctor can apply risky therapies in order to save a patient's life, keep an organ in function, etc., by first comparing the risky action and its potential outcome.

In order to protect the doctor while his medical activity, the WMA adopted a Declaration on the independence and professional freedom of the doctor, which stated that «Doctors should have the professional freedom to provide care to their patients without external influences. The professional prescriptions of the physician, as well as his freedom in making clinical or ethical decisions in treating and assisting patients, should be safeguarded and protected»[6]. Therefore, the doctor may exercise the right to professional freedom , while making decisions and choose a treatment method that is risky, taking into account the condition and features of the patient's illness.

Thus, by analyzing WMA acts, we can conclude that they envisage the doctor's obligation to provide medical care, the doctor's right to medical risk and freedom in making professional decisions, which are interrelated elements. However, the lack of detailed regulation of medical risk, a clear indication of when it starts and ends leads to arbitrariness when considering criminal proceedings and the unlawful prosecution of doctors. C. Rodriguez and other authors in their article point out that the lack of detailed regulation of medicinal risk in the legislation does not contribute to its correct enforcement [7, p.10, 11].

The doctor's right to medical risk is enshrined in the laws of individual European countries. For example, in part 1 of art. 34.1 of the Polish Law on the Profession of the Doctor and the Dentist states that a doctor may perform surgery or apply a method of treatment and diagnosis that creates an increased risk for the patient only after having received the patient's consent [8]. At the same time, paragraph 7 of this article states that a doctor may decide on risky actions without the consent of the patient in the event that delay in obtaining consent may threaten negative consequences.

A similar provision is contained in articles 42 and 43 of the Fundamentals of the Legislation of Ukraine on Health Care [9].

It is also known that the patient's consent to any manipulation is mandatory, and the violation of this prescription is a ground for compensation for the harm caused to a patient. M. Paszkowska emphasizes that the patient's consent to the use of risky treatment is a guarantee for the protection of both the healthcare provider and the doctor himself from criminal liability [10, p. 1240]. Other researchers believe that the intervention is possible without the consent of the patient, if such intervention is in the best interests of the patient. Consent matters when a patient has received the necessary information about his or her health condition and has been aware of the risks and consequences of medical intervention [11, p. 324].

In order to evaluate the category of medical risk in the doctor's practical activity and to increase the level of protection of their rights, an anonymous survey was conducted among doctors of different specialties from Kiev, Kharkiv, Donetsk, Mariupol, Odessa, Lviv, Uzhhorod, which was conducted from April to September 2019. 92 respondents took part in the survey: 24 of them are dentists, 10 surgeons, 10 ophthalmologists, 6 cardiologists, 7 therapists, 12 neurologists, 2 pediatricians, as well as 3 psychiatrist, 1 otolaryngologist, 1 endocrinologist, 1 endoscopist, 5 dermatologist. Those who took part in the survey, 9% exercise their professions from 5 to 10 years; 30% - from 10 to 20 years; 45% - from 20 to 30 years; 10% - from 30 to 40 years; 6% - 40 years and more.

The questions included in the questionnaire were aimed at clarifying the level of understanding of the concept of medicinal risk, its purpose and the commencement. For each of the questions, doctors were offered several options, one of which provided the opportunity to express their own position.

The first question was aimed at assessing the understanding of medical risk as a phenomenon in practice, namely: «What do you think is medical risk?» And several options were suggested: A) the possibility of adverse effects of treatment over a period of time; B) deviation from the protocol or standard of treatment; C) a specific set of actions taken by the physician at his or her own discretion in the event of a critical condition of the patient, if the course of the disease or medical procedure is atypical and it's impossible to act in accordance with the prescribed rules; D) another option.

Among those interviewed, 43 people (47%) believe that option C most accurately describes «medical risk» as a phenomenon, 37 people chose option A (40%), 7 persons (8%) chose option D and only 5 person chose option B (5%) (Fig. 1).

It is also important to determine when medical risk begins. To clarify this, a question was formulated as follows: «When do you think a medical risk begins?», and the following options: A) from the moment of identification of circumstances that have a potential negative impact on a patient's life and health; B) from the moment of deviation from the protocol or standard of treatment; C) from the onset of adverse effects on the life and health of the patient; D) another option. Of those questioned, 17 people chose option A, 14 people chose option C, 3 people chose option D, 1 person chose option B. 3 people, who chose option D, indicated that determining the commencement of medical risk is a difficult task, as risk always exists (Fig. 2).

In order to confirm or refute the thesis of how often medical risk occurs in the practice, the questionnaire separately revealed whether respondents or their colleagues had to take risks. The survey showed that 82% of doctors had to take risks personally, 16% did not take risks personally, but they did encounter risks in the practice of their own colleagues. 2 of the respondents chose the option «No, I did not encounter cases of risk neither in my own practice nor in the practice of my colleagues», which demonstrates the inalienability of medical risk in the practice of doctors.

To the question: «Are you consciously ready to take a medical risk?» 75% answered that they are ready to take a medical risk in any case, 25% are ready to take a risk only in exceptional cases, and none of the doctors answered that they are not ready to take a medical risk.

The following question was aimed at analyzing the goal of medical risk in the practice and was formulated as follows: «What can make you to take a medical risk?» And the following options were suggested: A) to save the patient's life and health if other ways are ineffective; B) the potential promotion and recognition as a specialist; C) the opportunity to gain experience, even if it is negative; D) all of the above-mentioned.

The survey found that most doctors (88 people) chose option A, i.e. they are ready to take a medical risk in order to save a patient's life and health, only 1 person chose option C (an opportunity to gain experience, though negative), 3 person chose option D (all listed) and none of the respondents chose option B (opportunity to gain experience, although it is negative) (Fig. 3).

When researching the concept of «medical risk» it should be noted that the regulation of treatment methods at international and national levels allows the doctor to choose alternative methods, taking into account the ratio of potential risk of the performed procedure and its results. In each of the methods, there is to varying of degrees specified element of risk (for example, identifying circumstances that were not known to the doctor before the medical manipulation), and therefore it is possible to expect the probability of negative consequences of the performed procedure.

By an order No. ACZ 1329-1317 dated 11 April 2018 of the Appeals Court of Civil Affairs in Poznan, it was stated that even if the medical service or treatment was carried out with proper adherence of professional duties, regulations and medical knowledge, the possibility of occurrence negative consequences for the life and health of the patient can't be excluded. In this case, it is a medical risk [13].

However, the onset of adverse effects is preceded by the physician's choice of a treatment or modalities for the implementation of medical procedure that may cause such

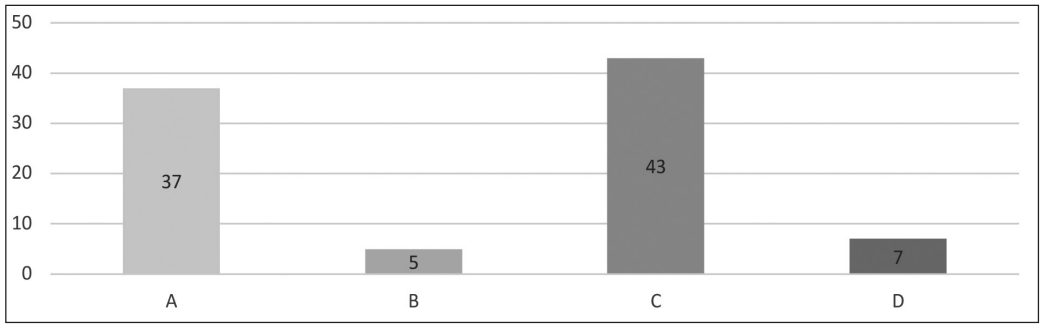

Fig 1. Definitions of medical risk
A. the possibility of adverse effects of treatment over a period of time
B. deviation from the protocol or standard of treatment
C. a specific set of actions taken by the physician at his or her own discretion
D. another option

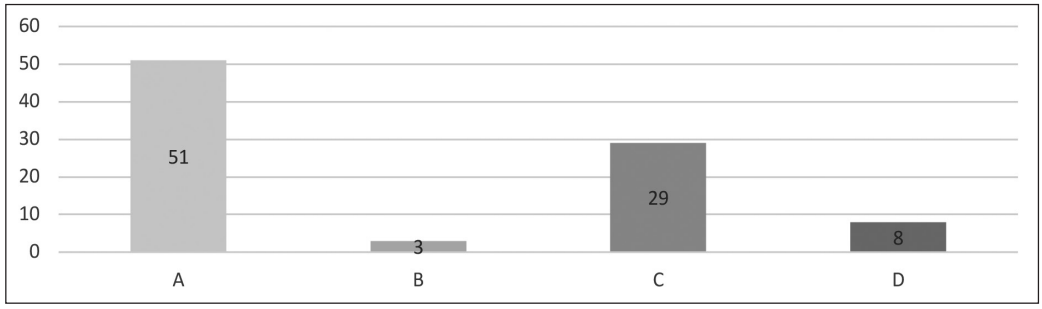

Fig 2. Medical risk start
A. from the moment of identification potential negative impact for patient
B. from the moment of deviation from the protocol or standard of treatment
C. from the onset of adverse effects on the life and health
D. another option

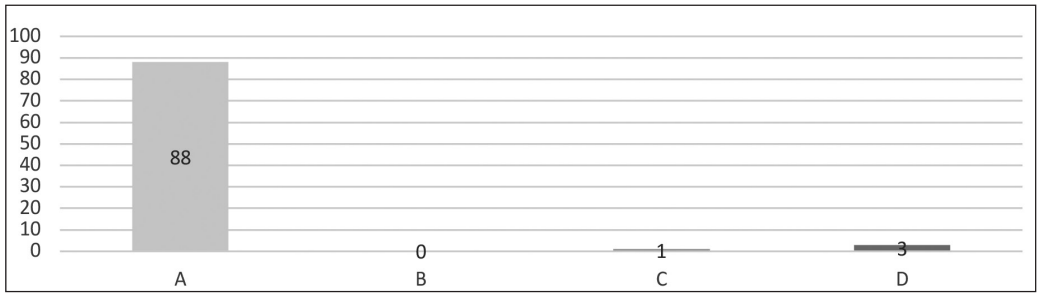

Fig 3. Goal of medical risk
A. to save the patient's life and health if other ways are ineffective
B. the potential promotion and recognition as a specialist
C. the opportunity to gain experience, even if it is negative
D. all of the above-mentioned

effects. This means that the most accurate characterization of the concept of risk was given by the 47% of the interviewed doctors, who said that the medical risk is a certain set of actions that the doctor does at his own discretion in the critical condition of the patient, if the disease or medical procedure is atypical and it is impossible to act according to the rules provided.

If a physician chooses a method of treatment, diagnosis or surgery that carries an increased level of risk, he or she may use the right to medical risk, which is a form of action related to the risk provided under art. 42 of the Criminal Code of Ukraine [12].

From the point of view of justified medical risk, the following can be traced in the criminal codes of individual countries as a circumstance that excludes criminal liability for harm to a patient. For example, the general concept of justified risk is established in Part 1 of art. 42 of the Criminal Code of Ukraine: «Risk is considered justified if the goal that was set could not be achieved by this action (or omission), which is not connected with risk, and the person who permits the risk reasonably expected that the measures that he or she had taken were sufficient to prevent harm to the patient's legally protected interests» [12]. Similarly, in most European countries, justified risk is recognized as a circumstance that excludes criminal liability. Something similar is the way of defining the risk in art. 33 of the Criminal Code of Latvia and in art. 34 of the Criminal Code of the Republic of Lithuania [14].

In proving the existence of justified medical risk, the criminal liability of the doctor is excluded due to the absence in his or her actions of a sign of the illegality of his or her behaviour. The basis of a medical risk is its justification, which is determined by three elements, the presence of which in conjunction is the basis for the mandatory exclusion of criminal liability for the harm caused to the patient.

Firstly, it is the existence of an objective situation that necessitates the achievement of a significant socially useful purpose and which may present a risk. The most frequently in medical practice the objective situation is the risk of a patient's death, a declining health, the likelihood of organ loss, or other serious health effects.

Secondly, the inability to achieve the goal of preserving a patient's life, significantly improving his or her health and so on by risk-free actions. For example, an atypical disease course or unforeseen worsening of a patient's health condition is the basis for choosing more risky treatment because the less risky methods and procedure will not lead to the desired results and the patient's life

must be preserved. However, if it is established that the physician had and was aware of a real possibility to apply non-risky methods, but he or she decided to apply, on the contrary, risky methods of treatment, then he or she could be held liable on a general basis for the harm caused to the patient.

As an example, it can be used the court sentence No. 0110/1844/2012 of 1 October 2012, Kirovsky District Court of the Autonomous Republic of Crimea, where the surgeon was found guilty of committing crime under part 1 of art. 140 of the Criminal Code of Ukraine, for improper performance of professional duties by a medical professional. The surgeon, as the doctor on duty, decided to puncture the soft tissue of the upper third of the left shoulder and further surgical procedure for the patient who was in treatment. As the result of these actions, it caused damage to the patient's left axillary artery, which led to external bleeding, resulting in death. The investigation revealed that the doctor did not examine the patient and was not convinced of the ineffectiveness of other treatments that were less risky than surgery [15].

Thirdly, the implementation of the necessary measures by a doctor, which gave him sufficient reason to reasonably expect to prevent harm to the patient's legally protected interests. This means that those risky actions that either do not cause or although do harm to the patient are considered justified, but this harm is due to other factors that could not have been foreseen at the time of the risky intervention. At the same time, if the inevitability of causing harm is known to the physician in advance, then the justification of the risk is excluded and he or she is liable on a general basis. A. Nafsika and R. Allison emphasize that before making a decision on risk, it is necessary to consider all possible options for the course of events taking into account a specific situation [16, p. 146].

As already mentioned, in case where there are all three of the above-mentioned elements of risk justification exist, the physician has grounds to exercise the right to a medical risk, which in turn is characterized by the following features. The first indication is the socially useful goal of risky action, which in medical risk cases is to save the patient's life and (or) significantly improve his or her health condition. It is this purpose that legitimate the risky action, regardless of whether it has been achieved. According to an anonymous survey, the driving force for a doctor's decision to exercise the right to risk is to preserve the patient's life and health.

The second sign of a risky act in the case of a medical risk is the nature of such an act, which means that such act outwardly coincides with the crime under the country's criminal code. In Ukraine, this crime (corpus delicti) is covered by Part 1 of art. 140 of the Criminal Code of Ukraine, which establishes responsibility for the non-compliance or improper performance of professional duties by a medical or pharmaceutical worker due to their negligent or careless attitude, if it has caused grave consequences for the patient. By doing so, the doctor threatens or actually harms the patient's life or health. However, due to the lack of wrongful act, the act of the physician is not a crime [12].

To illustrate, we give the following example. The judgment of the Court of Appeal in Szczecin No. I ACa 6/17 of 12 April 2017, the surgeon's actions were recognized as justified medical risk. To stop the degenerative changes and eliminate the cause of cervical instability, it was decided to have surgery that led to dysphonia, which is a frequent occurrence in this type of surgery. The court acknowledged that the surgeon had acted in compliance with the protocol of the operation and the damage caused was far less than the potential threat to the patient's life [17].

The following indication of a risky action is its timeliness, which is that such an act must be committed only during the existence of time of a risk justification. In assessing timeliness, a number of factors should be considered, such as age, condition, underlying and additional diseases, their duration, etc. If a risky act was committed before or after the end of time of a justifiable risk, then the risky act cannot be considered justified.

Particular attention should be paid to the moment when the medical risk status begins. Of those interviewed respondents, 56% chose option A (from the moment of finding circumstances that have a potential negative impact on the life and health of the patient), 32% chose C (since the adverse effects on the life and health of the patient), 9% chose D (other variant), 3% - B (since deviation from protocol or standard of treatment). Choosing option D, 8 doctors stated that determining the onset point of medical risk was a difficult task, as risk always exists. This point of view is not new, and many scientists agree. For example, N. Rahman and others argue that when performing any medical procedure and treatment plan, there are internal risks that may arise from the atypical disease of the patient or when proven treatments do not help [7, p.3]. From the point of view of criminal law, the moment of commencement of a risky act is directly physician's actions or omissions, which are risky, with the purpose of saving patient's life or health.

The Criminal Code of Ukraine does not specify the limits of justifiable risk, which gives grounds to conclude that when the risk is justified the harming is legitimate and covers both the infliction of injures of various severity and causing the death of a patient, but only if it was impossible to use non-risky methods of treatment and the doctor reasonably expected that the measures taken were sufficient to prevent harm to the patient's legally protected interests.

The results has made it possible to see that the medical risk is present in the practical activity of each of the doctors, and the main purpose is to save the life and health of the patient.

The analysis of court judgements shows that due to the insufficient regulation of risk, its onset and basic features of most of the concepts are evaluative, which leads to an absence of uniformity in judicial practice in matters of doctors' risk and the unlawful criminal prosecution of doctors.

When considering a problem of medical risk, we should take into account the object of causing harm, which in the case of risky action advocates the legally protected interests of the person, first of all the life and health of the patient.

CONCLUSIONS

A person and his or her life are the supreme value, and an illegal attempts on one's life and health is a criminal offence. Physicians' actions aimed at protecting and maintaining the patient's life and health, due to the presence of a number of factors (such as weakened immunity, allergic reaction, etc.), make it impossible to apply the treatment to such a patient, even if this treatment has low level of risk. Instead, the use of risky methods often leads to patient's death, deterioration of the health, loss of organs or their dysfunction, etc. However, justifiable medical risk eliminates liability for damage caused to the patient, since justified risky intervention is always done to preserve the life and health of the patient.

The questionnaire of physicians focused on the main aspects of justified medical risk, which made it possible to formulate the concept of justified medical risk, the moment of its initiation and to identify implementation trends of justified risk in practice.

Based on the identification of key features, we can conclude that justified medical risk is the physician's risky action or omission within international and national standards, protocols and instructions for diagnosis, prevention and treatment that are supposed to be done to preserve a patient's life, significantly improve his or her health, keep the organ or organ system in function, if the goal cannot be achieved by other, non-risky actions or omissions, and the doctor reasonably expects that the measures taken by him or her are sufficient to prevent harm to the patient's legally protected interests.

REFERENCES

1. Hladun, Z. Medytsyna i prava patsiientiv. [Medicine and patient rights] Medical law, 2008;1:7-26.
2. Dudash T.I. Case law of the European Court of Human Rights: textbook tool. / 3rd edition, stereotyped. K: Alerta, 2016. 488 p.
3. Case of Ksomo v. Romania, application no 8759/05, judgment of 15 January 2013 Available from: https://www.echr.com.ua/publication/reproduktivni-prava/ [reviewed 2019.09.04]
4. Baulin Y. Rohozhyn B. Vyshnevska I. Legal regulation of professional obligations of physician in Ukraine Wiad Lek 2019;72(9) cz II: 1839-1843
5. Mizhnarodnyi kodeks medychnoi etyky vid 01.10.1983 [An international code of medical ethics of the World medical association is from 01.10.1983] Available from: https://zakon.rada.gov.ua/laws/show/990_002 [reviewed 2019.09.04] (Ua)
6. Helsinska deklaratsiia Vsesvitnoi medychnoi asotsiatsii "Etychni pryntsypy medychnykh doslidzhen za uchastiu liudyny u yakosti obiekta doslidzhennia" vid 01.10.2008 [Helsinki declaration of the World medical association is "Ethic principles of medical researches with participation of man in quality of research" by the state on 01.10.2008] Available from: https://zakon.rada.gov.ua/laws/show/990_005 [reviewed 2019.09.04] (Ua)
7. Rodriguez C., Rahman N.A., London K., Naples R., Buttar S., Zhang X.C., Lee H., Rudner J., Papanagnou D. An Evaluation of Risk Attitudes and Risk Tolerance in Emergency Medicine Residents. 2019; 13,11(4):e4451 doi: 10.7759/cureus.4451.
8. Ustawa z dnia 5 grudnia 1996 r. o zawodach lekarza i lekarza dentysty. Available from: http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU19970280152/U/D19970152Lj.pdf [reviewed 2019.08.11]
9. Osnovy zakonodavstva Ukrainy pro okhoronu zdorovia: zakon Ukrainy № 2801-XII vid 19.11.1992 r. [Bases of legislation of Ukraine about a health protection : Law of Ukraine № 2801-XII 19.11.1992] Available from: https://zakon.rada.gov.ua/laws/show/2801-12 [reviewed 2019.08.11] (Ua)
10. Paszkowska Małgorzata Podstawowe standardy prawne wykonywania zawody lekarza Wiad Lek 2018, 71, 6 : 1239-1244
11. Herts, A A. Dohovirni zobov'iazannia u sferi nadannia medychnykh poslu. [Contractual obligations in the field of medical services] the Dissertation for obtaining the degree of Doctor of Laws 2016 Available from: http://idpnan.org.ua/files/gerts-a.a.-dogovirni-zobov_yazannya-u-sferi-nadannya-medichnih-poslug-_d_.pdf [reviewed 2019.08.11] (Ua)
12. Kryminalnyi kodeks Ukrainy: zakon Ukrainy № 2341-III vid 5 kvitnia 2001 r. [Criminal code of Ukraine: Law of Ukraine № 2341-III adopted on April 5, 2001] Available from: https://zakon.rada.gov.ua/laws/show/2341-14 [reviewed 2019.08.11] (Ua)
13. Wyrok z uzasadnieniem Sąd Apelacyjny w Poznaniu z 2018-04-11 №I ACa 1128/17 Available from: http://orzeczenia.ms.gov.pl/content/ryzyko$0020medyczne/153500000000503_I_ACa_001128_2017_Uz_2018-04-30_001 [reviewed 2019.08.11]
14. Criminal codes of OSCE participating States Available from: https://www.legislationline.org/documents/section/criminal-codes [reviewed 2019.08.11]
15. Vyrok Kirovskoho raionnoho sudu ARK vid 05 zhavtnia 2012 roku sprava № 0110/1844/2012 [Judgment of the Kirov District Court of the ARC of 05 October 2012 Case No. 0110/1844/2012] Available from: http://reyestr.court.gov.ua/Review/27226125 [reviewed 2019.08.11] (Ua)
16. Athanassoulis Nafsika and Ross Allison Luck and Risk in Medicine. Reconceiving Medical Ethics/ edited by Christopher Cowley. 2012: 148-160
17. Judgment of the Court of Appeal in Szczecin No. I ACa 6/17 of 12 April 2017 Available from: https://www.temidium.pl/artykul/glosa_do_wyroku_sadu_apelacyjnego_w_szczecinie_z_12_kietnia_2017_r_w_sprawie_i_aca_617-4836.html [reviewed 2019.08.11]

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MEDICAL ERRORS: PATIENTS' OPINION, LAWYERS' STANDPOINT, MEDICAL DOCTRINE AND PRACTICE OF THE EUROPEAN COURT OF HUMAN RIGHTS

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ABSTRACT

Introduction: The problem of medical errors is always relevant in medical literature and law. Meanwhile, it is understood diametrically opposite by doctors, patients, and lawyers. This has a negative impact on patients' trust in medical professionals, and sometimes leads to criminal prosecution for a so-called "medical error", which in fact is conscientious deception, not a crime, and should exclude criminal liability.

The aim: The aim of this work is the illustration of diametrically opposed approaches to understanding the essence of the concept of "medical error" from patients', doctors', and lawyers' views that are often generated by subjective approaches and results in distrust between doctors and patients, medical professionals and lawyers. The aim of the article is also to realize the ECHR's approach to understanding the essence of a medical error and distinguishing it from the negligence that should lead to liability of the medical professionals.

Materials and methods: In this research a legal doctrine, scientific works, provisions of international legal acts, in particular, the Convention for the Protection of Human Rights and Fundamental Freedoms were used, as well as the practice of the ECHR (12 relevant ECHR decisions), where the Court considered cases related to "medical errors" and formulated positive obligations of the state in the field of health care were analyzed. A complex set of general and special methods of cognition was used to achieve the aim, they are comparative legal method, systemic and structural method, methods of generalization, analysis and synthesis, sociological method, hermeneutical method, etc.

Results: A survey of patients, medical professionals and lawyers conducted by the authors (300 persons), analysis of doctrinal approaches are illustrated the gap between the doctrinal approaches existing in the understanding of the essence of the "medical error" phenomenon and the perceptions of the medical services recipients, which indicates the need of understanding the essence of the phenomenon of medical error in order to increase the confidence in the medical profession, the inadmissibility of doctors liability for a medical error.

Conclusions: The research gave the authors a reason to conclude that both medical and legal sciences are still far from the unity of views on the concept of "medical error". Medical errors significantly affect the authority of a medical institution, a particular doctor, or the state as a whole, and have severe consequences for patients. An analysis of the medical literature and ECHR practices has led to the conclusion that a medical error occurs when it is possible to completely exclude the guilt of medical professionals in the form of intent or negligence. In case of a medical error the criminal liability of the doctor is excluded.

KEY WORDS: medical error, medical negligence, patient rights, ECHR practice, the positive obligations of the state in the field of health care

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INTRODUCTION

In medical and legal literature, it has been often raised the issue of increasing the number of "medical errors" that have led to complications of the disease, misdiagnosis, and sometimes even the death of a patient as a result of doctors' actions. Patients, dissatisfied with the quality of health care services, or their relatives are applying to the court to protect their violated rights, achieve compensation, punish the guilty person and, in case of not finding protection at the national level, have to seek justice in supranational courts, and in particular the ECHR. It should be noted that the term "legal error" is absent in traditional legal terminology. Most often it is used in everyday communication. Often, when examining complaints of maladministration of positive obligations to ECHR citizens by doctors or the state, a violation of Art. 2 "The Right to Life", Art. 3 "Prohibition of Torture", Art. 8 "The Right to Respect for Private and Family Life" of the Convention for the Protection of Human Rights and Fundamental Freedoms (hereinafter referred to as the Convention) is stated. Considering the severity and urgency of the problems raised on the one hand, and the delicacy of them on the other hand, since in some cases the finding of a "physician error" is only a subjective view of the patient, the authors decided to choose the non-standard approach and conducted a blitz survey of three individuals' groups: medical professionals, patients and lawyers; inviting them to express their views on the concept of "medical error", as well as referring to the case law of the ECHR, they highlight the positive obligations of the state to ensure the proper functioning of the health care system.

THE AIM

The aim:of the article is to analyze the views of medical professionals, patients and lawyers on the phenomenon

of "medical error" for the sake of awareness of the people who use medical services, their providers and lawyers, that is, people who form their views on the basis of the national legislation. The hypothesis introduced by the authors is that a misconception about the concept of "medical error" has been formed in society, which leads to the distrust of patients to doctors, and sometimes to the doctors' criminal liability. In addition, the aim of the article is to analyze the case law of the ECHR, in which it considered the issues of "medical errors" that led to the violation of the ECHR, an awareness of the ECHR's attitude to this phenomenon.

MATERIALS AND METHODS

In this research a legal doctrine, scientific works, provisions of international legal acts, in particular, the Convention for the Protection of Human Rights and Fundamental Freedoms were used, as well as the practice of the ECHR (12 relevant ECHR decisions), where the Court considered cases related to "medical errors" and formulated positive obligations of the state in the field of health care were analyzed. A complex set of general and special methods of cognition was used to achieve the aim, they are comparative legal method, systemic and structural method, methods of generalization, analysis and synthesis, sociological method, hermeneutical method, etc.

RESULTS

The concept of "medical error". The term "medical error" is quite often used in everyday discourse, it is hard to define when it was put into circulation. Being aware of its content is not difficult for the average citizen, because every adult in general understands what the issue is about. The authors of the article conducted a blitz survey of three groups of persons: 1) average citizens who were treated in hospitals or consulted by doctors (100 persons) during the last year; 2) lawyers (100 persons including 56 attorneys, 18 judges, 26 prosecutors); 3) 100 doctors, paramedics and nurses. Respondents were asked several questions, one of which was: "How do you understand the concept of "medical error"?" The answers differed significantly depending on the group to which the persons who agreed to answer was belonged. Various approaches to the essence understanding were identified by patients. By "medical errors", for example, they referred to "any actions (or omissions) by doctors that had adverse effects on the patient"; "misdiagnosis"; "failure to provide assistance (or qualified assistance)"; "doctor's indifferent attitude to the patient"; "unprofessionalism"; "unskillfulness"; "undesirable treatment outcome"; "defect in the provision of medical care associated with improper treatment"; "violation of medical ethics"; "accident"; "negligence"; "doctor's inattention"; "guilty act or omission of a doctor"; "conscious actions of a doctor"; "improper medical manipulation"; "negligence in the performance of professional medical duties, resulting in insufficient medical care or due diligence"; "untimely provision of medical care"; "incomplete examination of the patient"; "procrastination in providing medical assistance"; "failure to provide a full range of medicines for the patient's recovery". As we could see, all the approaches are diverse, but they share one thing – patients are deeply convinced that these actions (or omissions) result in harm to a patient's health, disability, or death. No respondent indicated that the cause of the medical error could be objective circumstances, and that the doctor could be mistaken and be convinced of the correct diagnosis and treatment.

Moreover, 86 people supported the introduction of criminal liability of doctors for medical errors that, in their opinion, will give an important social effect in the form of increasing doctors self-demand and their responsibility for the result of their activity.

This patients' approach testifies a deep gap between the doctrinal approaches to the awareness of the phenomenon essence of "medical error" and the perceptions of the medical services' recipients. In our opinion, it is rather situational-emotional; however, it illustrates dissatisfaction with the quality of medical services provided, social tension and desire to change the situation by introducing more stringent measures for doctors and medical staff.

As for doctors' answers to the question of how they consider the "medical error" concept, they have shown much more weight, professionalism and unity in their views, emphasizing that this is a "conscientious misconception." Summarizing the doctors' responses on the question that has been asked leads to the conclusion that they consider another aspect of the medical error, namely, an "undesirable treatment outcome"; "automated diagnosis error"; "the result of improper organization of the treatment or work of a medical facility"; "coincidence of circumstances during treatment due to external (or objective) factors"; "failure to achieve the desired result during treatment due to patient neglect of the doctor's prescriptions"; "an accident that does not depend on the will of the doctor"; "the unpredictable course of the disease". Generalizing fact in the approaches of physicians was that a medical error is existing in the faithful actions of the doctor and completely eliminates their guilt, since even in case of a negative impact on the health of a patient or their life and the causal connection between treatment and these consequences, the doctor doesn't want them to occur. That is why a medical error should exclude any liability, including criminal liability.

Among the lawyers there were much more polar thoughts. Some of them (16 persons) understood medical error as an unlawful act (or omission) of a doctor, which is most often done with indirect intent, resulting in harm to the patient's health, disability or even death. And a prerequisite is a direct causal link between the doctor's action (or omission) and the unlawful consequences.

The second group of lawyers (11 persons) stated that the concept under consideration is a complex assessment category and, before qualifying the doctor's actions, it is necessary to take into account all the factual circumstances and familiarize themselves with the job descriptions.

A third group of lawyers (73 persons) stated that there was no definition of "medical error" in the legislation, so this phrase could not be considered legal. Moreover, based on the etymology of this concept, "medical error" is a conscientious assumption, and misconception regarding the clinical

diagnosis of the patient, intended treatment, etc., so criminal liability for the "medical error" is inadmissible.

Analysis of the medical and legal sources gives reason to state even more divergence in the views of scientists on the concept of "medical error". In particular, according to Yu.D. Sergeev and S.V. Erofeev, the medical literature contains at least 65 definitions and characteristics of medical (medicinal, therapeutic, diagnostic, technical, tactical, prognostic, etc.) errors [1, p. 13-14]. In the medical literature, the most common approach is I.V. Davydovskiy's, who in 1941 has defined medical error as "a conscientious deception of a doctor based on the imperfection of the medical science and its methods, or as a result of an atypical course of the disease or inadequate training of the doctor, if it does not contain the elements of negligence, inattention and medical ignorance" [2, p. 3-5, 16-18].

Case law of the European Court of Human Rights on medical errors.

The ECHR case of Vo v. France is indicative in this regard [3]. The applicant, Mrs. Thi-Nho Vo, who is of Vietnamese origin, attended the hospital for a medical examination scheduled during the sixth month of pregnancy. The same day another patient with a similar name (Mrs. Thi Thanh Van Vo) was due to have a contraceptive coil removed at the same hospital. The doctor mistakenly mistook the applicant for her namesake and proceeded to remove a contraceptive coil without examining the patient beforehand. During the procedure, the doctor pierced the amniotic sac causing the loss of a substantial amount of amniotic fluid. After examining the patient, the doctor ordered a scan, after which he realized that there had been a case of mistaken identity. The applicant was hospitalized urgently, but the doctors concluded that it was necessary to terminate the pregnancy. Further, the case on charges of negligent harm to the applicant's health and the death of the child had been prosecuted and subsequently brought to court.

An act of amnesty was applied to the crime against the applicant's personality. As regards the act on the fetal fetus, the Court of Cassation of France refused to classify the doctor's actions as killing the unborn fetus by negligence.

Not assessing the ECHR's approach to interpreting the right to life of an unborn child within the meaning of Art. 2 of the Convention, as it is beyond the scope of the article, we note that in this case the Court uses the notion of "medical error" and negligence: "The artificial termination of a pregnancy against the will of the mother (and father) as a result of medical negligence or medical error is a gross assault on the rights of the patient, since in this case the rights of the mother and the child clearly coincide" [3]. Thus, in the present case, the ECHR distinguishes between the concept of "medical error" and negligence, which in this context is a crime committed by negligence in the form of carelessness that is, the doctor did not foresee the possibility of occurrence of socially dangerous consequences of his actions, although he should and could have foreseen them.

In another case, R.R. v. Poland [4], a violation of Art. 3 "Prohibition of Torture" by the Convention was found, which was associated with procrastination of doctors in establishing diagnosis and diagnostic procedure. In particular, after the ultrasound had detected suspected genetic abnormalities in the development of the fetus, the applicant decided to have an artificial termination of pregnancy. She has repeatedly sought medical advice from doctors and requested a genetic examination to determine the fetal disease and severity of the disease, which are legal prerequisites for an abortion. The applicant repeatedly appealed to the doctors to expedite the research and diagnosis and lengthy process by doctors who refused to make decisions, delayed the resolution of her problem. The referral to the genetic examination and its results, which confirmed the presence of the disease, were received within the period at which, under Polish law, the abortion was no longer allowed, so the applicant gave birth to a sick child. Despite the fact that the national courts addressed by the applicant upheld the claims of a violation of her rights, in the applicant's view, they had avoided analyzing the systemic problem of the application of Polish law in the form of untimely decisions on the necessary researches by doctors and awarded her insufficient compensation.

The ECHR noted that the nature of the circumstances surrounding a woman's decision to terminate her pregnancy were of considerable importance. The procedures provided must ensure that doctors make their decisions promptly. The legislation clearly imposes on doctors the obligation to provide patients with clear information about their condition, diagnosis, methods of diagnosis and treatment, predictable consequences, decisions about their use, possible results of treatment. In addition, the Court concluded that there was an unreasonable procrastination in the decision to conduct an examination of genetic abnormalities in the development of the fetus, the results of which are a prerequisite for legal abortion, the need to undergo painful uncertainty about the health of the fetus, its future, future family and the prospects of raising a child suffering from an incurable disease violate Article 3 of the Convention [4].

As it was mentioned above, patients consider failure to prescribe the necessary treatment when it is available as a "medical error". However, the ECHR does not always consider such a situation as a violation of patients' rights. In particular, in the case of Hristozov and Others v. Bulgaria [5], ten applicants complained to the Court that they had been denied the access to experimental medicines whose authorization had not yet been obtained. Having exhausted a number of conventional anticancer drugs, applicants received information from a private clinic about free-of-charge experimental drugs developed in Canada. They asked the respondent state to allow them to use this medicine. They were denied in it, because of the fact that such a drug authorization could only be granted if the medicine was authorized in another country. They were indeed allowed for "compassionate use" in a number of countries, but they were not officially authorized in any country.

In this case, the ECHR noted that "Suffering from a natural disease may fall under Article 3 if they are compounded by treatment-related measures for which the authorities may be held responsible... However, the severity threshold in such situations is high, because the alleged harm comes not from the actions or omissions of the authorities, but from the illness

itself." The refusal to prescribe such treatment does not reach a degree of severity to characterize it as inhuman treatment. Article 3 of the Convention does not impose on the State an obligation to close the gap between the levels of care in different countries. Therefore, such refusals cannot be regarded as insulting or degrading to the applicants.

It is essential in this situation to strike a fair balance between the competing interests of the individual and society as a whole, with due regard for the limits of the discretion of the state. The applicants' interest was "the freedom to choose as an extreme measure of untested treatment that could have posed a threat, but which the applicants and their doctors considered appropriate in these circumstances as an attempt to save their lives." Counter-public interest is threefold: it is, first of all, to protect patients from the threats posed by illicit treatment; second, to ensure compliance with the regulatory framework governing the use of illicit drugs; third, to ensure that the development of medical products is not at risk, such as reduced patient involvement in clinical trials.

Therefore, not giving mortally ill citizens the opportunity to use experimental medicines that are not allowed in any other state for treatment purposes does not violate Article 3 of the Convention and is therefore not a doctors' error.

Key findings were made by the ECHR in the well-known case of Lopes de Sousa Fernandes v. Portugal, in which the Court stated that "criminal-law remedies must be available where it is established that the negligence attributable to State officials or bodies goes beyond an error of judgment or carelessness, in that the authorities in question, fully realizing the likely consequences and disregarding the powers vested in them, failed to take measures that were necessary and sufficient to avert the risks inherent in a dangerous activity" [6].

The ECHR also examined a number of cases in which situations related to negligence committed by medical workers were evaluated – prescribing drugs for a disabled child, despite his mother's disagreement [7]; death of an elderly woman from bronchopneumonia [8]; death of a pregnant woman suffering from ulcerative colitis [9]; death in the hospital associated with pulmonary complications and patient refusal of treatment [10]; the death of a pregnant woman due to the refusal of the doctor to perform an emergency operation due to the impossibility of payment [11]; the death of a newborn in an ambulance after they were refused treatment at several state hospitals [12]; death after a heart attack caused by the prescription of a drug [13].

Moreover, the ECHR in the case of Oyal v. Turkey stated that the state should ensure that the injured party provided with remedies in civil proceedings, either alone or in combination with criminal defense in criminal proceedings, which will establish the responsibility of doctors and ensure appropriate civil legal protection in case of medical negligence [14].

Thus, a generalization of the ECHR's practice leads us to conclusion that the Court distinguishes between a medical error and negligence, which is very important for the doctrine and for the purpose of establishing the liability of doctors, and emphasizes the possibility of prosecuting doctors in cases where the actions of a doctor go beyond error, there is a negligence of doctors.

DISCUSSION

Certainly, the problem of medical errors is not new to scientific discourse. However, it is known that the concept of "medical error" still raises many disputes and cannot be considered resolved. Moreover, it should be noted that the awareness of this concept essence differs significantly depending on the field in which it is considered. In particular, scientists assume "medical error" as a crime or disciplinary act [15, p.10]; "failure to perform a planned action not in the way originally intended, or to use the wrong plan of action to achieve a goal that does not preclude intentional or negligent actions that cause harm to the patient" [16, p.64]; "the failure of a planned action to be completed as intended (an error of execution) or the use of a wrong plan to achieve an aim (an error of planning)" [17, p. 302]; "an unintended act (either of omission or commission) or one that does not achieve its intended outcome" [18]; "a preventable adverse effect of medical care, whether or not it is evident or harmful to the patient" [19]; "an act of omission or commission in planning or execution that contributes or could contribute to an unintended result" [20]; "an act of commission (doing something wrong) or omission (failing to do the right thing) that leads to an undesirable outcome or significant potential for such an outcome" [21]; "a failure in the treatment process that leads to, or has the potential to lead to harm to the patient" [22]. There is an approach according to which scientists propose to introduce the notion of excusable and non-excusable medical error [23]. Scientists also consider it necessary to abandon this concept because it is not legal and leads to a confusion of terminology [24].

The above points of view on the concept under consideration clearly illustrate the polarization in approaches, which leads to complexity in the professional activities of medical professionals, in the law-enforcement process, and which is also important, does not promote trust between patients and doctors.

CONCLUSIONS

1. The conducted research leads to the conclusion that both medical and legal sciences are still far from the unity of views on the concept of "medical error", differentiating it from other concepts, such as "accident", "conscientious misconception", "adverse outcome of treatment", as well as crimes involving medical professionals, such as "illicit medical activity", "improper performance of professional duties that have caused the person to contract the human immunodeficiency virus or other incurable disease", "failure to provide assistance to a person in a life-threatening condition", "failure to assist a patient by medical staff", "violation of the patient's rights", etc. It is sometimes very difficult to differentiate between a true medical error that is related to a bona fide misconception and a crime.
2. The development of the state and society, the proclamation of a person, their life and health of the highest value attests to the need of improvement scientific approaches, requires states to fulfill positive obligations aimed at ensuring the proper functioning of the state health care system, the implementation of measures aimed at preventing med-

ical errors and, if available, conducting prompt and full investigations within a reasonable time.
3. An analysis of the medical literature and ECHR practices gives us a reason to conclude that a medical error occurs when the guilt of medical workers in the form of intent or negligence can be completely excluded. It is the result of a conscientious delusion based on the imperfection of the medical science itself, its methods, and means of diagnosis or the result of an atypical course of the disease. The finding of a medical error completely excludes the criminal liability of doctors.
4. In any case, the problems of "medical errors" significantly affect the authority of a medical institution, a particular doctor, the state as a whole and have serious consequences for patients.

REFERENCES

1. Sergeev Yu.D., Erofeev S.V. Neblagopriyatnyiy ishod okazaniya meditsinskoy pomoschi [Adverse outcome of medical care]. Moscow-Ivanovo: 2001;251. (Ru)
2. Davydovskiy I.V. Vrachebnyye oshibki [Medical errors]. Soviet medicine. 1941;3:3–18. (Ru)
3 Case of Vo v. France, application no. 53924/00, judgment of 8 July 2004. Available from: http://hudoc.echr.coe.int/eng?i=001-61887 [reviewed 2019.08.20]
4. Case of R.R. v. Poland, application no. 27617/04, judgment of 26 May 2011. Available from: http://hudoc.echr.coe.int/eng?i=001-104911 [reviewed 2019.08.20]
5. Case of Hristozov and Others v. Bulgaria, applications no. 47039/11 and no. 358/12, judgment of 13 November 2012. Available from: http://hudoc.echr.coe.int/eng?i=001-114492 [reviewed 2019.08.20]
6. Case of Lopes de Sousa Fernandes v. Portugal, application no. 56080/13, judgment of 19 December 2017. Available from: http://hudoc.echr.coe.int/eng?i=001-179556 [reviewed 2019.08.20]
7. Case of Glass v. United Kingdom, application no. 61827/00, judgment of 9 March 2004. Available from: http://hudoc.echr.coe.int/eng?i=001-61663 [reviewed 2019.08.20]
8. Case of Sevim Güngör v. Turkey, application no. 75173/01, judgment of 14 April 2009. Available from: http://hudoc.echr.coe.int/eng?i=001-92569 [reviewed 2019.08.20]
9. Case of Z v. Poland, application no. 46132/08, judgment of 13 November 2012. Available from: http://hudoc.echr.coe.int/eng?i=001-114521 [reviewed 2019.08.20]
10. Case of Arskaya v. Ukraine, application no. 45076/05, judgment of 5 December 2013. See at: http://hudoc.echr.coe.int/eng?i=001-138590 [reviewed 2019.08.20]
11. Case of Mehmet Şentürk and Bekir Şentürk v. Turkey, application no. 13423/09, judgment of 9 April 2013. Available from: http://hudoc.echr.coe.int/eng?i=001-118722 [reviewed 2019.08.20]
12. Case of Asiye Genç v. Turkey, application no. 24109/07, judgment of 27 January 2015. Available from: http://hudoc.echr.coe.int/eng?i=001-151025 [reviewed 2019.08.20]
13. Case of Altuğ and Others v. Turkey, application no. 32086/07, judgment of 30 June 2015. Available from: http://hudoc.echr.coe.int/eng?i=001-155710* [reviewed 2019.08.10]
14. Case of Oyal v. Turkey, application no. 4864/05, judgment of 23 March 2010. Available from: http://hudoc.echr.coe.int/eng?i=001-97848 [reviewed 2019.08.5]
15. Florya V.N. Vrachebnyye prestupleniya nedokazuyemyye i nenakazuyemyye? (meditsina i pravo) [Are medical crimes unprovable and unpunishable? (Medicine and Law)]. Kishinev: 2001; 58. (Ru)
16. Liang B.A. A system of medical error disclosure. Qual Saf Health Care 2002; 11:64–68. doi: 10.1136/qhc.11.1.64
17. Reason J. Human error. Cambridge. 1990; 302 doi: 10.1017/CBO9781139062367
18. Leape L. Error in medicine. JAMA 1994; 1851–7. doi:10.1001/jama.1994.03520230061039
19. Hofer T.P., Kerr E.A., Hayward R.A. What is an error? Eff Clin Pract. 2000;Nov-Dec.3(6):261–9.
20. Ethan D. Grober, John M.A. Bohnen. Defining medical error. Can J. Surg. 2005; Feb.48(1):39–44. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3211566/ [reviewed 2019.07.20]
21. Report of an Expert Panel Convened by The National Patient Safety Foundation. Free from Harm. Accelerating Patient Safety Improvement Fifteen Years after to Err is Human. 2015;59. Available from: https://cdn.ymaws.com/npsf.site-ym.com/resource/resmgr/PDF/Free_from_Harm.pdf [reviewed 2019.08.15]
22. Ferner R.E., Aronson J.K. Clarification of terminology in medication errors: definitions and classification. Drug Saf. 2006;29:1011–22 doi:10.2165/00002018-200629110-00001
23. Gornostay A., Ivantsova A., Mykhailichenko T. Medical Error and Liability for it in some Post-Soviet Countries (Belarus, Kazakhstan, Moldova, Ukraine). Wiad Lek. 2019;72(5)I:877–882.
24. Tikhomirov A.V. Vrachebnaya oshibka ili…? [Medical error or ...?]. Medical examination and law. 2015;5:4–10. Available from: https://aquareus.ru/wp-content/uploads/2016/04/avt-2015-09.pdf [reviewed 2019.07.15] (Ru).

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ENFORCEABILITY OF NON-COMPETE AGREEMENTS IN MEDICAL PRACTICE: BETWEEN LAW AND ETHICS

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ABSTRACT

Introduction: The core of physician's non-compete agreements problematics lies in complex system of controversial interests, rights and goals of subjects involved. On the one hand non-compete restrictions and their enforceability is an obvious part of employer's legitimate business interest based on the freedom of contract, on the other – free unrestricted market, preventing of monopolization, availability of medical assistance and healthcare, right to choose a doctor are social standards and thus – a part of public interest, in addition to this – non-compete restrictions impact physician's right to work. Balance between these components is pretty sensitive and hard to achieve.

We can find enforceability of physician's non-compete provisions in different types of relations: employment contracts, partnership agreements, sale of medical practice. But complexity of mixing law, ethical, social issues along with different approaches of legal regulations rises the relevance of research.

Material and methods: This study is based on German, British, Spain, Swiss, USA regulation acts, scientific researches and opinions of progressive-minded people in this sphere. The article is based on dialectical, comparative, analytic, synthetic and comprehensive methods.

Results: Non-compete agreements may have social benefits in some situations: serve as an instrument to protect trade secrets thus stimulate innovation; reducing of worker's exit probability could increase quality of medical services due to training of employees etc. But also, there are some serious risks to employee, to employer and to society as a whole. Analyzing the sense of non-compete clause in general we can assume that it includes seven main points: the subject; the form; the time; the territory; the scope and type of restrictions; "buy out" of the clause and the compensation. These characteristics are the core of non-compete clause, and, taking into account the principle of freedom in terms of agreement conclusion, it is up to law enforcement practice to determine minimal and maximal limits of such restrictions.

US legal concept is clearly based on implementing of legally prescribed restrictions for non-compete with physicians (along with other categories). European practice being pretty similar in view on what non-compete agreement is and what principles it is based on however is obviously different in approach chosen because of absence of special legal provisions for physicians' non-compete regulation.

Conclusion: Lack of legal regulation and law enforcement practice in this sphere worldwide is obvious, so the starting point in resolving of physician's non-compete enforceability issue will be choosing of suitable concept. Analyzing of proposed concepts, we came to the conclusion that the most perspective will be an approach of specification and clarification of "reasonability" meaning in terms of evaluation physicians' non-compete agreement validity and their impact on public interest.

KEY WORDS: non-compete agreement, non-compete clause, covenant not to compete, physician employees, medical staff

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INTRODUCTION

Non-compete practice is a widespread phenomenon of nowadays' employment relations. Taking start from USA/United Kingdom [1, p. 646-47] it is covering now more and more new countries, involving new and new professions and spheres. And whereas in some technologically-based and innovative areas such non-compete clauses are justified, in others – they seem nothing, but restriction (or even violation) of employee's rights [2]. It is obvious that employer wants to eliminate (or at least minimize) the competitive effect of his former employee, because: a) employee is a "carrier of confidential information", b) employee is a "business instrument", c) employee is an "investment object", d) employee is a potential competitor.

But there can be not just employer VS employee interest. What if (and it often true) the public interest is also engaged? What if this public interest is far surpassing local employer/employee interests? Will such non-compete clause be enforceable and if yes – what criteria must be used for its enforceability?

MATERIALS AND METHODS

This study is based on German, British, Spain, Swiss, USA regulation acts, scientific researches and opinions of progressive-minded people in this sphere. The article is based on dialectical, comparative, analytic, synthetic and comprehensive methods.

RESULTS AND DISCUSSION

The classical example of abovementioned problematics is exercising of non-compete provisions in healthcare. So, what is a case of non-compete practice in healthcare?

A physician restrictive covenant, also referred to as a "non-compete agreement" or "non-compete clause" is a

clause or section in a physician's contract whereby the physician (employee) agrees not to engage in his or her chosen profession in competition with the employer. Such restriction concerns public and private medical practices. Specialty of healthcare area problematic in non-compete context is based not only on potential violation of medial personnel's' right or employer's right, but on probable affection of patients' right and interest in general, which are a part of public interest.

Non-compete agreements may have social benefits in some situations: serve as an instrument to protect trade secrets thus stimulate innovation; reducing of worker exit probability could increase quality of medical services due to training of employees etc. But also, there are risks to employee, to employer and to society as a whole.

That is why the key issues of non-compete clauses for physicians are both legal and ethical. The most experienced countries in terms of non-compete clauses implementation is USA where such practice in modern concept arises in the beginning of XX century, Germany and some others [3 p. 229]. Although there's a variety of approaches among different states, all of them are based on the same main characteristics: 1) the scope: types of agreements and types of non-compete terms in the agreement; 2) the model of law-enforcement practice in terms of non-compete clauses implementation, their enforceability. We will start the discussion from the general positions on non-compete clauses then extrapolating them on healthcare sphere.

Non-compete clauses is widely applicable and could be founded in employment agreements, partnership agreements, and agreements for the sale of a medical practice [4]

Analyzing the sense of non-compete clause in general we can assume that it includes seven main points: the subject; the form; the time; the territory; the scope and type of restrictions; "buy out" of the clause and the compensation. These characteristics are the core of non-compete clause, and, taking into account the principle of freedom in terms of agreement conclusion, it is up to law enforcement practice to determine minimal and maximal limits of such restrictions.

Subject. Subject who covered by non-compete clause must be identified – it is obvious and needs no clarifications. More interesting is that not every employee, not every medical staff member really needs to be bounded by such restrictions because of their minimal or absent impact on competition because of no connection with some sensitive commercial information of employer. But often such approach of limiting the subjects scope is not used by employers and they tend to cover with non-compete restrictions as much as possible. Such practice is highly discussed now in the US [5] and we have some positive restrictive examples in the EU countries (Germany and Belgium for instance) where the applicability of restriction is grounded on the rate of annual incomes of employee and some other restrictions [6].

Form. Non-compete clause by its restrictive nature must be clear, understandable and interpretable, so, it is obvious that such demands could be fulfilled only in the form of written mutual agreed provision, which can be a part of the existing agreement or a separate clause between the parties. But the terms of non-compete clause and agreement for their execution must be formally accepted by both parties. Such concept is general among the countries because of the fact that non-compete agreement (or clause) must meet general contractual requirements [7]

Time. Another term of non-compete clause is the period during which employee agrees not to compete with his employer as during the contract term, but such term can't be unlimited. The practice of such term is pretty common and varies between one to three years after the contract termination. European practices are the same with US in this regard [8] and it usually determine the term of restriction during the employment and for a period of time afterward. Court might further limit the duration of a non-compete restriction as he thinks appropriate to different periods, for example – a period of time needed to hire and train a new employee; the time needed for vanishing of customers' association between former employee and employer's business; period of time for confidential information to become obsolete etc.

Territory. The territorial scope could not be unlimited or not strictly defined, different countries use different approaches, it could be distance range (circle with the center – main office of the employer), it could be the administrative division (city, county, region etc.), it could be ZIP postal code area or else. Main point - it must be reasonable geographical area considering the size of the employer's market and the size of the area serviced by the employee.

Scope and type of restrictions. Types of prohibited or restricted activities must be clearly defined, be connected with employee functions. Such provisions could not be broad or not properly defined. Moreover, their definition must be connected with category of employer's "legitimate business interest" in terms of how they impact each other.

"Buy out" clause. The employee must have the right to buy-out from restriction by paying to employer some contractually predefined fee. Such clause renews the "status quo" of both parties and legitimates further possible competition and also needs to be "reasonable".

Compensation. Non-compete clause could not be just one-way obligation for the employee, such an agreement should be mutually favorable and not providing of compensation for employee for the restrictions bearing by him on the basis of non-compete agreement might be the reason of such contract (or clause) invalidity. Such practice is applicable in some US states, Germany, Belgium [9] and other countries.

So, what is the specialty of non-compete clauses regulation for physicians? The answer to this question depends on the approach chosen and may highly vary among different countries.

In US there are different approaches among the states as to how applicable non-compete agreements at all and how special is their regulation for such sensitive category of employees like physicians [10]. There are states that prohibit non-compete provision application, states that threat them

as partly-applicable and states that threat such provisions as fully-applicable (with some general restrictions) [11].

For the states in US where non-compete clauses are enforceable there are three types of law-enforcement doctrine: "Red-pencil doctrine" – courts must declare an entire non-compete contract void if one or more of its provisions are found to be defective under state law or precedent; Blue-pencil doctrine – courts delete provisions of a non-compete contract that render it overbroad or otherwise defective, retaining the enforceable subset of the contract; "Equitable reform" doctrine – courts may rewrite a non-compete contract so as to render it non-defective (this may entail insertions of new text). [5, p. 14].

The complexity of regulation approaches is even higher when we are analyzing this problematic in connection with physicians and medical professionals because some states taking into account the uniqueness of medical profession apply special rules to covenants that restricts such medical practice because of involvement of public interest, in particular the potential shortage of doctors in the area, impact on the patient's rights to obtain healthcare treatment, to choose a doctor or other medical professional etc.

Thus, even if it is declared by the state law that non-compete restrictions are generally allowed (as reasonable and legitimate) there may be a non-enforcement clause with regard to physicians. For example, Massachusetts where prohibition of physicians non-compete provisions is established since 1977 and any non-compete provision restricting "the right of a physician to practice medicine in a particular locale and/or for a defined period of time." [12, Ch. 112 § 12X] is illegal. Literally the same with Delaware [13, Title 6, Ann. § 2707], Colorado [14, § 8-2-113], Rhode Island [15, §5-37-33].

There is another approach where some states aree not prohibiting non-compete clauses for physicians in general applying to them deeper and stricter prescriptions and limits. For instance, Tennessee where there are additional restrictions for non-compete clauses with physicians in terms of duration (no longer than two years), geographical (not greater than the county of employment or 10 miles radius) facility restrictions. [16, Ann. § 63-1-148]; in Texas non competes for physicians are allowed but restrictions must not "deny the physician access to a list of the patients seen or treated within one year of termination of employment; provide access to medical records of the physician's patients upon proper authorization; provide for a buyout of the covenant by the physician at a reasonable price; and allow the physician to provide continuing care and treatment to a specific patient or patients during the course of an acute illness" [17, Ann. § 15.50]; in New Mexico there is a prohibition of agreements with restrictions to provide clinical healthcare services (except when such restrictions applied to shareholders, owners, partners, directors) but also an allowance of non-disclosure and non-solicitation provisions and very interesting rule for healthcare practitioners employed by the practice for less than three years which may be required, upon termination, to pay back certain expenses to the practice (including loans; relocation expenses; signing bonuses or other incentives related to recruitment; and education/training expenses). [18, § 24-1l-1]; in Connecticut there is limitation of non-compete clause duration (no longer than one year) and territory (not more than fifteen miles from primary site) and cause of termination (non-compete clause is unenforceable after contract termination without the cause). [19, §20-14p(b)(2)]

As we can see, nevertheless of approaches variety there is a clear trend for specification of physician's non-compete clauses regulation. US legal concept is clearly based on implementing of clear legally prescribed restrictions for non-compete with physicians.

European practice being pretty similar in view on what non-compete agreement is and what principles it is based on however is obviously different in approach chosen because of absence of special provisions for physicians' non-compete regulation [8].

In Germany non-compete provisions are regulated by different law acts [9, p. 333-335]. Such practice is regulated by Commercial Code (e.q., sec. 60, 112 HGB) [6], German Federal Labor Court (BAG), in AP-No. 7 to § 611 BGB Treuepflicht [20]; sec. 242 Civil Law Code [21]. There are no special rules for physicians or medical staff members, specialization of the approach used is based not on legal prescriptions (like in USA) but on law enforcement practice, which must observe "reasonableness" [22] of restrictions thus taking into account not only the balance of employer and employee interests, but also an impact on public interest assuming the value of medical profession.

In Spain legal regulation of covenants not to compete is different for restrictions during the employment relationship and after their termination. For the first situation such restriction is compulsory [23, art. 8.1]. There is also no special regulation for medical staff and the "difference" is made by law enforcement practice by implementing of "reasonableness" evaluation concept.

In Switzerland non-compete agreements regulation during the term of the contract is differed among employment contracts [24, Section 321a], agency [24, Section 418d), partnership [24, Section 536], partnership [24, Section 561] and Limited Liability Company [23, Section 818]. After the contract termination such restrictions are specifically regulated only in regard of employment agreements. [24, Sections 340]. Reasonableness test is in place also but no special rules for physicians.

United Kingdom. The main concept is based on evaluation of any non-compete restrictions between an employer and an employee as void on the basis of their contradictory nature to public policy. To implement such a restriction employer must show legitimate business interest that needs such protection and "reasonableness" of restriction – no further than the protection of business interest [25; 26; 27; 28]. The main goal of restriction is not limitation of competition but restriction of unfair use of employer's trade secrets or business connections [26;27] and reasonableness of restriction must be evaluated on the date of signing the contract (reasonable from beginning) [29]. As in other

European countries, in UK we can't see the legal basis for specialization of physicians' non-compete agreements. Such specialization is grounded on law enforcement practice of evaluation such categories as "legitimate business interest", "public interest", "employee's rights" etc.

As we can see from abovementioned, the divergence between US and European approaches (however they are similar in basic understanding of non-compete at all) is obvious – the US model tends to provide legally defined special restrictions for non-compete agreements with physicians while European model tends to rely the specialization of such agreements on law enforcement and judicial practice. But what is uniting both these approaches is the goal achieved – the inclusion of public interest as a main element of evaluation while qualifying the restriction. So, what is the impact of public interest in this scope, what question does it bring up in this regard?

We must say that "public interest" with regard to physicians' non-compete agreements should be deemed widely and include not only the economic aspect (as for "classical" non-compete restriction) but also the evaluation of "medical" impact of them. Nevertheless of "sensibility" of abovementioned sphere we can admit that public interest category has some aspects that "favors" and "disfavors" non-compete agreements with physicians.

On the "positive side" there are obvious categories of the freedom of contract, which is a publicly defended principle, investment in employee's development, decentralization and territorial balance of physicians.

As to **freedom of contract** – its value is obvious, but what if contract impacts (or even violates) third party's legitimate interests or rights, which is not a party of the contract and has no ability to become one? From our view in that scope the freedom of contract should be appropriately narrowed, because, for example, the right of a patient to choose treating physician is obviously affected by physician restrictive covenants. Current law enforcement practice already has such examples of contract's freedom restrictions on the basis of ensuring public interest, so one of those could be the impact of physician's non-compete clause.

Regarding **encouraging of investment in development** of young physicians, non-compete restrictions really could guarantee that employer will have the ability to recoup capital outlay spent on employee training. Without restrictive measures such as non-compete agreements potential employers will be less willing to invest in physician employees and all that will impact healthcare services availability in general.

Talking about **decentralization and territorial balance** of physicians we must admit that non-compete restrictions could have positive public impact by encouraging them to move to rural areas (or areas with low level of medical services) thus providing broader availability of healthcare.

On the "negative side" we can admit pretty obvious problematics of impact on public interest [30, p.3] – they are patient's right to freely choose a doctor, a problem of healthcare availability (especially when it comes to non-compete restrictions for highly-qualified specialists), public health, ability to preserve continuity of care in cases where it is important (parental care, chronical deceases), ethical aspect of restriction itself and so on.

General position of **discouraging of non-compete agreements** for physicians are global [31; 32] and needs no clarification. It is obvious that any restriction of physician's professional activity inevitably will bring up ethical concerns.

Same with the **right to choose a doctor** – it is a worldwide standard, and restriction of it will impact satisfaction of the patient, quality of services etc. [30, p.3-4]. The resulted impact will depend on the geographical and time scales of restriction but the fact of negative effect is undoubtful.

Shortage of physicians also could be an example of negative impact of non-compete agreements in this sphere on public interest. It is obvious that above restrictions could create a problem of physician's shortage in territories where there was no such problem before and could deepen the problem where it already exists. And a lot of countries already faced such issue, including US [33, 34], Europe [35]

Assuming the abovementioned, what regulative options do we have? If we look at the problem more generally there are three conceptual approaches as to how to treat non-compete agreements (covenants, clauses) with physicians. Let's name them: 1) "commercial public interest" concept; 2) "invalidity of any restrictions" concept; 3) "broadening of reasonability" concept. We are not pretending on deep analysis of each abovementioned approaches due to this could be a basis for the separate research, but we will try to accommodate here a brief overview of them.

Lack of legal regulation and law enforcement practice in this sphere worldwide is obvious, so the starting point in resolving of physician's non-compete issue will be choosing of suitable concept.

"Commercial public interest" concept is based on extrapolation of traditional understanding of public interest and assessment of impact on it as an economical category. Such approach is somehow mixing the interests of employer and public interest, and defining public interest as a complex of economical (efficiency of business, employment costs in case of enforcing of non-compete clause) and socio-economical (right to work, standard of living etc.) categories. But such an approach gives us no answer to the public impact that could not be economically evaluated – public health, public safety, healthcare availability etc. Thus, described approach couldn't be deemed appropriate.

"Invalidity of any restrictions" concept is pretty clear and is grounded on the point of view that any restrictions of physician's professional activity are anyway against the public interest. Universality of this approach has also a negative side – not every non-compete agreement poses equal threat (or equal unfluence) to public interest. Moreover, absence of restrictions will more or less initiate rise of concerns that encourage non-compete restrictions from the point of view of "public interest", will eliminate all their positive social impact. That is why, along with previously

mentioned, such model hardly could be effective in long-term perspective.

"Broadening of reasonability" concept is based on necessity of understanding the definition of "reasonability" as an essential criteria of legitimacy evaluation of non-compete agreements in broader sense taking into account their impact (not only economic) on public interest. Physicians' restrictive non-compete clauses could not be simply compared to similar commercial covenants because of their services nature because of involvement of categories such as public health, medical ethics and others. Thus, the law enforcement practice must evaluate physicians' non-compete restrictions with three main points as a base: existence of legitimate business interest and employer actions must be strictly and truly directed to protect them, non-compete restriction is constructed as strictly as possible to protect such interests, the public interests are treated widely then just an economic category and thoroughly vetted, balanced and evaluated. From our view the abovementioned model by avoiding disadvantages of both previous could be deemed as perspective one even regardless of its obvious complexity. It is a vice balance of individual (employer and employee) and public interests.

CONCLUSION

Beyond the differences between European and US approaches there's a clear understanding of non-compete clauses' use unstoppable widening. But while the general concept of such restrictions and their enforceability are properly determined as in doctrine and law, their enforcement for special categories such as physicians needs particular attention and specification of law regulation. Because restriction (even on the basis of legitimate business interest) of physician's professional activity gives rise to a massive scope of concerns, involving those of public interest.

We clearly distinguish that the main regulative difference between European and US approaches lies in the instruments used for regulation: US concept favors inclusion of special provisions into laws while European one prefers to keep non-compete as a unite concept regardless profession thus relying the necessity of evaluation of "reasonability" of restriction on law enforcement bodies.

Results of research conducted drive us to the conclusion that physician restrictive non-compete clauses could not be simply compared to similar commercial covenants because of services nature and involvement of categories such as public health, medical ethics and others to the scope. Regulation also should not restrict non-compete clauses for physicians at all because the side effects of that could contradict public interests. From our point of view the concept of regulation must be grounded on enhancements of understanding the "reasonability" as a special category when it comes to physician's non-compete clauses. Law enforcement practice must evaluate if there's a legitimate business interest and employer's actions truly directed to protect them, is non-compete restriction is constructed as strictly as possible to protect such interests, are public interests treated widely then just an economic category and thoroughly vetted, balanced and evaluated. Implementation of such an approach will be a vice balance of individual and public interests.

REFERENCES

1. Harlan M. Blake, Employee Agreements Not to Compete, 73 HARV. L. REV. 625, (1960) doi: 10.2307/1338051
2. Steven M. Harris Physician Noncompete Clauses. The Hospitalist. 2012 July;2012(7). Available from: https://www.the-hospitalist.org/hospitalist/article/125197/physician-noncompete-clauses [reviewed 2019.08.15]
3. Whalley, M.; Semler, F.-j. (eds). International Business Acquisitions: Major Legal Issues and Due Diligence. 3rd ed. The Hague London: Kluwer Law International, 2007, p. xi, 169, 268. 5 Ibid.
4. Ferdinand S. Tinio, Annotation, Validity and Construction of Contractual Restrictions on Right of Medical Practitioner to Practice, Incident to Employment Agreement, 62 A.L.R.3d 1014(1975)
5. Non-compete Contracts: Economic Effects and Policy Implications / Office of Economic Policy, U.S. Department of the Treasury. Available from: https://www.treasury.gov/resource-center/economic-policy/Documents/ [reviewed 2019.08.15]
6. German Commercial Code. Available from: https://www.gesetze-im-internet.de/hgb/__74.html [reviewed 2019.08.15]
7. Shadowen, S. d.; Voytek, K. economic and critical analyses of the law of covenants not to compete. Georgetown Law Journal. 1983–1984, 72(4): 1425–1450.
8. Norton Rose Fulbright. A comparison of laws in selected EU jurisdictions relating to post-contractual, non-competition agreements between employers and employees. Available from: https://www.nortonrosefulbright.com/en/knowledge/publications/9807eea3/a-comparison-of-laws-in-selected-eu-jurisdictions-relating-to-post-contractual-non-competition-agreements-between-employers-and-employees [reviewed 2019.08.15]
9. Summary of Covenants Not To Compete: A Global Perspective Compliments of Fenwick & West LLP, a member of The TechLaw Group. Available from: https://www.fenwick.com/FenwickDocuments/RS_Summary-of-Covenants.pdf [reviewed 2019.08.15]
10. Aaron Hall. Physician Noncompete Agreements: Enforceable in Medical & Healthcare Organizations Available from: https://aaronhall.com/physician-noncompete-agreements-enforceable-in-medical-healthcare/ [reviewed 2019.08.15]
11. 11. Employee Noncompetes. A State by State Survey / Beck Reed Riden LLP Available from:
12. https://www.faircompetitionlaw.com/wp-content/uploads/2019/10/Noncompetes-BRR-50-State-Survey-Chart-20191019.pdf [reviewed 2019.08.15]
13. Massachusetts General Law Ch. 112 § 12X. Available from: https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section12x [reviewed 2019.08.15]
14. Delaware Code, Title 6, Ann. § 2707, Available from: https://delcode.delaware.gov/title6/c027/sc01/index.shtml [reviewed 2019.08.15]
15. Colorado Revised Statute § 8-2-113. Available from: https://law.justia.com/codes/colorado/2018/title-8/labor-i-department-of-labor-and-employment/article-2/part-1/section-8-2-113/ [reviewed 2019.08.15]
16. Rhode Island General Laws Title 5. Businesses and Professions § 5-37-33 Available from: https://codes.findlaw.com/ri/title-5-businesses-and-professions/ri-gen-laws-sect-5-37-33.html [reviewed 2019.08.15]

17. Tennessee Code Title 63 Available from: https://law.justia.com/codes/tennessee/2010/title-63/chapter-1/part-1/63-1-148 [reviewed 2019.08.15]
18. Texas Business and Commerce Code. Available from: https://codes.findlaw.com/tx/business-and-commerce-code/bus-com-sect-15-50.html [reviewed 2019.08.15]
19. New Mexico Statutes. Chapter 24: Health and Safety. Available from: https://law.justia.com/codes/new-mexico/2011/chapter24/ [reviewed 2019.08.15]
20. Connecticut General Statutes 20-14p. Available from: https://www.lawserver.com/law/state/connecticut/ct-laws/connecticut_statutes_20-14p [reviewed 2019.08.15]
21. Achim Seifert, Elke Funken-Hötzel Wrongful Dismissals In The Federal Republic Of Germany. Available from: https://www.upf.edu/documents/3885005/3888714/AchimSeifertGermany.pdf/78df9b21-8b1b-4575-89c9-182e6f74acd8 [reviewed 2019.08.15]
22. German Civil Code BGB. Available from: https://www.gesetze-im-internet.de/englisch_bgb/ [reviewed 2019.08.15]
23. German Federal Court of Justice (BGHZ 91, 1). Available from: https://germanlawarchive.iuscomp.org/?p=189 [reviewed 2019.08.15]
24. REAL DECRETO 1382/1985, Available from: http://www.juntadeandalucia.es/empleo/anexos/ccarl/2_86_1.pdf [reviewed 2019.08.15]
25. Federal Act on the Amendment of the Swiss Civil Code. Available from: https://www.admin.ch/opc/en/classified-compilation/19110009/index.html [reviewed 2019.08.15]
26. Mason v Provident Clothing & Supply Co Ltd [1913] AC 724. Available from: https://www.lawteacher.net/cases/mason-v-provident-clothing.php
27. Herbert Morris Ltd v Saxelby [1916]. Available from: https://www.lawteacher.net/cases/morris-v-saxelby.php [reviewed 2019.08.15]
28. Stenhouse Australia Ltd v Phillips [1974]. Available from: https://www.i-law.com/ilaw/doc/view.htm?id=146833 [reviewed 2019.08.15]
29. TFS Derivatives Ltd v Morgan [2005]. Available from: https://uk.practicallaw.thomsonreuters.com/D-015-4756?transitionType=Default&contextData=(sc.Default) [reviewed 2019.08.15]
30. Rex Stewart Jeffries Parker Ginsburg Ltd v Parker [1988]. Available from: https://uk.practicallaw.thomsonreuters.com/D-015-4756?transitionType=Default&contextData=(sc.Default)&bhcp=1 [reviewed 2019.08.15]
31. Jeanne M. Lambrew, "Choice" in Health Care: What Do People Really Want?, ISSUE BRIEF, (The Commonwealth Fund, New York, N.Y.), Sept. 2005, Available from: http://www.commonwealthfund.org/usr_doc/lambrew__853_choice__ib.pdf?sections=4039 [reviewed 2019.08.15]
32. Amaerican MED. ASS'N, CODE OF MEDICAL ETHICS § E-9.02 (2009), Available from: http://www.ama-assn.org/amal/pub/upload/mm/Code_of_Med_Eth/toc.html
33. Principles of European Medical Ethics. Available from: http://www.ceom-ecmo.eu/en/view/principles-of-european-medical-ethics [reviewed 2019.08.15]
34. America's aging population is leading to a doctor shortage crisis. Available from: https://www.cnbc.com/2019/09/06/americas-aging-population-is-leading-to-a-doctor-shortage-crisis.html [reviewed 2019.08.15]
35. Miriam A Knoll. Doctoring The Doctor Shortage. Available from: https://www.forbes.com/sites/miriamknoll/2019/03/07/doctoring-the-doctor-shortage/#62be107876f3 [reviewed 2019.08.15]
36. Europe faces a shortage of doctors. Available from: https://voxeurop.eu/en/2018/public-health-5122358 [reviewed 2019.08.15]

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INFORMATION TECHNOLOGY OF VERIFICATION OF ALGORITHMIC OF MEDICAL REGULATIONS

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ABSTRACT

Introduction: In the medical field, using of information-analytical technologies and expert systems is becoming increasingly common. Therefore, the problem of quality of normative acts (documents), which unify the standards of the newest methods of medical activity, becomes urgent. But, unfortunately, legal experts state that there is a problem of errors in regulations of different branches of rulemaking. A rulemaking error can be recognized as inconsistency of a text or a rule of law's content regarding its purpose. There are two types of legal errors: purely textual and substantive (algorithmic).

The aim: The aim of the article is to demonstrate the possibilities of using information technology based on BPMN to display algorithms and identify algorithmic errors in regulations that adjust activities of health care professionals.

Materials and methods: It is used BPMN (Business Process Model And Notation) technology in the research. With its help, a logical-analytical check of algorithm scheme for treatment of abnormal uterine bleeding, provided in the normative document of the Ministry of Health of Ukraine "Unified Clinical Protocol of Primary, Secondary (specialized) and Tertiary (highly specialized) Medical Care. Abnormal Uterine Bleeding", approved by the order of the Ministry of Health of Ukraine on 13.04.2016, No. 353. Algorithmic errors in the scheme were checked using Microsoft Visio software. According to the results of the logical-analytical examination of the mentioned normative act's text, a scheme of algorithm for treatment of abnormal uterine bleeding in BPMN was constructed.

Results: The use of the proposed BPMN-based information technology and Microsoft Visio software allows you to control the algorithmic nature of regulated medical practice processes and to detect errors, to create visual models of schematically regulated medical practice algorithms.

Conclusions: The proposed information technology, based on BPMN can be used to display algorithms and detect errors in regulatory acts that adjust activity of medical professionals.

KEYWORDS: algorithmic, BPMN, errors in regulations

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INTRODUCTION

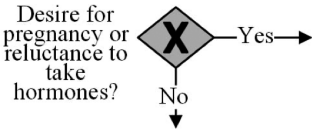
The intellectual aspect of conscious human activity implies an awareness of its purpose and algorithms of achievement. However, the activity itself is considered algorithmic (that is, built on an algorithm) if it has a set of logically related and undeniable actions sufficient to achieve the intended result. Inconsistency of the planned person's actions with rational algorithms of achievement of the specific goal is recognized as an error of algorithmization. Such situations are particularly dangerous in the field of medical practice, where the activities of specialized professionals ensure the life and health of people, and irrational actions can have fatal consequences.

At all times, qualitative and algorithmic activity of medical specialists was based not only on the latest developments in medicine, but also on the developments of other sciences. However, in recent years, advances in science and technology, whose understanding requires specific knowledge of other scientific fields, have been increasingly used here by medical professionals. For example, in the researches of Melnyk K., Goloskov A. [1], Sanjeev Kumar, Gursimranjeet Kaur [2] procedures for diagnosing a patient's cardiovascular system based on fuzzy logic are proposed. Yakubovskaya S., Vysotska E., Porvan A., Elchaninov D., Linnik E. have developed a technique for predicting the likelihood of recurrent myocardial infarction based on an interpolation diagnostic polynomial [3].

In the medical field, the practice of using information-analytical technologies and expert systems is becoming more widespread. Thus, in the paper of [4] Ramandeep Kaur, the author described the methodology of expert system for predicting the outcome of heart disease, developed on the principles of "decision tree" and agent approach. Onuwa A. B. proposed an expert system for the diagnosis of malaria [5]. Other expert systems, some of which are intended for use in personal mobile devices, are described by Furmankiewicz M., Sołtysik-Piorunkiewicz A., Ziuziański P. [6].

In the research of [7] Igor Ogorodnyk, Olena Vusotska, Mykola Ternyuk, Nanna Bilovol it is proposed a method of structural-parametric synthesis of "Quanton" diagnostic-health complex. In [8] Hanna Dobrorodnia, Olena

Table I. IT Graphic Elements based on BPMN.

Graphic Element	Graphic image, application example
Start Event of Process	
End Event (Result) of Process	
Tasks to perform in the Process	
Task sequence	
Gateways - cases of branching the Process, when the result of the Task can be different (ambiguous), and each of the possible results creates its own Scenario for the development of the Process	

Vusotska, Marine Georgiyants and others it is described the mathematical support for diagnostic system of metabolic disorders and influence of gender, territorial, age characteristics on metabolic processes' balance in humans. In the research of [9] Lyubov Rysovana, Olena Vusotska, Helen Falyova, Marine Georgiyants, Viktoriia Klymenko it is proposed the factor analysis' using to study the risk factors of a crisis in family relationships that lead to dyscirculatory encephalopathy. Viktor M. Bobyryov, Sergij K. Kulishov, Andrij V. Vakhnenko, Olena V. Vlasova have proposed a genetic algorithm for deciding on pharmacotherapy in patients [10]. Vladyslav A. Smiianov, Natalia O. Dryha, Olha I. Smiianova, Victor K. Obodyak., Tatyana O. Zudina offered information technology on mobile and electronic devices' using to build a mobile health service [11]. Andrzej Kajetanowicz, Aleksandra Kajetanowicz provided information on modern information technology in the medical field [12].

The first sensory demonstration functionality of the Service is to receive the Duodecim solution, so that you can use the EBMEDS information system. For the sake of the system of information on a patient's state, you can use electronic forms and medical information for a specific doctor [13].

The further increase in the amount of specific knowledge in methods of providing medical care exacerbates not only the problem of understanding non-core information by medical professional. The problem of quality of normative acts (documents), which unify the standards of the newest methods of medical activity, becomes more urgent.

Our collations indicate that documenting the algorithms of medical activity is common practice in different countries [14]. It is therefore essential for healthcare professionals that the texts of these documents be correct. However, unfortunately, legal experts state the imperfection of technique of creating legal texts and the presence of errors problem in normative acts of different branches of rulemaking. [15]

A rule-making error can be recognized as consistency of text or content of a rule of law regarding to its purpose. On this basis, there are two types of law's errors – purely textual and substantive (algorithmic). Text-making errors are manifested in the apparent inconsistency of rule's text regarding its content. Substantial (algorithmic) errors occur when inaccuracies are found in description of goal achievement algorithm - it does not meet the logic (algorithm) of the norm.

As for the latter, we must point out that any conscious human activity objectively has the following elements: 1) subjects; 2) subject-matter; 3) algorithm of actions; 4) means (tools, resources); 5) time characteristics; 6) territorial characteristics. Accordingly, meaningful (algorithmic) errors can be: 1) an error in description of the subjects of activity; 2) an error in description of the subject-matter (object) of the activity; 3) an error in description of the algorithm of actions of the subject of activity; 4) an error in description of the means (tools, resources) of activity; 5) an error in describing the temporal characteristics of the activity; 6) an error in describing the territorial characteristics of the activity.

Until recently the quality of displaying the algorithmic nature of actions regulated in legal texts was controlled solely by mental activity of their developers. But we believe that in modern conditions to control the algorithmic procedures enshrined in legal texts (logical connection, their completeness, absence of errors) is already possible with the help of information technology (IT).

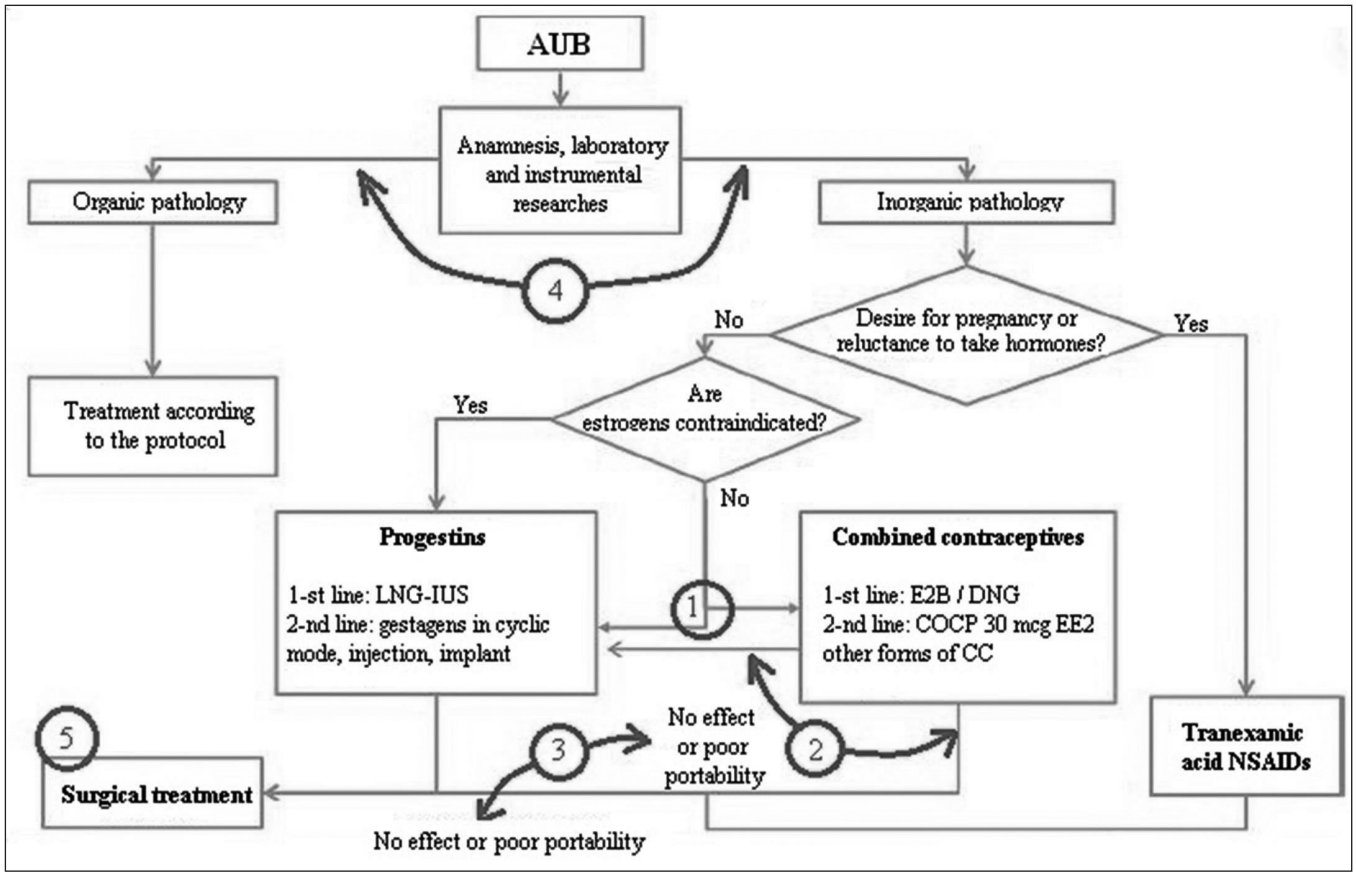


Fig. 1. AUB Treatment Algorithm from the Protocol, with Display of Sheme Elements, for which, According to Results of Logical and Analytical Examination, Questions Have Been Raised (red indicated)

Earlier in the research [16], we had already disclosed the IT validation of logical connections and completeness of textual procedures describing branching processes based on visualization using BPMN notation. The effectiveness of this technology has been demonstrated through examples of verification of regulations' texts on administrative, judicial and tax activity in Australia, the European Union, the Russian Federation, the United States of America and Ukraine [17]. But medical records in these studies were not checked.

THE AIM

Proceeding from the above mentioned, the purpose of the article is to demonstrate the ability to use original information technology that uses mapping algorithms based on BPMN and detects algorithmic errors in medical regulations.

MATERIALS AND METHODS

BPMN (Business Process Model And Notation) notation, which we propose to use in information technology analysis of algorithmic procedures of medical regulations (documents), has been used in various fields for a long time. This is a graphical language that allows you to display processes when modeling workflows in a system under test using specification of graphical elements (some of which are listed in Table I).

The procedure for analyzing the algorithmic nature of legal texts according to the proposed methodology includes three stages:

1) converting a legal text describing the process into a graphical diagram using BPMN's symbols;
2) verification of the developed scheme for algorithmic (logical coherence and completeness) – intelligent, which is carried out by an expert and software, and/or by software, such as Microsoft Visio, in accordance with the rules laid down in it;
3) confirmation or denial of errors found when discussing with developers of a text (in case of confirmation, there should also be elaboration of proposals for amendments to the text of legal norm).

We have tested the algorithm for treating abnormal uterine bleeding (hereinafter referred to as AMC) as provided in the normative document of the Ministry of Health of Ukraine "Unified clinical protocol of primary, secondary (specialized) and tertiary (highly specialized) medical care. Abnormal Uterine Bleeding" (hereinafter – "the Protocol", unless otherwise noted) approved by the order of the Ministry of Health of Ukraine No. 353 on 13.04.2016, as amended by No. 994 on September 23, 2016 [18]. This document provides an overview of existing methods for diagnosis and treatment of abnormal uterine bleeding and algorithms for diagnosis and treatment of this patients' pathology in Ukraine. The document presents (page 26) an algorithm for therapeutic tactics in abnormal uterine bleeding

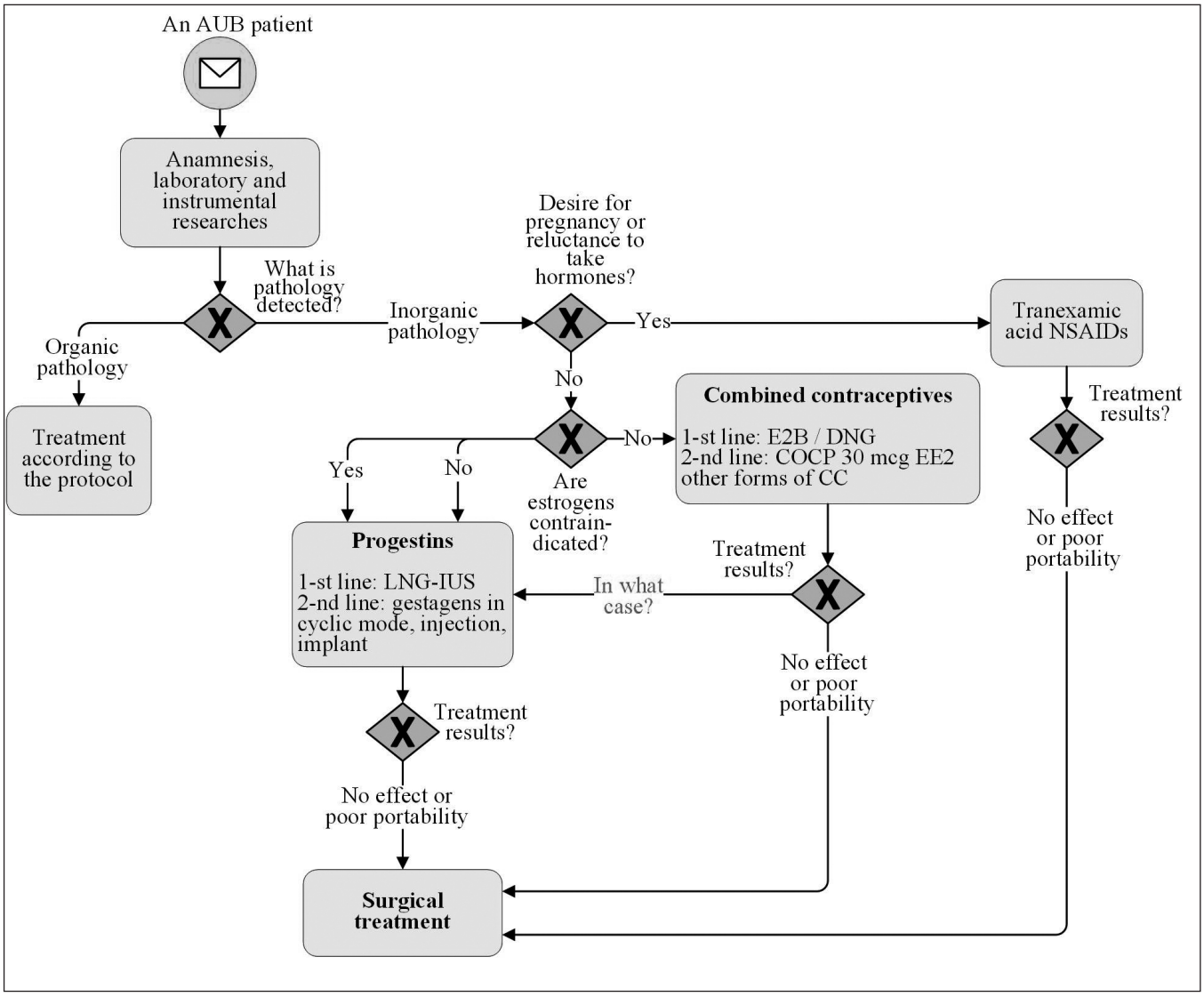


Fig. 2. AUB Treatment Algorithm Identical to the Protocol Algorithm (p.26) but Constructed Using BPMN

(hereinafter – AUB), depending on etiology, reproductive plans and preferences of a patient, performed in the flowchart notation FlowChart algorithms. We take notice that this scheme is not a graphic representation of regulatory document's text for its explanation, but is a separate methodological unit.

The possibility of using of the proposed information technology was confirmed by the conclusion of the Department of Criminology and Criminal Enforcement Law of Yaroslav the Wise National Law University of September 10, 2019 when giving consent to this article's publication.

RESULTS

The results of our logical and analytical examination of AUB treatment regimen under the Protocol are presented in Fig. 1, where the corresponding numbers indicate which questions were raised (indicated by the arrows in red).

Question 1. According to the scheme, if estrogens are contraindicated, it is provided the use of either progestins or combination contraceptives. But there are no circumstances that determine one of these options. If they are used in all cases when estrogens are contraindicated, then these warrants should be bundled into one and further options for further development of events should be indicated.

Question 2. In the scheme as a result of the conditioned process (function) "Combined contraceptives" the arrows indicate the options "Progestins" and "Surgical treatment". But why is there no block (rhombus) with conditions of options' choise, that is, in which case after the use of combined contraceptives it is necessary to apply progestins, and in what surgical treatment? Which of these variants is the text "No result or poor tolerability" listed between the scheme's elements "Progestins" and "Combined contraceptives"?

Question 3. As a result of Progestins and Combined Contraceptive functions only the cases of "No effect or poor tolerability" are indicated. But what are the options for specialist action if there is an effect?

Question 4. Output process (function) "Anamnesis, laboratory and instrumental studies" as options are specified the functions "Organic pathology" and "Inorganic pathol-

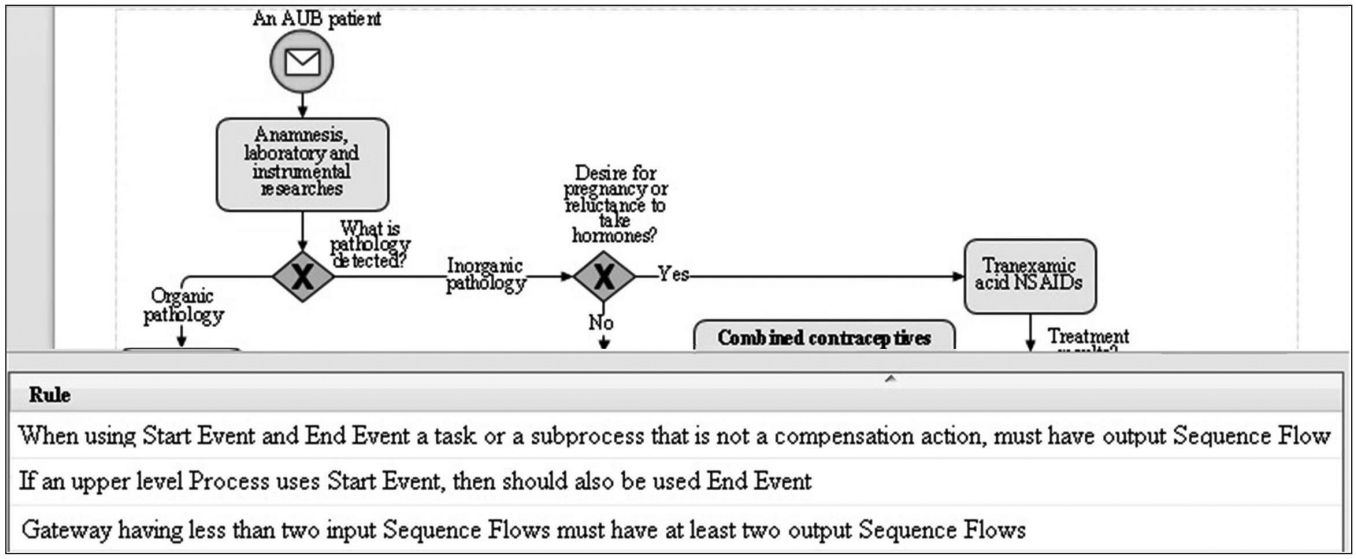


Fig. 3. Screenshot of Algorithmic Errors in the AUB Treatment Scheme Detected by Microsoft Visio.

ogy". But these are not the functions, but the conditions under which further options are chosen. And they must be specified through a block (rhombus) with branching conditions (as in the diagram in other cases).

Question 5. Transition to the function "Surgical treatment" comes after detection of no effect or poor tolerability during the drug therapy's use. But why is this option not indicated when such therapy is not possible at all, since the situation is mentioned in the Protocol's text (clause 4.5.3). So why is there no block (rhombus) with branching conditions for this case?

The validity of our comments and inquiries was verified by the software. Unfortunately, the Protocol flowchart under the FlowChart notation (flowchart) could not be validated directly by the existing software. Therefore, we have constructed an AUB treatment algorithm that is identical to the algorithm of the Protocol (with duplication of the circumstances that raised the issue from the point of view of algorithmic scheme design), but using BPMN. The result of this work is shown in Fig. 2.

The authors then analyzed this scheme using Microsoft Visio software. This analysis' results are recorded in Fig. 3, which is a screenshot from the screen.

The program detected errors of three types, which are identical in content to the primary scheme's errors, which are shown in Fig. 2:

1. When using Start Event and End Event a task or a subprocess that is not a compensation action, must have output Sequence Flow – identical to question 3 and 5;
2. If an upper level Process uses Start Event, then should also be used End Event – identical to question 3;
3. Gateway having less than two input Sequence Flows must have at least two output Sequence Flows – identical to question 1 and 3.

In order to evaluate these issues' validity and correct the identified errors, we have consulted with medical professionals.

In Fig. 4 it is presented the algorithm of AUB treatment, which takes into account the corrected errors.

The suggested additions are shown here in red text and dotted lines. We tested this diagram for errors using Microsoft Visio – no errors were found.

DISCUSSION

Our research has confirmed that FlowChart notation is now a common tool for building flowcharts of algorithms reflected in medical records [14]. However, this notation is more functionally limited in visualization and analysis than BPMN. The example presented in the article demonstrates the functionality of our proposed technique using BPMN and related software to detect algorithmic errors in construction of medical activity algorithms. In this case, intellectual analysis carried out by a human expert, gives a more effective result than program analysis. This is due to the fact that human mind is a more sophisticated tool in terms of detecting deficiencies in mapping of essential circumstances of medical algorithms than any existing software that operates on a limited set of rules. This explains the lack of comment by Microsoft Visio on the essential circumstances of AUB treatment, which we addressed in questions 2 and 4.

The research results are the original development of a methodology using IT, based on BPMN, and related software for the detection of algorithmic errors in the construction of medical activity algorithms.

Our proposed method allows:

– to create visual models – schemes of normatively regulated algorithms of medical practice;
– to control the algorithmic nature of regulated processes and to detect errors.

Therefore, it can be used to improve the rulemaking in the medical field and to improve (comprehensibility) regulations' quality. The functionality and specifications

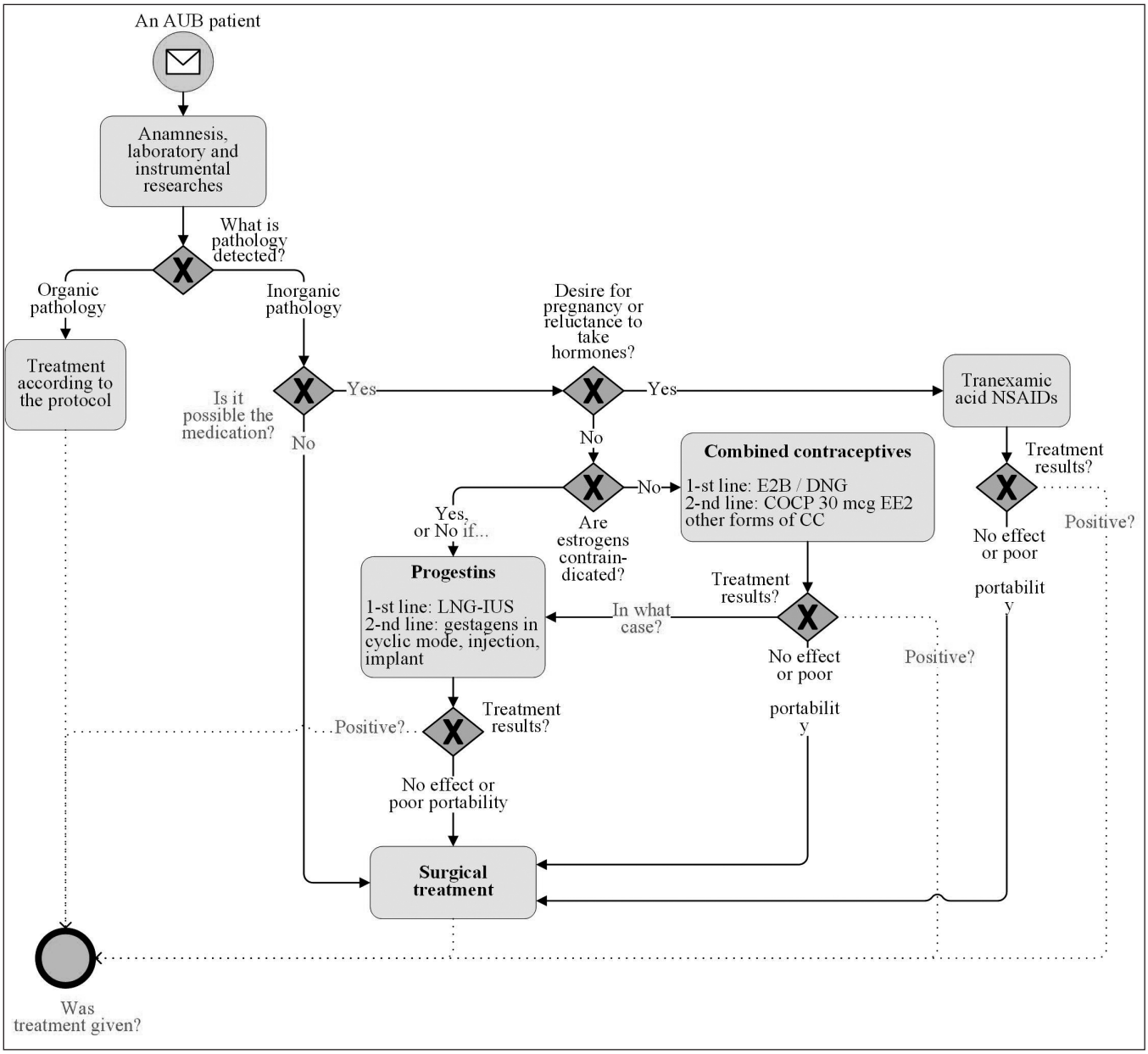


Fig. 4. AUB Treatment Algorithm, Constructed Using BPMN, Taking into Account the Detected Algorithmic Errors

of BPMN graphical elements make it possible to reflect substantially the algorithms of medical activity of arbitrary complexity.

The following example of logic analysis has demonstrated that the proposed IT can detect errors in the description of procedures:

– lack of tasks or goals (process break);
– lack of description of possible scenarios for development of procedure (breaks in logical/technological linkages of the process and lack of results' resolution).

It should be borne in mind that it is not possible to check the algorithmic nature of schemes executed using FlowChart notation without specialized software, unlike BPMN schemes, which are sufficiently validated by the fairly common Microsoft Visio software from Microsoft Office. In these cases, schemes similar to regulations, but not BPMN, need to be developed. And then analyze those projects, including using Microsoft Visio software.

It is important that the proposed IT can also be used to develop documents with visualization of medical activity algorithms.

CONCLUSIONS

Previously, the authors outlined the article's purpose - to demonstrate the ability to use BPMN to display algorithms and identify errors in regulations that govern the activities of health care providers in the performance of their duties. We believe that this was demonstrated by the logical-analytical examination of the AUB treatment set out in the Protocol.

With this paper the authors wanted to draw attention to the schemes' imperfection in legal documents that enshrine the algorithms of medical activity and to propose the use

of IT based on BPMN for visualization and verification of algorithms of such documents.

In favor of the proposed IT is evidenced by the fact that for humans, a picture remains the universal and most understandable means of transfer of meaning (knowledge). It is significant that experts – lawyers and medical professionals who participated in this research, even in the absence of programming knowledge, actually immediately understood the proposed IT and were able to use it in their work. Therefore, the proposed IT makes it possible to increase the clarity of even those texts where medical practice algorithms with non-core information are fixed.

REFERENCES

1. Melnik K., Goloskov A. Procedura diagnostirovaniya sostoyaniya serdechno-sosudistoj sistemy pacienta na osnove nechetkoj logiki [The procedure for diagnosing a patient's cardiovascular system based on fuzzy logic]. Bulletin of NTU "KPI". Informatics and modeling. 2008; 49: 101-104. (Ru)
2. Sanjeev Kumar, Gursimranjeet Kaur. Detection of Heart Diseases using Fuzzy Logic. International Journal of Engineering Trends and Technology. 2013; 4(6): 2694-2699.
3. Sofia Yakubovska, Olena Vysotska, Andrei Porvan, Dmytro Yyelchaninov, Elena Linnyk. Developing a method for prediction of relapsing myocardial infarction based on interpolation diagnostic polynomial. East European Journal of Advanced Technology. 2016; 5(9(83)): 41-49. doi:10.2016/j.applthermaleng.2005/06/011
4. Ramandeep Kaur, Prabhsharn Kaur. A Review – Heart Disease Forecasting Pattern using Various Data Mining Techniques. International Journal of Computer Science and Mobile Computing. 2016; 5(6): 350-354.
5. Ojeme Blessing Onuwa. Fuzzy expert system for malaria diagnosis. Oriental journal of computer science and technology. 2014; 7(2). Available from: http://www.computerscijournal.org/?p=1084. [reviewed: 2019.09.05]
6. Furmankiewicz M., Sołtysik-Piorunkiewicz A., Ziuziański P. Artificial intelligence systems for knowledge management in e-health: the study of intelligent software agents. Informatyka Ekonomiczna. 2014; 2(32): 51-63. doi: 10.15611/ie.2014.2.05
7. Igor Ogorodnyk, Olena Vysotska, Mykola Ternyuk, Hanna Bilovol. Development of the method of structural and parametric synthesis of the quanton diagnostic and health complex. International Journal of Engineering Trends and Technology. 2019; 4(9 (100)): 41-49. doi: https://doi.org/10.15587/1729-4061.2019.176174.
8. Hanna Dobrorodnia, Olena Vysotska, Marine Georgiyants, Yurii Balym, Larisa Rak, Olena Kolesnikova, Victor Levykin, Olexandr Dovnar, Konstantin Nosov, Andrii Porvan. Development of an approach to mathematical description of imbalance in methabolic processes for its application in the medical diagnostic information system. International Journal of Engineering Trends and Technology. 2018; 5(2(95)): 41-49. doi: https://doi.org/10.15587/1729-4061.2018.141451.
9. Lyubov Rysovana, Olena Vysotska, Helen Falyova, Marine Georgiyants, Viktoriia Klymenko. Factor analysis of crisis emergence in family relations, contributing to the development of dyscirculatory encephalopathy. International Journal of Engineering Trends and Technology. 2018; 5(2(95)): 41-49. doi: https://doi.org/10.15587/1729-4061.2017.91428.
10. Viktor M. Bobyryov, Sergij K. Kulishov, Andrij V. Vakhnenko, Olena V. Vlasova. Genetic algorithm for making pharmacotherapy decision in the patients with multimorbidity: approaches for clinicians. Wiad Lek. 2017; 70, 6 cz. I: 1142-1145. Available from: http://wl.medlist.org/06cz1-2017-22/ [reviewed: 2019.09.05]
11. Vladyslav A. Smiianov, Natalia O. Dryha, Olha I. Smiianova, Victor K. Obodyak., Tatyana O. Zudina. Development of informational-communicative system, created to improve medical help for family medicine doctors. Wiad Lek. 2018; 71, 2 cz. II: -334. Available from: http://wl.medlist.org/02b-2018-15/ [reviewed: 2019.09.05]
12. Andrzej Kajetanowicz, Aleksandra Kajetanowicz. Pros and cons of technology for patients. Wiad Lek. 2019; 72, 6: 1178-1182. Available from: http://wl.medlist.org/2019_06_05/ [reviewed: 2019.09.05]
13. Duodecim: Reliable and easy-to-use medical information for health care professionals as well as for the general public. Available from: https://www.duodecim.fi/tuotteet-ja-palvelut/paatoksentuki-ebmeds/ [reviewed: 2019.09.05]
14. Dzherela dokazovoi medytsyny [Sources of evidence-based medicine]. Site Ministry of health of Ukraine. 2017 Available from: https://moz.gov.ua/article/protocols/test3 [reviewed: 2019.09.05] (Ua).
15. Kozhokar I.P. Defekty normativno-pravovogo regulirovaniya. [Regulatory Defects]. Moskva: Prospekt [Moscow: Avenue], 2019. (Ru)
16. Oleh Hutsa, Nataliya Igumentseva, Nina Dovgopol, Sofiia Yakubovska. Factor analysis of crisis emergence in family relations, contributing to the development of dyscirculatory encephalopathy. International Journal of Engineering Trends and Technology. 2016; 5(2(89)): 55-64. doi: https://doi.org/10.15587/1729-4061.2017.110660.
17. Hutsa O.M. Analiz algoritmichnosti protsedur v yuridicheskih tekstah ili Zakonov pisateli, davayte porisuem… [Analysis of the algorithmic of procedures in legal texts or Laws writers, let's draw...]. Available from: http://finexpert.ru/view/analiz_algoritmichnosti_protsedur_v_yuridicheskikh _tekstakh_ili _zakonov_pisateli_davayte_porisuem/942 [reviewed: 2019.09.05] (Ru)
18. Unifikovanyi klinichnyi protokol pervynnoi, vtorynnoi (spetsializovanoi) ta tretynnoi (vysokospetsializovanoi) medychnoi dopomohy. Anomalni matkovi krovotechi [Unified clinical protocol of primary, secondary (specialized) and tertiary (highly specialized) medical care. Abnormal uterine bleeding]. Available from:https://zakon.rada.gov.ua/rada/show/ru/v0353282-16 [reviewed: 2019.09.05] (Ua).

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The Authors declare no conflict of interest.

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ENERGY INFRASTRUCTURE OBJECTS OF UKRAINE AS A PUBLIC HEALTH THREAT: CRIMINOLOGICAL ANALYSIS

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ABSTRACT

Introduction: There are currently a number of energy infrastructure objects in Ukraine, including nuclear power plants whose failure or destruction due to various factors, including criminogenic ones, can have serious and even irreversible negative consequences not only for the state's national security but also for public health and environment as a whole at local, regional, national and even interstate levels. In the context of the recent criminal violence's escalation that has been observed in Ukraine, such objects can be deliberately harmed, which will inevitably lead to an environmental disaster. Therefore, it is obviously necessary to conduct criminological monitoring of threats for public health related to possible disruptions in operation of critical infrastructure in the energy sector.

The aim:of this research is to assess the risks for public health resulting from the critical infrastructure's operation in the energetical field of Ukraine by criminological analysis of certain crime types and propose measures to minimize their negative impact on public health.

Materials and Methods: The study is grounded on dialectical, hictorical, comparative, logical, analytical, synthetic, statistical comprehensive and cartographic research methods. The calculations and mapping were done using Adobe Photoshop CS6, Microsoft Excel 2016, Microsoft Word 2016 and QuickMap 2.2. The sources of the study are the statistical reports of Ukrainian law enforcement agencies, analytical materials of the Organization for Security and Co-operation in Europe, specialized literature on medicine and law.

Results: The country's energy system, including its nuclear, gas and oil pipelines, belongs to the country's critical infrastructure, since any disruption to their operations or their destruction will inevitably lead to a number of negative consequences, including damage for public health in a large area as a result of environmental pollution. The analysis of criminological statistics shows that the real threat to the functioning of such objects in Ukraine is currently represented by criminal acts, which can lead to disruption of the analyzed objects (terrorism, cases of illegal handling of weapons, ammunition, or explosives, creation of non-statutory paramilitary or armed formations, etc.). At the same time, it has been established and clearly demonstrated by the mapping method that there is an increased level of violence and auto-aggression (suicide) in the areas of nuclear energy facilities deployment. This fact does not exclude the negative impact of energy infrastructure functioning on public health.

Conclusion: By the time that critical energy infrastructure facilities operate fully and in a normal mode, it is extremely dangerous to conduct any large-scale military operations in Ukraine. Even a minor disturbance in the normal operation of such facilities is a potential danger for public health over a large area. The danger of such objects being violated is also emphasized by the fact that under normal rating their impact on public health is evident, which is confirmed by statistics, in particular, on suicides among local community, level of pre-meditated murders on the territories of relevant regions, etc. In addition, such objects are a potential target for acts of terrorism, the results of which can also be catastrophic. In this regard, the development of measures' system of minimizing the negative impact on mental and physical health of people living in the territory of critical infrastructure's location is particularly relevant.

KEY WORDS: cancer, health protection, public health, psychosocial disabilities, sickness, X-ray

Wiad Lek 2019, 72, 12 cz. II, 2434-2440

INTRODUCTION

Modern society is a very complex social organism, in which it is possible to distinguish certain links, elements, sectors, systems, resources or networks, from which life's quality of the whole society depends directly on uninterrupted and safe functioning. Therefore, any abnormalities and deviations from the normal functioning of these entities, in particular as a result of criminal acts, can lead to serious and even irreversible negative consequences for both public health and environment at local, regional, national and interstate levels. Currently, such entities are commonly referred to as critical infrastructure.

For the first time in the world, such objects began to be mentioned on the European continent in the late 1990s, due to the threat of numerous terrorist challenges. Following the tragic events of the terrorist attacks in New York on September 11, 2001, the issue of the need to protect critical infrastructure has gained new relevance and global scope. The National Strategy for the Physical Protection of Critical Infrastructures and Key Assets was introduced in the United States in early 2003 [1].

Critical infrastructure objects are enterprises and institutions (regardless of ownership) of such sectors as energy, chemical industry, transport, banks and finance, information technology and telecommunications (electronic communications), food, health, public services are strategically important for the functioning of economics

and security of state and society [2]. Therefore, failure or destruction of objects in these industries can have very negative consequences for the national security and defense capability of a state, its natural environment, public health, etc. Thus, as a result of the notorious accident at the Chornobyl NPP, which happened due to criminal negligence, the entire ethnocultural region was destroyed, as 350,000 residents of the surrounding areas were evacuated from the radiation contaminated area. In addition, due to late evacuation, people was affected by doses of radiation that ten times higher than the allowable limit. Approximately 600,000 people who eliminated the catastrophe's effects also affected by huge doses of radiation [3]. However, it is still unknown how many of them have died or have health deviations. There are no relevant researches have been conducted in medical, ecological or any other related aspects.

As we can see, a direct object of critical infrastructure - the contry's energy system, including the nuclear, as well as gas and oil pipelines is recognized as a special priority. By the way, in any country that is concerned with the protection of critical infrastructure, the energy system is classified as such [4, p. 9; 5]. As correctly defined in the literature, effective identification of critical assets enables protection programs to prioritize asset lists (C. Izuakor and R. White, 2016) [6]. Detailed risk assessment can then be limited to key assets, such as those whose disruptions could have debilitating effects on security, national economic security, national public health and safety, or any their combinations [7].

THE AIM

The aim of this article is to assess the risks to national security, environment, public health, etc. related to critical infrastructure in the energy sector of Ukraine by conducting a criminological analysis of certain types of crime that could directly or indirectly harm such objects and those which, in turn, may be conditioned by some adverse effects of such objects' operation. However, the purpose of the article is also to draw public attention to the problems of possible interconnection of any pollution (including radioactive radiation) due to natural, man-made disasters or criminal acts with disorders of human psyche, which, in turn, can be cause of criminal acts, for example, of a violent nature.

MATERIALS AND METHODS

This study was conducted during 2017-2019 and is based on the research's results: 1) official statistics data of the Department of Information and Analytical Support of the Ministry of Internal Affairs of Ukraine and Office of Organizational Support of the Unified Register of Pre-trial Investigations and Information and Analytical Work of Prosecutor General's Office of Ukraine; 2) analytical materials from the Organization for Security and Co-operation in Europe; 3) quantitative and qualitative indicators of crimes against life and health of a person, public safety, as well as suicides during modeling an existing situation with these offenses in certain regions of Ukraine by visualizing the latter with the help of geographical maps and relevant tables that perform an additional explanatory function in assessing threats to public health in Ukraine in the context of protecting the state's energy infrastructure. The empirical and statistical data collected are processed, summarized, and analyzed using descriptive statistics capabilities. The article is based on dialectical, comparative, analytical, synthetic, statistical and comprehensive research methods. The calculations and mapping were done using Adobe Photoshop CS6, Microsoft Excel 2016, Microsoft Word 2016 and QuickMap 2.2. Theoretical basis of the article is specialized literature on medicine and law.

RESULTS AND DISCUSSION

The specific literature identifies certain types (categories) of threats that should be covered by critical infrastructure protection. Such threats include: accidents and technical failures, in particular, aviation accidents, nuclear accidents, fires, accidents in energy supply systems, emissions of hazardous substances, system failures, accidents and emergencies caused by negligence, organizational errors, etc.; natural hazards, including extreme weather, forest, steppe and peat fires, seismic phenomena, epidemics and pandemics, space phenomena, hurricanes, tornadoes, earthquakes, tsunamis, floods, etc.; malicious acts, in particular, malicious acts of groups or individuals such as terrorists, criminals and saboteurs, as well as hostilities during war [4, p. 12]. As was noted, the subject of our in-depth analysis is, first, the criminological estimation of public health threats in Ukraine, primarily as a result of unlawful acts affecting critical energy infrastructure facilities and, second, disclosure of a possible link between environmental pollution that results from operation of some of these objects in regular mode, or which has occurred as accidents' results or criminal activities at these objects, and disorders of human psyche, that in the etiology of criminal behavior as a manifestation of destructive aggression in the broad sense may subsequently play some negative role.

The listed threats potentially carry an enormous risk of disruption and even collapse in uninterrupted energy supply of a state with long-term environmental consequences. In fact, they determine the likelihood of corresponding negative changes in critical infrastructure's objects. Risk is defined as the possibility of loss, damage or injury [8, p. 90]. Thus, risk is always associated with dangers' presence and threats, the likelihood of any harm to public health of a country as a whole and its regions, in particular. The criminological assessment of threats to the protection of critical infrastructure should be considered as an effective mechanism for analyzing the state of protection of Ukraine's territory from any criminogenic events. In mathematics and economics, analyzing certain types of threats, attention is always drawn to identifying potential risks based on statistics, scientific, technical and expert judgment. Such an approach we used to build the scheme and outline the main results of our research.

It is emphasized that the Organization for Security and Co-operation in Europe is in fact calling for the recognition of importance of critical energy infrastructure in the modern world, which in its Decision 6/07 on protecting critical energy infrastructure from terrorist attacks determines that critical energy infrastructure, including nuclear power plants, dams of hydroelectric power plants, oil and gas producers, refineries, transmission facilities, supply routes and facilities, energy storage facilities as well as hazardous waste storage facilities, may be vulnerable to terrorist attack [9].

Today, the energy system of Ukraine consists of comprehensive structure of such objects. Among the most valuable of them are: 1) an extensive gas transportation system extending from eastern to western and from northern to southern borders of Ukraine; 2) four operating nuclear power plants (South Ukrainian NPP – 3,000 MW; Khmelnitsky NPP– 2,000 MW; Rivne NPP – 2 880 MW; Zaporizhzhya NPP - 6,000 MW [10, p. 22]). The Chornobyl NPP is still partially operational (its capacity before the disaster was 3,200 MW) [11].

Particular attention should be paid here to those threats to public health related to nuclear power, especially when it comes to criminal events related to man-made disasters or conducting military operations in the territories of those countries where such facilities are located. As is known, the world's first nuclear reactor was built in 1942 in the United States, and Ukrainian nuclear power was started in 1977, when the first Chornobyl NPP was put into industrial operation [12]. Nowadays, nuclear power plants are operating in 30 countries. Ukraine ranks 10th in the number of nuclear reactors (power units) in the world [10, p. 21].

In 1986, Ukraine suffered the tragic consequences of NPP failure, extent and depth of which cannot yet be fully determined. Only immediately after the accident in clinical cases of mild acute radiation sickness (hereinafter–ARS) (1st degree of severity, radiation dose is 0.8-2.1 Gy) the patients were diagnosed with vascular dystonia and neurotic disorders, in cases of moderate ARS (2nd degree of severity, 2- 4 Gy) also vegetative vascular dystonia was diagnosed; with severe ARS (3rd degree of severity, 4.2–6.3 Gy) – acute radiation and radiation-toxic encephalopathy, acute psychosis with visual and auditory hallucinations, brain edema, and with very severe ARS (4th degree of severity), 6-16 Gy) – acute radiation and radiation-toxic encephalopathy, subarachnoid-parenchymal hemorrhage, marked edema and swelling of the brain were diagnosed [13, pp. 48-52]. The situation is complicated by the fact that emergency radiation is necessarily connected with: 1) non-radiation factors, especially psychological and social stress, and 2) lack of objective baseline (before exposure) data on human health [14]. Among those who suffered the most from the Chernobyl accident, 600 thousand liquidators of this accident. Mental disorders in them are detected twice as often as in the rest of population, and suicides among them were 20 times more; many of them need psychiatric treatment [15].

Interesting data are provided by K. Loganovsky and co-authors. They have conducted standardized psychiatric interviews using the Composite International Diagnostic Interview with 295 clean-up workers and 397 controls 16-18 years after catastrophe and report on common psychiatric disorders, suicide ideation and severe headaches. So, clean-up workers had significantly higher rates of depression (18.0% vs. 13.1%) and suicide ideation (9.2% vs. 4.1%) after catastrophe, but not alcoholism or intermittent explosive disorder. In the year preceding the interview, depression rates (14.9% vs. 7.1%), PTSD (4.1% vs. 1.0%), and headaches (69.2% vs. 12.4%) were elevated (Loganovsky et al. 2008) [16].

Since 1990, the Ukrainian Institute of Social and Forensic Psychiatry has conducted a survey of liquidators, which has led to the hypothesis that high doses of radiation lead to dementia and give rise to mental illness such as schizophrenia [15]. In this regard, it is not for nothing that the long-term mental health consequences have been recognized by the UN Chernobyl Forum and supported by further evidence-based International Studies as one of the major medical and social problems of the Chernobyl catastrophe aftermath [17, p. 22].

It should be noted that in addition to the obvious impact on individual health (leukemia, thyroid cancer, breast cancer, other cancers, cataract, mental health) [18, etc.], man-made disasters such as Chornobyl or Fukushima (Japan) also have obvious but not recognized implications for public health. Among the latter: loss of territories for residence and territorial redistribution of population, degradation of population structure of radioactively contaminated territories, mortality in population of radiologically contaminated territories and mortality victims of catastrophes, demographic losses, disability, non-cancer health effect ets. [19] The most likely emergency scenarios in Ukraine at present are: 1) nuclear and radiological accidents and incidents (any event related to transportation, storage and use of radioactive materials and radiation sources [above all, NPPs and nuclear reactors], including the loss and theft of radiation sources and detection of hostile sources); 2) nuclear terrorism (first of all capture of a nuclear power plant or other civilian object working with radioactive materials, its mining and explosion); 3) use of tactical and/or strategic nuclear weapons [20, p. 5].

Modern humanity is in a symbolic closed circle: energy infrastructure objects have a negative impact on population's health (especially in satellite cities of NPPs, TPPs, etc.), which does not exclude outbreaks of unlawful excesses related, in particular, to aggression and auto aggression. However, while this assumption still requires serious medical and psychological research, the impact of criminal actions aimed at work's disrupting of the analyzed objects is quite obvious as they always leads to accidents and contamination of the environment and therefore irreparable damage to public health.

An analysis of the geography of major critical energy infrastructure facilities' location in Ukraine which are of high risk indicates that they are predominantly located in the areas of increased criminogenic threats (Fig. 1). Even where the crime area is relatively "favorable" as a whole, since the level of criminal threats is not high but the energy infrastructure of the critical infrastructure is located on its territory, the corresponding indicators still tend to reach the maximum limit of criminal intensity's level inherent

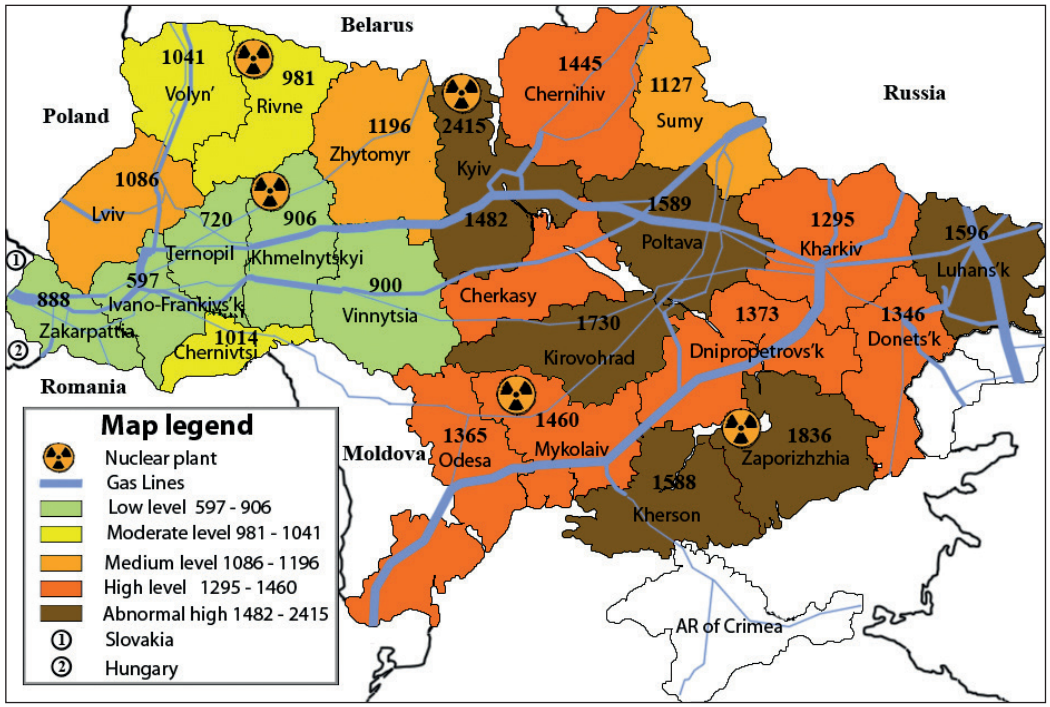

Fig. 1. Geography of Crime Rate in Ukraine per 100,000 Population in 2018

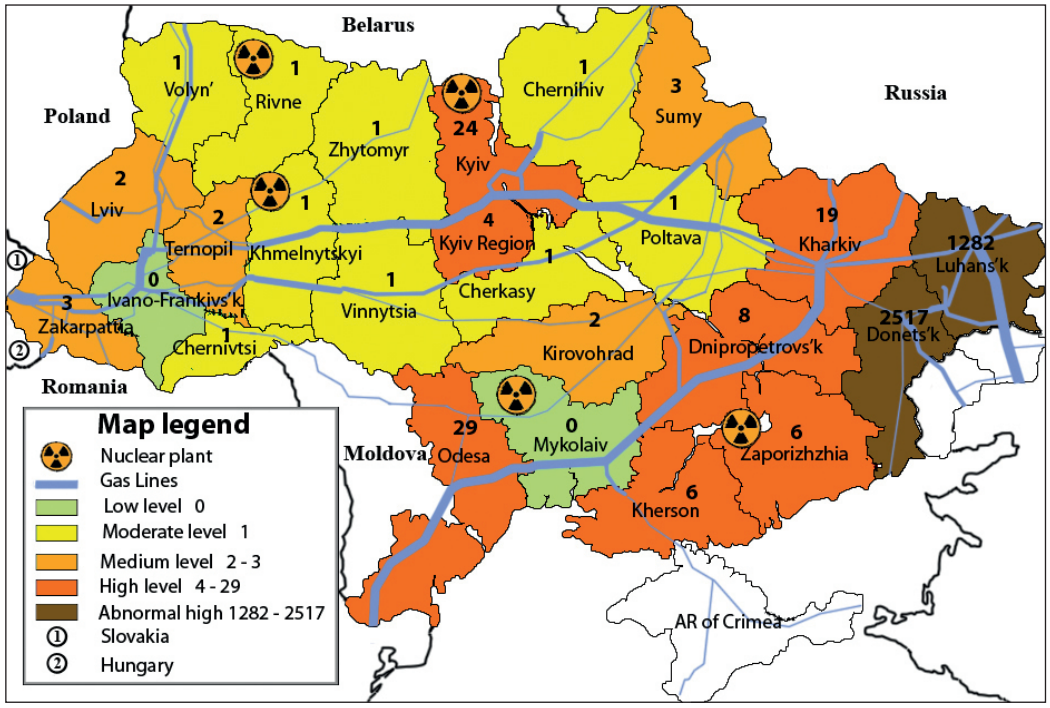

Fig. 2. Geography of Terrorist Acts and Creation of Terrorist Groups or Organizations (2017-2018)

Table I. Dynamics of Terrorist Acts (Art. 258 of the Criminal Code of Ukraine) Committed in Ukraine (2009-2018)

Years	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Quantity	-	-	-	-	4	1 499	1 295	1 865	1 385	950

in of one or another criminogenic group. This situation threatens the «transition» to the next, less favorable in terms of criminogenic, group of indicators.

Indeed, the maps below show that many of these energy facilities, in particular nuclear and gas transportation systems and their networks, are located in regions with high levels of terrorist threat, social tension, high rates of homicide and suicide (Fig. 2, 3, 4).

Regarding crimes related to terrorism, while in 2013 only 4 facts were fixated since 2014 more than one thousand crimes have been consistently committed (Table I).

Terrorism was a completely new phenomenon for Ukraine. If previously such cases were not recorded at all due to their absence, 894 terrorist acts (Art. 258 of the Criminal Code) and 427 cases of a terrorist group or terrorist organization establishing (Art. 258[3] of the Criminal Code) were recorded in 2014. In 2015

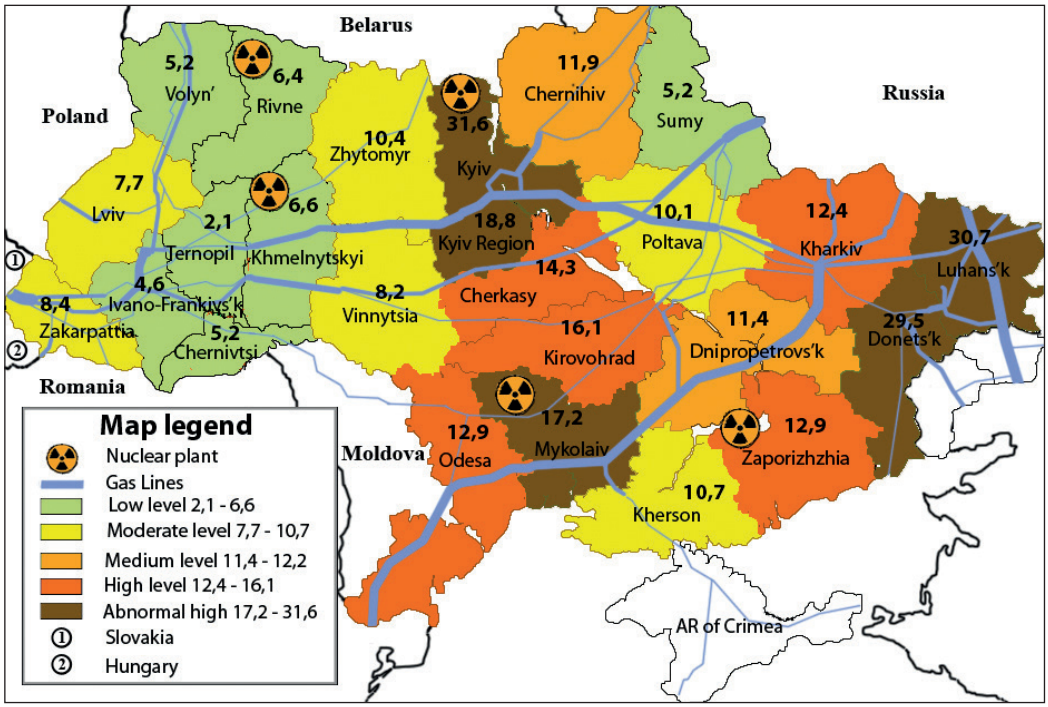

Fig. 3. Geography of Homicide Rate in Ukraine per 100,000 Population in 2018

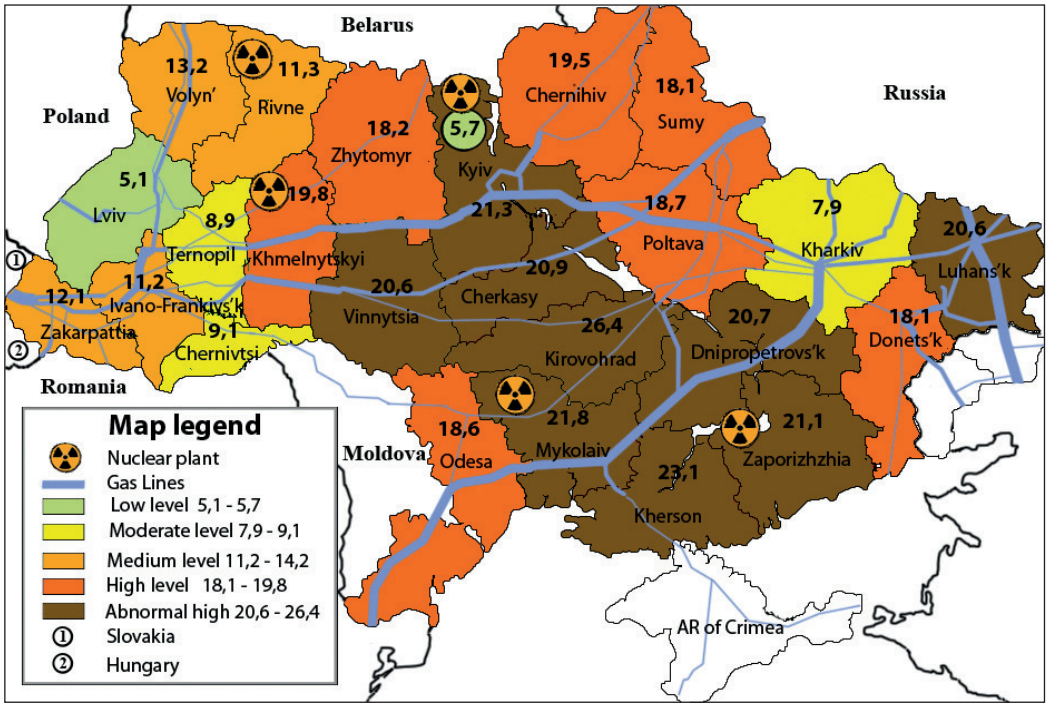

Fig. 4. Geography of Suicide Rate in Ukraine per 100,000 population in 2018

it was accounted 1 295 reported terrorist acts (ie + 50%) and 849 cases of a terrorist group or terrorist organization establishment; in 2016 – 1,602 (+ 24%) and 391; in 2017 – 1,283 and 277; in 2018 – 838 and 175 crimes respectively [21; 22; 23; 24; 25; 26].

The most dangerous in this regard were the territories of Donetsk, Lugansk, Odessa, Kyiv and Zaporizhzhya regions. It should be reminded that in these territories some of the nuclear power plants and most of gas transmission system and its networks are located. Even one instance of terrorism at, or adjacent to, critical energy infrastructure in these areas may be sufficient for a major disaster.

The reality of criminological threats to energy infrastructure in our country can be amplified by the catastrophic depreciation of both one's own life and that of another person. This is clearly indicated by the high intensity of homicides and suicides in the regions of Ukraine (Map 3, 4). Again, this can be a consequence of environmental discomfort, which increases the likelihood of human acquisition, including any mental anomalies. Thus, it is possible that the influence of oil, gas transmission system, nuclear power objects etc. on public health leads to increased levels of criminal aggression in the broad sense.

This data demonstrates that the most dangerous territories for Ukraine are the cities of Kyiv (31) and Kyiv region (18.8), as well as Lugansk (30.7), Donetsk (29.5), Mykolaiv (17.2), Odessa (12.9), Zaporizhzhia (12.9) and a number of other regions of Ukraine (Fig. 3, 4). As we can see, the homicide rate per 100,000 of population in some cases far exceeds the so-called epidemiological threshold, which is equal to 7.6 cases per 100,000 of population [27]. If we combine these data of criminal statistics with the location's map of nuclear facilities, it can be seen that, with the exception of the Lugansk and Donetsk regions, in the mentioned regions or near them there are such NPPs as South Ukrainian, Zaporizhzhia (the largest in Europe) and Chernobyl . As for the Luhansk and Donetsk regions, they are naturally more violent than any other region as a result of hostilities.

Regarding suicides, in 2017, Ukraine, as in previous years, again ranked 25 countries with the highest suicide rates in the world. This figure was 15.3 cases per 100 thousand of population of the country [28], that is, six and a half thousand Ukrainians voluntarily died. In 2018, this figure was 15.8 cases per 100,000 of people [28]. In this respect, the current situation in Ukraine is alarming and does not show a stable tendency to reduce the number of such cases.

Thus, the presented results indicate that the territories of critical infrastructure locations in the energy sector of Ukraine are extremely saturated not only with so-called general crime, but also with terrorist offenses, homicides and suicides (Map 1, 2, 3, 4). Map 3 and 4 show data that our country is in a hazardous area.

CONCLUSIONS

Power plants of various types, including nuclear, oil and gas transmission systems, are the most important types of critical energy infrastructure in Ukraine, since they are: first, the main sources of energy for internal consumption; secondly, provide electricity exports to other countries and, accordingly, profits for Ukraine; thirdly, they are the guarantors of socio-economic and political stability in some parts of the European continent. As long as critical energy infrastructure facilities are fully operational and full-time, any large-scale military operation is extremely dangerous in Ukraine. At the same time, the termination of these facilities can lead not only to economic and social, but also to political imbalances that can cause negative geopolitical consequences.

The stable functioning of power plants, in particular NPPs, oil and gas transportation system of Ukraine and, consequently, geopolitical stability in Ukraine, can be hindered by criminological threats such as: 1) high intensity of criminal manifestations in some regions; 2) terrorist crimes; 3) high inclination of certain categories of people to violence; 4) negative state of social and socio-psychological situation (high suicide rate, unemployment, social tensions, etc.); 5) geopolitical factors etc. In the case of man-made accidents, natural disasters and acts of crime (both intentional and reckless), negative impact of these objects becomes extremely dangerous for public health in large territories, taking even the magnitude of the planetary character due to environmental pollution. Therefore, a large number of people (radiation sickness, cancer, mental disorders, etc.) always result from «incorrect» functioning or destruction of the critical infrastructure.

Analysis of quantity and geography of committing certain types of criminal acts (primarily terrorist acts) in Ukraine confirms the existence of a real threat to uninterrupted and safe functioning of nuclear facilities, oil refining and gas transportation systems. In turn, increased levels of premeditated murders and auto-aggression (suicide) cases are recorded in areas adjacent to nuclear facilities (nuclear power plants). Thus, critical energy infrastructure assets represent both a real and a potential threat to public health. In this regard, the development of a system of measures to minimize the negative impact on the mental and physical health of the population living in the territory of location of the critical infrastructure is particularly relevant.

REFERENCES

1. The National Strategy for the Physical Protection of Critical Infrastructures and Key Assets. Available from : https://www.hsdl.org/?view&did=1041. [reviewed 2019.07.12]
2. Poryadok formuvannya pereliku informacijno-telekomunikacijnih sistem ob'єktiv kritichnoi infrastrukturi derzhavi: zatv. postanovoyu Kabinetu Ministriv Ukraini vid 23.08.2016. № 563. Oficijnij visnik Ukraini. 2016. № 69. St. 2332 [Order of Formation of the List of Information and Telecommunication Systems of Objects of Critical Infrastructure of the State: approved resolution of the Cabinet of Ministers of Ukraine of August 23, 2016. No. 563]. Official Bulletin of Ukraine. 2016; 69 : 2332 [reviewed 2019.07.12] (Ua).
3. Chornobil's'ka katastrofa: yak naspravdi stalasya tragediya [Chernobyl disaster: how the tragedy actually happened]. Available from: https://znaj.ua/society/chornobylska-katastrofa-yak-naspravdi-stalasya-tragediya [reviewed 2019.08.20] (In Ukrainian).
4. Biryukov D.S., Kondratov S.I., Nasvit O.I. et al. Zelena kniga z pitan' zahistu kritichnoï infrastrukturi v Ukraïni [Green Book on the Protection of Critical Infrastructure in Ukraine]. Kyiv: National Institute for Strategic Studies, 2015. 35 p. (Ua).
5. Alcaraz C., Zeadally S. Critical Infrastructure Protection: Requirements and Challenges for the 21st Century. IJCIP. Elsevier Science. 2015; 8:53–66. doi: 10.1016/j.ijcip.2014.12.002.
6. Izuakor C., White R. Critical Infrastructure Asset Identification: Policy, Methodology and Gap Analysis. Critical Infrastructure Protection X: ICCIP: International Conference on Critical Infrastructure Protection (March 14-16, 2016). Arlington: Springer, 2016: 27–41. doi: 10.1007/978-3-319-48737-3_2.
7. U.S. Government, Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA Patriot Act): Act of 2001, Public Law 107–56. Washington, DC (2001). Available from: https://www.govinfo.gov/content/pkg/PLAW-107publ56/pdf/PLAW-107publ56.pdf. [reviewed 2019.08.20]
8. Good Practices Guide on Non-Nuclear Critical Energy Infrastructure Protection (NNCEIP) from Terrorist Attacks Focusing on Threats Emanating from Cyberspace. Vienna: Organization for Security and Co-operation in Europe, 2013. 100 p.
9. Decision No. 6/07 Protecting Critical Energy Infrastructure from Terrorist Attack: Second day of the Fifteenth Meeting. MC(15). Journal No. 2. Agenda item 8. Available from: https://www.osce.org/mc/29482?download=true. [reviewed 2019.08.19]

10. Markevych K., Omel'chenko V. Yaderna enerhetyka u sviti ta Ukraini: potochnyj stan ta perspektyvy rozvytku (analitychnyj ohliad). [Nuclear power in the world and Ukraine: current state and prospects for development (analytical review)]. Kyiv: Razumkov Center, 2015, 26 p. (Ua).
11. Chornobyl's'ka katastrofa [The Chornobyl disaster]. Available from: https://uk.wikipedia.org/wiki/Чорнобильська_катастрофа#Характеристика_ AEC. (Ua).
12. Yadernyj reaktor [Nuclear reactor]. Available from: https://uk.wikipedia.org/wiki/Ядерний_реактор#cite_note-zeep-cstm-1. (Ua).
13. Torubarov F.S., Blagoveshchenskaya V.V., Chesalin P.V. et al. Sostoyanie nervnoj sistemy u postradavshih pri avarii na Chernobyl'skoj atomnoj elektrostancii (CHAES). [The State of the Nervous System of the Victims of the Accident at the Chernobyl Nuclear Power Plant (Chernobyl). Journal Neuropathology and Psychiatry Named by S. S. Korsakov. 1989; 2 : 48–52. (Ru).
14. Loganovs'kij K.M., Zdanevich N.A. «Postradiacijnij» posttravmatichnij stresovij rozlad. Problemi radiacijnoï medicini i radiobiologii. [«Postradiation» post-traumatic stress disorder]. Problems of radiological medicine and radiobiology. 2011; 16 : 138–149 (Ua).
15. Miroshnikova A. Kak na psihiku vliyaet Chernobyl'? [How the mentality is influenced by Chernobyl?]. Part I. Available from: http://www.likar.info/psihologicheskie-problemyi/article-77176-kak-na-psihiku-vliyaet-chernobyl-chast-1. [reviewed 2019.08.19] (Ru).
16. Loganovsky, K., Havenaar, J.M., Tintle, N.L. et al. The mental health of clean-up workers 18 years after the Chernobyl accident. Psychol Med. 2008 ; 38 (4) : 481–488. doi: 10.1017/S0033291707002371.
17. Omelianets N., Bazyka D., Igumnov S., Loganovsky K., Prysyazhnyuk A., Stepanova E., Afanasev D. Heallth Effects of Chernobyl and Fukushiima: 30 and 5 years down the liine. Brussels: Greenpeace, 2016. 98 p. doi: 10.13140/RG.2.1.1188.5202.
18. Likhtarov I., Kovgan L., Vavilov S. et al. Post-Chernobyl Thyroid Cancers in Ukraine. Report 2: risk analysis. Radiat. Res. 2006; 166 (2): 375–386. doi: 10.1667/RR3593.1
19. Gun'ko N. V., Omel'yanec' M. I., Ozerova Yu. ta in. Ocinka stanu vikonannya viznachenih zakonodavstvom zahodiv protiradiacijnogo, medichnogo ta social'nogo zahistu zhiteliv radioaktivno zabrudnenih teritorij vnaslidok Chornobil's'koï katastrofi ta propoziciï shchodo napryamkiv iih korekciï. [The estimation of a condition of performance of the measures, established by the legislation, of antiradiating, medical and social protection of the inhabitants of territories, is radioactive contamination in result of Chernobyl catastrophe, and offer till them correction]. Problems of radiation medicine and radiobiology. 2010; 15 : 114–126) (Ua).
20. Loganovs'kij K.M., Petrichenko O.O., Morozov O.M. ta in. Ohorona psihichnogo zdorov'ya pri radiacijnih avariyah na yadernih reaktorah ta zastosuvanni "brudnoï bombi" i taktichnoï yadernoï zbroï: metodichni rekomendaciï. [Protection of Mental Health in Radiation Accidents at Nuclear Reactors and the Use of "Dirty Bomb" and Tactical Nuclear Weapons: Guidelines]. Kyiv: State Institution "National Scientific Center of Radiation Medicine of NAMS of Ukraine", 2014. 26 p. (Ua).
21. Yedinij zvit pro kriminal'ni pravoporushennya za sichen'-gruden' 2018 roku [Unified Report on Criminal Offenses for January-December 2018]. Prosecutor General's Office of Ukraine, 2019. Available from: https://www.gp.gov.ua/ua/stst2011.html?dir_id= 113653&libid=100820&c= edit&_c=fo [reviewed 2019.08.19] (Ua).
22. Yedinij zvit pro kriminal'ni pravoporushennya za sichen'-gruden' 2013 roku / [Unified Report on Criminal Offenses for January-December 2013]. Prosecutor General's Office of Ukraine, 2014. Available from: http://www.gp.gov.ua/ua/stst2011. html?dir_id=112173&libid=100820 [reviewed 2019.08.19] (Ua).
23. Yedinij zvit pro kriminal'ni pravoporushennya za sichen'-gruden' 2014 roku [Unified Report on Criminal Offenses for January-December 2014 / Prosecutor General's Office of Ukraine, 2015]. Available from: http://www.gp.gov.ua/ua/stst2011.html?dir_id =112173&libid=100820. [reviewed 2019.08.19](Ua).
24. Yedinij zvit pro kriminal'ni pravoporushennya za sichen'-gruden' 2015 roku [Unified Report on Criminal Offenses for January-December 2015 / Prosecutor General's Office of Ukraine, 2016]. Available from: http://www.gp.gov.ua/ua/stst2011.html?dir_id=112173&libid=100820. [reviewed 2019.08.19] (Ua).
25. Yedinij zvit pro kriminal'ni pravoporushennya za sichen'-gruden' 2016 roku [Unified Report on Criminal Offenses for January-December 2016]. Prosecutor General's Office of Ukraine, 2017. Available from: http://www.gp.gov.ua/ua/stst2011.html?dir_id =112173&libid=100820. [reviewed 2019.08.18] (Ua).
26. Yedinij zvit pro kriminal'ni pravoporushennya za sichen'-gruden' 2017 roku [Unified Report on Criminal Offenses for January-December 2017]. Prosecutor General's Office of Ukraine, 2018. Available from: http://www.gp.gov.ua/ua/stst2011.html?dir_id =112173&libid=100820&c=edit&c=fo[reviewed 2019.08.19] (Ua).
27. International Statistics on Crime and Justice / Edited by S. Harrendorf, M. Heiskanen, S. Malby. Helsinki: European Institute for United Nations Office on Drugs and Crime (UNODC) Crime Prevention and Control 2010. 177 p.
28. V Ukraine ozvuchili plachevnuyu statistiku samoubivstv [In Ukraine deplorable statistics of suicides is read]. Available from: https://bdzhola.com /news/v-ukraine-ozvuchili-plachevnuju-statistiku-samoubijstv [reviewed 2019.08.19] (Ru).

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PRACA ORYGINALNA

HEALTH CARE FOR CRIMEAN RESIDENTS: INTERSTATE CONFLICT CHALLENGES AND POSSIBLE LEGAL AND ORGANIZATIONAL SOLUTIONS

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ABSTRACT

Introduction: Attempt of Crimea annexation by Russia, further sanction and legal isolation of the peninsula created specific conditions for the local medical infrastructure and health protection.

The aim:of this article is to determine the current legal and organizational policies of Russia and Ukraine regarding health protection for the Crimean residents, evaluate their results after the five years of Russian effective control over Crimea.

Materials and methods: Author analyzed the legal acts and reports regarding to the medical, demographic and migration issues for Crimeans, issued by international structures, by the Ukrainian bodies and Russian de-facto authorities.

Results: Research shows that the attempt of Russia to establish since 2014 its own model of health care in Crimea caused the system medical crisis, connected with lack of medic units and personnel, possibly low quality of the pharmacy. Ukraine did not reflect the specific duties of the Crimean residents in its own medical policy and reforming. The needs of healthcare for such numerous people that temporarily relocated from peninsula to the government-controlled territory stays not well-satisfied.

Conclusions: International organizations with the relevant mandate must pay more attention to the healthcare issues for the Crimeans, such circumstances should be monitored by the UN and OSCE missions and be covered by the ICRC mission in Kyiv. Ukrainian health care reform must consider the requirements for medical aid of Crimeans that temporarily relocated from peninsula.

KEY WORDS: Crimea, Health Care, Insurance, Migration

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INTRODUCTION

In March 2014 Russian Federation attempted to annex the Crimean Peninsula, as the Ukrainian territory with two regions – Autonomous Republic of Crimea (ARC) and Sevastopol City and more than two million residing persons. This attempt was not recognized neither by Ukraine nor by absolute majority of third countries, also as by the international organizations, that adopted the relevant acts, like UN General Assembly Resolutions 71/205 and 72/190 [1, 2], some resolutions of Parliamentary Assemblies of OSCE and Council of Europe, of European Parliament [3] etc. As the UN GA acts are obligatory for the World Health Organization, for other UN regional and specialized bodies, they certainly form the international agenda on Crimean issues, including the issues of medical protection and health care, medical education, export and import of drugs and equipment etc. Further sanction and legal isolation of the peninsula created specific conditions for the local medical infrastructure and health protection.

At the same time Russia declared the Crimea as its own territory, including two "subjects" like "Republic of Crimea" (RC) and "Federal Significance City Sevastopol", and after the short "transitional period" from the 1st of January 2015 has implemented its national legislation in peninsula, including Russian medical law, relevant legal and organizational standards, protocols etc. Within the territory controlled by Ukraine there are medical reforms that started in 2016 with perspectives of changing the framework of the post-soviet "free" medical aid to the insurance health-care system and this transitional period is still not finished.

Crimean residents (Crimeans) are recognized by both conflict parties as "their own citizens", except thousands that refused the Russian citizenship in 2014 and about two hundred thousand of persons, resettled from Russia to Crimea, violating by this the Ukrainian laws after 2014. So Crimeans may demand from de-facto Russian authorities in Crimea provision of the health care services and use the ability for the medical aid on the controlled territory of Ukraine. Such politic situation caused the very specific framework of medical aid system for Crimeans and its impact on real healthcare for Crimeans which may be a fruitful topic of the scientific researches.

THE AIM

The aim of this article is to determine the current legal and organizational policies of Russia and Ukraine regarding the health protection provided for the Crimean residents, evaluate their results after the five years of Russian effective control over Crimea. Following such an approach

we are going to establish the specification of the relevant regulation mechanisms, to compare them with the statistics, presented by the both states, to make prognosis of development of the healthcare situation with Crimeans for a nearest future.

MATERIALS AND METHODS

Author analyzed the legal acts and reports regarding to the medical, demographic and migration issues for Crimeans, issued by international structures, by the Ukrainian bodies and Russian de-facto authorities. Special attention were paid for the published reports of the Special Monitoring Mission of OSCE in Ukraine and UN Human Rights Monitoring Mission in Ukraine, to the ICRC activities in Ukraine, also as for the reports of the de-facto "Ministry of Health Care" of RC, of Mission of the President of Ukraine in ARC etc. Analysis of the relevant legislation was done by author in full compliance with ethic demands of his current job (Legislation Institute of the Verkhovna Rada of Ukraine). Moreover, the author used he's own experience as the Permanent Representative of the President of Ukraine in the ARC, appointed on this position by the Presidents decree on 17th of August, 2017, № 220/2017 and dismissed from this post by decree on 2nd of December, 2018 [4] with full compliance with demands of Ukrainian public service ethic rules.

In this article such key materials as the References and Reports, prepared by Mission of the President of Ukraine in ARC in 2018 and presented to the Ukrainian government, international monitoring missions and available on Mission`s website were used [5-8]. The scientific publications, devoted to the situation in Crimea after 2014, are in common concentrated on issues of the international humanitarian law and human rights, they do not reflect in details the issues of medical law, relevant social care and assurance 0f the right to health [9-15].

RESULTS

Regarding to data presented by Russian de-facto authorities the healthcare in Crimea (controlled by the "Ministry of Health Care" of the RC ("Ministry")) includes seven structural offices (on medical aid for adults, on medical aid for children, mothers and resort care, on strategic development, on material basis and state programs, on planning and economics, on providing drugs, on informatization, civil protection and labor security, on legal support and licenses, on personnel policy) and three sectors, including the medical safety control.

The "Ministry" governs over 68 hospitals, 12 sanatoriums, five Crimean educational institutions – four "colleges" in Evpatoria, Kerch, Simferopol and Yalta and "certification training center" and two "scientific research institutions" – on physical methods of treatment, medical climatology and rehabilitation, also as on children`s balneology, physiotherapy and medical rehabilitation, also as some "enterprises" like "Krymzdrav", "Medtekhnika", "Crimean Medical Informational-Analytic Centre", "Medical Prophylactics Center" and regional medical library. At the same time, no special governing structure devoted to Crimean issues was created by the Ukrainian government since 2014 [5].

At the same time, the "Ministry" as the part of de-facto Russian authorities in Crimea has its goals in realization of the "federal and departmental target programs". In framework of the program "Modernization of the State Health Care Departments with their Accordance to the Federal Programs" more than 681,7 million Russian rubles from state budget are foreseen for 2018-2020. More than 8676,6 million Russian rubles from state budget were established for the "Road Map for Modernization the Regional District and Town Hospitals" for 2019-2023 and more than 106,7 million were granted on 2018-2020 for the program "Accessible Environment". Such sums may not be considered as sufficient for the development of the Crimean medical system. The main annual priority of "Ministry" in 2018 was the oncology problem treatment, including changes in legal regulation, early diagnostic, informatization of the oncology hospital units, etc. [6].

Regarding to statistics, provided by "Ministry", the total quantity of the Crimean doctors, comparing between 2014 and 2017 years, arose from 8000 to 8444 persons (but common number of pediatrists and hygienists decreased), and medical medieval personnel – from 17821 to 20171 persons. But at the same time the quantity of Crimean medical structures reduced from 117 to 88 including reducing of the number of dispensaries from 61 to 57 and the hospital beds of 24/7 hospitals – from 16328 to 15109 also as the beds for pregnant women and women after birth, reduced in 2014-2017 from 938 to 791. Such paradox may be explained by enlarging not the actual medic personnel of hospitals but the Crimean medical bureaucracy under the Russian control and medical standards, when more persons are involved in the same manipulations and procedures. At the same time, quantity of registered daily visits to Crimean ambulatories and polyclinics arose in 2014-2017 from 24931 persons per day to 36099 persons per day [6]. Such change may be explained by the attempt of Russia to implement its own insurance system in Crimea and to tight up the account of the patients.

At the same time, regarding to the "Ministry" reports, common lack of medical personnel in Crimea is over 25% for medicals (doctors) and about 800 for medical medieval personnel in cities (no data for the rural area situation was presented). Four of abovementioned "colleges" every year issue "diplomas" for a thousand of medics but they do not stay in Crimea or while staying they are employing in pharmacies or other relevant business structures. The only medical high school of this region – Crimean State Medical University in 2014 was united as "Medical academy" with some non-medical Crimean high schools into the so called "Crimean Federal University"; now it is subordinated to the ""Ministry of Education" of RC [6].

Common healthcare situation in Crimea is stabile but the active growth of diagnosis during 2014-2017 demonstrates

the rise of oncologic diseases (from 6845 to 7481 cases) and hepatitis (from 326 to 548 cases), but the venereal diseases decreased from 3939 to 1491 cases in four mentioned years and also tuberculosis from 1446 to 1186 cases. Moreover, number of circulatory system diseases reduced from 57493 to 44459 cases and of diabetes from 4464 to 3826 new cases [6]. Such data changes can`t be explained by the natural, hygienic or epidemic grounds and may have the only explanation for the quite other diagnostic methodology, implemented by the Russian de-facto authorities.

So, this research shows that the attempt of Russia to establish its own model of health care in Crimea since 2014 caused the system medical crisis, connected with lack of medic units and personnel, possibly low quality of the pharmacy. Ukraine did not reflect the specific duties of the Crimean residents in its own medical policy and reforming. The needs for the health care of such persons that temporarily relocated from peninsula to the government-controlled territory stays not well-satisfied.

DISCUSSION

On the other hand, Ukraine made attempts to provide special health care services for Crimean only in 2018. By the Governmental Prescript on 28th of March 2018 № 218-p the Action plan for the realization of some state internal policy steps regarding Crimea was adopted. The article 11 of this Plan established special tasks for the Ukrainian Ministry of Health Care, Ministry of Finances, Ministry of Informational Policy, National Academy of Medical Science and Kherson Regional State Administration in healthcare to the Crimeans, which should be generally solved till the end of 2018. Those tasks foreseen the improving of Kherson regional medical institution capacities for the early diagnostic and transferring of persons to the specialized medical institutions of the national level. Also, the duty to establish the special mechanisms of medical aid and drug support for Crimeans to cure hepatitis, heart diseases, tuberculosis, diabetes, AIDs on Ukrainian mainland, also as the phenylketonuria therapy. This Action Plan`s tasks also foreseen the duty to establish special mechanism of Crimeans' registration for providing them with medical services on the mainland and promotion of the information for the Crimeans [16].

This Action plan has got no financial support from the Ukrainian State Budget and de-facto was not realized, neither in 2018 nor later. Other Ukrainian program document of that period, Urgent Action Plan of Counteraction on the Russian Aggression from the Temporarily Occupied Territory of Ukraine in Crimea, of Defense the State, Ukrainian Citizens' and Ukrainian Legal Entities' Interests in Crimea for 2018-2019, approved on 28th of June 2018, foreseen in its task 14.6 providing the qualified medic aid to Crimeans on the Ukrainian mainland. It established a duty of quarterly control of the abovementioned Action Plan realization and establish the annual seminar with international structures` representatives on the issue of providing vaccines, drugs, serosity and establishing the real epidemic situation and healthcare state in Crimea. Realization of this duty should provide the interregional dissemination of Crimeans for getting medic aid on the Ukrainian mainland and reflection of the real medical problems of Crimeans in international reports and scientific publications [17].

Along with the Action Plan, the Urgent Action Plan has paid special attention on medical aid for Crimeans temporarily relocated to the Ukrainian mainland, but not for the internally displaced persons (IDPs) from Crimea. As current statistic shows, no more than only 40 thousands of such IDPs were registered in all regions of the government-controlled territory of Ukraine and, according to the reports of Mission of the President in ARC there was less than 35 thousands of IDPs in June, 2018 and part of such persons after getting the IDP certificate has returned to Crimea. Moreover, less than one hundred IDP families from Crimea resides in the compact residing camps and the epidemiologic and sanitary situation for almost all the Crimean IDPs are the same as for general residents. In general, IDPs have no discrimination in achieving of medical aid in regions of their temporal settlement while do not have special preferences in hospitals and policlinics. About 10 thousand of IDPs only are registered as patients of Ukrainian mainland medical institutions, and only 4 thousand of them get special medic aid in 2014-2018 [7]. At the same time more than one million persons cross the administrative border between Crimea and mainland every year and major part of them are Crimeans, temporarily visiting the controlled territory [8]. It shows that the strategy of Ukrainian government for providing healthcare mechanisms for Crimeans is well-planned but not properly realized. So, now we could admit that main problems of healthcare and medical aid for Crimeans could be determined (and it was done in this original research) with perspectives of elaborating of the adequate support mechanisms on Ukrainian national level and within international structures.

CONCLUSIONS

Modern attempts of Ukraine to provide the special mechanisms of medical aid for Crimeans did not lead to certain positive result. International organizations with the relevant mandate must pay more attention to the healthcare issues of the Crimeans, such circumstances should be monitored by the UN and OSCE missions and be covered by the ICRC mission in Kyiv. Ukrainian healthcare reform must consider the needs for medical aid of Crimeans that temporarily relocated from peninsula.

REFERENCES

1. UN General Assembly Resolution 71/205. Situation of human rights in the Autonomous Republic of Crimea and the city of Sevastopol (Ukraine) Available from: https://mfa.gov.ua/mediafiles/sites/vienna/files/N1645574.pdf [reviewed 2019.08.15]
2. UN General Assembly Resolution 72/190. Situation of human rights in the Autonomous Republic of Crimea and the city of Sevastopol, Ukraine Available from: http://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/72/190 [reviewed 2019.08.15]

3. European Parliament resolution on the Ukrainian prisoners in Russia and the situation in Crimea (16 March 2017, 2017/2596(RSP)) Available from: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2017-0087+0+DOC+XML+V0//EN [reviewed 2019.08.15]
4. Pro zvilnennya B. Babina z posady Postiynoho Predstavnyka Presidenta Ukrainy v ARC : Ukaz Prezidenta Ukrainy [On Dismissing B. Babin from Post of the Permanent Representative of the President of Ukraine in the ARC, Decree of President of Ukraine] № 405/2018 02.12.2018 r., Available from: https://zakon.rada.gov.ua/laws/show/405/2018 [reviewed 2019.08.15] (Ua)
5. Analitychno-informatziyna dovidka shchodo struktury organiv okupatziynoi vlady v Krymu ta organiv derzhavnoi vlady Ukrainy z pytan Krymu [Analytical-informational Review on Structure the Occupier Power Bodies in Crimea and Ukrainian State Bodies for Crimea] Mission of the President of Ukraine in ARC, 2018 Available from: http://www.ppu.gov.ua/13727-2/analitychno-informatsijna-dovidka-shhodo-struktury-organiv-okupatsijnoyi-vlady-v-krymu-ta-organiv-derzhavnoyi-vlady-ukrayiny-z-pytan-krymu/ [reviewed 2019.08.15] (Ua)
6. Analitychno-informatziyna dovidka shchodo stanu okhorony zdorovya na tymchasovo okupovaniy teritoriyi Ukrainy v Krymu [Analytical-informational Review on Level of Health Care on the Ukrainian Temporarily Occupied Territory in Crimea] Mission of the President of Ukraine in ARC, 2018 Available from: http://www.ppu.gov.ua/13727-2/analitychno-informatsijna-dovidka-shhodo-stanu-ohorony-zdorovya-na-tymchasovo-okupovanij-terytoriyi-ukrayiny-v-krymu/ [reviewed 2019.08.15] (Ua)
7. Analitychno-informatziyna dovidka shchodo sytuatziyi iz dotrymannyam prav shchodo sotsialnogo zakhystu vnustishnyo peremishchenykh osib ta osib shcho prybuvayut z tymshasovo okupovanoho Krymu [Analytical-informational Review on Situation of Providing the Rights for Social Care of the Internally Displaced Persons and Persons, Coming from the Temporarily Occupied Crimea] Mission of the President of Ukraine in ARC, 2018 Available from: http://www.ppu.gov.ua/13727-2/analitychno-informatsijna-dovidka-shhodo-sytuatsiyi-z-dotrymannya-prav-sotsialnogo-zahystu-vutrishno-peremishhenyh-osib-ta-osib-yaki-prybuvayut-z-tymchasovo-okupovanogo-krymu/ [reviewed 2019.08.15] (Ua)
8. Zvit pro rezultaty diyalnosti Predsavnytztva Prezidenta Ukrainy v ARC [Report on the Mission of the President of Ukraine in ARC activities in 2018] Mission of the President of Ukraine in ARC, 2018 Available from: http://www.ppu.gov.ua/zvity-pro-rezultaty-diyalnosti-predstavnytstva/zvit-pro-rezultaty-diyalnosti-predstavnytstva-prezydenta-ukrayiny-v-avtonomnij-respublitsi-krym-za-2018-rik/ [reviewed 2019.08.15] (Ua)
9. Babin B., Grinenko O., Prykhodko A. Legal Statute and Perspectives for Indigenous Peoples in Ukraine. In: Indigenous, Aboriginal, Fugitive and Ethnic Groups Around the Globe. London: IntechOpen; 2019:1-18. doi: 10.5772/intechopen.85560
10. Babin B. Rights and Dignity of Indigenous Peoples of Ukraine in Revolutionary Conditions and Foreign Occupation. Evolution of the Statute of the Indigenous Peoples of Ukraine, as Legal Grounding for Crime. Anthropology & Archeology of Eurasia. 2014;53(3):81-115. doi: 10.1080/10611959.2014.1024080
11. Czapliński W., Dębski S., Tarnogórski R., et al. The Case of Crimea's Annexation under International Law. Warsaw: Scholar Publishing House; 2017, 355 p.
12. Geiß R. Russia's Annexation of Crimea: The Mills of International Law Grind Slowly but They Do Grind. International Law Studies. 2015;91(425):325-349.
13. Grant. T. D. Aggression Against Ukraine: Territory, Responsibility, and International Law. London: Palgrave Macmillan; 2015, 283 p.
14. Marxsen C. The Crimea Crisis. An International Law Perspective. Kyiv-Mohyla Law and Politics Journal. 2016;2:13-36.
15. Sayapin S., Hendel N., Tsybulenko E. et al. The Use of Force against Ukraine and International Law. Jus Ad Bellum, Jus In Bello, Jus Post Bellum. Hague: Asser Press, 2018, 470 p.
16. Pro zatverdzhennya planu zakhodiv, spryamovanykh na realizatsiyu deyakykh zasad derzhavnoyi vnurtishnyoi polityky shchodo tymchasovo okupovanoi teritoriyi Avtonomnoi Respubliky Krym ta m. Sevastopolya : rozporyadzhennya Kabinetu Ministriv Ukrainy [On Adoption the Action Plan for Realisation Some Grounds of the State Internal Policy for the Temporarily Occupied Territory of ARC and Sevastopol: Prescript of Cabinet of Ministers of Ukraine] № 218-p on 28th of March, 2018 r. Available from: https://zakon.rada.gov.ua/laws/show/218-2018-p [reviewed 2019.08.15] (Ua)
17. Pro zatverdzhennya planu nevidkladnykh zakhodiv z protydiyi rosiyskyi ahresiyi z tymchasovo okupovanoi teritoriyi Ukrainy v Krymu, zakhystu interesiv derzhavy, hromadyan Ukrainy ta ukrainskykh yurydychnykh osib v Krymu ta yoho spryamuvannya : rozporyadzhennya Postiynoho Predstavnyka Prezydenta Ukrainy v Avtonomniy Respublitzi Krym [On Adoption the Urgent Action Plan of Counteraction the Russian Aggression from the Temporarily Occupied Territory of Ukraine in Crimea, of Defence the State, Ukrainian Citizens' and Ukrainian Legal Entities' Interests in Crimea for 2018-2019 and Its Transfer] № 17 20.06.2018 r. Available from: https://zakon.rada.gov.ua/rada/show/v0017755-18 [reviewed 2019.08.15] (Ua)

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ORIGINAL ARTICLE
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EUROPEAN STANDARDS OF RESPECT FOR HUMAN RIGHTS IN THE APPLICATION OF COMPULSORY MEDICAL MEASURES IN CRIMINAL PROCEEDINGS

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ABSTRACT

Introduction: The article is devoted to the research of topical issues of ensuring the rights of persons suffering from mental disorders and who are subject to criminal proceedings on the application of compulsory medical measures (hereinafter – CMM). The research was conducted in the context of international standards and interpretative practice of the European Court of Human Rights (hereinafter referred to as the ECHR or the Court).

The aim: The aim of this study is to analyze international acts concerning the protection of the rights of mentally ill persons when applying compulsory medical measures; to highlight and analyze the ECHR's key positions in the context of respect for the right to liberty and security of person (Article 5 § 1 (e) of the European Convention on Human Rights (hereinafter referred to as the Convention)) and the right to a fair trial (Article 6 of the Convention) in criminal proceedings concerning the use of CMM; to analyse the law enforcement practice and activities of psychiatrist experts on compliance with European standards for the protection of the rights of persons with mental disorders who are subject to criminal proceedings.

Materials and methods: rescent scientific researches; provisions of international legal acts in the field of psychiatric care; the legal standpoint of the ECHR in respecting the rights of persons with mental disorders (15 decisions were analyzed in which the ECHR addressed these issues in the context of the requirements of Articles 5 and 6 of the Convention); criminal procedural legislation of foreign states (Belarus, Kazakhstan, Moldova, Russian Federation, Estonia, Uzbekistan, Germany); the results of the survey of 20 psychiatrists and experts conducted by the authors were used in this article

To achieve this aim of research process a set of general scientific and special methods of cognition, including comparative and legal method, system and structural method, method of generalization, method of analysis and synthesis, method of sociological research, method of expert evaluation, etc. bein used.

Results: summarized and generalized ECHR's standpoints concerning: a) minimum conditions without which a person cannot be considered as "mentally ill" and imprisoned; b) the aspects taken into account by the ECHR within each minimum condition in the context of ensuring the right to liberty and security of person (Article 5 § 1 (e) of the Convention); c) the peculiarities of the personal participation of an individual with a mental disorder in the judicial review of the application of CMM in terms of observing its right to a fair trial (Article 6 of the Convention). The degree of extrapolation of these standpoints to the activity of psychiatrists was identified and analyzed.

Conclusions: the current practice of applying CMM in criminal proceedings does not fully comply with the international standards and legal positions of the ECHR in terms of providing a person with a mental disorder the right to liberty and security of person and the right to a fair trial (in particular, the minimum conditions without which a person cannot be considered as "mentally ill" and be imprisoned are not always met).

KEY WORDS: criminal proceedings, ECHR practice, compulsory medical measures, psychiatric care, psychiatric examination

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INTRODUCTION

In today's realities, most countries of the world are concerned about the global problem of deteriorating peoples' mental health. According to the World Health Organization, about 15% of the world's population (450 million people) suffer from mental disorders and need psychiatric help [1, p. 12]. Recently, there has been an increase in the number of socially dangerous acts committed by such persons, which makes it necessary to apply CMM to them. The legal and factual situation of such individuals is dualistic: they require not only additional procedural guarantees to implement the protection function in criminal proceedings, but also the creation of adequate conditions by the state for obtaining qualified psychiatric care. Today, the specific nature of its granting is often bordered on violations of human rights guaranteed by the Convention. Although the normative approach to the provision of psychiatric care in the context of the rights, freedoms and legitimate interests of persons with mental disorders is substantively changed, the issue of respect for their right to liberty and security of person and the right to a fair trial (Article 6 of the Convention) remain relevant (Article 5 § 1 (e) of the Convention). However, it is well-established practice of the ECHR to find systematic violations of these rights of persons, which determines the relevance of the issue.

THE AIM

The aim of this study is to analyze international acts concerning the protection of the rights of mentally ill persons

when applying compulsory medical measures; to highlight and analyze the ECHR's key positions in the context of respect for the right to liberty and security of person (Article 5 § 1 (e) of the European Convention on Human Rights (hereinafter referred to as the Convention)) and the right to a fair trial (Article 6 of the Convention) in criminal proceedings concerning the use of CMM; to analyse the law enforcement practice and activities of psychiatrist experts on compliance with European standards for the protection of the rights of persons with mental disorders who are subject to criminal proceedings.

MATERIALS AND METHODS

Rescent scientific researches; provisions of international normative acts in the field of psychiatric care; the legal position of the ECHR in respecting the rights of persons with mental disorders (15 decisions were analyzed in which the ECHR addressed these issues in the context of the requirements of Articles 5 and 6 of the Convention); criminal procedural legislation of foreign states (Belarus, Kazakhstan, Moldova, Russian Federation, Estonia, Uzbekistan, Germany); the results of the survey of 20 psychiatrists and experts conducted by the authors bein used.

To achieve this aim in the research process a set of general scientific and special methods of cognition, including comparative and legal method, system and structural method, method of generalization, method of analysis and synthesis, method of sociological research, method of expert evaluation, etc. was used.

RESULTS

The current model of legal regulation of proceedings for the application of CMM, being a specific form of criminal procedural activity, is based on international standards and case law of the ECHR. The peculiarities of judicial proceedings against persons with mental disorders and the principles of their compulsory treatment are embodied at the level of international legal acts, such as: Convention on Human Rights and Biomedicine of 4 April 1997; United Nations General Assembly Resolution on Principles of the Protection of Persons with Mental Illness and the Improvement of Mental Health Care, No. 46/119 of 18 February 1992; Recommendation of the Committee of Ministers to the member states concerning the legal protection of persons suffering from a mental disorder placed as involuntary patients, No. R(83)2 of 22 February 1983; Recommendation No. 1235 on Psychiatry and Human Rights of 1 January 1994; Recommendation 818 on the Situation of Mental Illness of 08 October 1977, etc.

The right of the person suffering from a mental disorder, liberty and security of person (Article 5 § 1 (e) of the Convention): key ECHR positions. Case law of the ECHR emphasizes that a person cannot be considered "mentally ill" and be deprived of his or her liberty unless three minimum conditions are met[1]: 1) the presence of a mental disorder requires objective medical examination; 2) the mental disorder must be of such a nature or degree as to cause the compulsory detention of a person in a psychiatric hospital; 3) the need for long-term detention in a psychiatric hospital depends on the persistence of such a disease.

The analysis and generalization of the case-law allows us to identify certain aspects of the ECHR's consideration of each minimum condition when resolving the issue of violations of the individual's right to liberty and security, provided by Art. 5 § 1 (e) of the Convention.

Minimum Condition 1. The presence of mental disorder requires objective medical examination. The main mechanism for verifying the mental state for the purposes of criminal justice is the compulsory psychiatric examination. The ECHR has repeatedly emphasized that deprivation of liberty of a person who is considered to be mentally ill cannot be considered as meeting the requirements of Art. 5 § 1 (e) if the decision on such deprivation was made without the opinion of a medical expert. Resolving the issue of compliance with this condition, the ECHR considers such aspects as: a) compliance with the International Statistical Classification of Diseases and Related Health Problems diagnosis; b) confirmation of the diagnosis by several independent specialists in the field of psychiatry; c) relevance of the expert's opinion on the mental state of the person at the time of the proceedings.

Compliance with the International Statistical Classification of Diseases and Related Health Problems diagnosis. Today, there is a global problem in the diagnosis of mental disorders. At international level, in particular the United Nations General Assembly Resolution on Principles for the Protection of Persons with Mental Illness and Improvement of Mental Care, No. 46/119 of 18 February 1992, diagnosis of a person suffering from a mental illness is made in accordance with internationally recognized medical standards (Principle 4) [5]. A statutory document that is used as a leading statistical and qualification framework in health care system and ensures the uniformity of methodological approaches and international verification of materials is the International Statistical Classification of Diseases and Related Health Problems. That is, when determining a mental illness, the diagnosis must meet its diagnostic criteria[2]. However, in some cases that were the subject of the ECHR, expert's opinion was based on an inaccurate diagnosis. Thus, in Case of Anatoliy Rudenko v. Ukraine in the course of psychiatric examinations, the applicant was diagnosed with a paranoid personality disorder. The ECHR noted that such a diagnosis could not be considered valid because it did not meet the diagnostic criteria of the International Statistical Classification of Diseases and Related Health Problems (para. 50) [6]. The inaccuracy of the diagnosis was also criticized in Case of Raudevs v. Latvia, in which the Court noted that taking

[1] See at: Case of Winterwerp v. the Netherlands, para. 39 [2]; Case of Hutchison Reid v. The United Kingdom, para. 48 [3]; Case of Zaichenko v. Ukraine, para. 73 [4], etc.
[2] This position is supported by 68% of the psychiatrists surveyed by us.

note of the experts' report that the applicant had "delusional plans" in relation to unidentified State officials, the applicant was by a final decision in January 2003 ordered to undergo compulsory inpatient medical treatment under guard. The Court points to the vague reasoning provided by the medical experts and national courts in connection with such a radical measure (para. 71) [7].

Confirmation of diagnosis by several independent specialists in the field of psychiatry. The ECHR gives particular importance to the independent psychiatry specialists' opinion on the mental health of individual. Certainly, the opinion of experts from one institution is dangerous in terms of the possible manifestation of their bias[3]. Thus, in Case of Anatoliy Rudenko v. Ukraine the ECHR has critically noted that all forensic psychiatric examinations, which referred to the need of CMM applying, were drawn up by specialists of the same hospital, without any other independent opinion (para. 113) [6].

The relevance (degree of limitation) of the expert's opinion on the mental state of the person at the time of the proceedings. In criminal proceedings concerning the use of CMM, the expert's opinion is the evidence on the basis of which the issue of the CMM application to the person is resolved. As the expert's opinion determines the depth of the mental disorder, which affects the ability to understand or realize the meaning of their actions and the ability to manage them, the law enforcers are interested in the medical aspect at first. However, it should be noted that psychiatric illnesses can be characterized by periods of exacerbation as well as periods of remission, so it is important to be guided by the expert's opinion regarding the mental state of the person at the time of the case when deciding whether to use CMM. For example, in Case of Yaikov v. Russia, the ECHR drew attention to the fact that the applicant was admitted to the hospital in January 2006 on the basis of the medical report dating back to July 2004, that is approximately a year and six months gap (para. 64). Thus, having regard to the obsolescence of the medical report on the basis of which the applicant was confined to the mental hospital, the lack of safeguards under the domestic law requiring a review of the medical necessity of compulsory medical measures before its execution and the delays in the execution of the applicant's transfer at the material time, the Court finds that the applicant's detention was carried out contrary to the principle established under Article 5 § 1 (e) that the existence of a mental illness warranting confinement in a hospital must be established at the time of its implementation. There has accordingly been a violation of Article 5 § 1 (e) of the Convention (paras. 64-67) [8].[4]

Minimum Condition 2. Mental disorder should be of a nature or degree that causes a compulsory detention of a person in a psychiatric hospital. Addressing the issue of its compliance, the ECHR considers such aspects as: a) the nature or degree of mental disorder necessitates the need for medical supervision of a person in order to prevent him or her from committing acts that directly threaten him or her or others; b) compulsory detention in a hospital, clinic or other appropriate institution authorized to detain such persons.

The nature or degree of mental disorder necessitates the need for medical supervision of a person in order to prevent him or her from committing acts that directly threaten him or her or others. In this aspect, the ECHR in Case of Hutchison Reid v. the United Kingdom noted that the confinement of a mentally ill person may be necessary not only where such a person needs therapy, medication or other clinical treatment to cure or alleviate his condition, but also where the person needs control and supervision to prevent him, for example, causing harm to himself or other persons (para. 52) [3].

Compulsory detention in a hospital, clinic or other appropriate institution authorized to detain such persons (see at: Case of L.B. v. Belgium (para. 93)) [9]; Case of O.H. v. Germany (para. 79) [10]). The Committee of Ministers of the Council of Europe in Art. 1 of Recommendation concerning the legal protection of persons suffering from mental disorder placed as involuntary patients, No. R(83)2 of 22 February 1983 stated that compulsory detention means hospitalization and detention for the treatment of a person with a mental disorder in hospital, other medical institution or appropriate place; such detention is not voluntary by the patient [11]. Considering this aspect in paragraph 78 of the Case of Proshkin v. Russia, the ECHR noted that prior to the applicant's referral to a psychiatric hospital, he was held in a cell for the mentally ill in a pre-trial detention center. Authorities did not explain the difference between the conditions of detention in a cell for the mentally ill and a regular detention cell. In addition, they did not claim that the applicant had received ongoing medical care or that his conditions of detention had created a setting for therapeutic treatment. The court recognized the applicant's detention cell as an institution that was not appropriate for the detention of mentally ill persons [12]. However, the ECHR recognizes that a person may be temporarily placed in an institution not intended for patients with mental disorders before being transferred to a proper institution, provided that his stay is not too long (see at: Case of Pankiewicz v. Poland (paras.44-45) [13]; Case of Brand v. the Netherlands (paras. 64-66) [14]. At the same time, the Court notes that a significant delay in the admission to a psychiatric hospital is due to the delay in starting treatment, which may affect the outcome of treatment in the future. In particular, in paragraph 79 of Case of Proshkin v. Russia the ECHR declared an inadmissible six-month delay

[3] More than 65% of psychiatrists surveyed by us have justified the requirement to confirm the diagnosis by several independent experts.

[4] Absolutely all (100%) of the psychiatrists surveyed by us agreed that when applying CMM, judges should be guided by the expert's opinion regarding the mental state of the person, relevant at the time of the trial. At the same time, the respondents' positions regarding how long the expert's opinion on the mental state of a person retains their relevance were divided as follows: within one month – 58%; within 6 months – 15%. Responses also included variants: «3-4 months», «depending on the situation».

[5] 100% of psychiatrists surveyed by us indicate that the untimely start of treatment for a mental disorder may affect the results of treatment in the future.

in the placement of a person in a psychiatric hospital in the absence of emergency [12].[5]

Minimum Condition 3. The need for prolonged stay in a psychiatric hospital depends on the persistence of such a disease. The ECHR considers such aspects as: a) determining the need to prolong compulsory hospitalization on the basis of current medical findings, taking into account the patient's current condition and the threat to him/her of his/her dangerous behavior to others; b) carring out a judicial review of the reasonableness of a person's stay in a psychiatric care facility with the assurance of his/her right to such review on his/her own initiative.

Determining the need to prolong compulsory hospitalization on the basis of current medical findings, taking into account the patient's current condition and the threat to him/her of his/her dangerous behavior to others. In this aspect in Case of Gajcsi v. Hungary, the ECHR noted that the relevant domestic law emphasises the prerequisite of dangerousness in order to justify compulsory hospitalisation and treatment. However, it finds that the domestic court decisions in the present case were devoid of any assessment of the applicant's alleged or potential "dangerous conduct". In these circumstances, the Court considers that the prolongation of the applicant's compulsory treatment was not prescribed by law. There has accordingly been a violation of Article 5 § 1 of the Convention (para. 21) [15].

Carrying out a judicial review of the reasonableness of a person's stay in a psychiatric care facility with the assurance of his/her right to such review on his/her own initiative. In this aspect, the Court reiterated that the key guarantee under para. 4 of art. 5 of the Convention is that a person forcibly detained in a psychiatric institution should have the right to a judicial review at his/her own will (see at: para. 44 of Case of Gorshkov v. Ukraine [16]; para. 43 of Musial v. Poland [17], etc.). In doing so, the ECHR noted that para. 4 of Art. 5 of the Convention requires, first and foremost, the existence of an independent remedy whereby the detained person is able to appear before a judge who will determine the legality of the prolonged detention. The access of the detained person to a court should not depend on the goodwill of the administration of the detention facility and to be used at the discretion of the management of the medical facility [16].

The right of a person suffering from a mental disorder to a fair trial (Article 6 of the Convention): key ECHR positions. Nowadays the issue of personal involvement of a person with a mental disorder in litigation regarding the use of CMM is relevant. Procedural safeguards and forms of exercise by such persons of the right to personal participation in a trial are provided at the international standards level. Thus, the Convention enshrines the right to a fair trial, a necessary element of which is guaranteed by law the possibility of the accused's personal involvement in the trial (Art. 6). United Nations General Assembly Resolution on Principles of the Protection of Persons with Mental Illness and the Improvement of Mental Health Care No. 46/119 of 18 February 1992 stipulates that the patient, personal representative and patient advocate must be entitled to be present, to participate and be heard in person at any hearing (paragraph 5 of principle 18) [5]. At the present stage, the criminal procedural law of many countries provides for the possibility of restricting the right of a person suffering from a mental disorder to participate in judicial proceedings based on the findings of a forensic psychiatric examination on the nature and degree of his or her illness (the Criminal Procedure Code of the Russian Federation (Art. 441); the CPC of Belarus (Art. 445); the CPC of Kazakhstan (Art. 511); the CPC of Moldova (Art. 496); the CPC of Estonia (Art. 400), the CPC of Uzbekistan (Art. 570)) and others. In this regard, another approach is demonstrated by the CPC of Germany, under §415, which provides for the possibility of such a trial without the person of the accused if his/her appearance is impossible due to his/her condition or impractical for reasons of public security or order. However, such deviation from international standards is, in essence, is offset by the rule of mandatory interrogation of the person by the court with the participation of an expert. Interestingly, the participation of a defense lawyer and legal representative during such an interrogation is optional.

If, on the whole, the legislative approaches of these states link the possibility of personal participation in judicial proceedings with the determination of the nature and degree of mental disorder, then the Ukrainian legislator made this point quite explicitly in Art. 512 of the CPC; judicial review is carried out with the obligatory participation of the person, to whom the application of CMM is addressed, his/her legal representative and defense counsel. Perhaps the position of the Ukrainian legislator is too radical, however, the importance of ensuring the direct participation in the trial of a person suffering from a mental illness is due to at least two factors. Firstly, following the principle of immediacy, the court, at the time of trial in the process of visual perception and verbal communication, has the opportunity to assess the mental state of such a person and to make a reasoned decision on the use of adequate CMM. Secondly, a person suffering from a mental disorder gets the opportunity to stand trial, to exercise his or her right to a defense, which is part of a fair trial.[6]

ECHR case law has formed the following approaches to the personal involvement of a person with a mental disorder in the proceedings.

1. *A person suffering from a mental disorder should have access to court and be heard in person or through any form of representation.* In general, the ECHR's position is dominated by the thesis that mental illness may be the cause of the restriction or modification of the way this right is exercised, but cannot justify a violation of the very substance of its exercise. Therefore, it may be necessary to apply special procedural safeguards to protect the interests of persons who, because of their mental disability, are unable to exercise them on their own (Case of Winterwerp v. The

[6] 73% of psychiatrists surveyed by us indicated the feasibility of participation in the proceedings of the person under the question of CMM application.

Netherlands, para. 60) [2]. However, the ECHR has often stated that the presence of a defense lawyer and legal representative could not compensate for the applicant's lack of opportunity to make his/her own case at trial (Case of Proshkin v. Russia, para. 104) [12].

2. *In the presence of contradictory findings of the examination concerning the mental state of a person, the latter's participation in the proceedings is of particular importance.* Thus, in Case of Anatoliy Rudenko v. Ukraine experts did not provide any explanation as to why the applicant's mental state was considered to prevent him from effectively participating in the court hearings. The Court stated that despite the importance of the subject-matter of the dispute to the applicant he was not personally heard or given the opportunity to comment on the expert's findings at the hearing at which the applicant was held in a mental institution (para. 114) [6]. Also, in Case of Romanov v. Russia the Court noted that the findings of psychiatrists were identical in diagnosis, but differed in the choice of measures to be applied to the applicant: outpatient treatment or confinement in a psychiatric hospital. The ECHR emphasized that such a discrepancy is of particular importance to the issue of the applicant's participation in the hearing. The district court could not have ruled without directly assessing the applicant's testimony, and the presence of the applicant's lawyer could not compensate for his absence (paras. 111-112) [18].
3. *If the trial involves an assessment of the person, his or her character and state of mind at the time of commiting a crime, and if its result can have significant negative consequences for such a person, his/her presence during the hearing and the opportunity to participate in the trial along with his/her lawyer is required* (See at: para. 101 of Case of Proshkin v. Russia) [12]. As a special procedure for criminal proceedings, a trial on the application of CMM is associated with an assessment of all the circumstances. However, the ECHR does not explicitly make such person obligatory in such proceedings, insisting only on the need for his/her presence.

DISCUSSION

The application of CMM is a complex institution, the subject of which has already been the subject of scientific debate in both criminal and medical aspects. Important theoretical and practical problems of CMM application have been revealed in scientific studies by A. Ya. Bersh [19], S.L. Sharenko [20], M.Ye. Shumyla, H.K. Teteriatnyk [21]. Some aspects of diagnostics complexity of mental illnesses are considered in the article of Igor I. Mytrofanov, Igor V. Lysenko, Mykola M. Ryabushko [22]. The peculiarities of the use of medical knowledge in the investigation of crimes, in particular, in the conduct of forensic psychiatric examination, were discovered by Victoriia O. Yaremchuk [23]. Issues related to the protection of the rights of mentally ill children in the context of the ECHR practice are illustrated in the study of Vitaliy Pashkov, Andrii Olefir [24]. At the same time, the review of the abovementioned papers makes it possible to state that nowadays a number of issues related to ensuring the rights of individuals in criminal proceedings regarding the application of CMM remain debatable. In particular, the question of the use of compulsory hospitalization in the aspect of the legitimacy of the individuals' rights restrictions requires further scientific research. In this research, the ECHR's standpoint in the context of ensuring the rights of persons with mental disorders is highlighted, but at the present stage it is necessary to understand the conformity of law enforcement practice with the precedent practice and international standards in general.

CONCLUSIONS

1. In the case law of the ECHR three minimum conditions without which a person cannot be considered as "mentally ill" and be deprived of his or her liberty are clearly set out: 1) the presence of a mental disorder requires objective medical examination; 2) the mental disorder must be of such a nature or degree as to cause the compulsory detention of a person in a psychiatric hospital; 3) the need for long-term detention in a psychiatric hospital depends on the persistence of such a disease.
2. Considering the issue of ensuring the right of the person suffering from a mental disorder, freedom and personal integrity in the context of the requirements of Art. 5 § 1 (e) of the Convention, the ECHR takes into account certain aspects in each minimum condition.

Minimum Condition 1. The presence of mental disorder requires objective medical examination. The ECHR considers such aspects as: a) compliance with the International Statistical Classification of Diseases and Related Health Problems diagnosis; b) confirmation of the diagnosis by several independent specialists in the field of psychiatry; c) relevance of the expert's opinion on the mental state of the person at the time of the proceedings.

Minimum Condition 2. Mental disorder should be of a nature or degree that causes a compulsory detention of a person in a psychiatric hospital. The ECHR considers such aspects as: a) the nature or degree of mental disorder necessitates the need for medical supervision of a person in order to prevent him or her from committing acts that directly threaten him or her or others; b) compulsory detention in a hospital, clinic or other appropriate institution authorized to detain such persons.

Minimum Condition 3. The need for prolonged stay in a psychiatric hospital depends on the persistence of such a disease. The ECHR considers such aspects as: a) determining the need to prolong compulsory hospitalization on the basis of current medical findings, taking into account the patient's current condition and the threat to him/her of his/her dangerous behavior to others; b) carring out a judicial review of the reasonableness of a person's stay in a psychiatric care facility with the assurance of his/her right to such review on his/her own initiative.

3. ECHR case law has formulated certain approaches to the personal involvement of a person with a mental disorder in judicial review in the context of respect for his/her right

to a fair trial: (a) a person suffering from a mental disorder should have access to court and be heard in person or through any form of representation; (b) in case of contradictory findings of the examination concerning the mental state of a person, the latter's participation in the proceedings is of particular importance; (c) if the trial involves an assessment of the person, his/her character and state of mind at the time of commiting a crime, and if the result could have significant negative consequences for such a person, his/her presence during the hearing and the opportunity to participate in the trial along with his/her lawyer is required.

REFERENCES

1. Shafranskyi V. V., Dudnyk S. V. Psykhichne zdorovia naselennia Ukrainy: stan, problemy ta shliakhy vyrishennia [Mental health of the Ukrainian population: status, problems and solutions]. Ukraine. Healthy nation. 2016; 3(39):12-18. (Ua).
2. Case of Winterwerp v. the Netherlands, application no. 6301/73, judgment of 24 October 1979. Available from: http://hudoc.echr.coe.int/eng?i=001-57597 [reviewed 2019.08.15]
3. Case of Hutchison Reid v. the United Kingdom, application no. 50272/99, judgment of 20 February 2003 Available from: http://hudoc.echr.coe.int/eng?i=001-60954 [reviewed 2019.08.15]
4. Case of Zaichenko v. Ukraine (№ 2), Application no. 45797/09, judgment of 26 February 2015 Available from: http://hudoc.echr.coe.int/eng?i=001-192503 [reviewed 2019.08.15]
5. Rezoliutsiia Heneralnoi Asamblei Orhanizatsii Obiednanykh Natsii "Pryntsypy zakhystu osib z psykhichnymy zakhvoriuvanniamy ta polipshennia psykhiatrychnoi dopomohy" [United Nations General Assembly Resolution on Principles of the Protection of Persons with Mental Illness and the Improvement of Mental Health Care]. 46/119 of 18 February 1992 Available from: https://zakon.rada.gov.ua/laws/show/995_905 [reviewed 2019.08.15] (Ua).
6. Case of Anatoliy Rudenko v. Ukraine, application no. 50264/08, judgment of 17 April 2014 Available from: http://hudoc.echr.coe.int/eng?i=001-171853 [reviewed 2019.08.15]
7. Case of Raudevs v. Latvia, application no. 24086/03, judgment of 17 December 2013 Available from: http://hudoc.echr.coe.int/eng?i=001-139268 [reviewed 2019.08.15]
8. Case of Yaikov v. Russia, application no. 39317/05, judgment of 18 June 2015 Available from: http://hudoc.echr.coe.int/eng?i=001-155193 [reviewed 2019.08.15]
9. Case of L.B. v. Belgium, application no. 22831/08, judgment of 2 October 2012 Available from: http://hudoc.echr.coe.int/eng?i=001-113295 [reviewed 2019.08.15]
10. Case of O.H. v. Germany, application no. 4646/08, judgment of 24 November 2011 Available from: http://hudoc.echr.coe.int/eng?i=001-107556 [reviewed 2019.08.15]
11. Rekomendatsiia Komitetu ministriv derzhavam-uchasnytsiam stosovno pravovoho zakhystu osib, yaki strazhdaiut na psykhichni rozlady, shcho prymusovo utrymuiutsia yak patsiienty [Recommendation of the Committee of Ministers to the member states concerning the legal protection of persons suffering from mental disorder placed as involuntary patients]. R(83)2 of 22 February 1983 Available from: https://zakon.rada.gov.ua/laws/show/994_074 [reviewed 2019.08.15] (Ua)
12. Case of Proshkin v. Russia, application no. 28869/03, judgment of 7 February 2012 Available from: ttp://hudoc.echr.coe.int/eng?i=001-108961 [reviewed 2019.08.15]
13. Case of Pankiewicz v. Poland, application no. 34151/04, judgment of 12 February 2008 Available from: http://hudoc.echr.coe.int/eng?i=001-85004 [reviewed 2019.08.15]
14. Case of Brand v. the Netherlands, application no. 48865 49902/99 judgment of 11 May 2004 Available from: http://www.bailii.org/eu/cases/ECHR/2004/196.html [reviewed 2019.08.15]
15. Case of Gajcsi v. Hungary, application no. 34503/03 judgment of 3 October 2006 Available from: http://hudoc.echr.coe.int/eng?i=001-77036 [reviewed 2019.08.15]
16. Case of Gorshkov v. Ukraine, application no. 67531/01 judgment of 8 November 2005 Available from: http://hudoc.echr.coe.int/eng?i=001-70855 [reviewed 2019.08.15]
17. Case of Musial v. Poland, application no. 24557/94, judgment of 25 March 1999 Available from: http://hudoc.echr.coe.int/eng?i=001-58225 [reviewed 2019.08.15]
18. Case of Romanov v. Russia, application no. 63993/00, judgment of 20 October 2005 Available from: http://hudoc.echr.coe.int/eng?i=001-70685 [reviewed 2019.08.15]
19. Bersh A. Ya. Prymusovi zakhody medychnoho kharakteru: pravova pryroda ta vydy [Compulsory medical measures: legal nature and types]. Odesa: 2017; 188. (Ua)
20. Sharenko S. L. Kryminalno-protsesualni problemy zastosuvannia PZMKh [Criminal procedural problems of CMM application]. Kharkiv: 2002; 208. (Ua)
21. Shumylo M. Ye., Teteriatnyk H. K. Okhorona prav i zakonnykh interesiv osoby, shchodo yakoi zdiisniuietsia provadzhennia iz zastosuvannia PZMKh, na stadii dosudovoho rozsliduvannia [Protecting the rights and legitimate interests of the person subject to the CMM application proceedings at the pre-trial stage]. Donetsk: 2012; 214. (Ua)
22. Mytrofanov II, Lysenko IV, Ryabushko MM. Mental illness as a consequence of criminal offence against the person. Wiad Lek. 2019;72(5)I:862-867.
23. Yaremchuk V. The use of medical knowledge in the crime investigation. Wiad Lek. 2019;72(1):103-106.
24. Pashkov V, Olefir A. Protection of children's rights in the health care: problems and legal issues. Wiad Lek. 2017;70(6)I:1122-1132.

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CHRONIC ALCOHOLISM TREATMENT IN CUSTODIAL FACILITIES: UKRAINE'S EXPERIENCE DURING INDEPENDENCE

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ABSTRACT

Introduction: Chronic alcoholism is a powerful catalyst for commission of many serious and particularly grave crimes - intentional homicide, bodily damage, robbery, plundering, traffic safety violations that led to fatalities. The vast majority of these offenders are sentenced to imprisonment. Although independent Ukraine refused their compulsory treatment, such experience, unfortunately, did not improve the situation. This will require finding new ways of solving the alcoholism problem that may be of interest to both post-Soviet countries and developed democracy countries.

The aim of this research is to trace the evolution of chronic alcoholism treatment in Ukrainian penitentiary institutions, identify the causes of its poor effectiveness under the current approach, and suggest some ways to minimize the negative impact of this disease on a patient and society.

Material and methods: The study is grounded in dialectical, historical, comparative, analytical, synthetic, statistical, monographic, sociological (interview) and criminological mapping research methods. The calculations and mapping were done using Microsoft Word 2016, Adobe Photoshop CS6 and Quick Map 2.2. According to the General Prosecutor's Office of Ukraine, criminal intensity of perpetrators of alcohol intoxication was calculated, and due to the analysis of medical and technological documentation on standardization of medical assistance to alcoholics, the peculiarities of voluntary treatment principle of convicted persons were established. The study group consists of 50 medical professionals working in the medical units of penitentiary and civilian healthcare facilities.

Results: According to 3/4 of the surveyed experts, about 50% of convicts need treatment for alcoholism. The factors that influence the increase in concentration of such persons in penitentiary institutions are: prevalence of alcoholism in the whole country; alcohol illegal use in penitentiary institutions; detaining of large mass of household alcoholics in penitentiary; exclusively voluntary treatment and medico-social rehabilitation; lack of alternative treatment methods for alcoholism and consolidation of the lasting effect of this treatment; etc. The consequences of the above are often further decay of alcohol; involvement in this pernicious habit of new unstable persons, especially young convicts; lack of qualified medical care, even in urgent cases that threaten person's life; genetic addiction of subsequent generations; relapse and recurrence of criminal behavior; etc.

Conclusions: There is a need for immediate monitoring of people with chronic alcoholism and alternative treatment modalities, such as substance abuse replacement therapy; allocation of material resources for implementation of specific measures aimed at reducing the alcoholism level of convicts; immediate receipt of licenses by medical units of penitentiary institutions that do not have them, etc.

KEY WORDS: alcoholism, alcohol addiction, prison, rehabilitation, treatment

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INTRODUCTION

The dangerous medical, social, moral and legal problem of our society was, and unfortunately is, the problem of alcohol addiction of large masses of the Ukrainian population. In terms of cultivation of negative traditions of almost daily alcohol consumption in the Ukrainian society there are a noticeable layer of population, for which alcohol became a habit, a norm of behavior, a constant of their existence. The danger of the abovementioned is compounded by the fact that such a model of leisure is becoming a powerful factor in attracting new individuals to alcohol addiction, hence the rapid spread of alcoholism [1, 35]. Therefore, it is no coincidence that Ukrainian narcologists state that if, in Ukraine, drug abused patients are potentially able to double their quantity almost every three years, then alcoholics - every two years [2]. Ukraine belongs to the countries of medium-high alcohol consumption (12 liters per year), ranking the fifth in the world in terms of alcohol consumption per capita [3, 8].

This could be a basis for assumption that today we have no progress in chronic alcoholism treatment in Ukraine, since alcoholism remains not only a background phenomenon of Ukrainians, but also a significant background of their unlawful acts, as well as an unresolved problem during confinement in penal institutions. By the way, the interconnection between a crime (especially violent) and an alcohol addiction is well known. Alcohol plays a role in 31 percent of homicides, but it is mentioned in only 2.6 percent of television reports, 7.3 percent of newspaper accounts, and 5.6 percent of magazine reports of violent crime, with even lower percentages in homicides reporting [4]. For example, in the United States drunk driving is the most common alcohol-related crime.

Each year, more than 1.1 million Americans are arrested for driving while intoxicated, and more than half of these arrests end with convictions [5]. Therefore, it is no coincidence that today there is a lot of scientific researches on analysis of interconnection between the alcohol addiction of a person and offenses' commission.

Certain achievements in this sphere have been accumulated in the articles of Fazel S. (2006), Rhem J. et al. (2009), Babor T. et al. (2010), MacAskill S. et al. (2011), Rhem J. et al. (2012), Graham L. et al. (2012), Skarupski K.A. (2018), Galbicsek C. (2019), Trangenstein, P.J. et al. (2019) and others. However, there has been no scientific research on alcoholism problem in penitentiary institutions of Ukraine. The problematics of detaining of convicted patients with chronic alcoholism is disclosed mainly by some foreign authors in their researches (Parkes T. et al., 2010, MacAskill S. et al., 2011, Carnie J. et al., 2011, Bernstein MH et al., (2015), Hussong, AM et al (2019)).

THE AIM

The purpose of the research is, at first – to analyze the evolution of approaches to combating alcohol addiction in penitentiary institutions, and secondly – to identify the causes of low effectiveness in overcoming or at least limiting of the alcoholism phenomenon in existing approaches to chronic alcoholism treatment; third – to develop propositions for minimizing of this disease's negative impact on the patient and the society as a whole.

MATERIALS AND METHODS

This study was conducted during 2018-2019 and is based on the results of the study of: 1) the Unified Register of Pre-trial Investigations and Information and Analytical Work of the Prosecutor General's Office of Ukraine and the State Judicial Administration of Ukraine; 2) UNODC analytical materials; 3) quantitative indicators characterizing the contingent of convicts; 4) interviewing of 50 healthcare professionals working in the medical units of penitentiary and civilian health care institutions; 5) intensities of crimes committed under the influence of intoxication, with visualization of this crime's criminological characteristic by means of geographical map, which performs an additional explanatory function in assessing the extent of alcoholism spread in the country; 6) medical-technological documentation on standardization of medical care in the system of the Ministry of Health of Ukraine, including for persons with chronic alcoholism, in particular, so-called standards of medical care (clinical protocols of providing medical care to patients with mental and behavioral disorders due to alcohol addiction, international treatment and diagnosis recommendations). The empirical and statistical data presented are summarized and analyzed using descriptive statistics tools. The research is based on the use of dialectical, historical, comparative, analytical, synthetic, statistical, monographic, sociological and criminological mapping research methods. The calculations and mapping were done using the Adobe Photoshop CS6, Microsoft Word 2016 and Quick Map 2.2 software applications.

RESULTS

According to the State Criminal Enforcement Service of Ukraine, as of July 1, 2019, there are 9 584 detainees in 17 pretrial detention facilities and 12 penitentiary facilities; there are 34 488 convicts in 113 penitentiary facilities; 114 convicts are in 6 juvenile correctional facility [6]. It is reported that of the total number of females serving sentences, patients with alcoholism or drug addiction are more than 30% of them, similar parameters are recorded among male [7, 259].

In recent years Ukraine has been experiencing a persistently negative drunk-crimes situation. Annually in our country 14-16% of persons are drunk when committing crimes [8; 9]. Often intoxication is accompanied by the commission of crimes of high public danger: 34% of crimes of medium gravity; 30% of grave and 5.5% of especially grave crimes. Among identified intoxicated offenders lucrative and lucrative-violent criminals were dominated - thieves, robbers, muggers, bandits etc. (40%); violent criminals (36%); criminals whose offenses related to traffic safety and traffic violations (7.6%). At the same time, 20% of the regions of Ukraine are characterized by an abnormally high crime rate per 100,000 population: Chernihiv (50), Poltava (49), Zaporizhia (46), Donetsk (46) and Kharkiv (45). Consistently high intensity of perpetration of intoxication crimes per 100 thousand population (24% of regions) is observed in such areas as: Mykolaiv (39), Kirovohrad (39), Volyn (39), Vinnytsia (38), Lugansk (33), Kherson (31) (Fig. 1). These are the regions of the highest penitentiary institutions concentration and the highest crime rate.

Many of these persons are sentenced to imprisonment. Therefore, when they will be detained in penitentiary institutions there will also be a problem of this bad habit, addiction combating. And this will be difficult to resolve under circumstances existing.

According to physicians of penal and civil health care institutions, if you look at the situation in Ukrainian penal institutions, the following factors should be mentioned among the factors that influence the concentration of alcoholics: 1) prevalence and increase of alcoholism in the whole country; 2) numerical facts of alcohol and its surrogates illegal use in penal institutions, including as a result of corruption component; 3) significant influx of so-called household alcoholics into these institutions in recent years, which of course affect the spread of this addiction; 4) imperfection of treatment and medico-social rehabilitation of alcoholic convicts regulation; 5) in some cases, the short-term of detention, during which effective treatment and lasting effect of this treatment is unachievable; 6) lack of proper conditions for medical and re-socialization measures; 7) impossibility of applying progressive, including alternative (for example, substitutional therapy for drug users) treatment methods for alcoholism and the absence of science-based program for medical-social rehabilitation of alcoholics; 8) insufficient funding of the measures used and the general crisis of the country's criminal justice system; 9) low efficiency of convicted alcoholics' treatment even with their voluntary help; 10) etc.

The situation in Ukraine is further complicated by the fact that 114 medical units operate at the penitentiary institutions and detention centers of Ukraine [10], only 3 (!) are licensed for medical practice. The lack of proper control over the medical activities' quality in penitentiary institutions gives rise to inef-

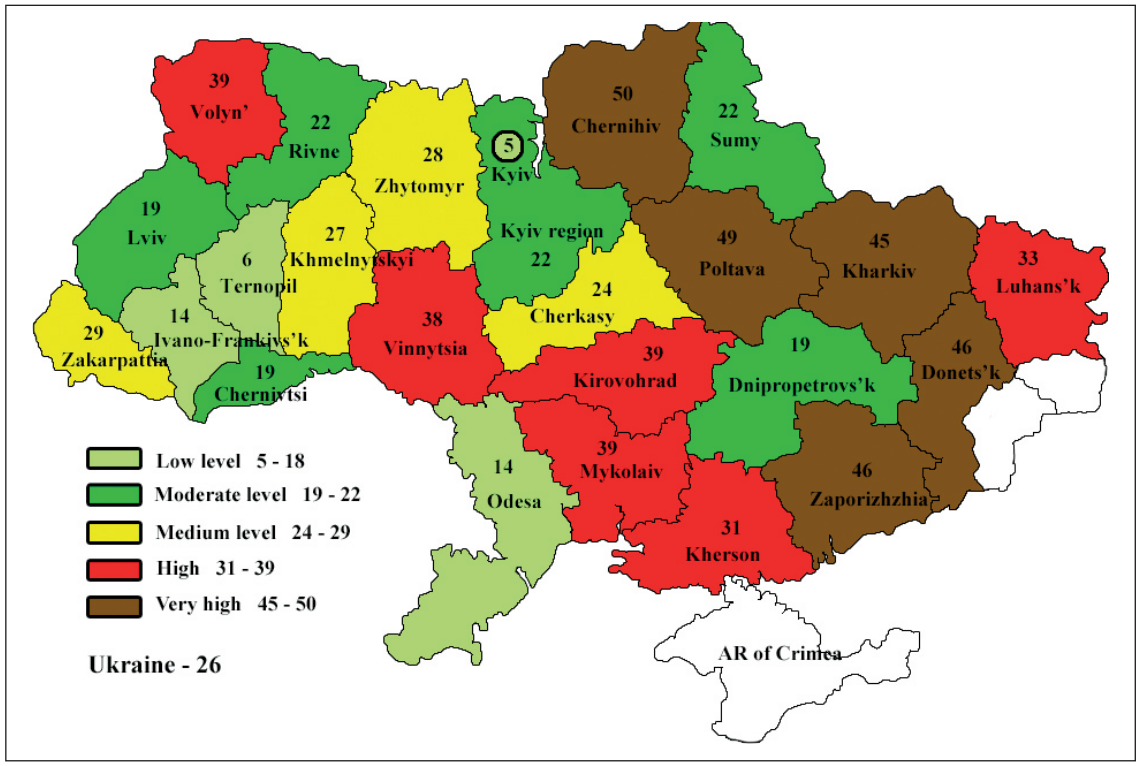

Fig. 1. Geography of intoxication crimes' intensity, per 100,000 population in Ukraine, 2018

fectiveness of any health care measures, which is resulted in: low level of medical care for patients, including chronic alcoholics; insufficiency of medical supply; personnel crisis; extent of high wear level of the so-called fixed assets of medical equipment; low level of access of patients to medical care in secondary and tertiary level hospitals; subjection of medical personnel to a prison facility administration, which often finds itself in a conflict situation between the need to provide quality medical assistance and administration's efforts to adhere to regime of detention and punishment of prisoners [11].

Experts of alcohol addiction in penitentiary institutions problematics were also asked about the number of people in need of alcoholism treatment. 76% of respondents said that about half of convicts were in need of medical treatment and that in their own will alcoholic patients in most cases are reluctant to consult a doctor. However, such persons do not mind, in their words, "to strengthen the general state of organism". However, the emphasis is not on the need to undergo treatment for alcoholism itself, but to overcome other emerging diseases that has emerged due to alcoholism. Special literature provides interesting data on the persons' health status who have repeatedly committed and convicted (so-called recidivists): vast majority of such persons dies from alcoholism, drug addiction or illnesses that has developed as a result of alcohol or drugs addiction (about 91-92%) (V. Batyrgareieve, 2009) [12, 202]. It should be noted that convicted alcoholics are a special kind of criminals. Their stubbornness in the continuation of their criminal activity in future is largely due to deceases resulted from addiction. Such persons' behavior is very difficult to correct, and because of dramatic shift of accents in their lives, it is quite often that they ignore any social demands.

The problem of chronic alcoholism treatment in penitentiary institutions is compounded by the fact that current practice does not provide any single method of treatment that is effective for all patients. It is generally accepted that treatment is based on disease period, namely: intoxication, acute abstinence and post-abstinence [13, 106]. Therefore, it is possible to state only about a certain sequence of therapeutic effect on alcoholics in penal institutions. Israeli doctors offer the most optimal chronic alcoholism treatment today. All treatment procedure is divided into 6 stages: 1) psychological and psychiatric assessment of addiction degree, motivation level for alcoholism treatment (these procedures are carried out outpatient); 2) detoxification, which is a prerequisite for continued alcoholism treatment and consists of eliminating symptoms of abstinent syndrome (this stage is usually 3-6 days long and is performed in a specialized clinic); 3) "coding" (voluntary); 4) development of an individual plan for inpatient or outpatient alcoholism treatment with a rehabilitation program of at least two months duration; 5) full course of psychotherapy interventions with a full spectrum of medical support, as well as including family psychotherapy, patient's support by a consultant who himself/herself (!) has undergone a course of alcoholism treatment, specially trained and has extensive experience in providing such assistance; 6) regular communication of patient and his/her psychotherapist online [14; 15]. It is interesting to admit that this program is also used in treatment of alcoholic offenders in Israel.

In order to find out the reasons for the ineffectiveness of chronic alcoholism treatment in Ukrainian penitentiary institutions, it is appropriate to analyze the approaches to solving this problem which existed in practice since at least the beginning of the 1990s – since Ukraine's independency.

Compulsory treatment of chronic alcoholism remained as a measure in penal institutions for a long time of Ukraine's independency as it was in the Soviet Union. The reason for this approach was the provision of criminal law, according to which the court, regardless of imposed criminal punishment, could send a convicted of a crime committed on alcoholism base to compulsory treatment carried out in penitentiary facilities. For this purpose, sentenced persons subjected to such treatment were placed in specialized correctional labor colonies. Convicts whose alcoholism had already been revealed in penitentiary institutions, but who refused the treatment, were also subject to compulsory treatment. By the way, refusal of treatment was regarded as a serious violation of detention regime. Compulsory treatment usually lasted up to 1 year and 6 months [16]. From an ideological point of view, this approach was explained by the fact that society and state were allegedly interested in re-socialization of even chronic alcoholics. However, forced re-socialization by its nature is completely nonsense from fundamental human rights' perspective. This approach, by the way, has long been used by the countries of Western and Central Europe, South America.

What is the current approach of chronic alcoholism treatment in Ukrainian penitentiary institutions? First, it should be noted that medical treatment for chronic alcoholics should be aimed at the urgent state of patients and effective treatment of mental and behavioral disorders resulting from alcohol use in combination with scientifically validated behavioral therapy. The purpose of these measures is to improve somatic and mental health and reduce the crime recurrence. For urgent conditions, that can occur in alcoholics patients and need of immediate medical attention, there are some forms of acute intoxication (acute intoxication with delirium, disorders of perception, coma, seizures, pathological intoxication), other abstinence, alcohol withdrawal syndrome) with delirium without convulsions or with convulsions, and psychotic disorders (mixed, schizophrenic, mostly delusional, hallucinatory, polymorphic, or with depressive or manic symptoms) [20]. It has been stated in the US Regulations for the Treatment of Persons with Alcohol Abuse Disorders (2016) that people with alcohol addiction who get to a correctional facility, have a high risk of developing alcohol withdrawal syndrome. If this state is not diagnosed and adequate treatment is not prescribed it can progress to delirium disorder and death. This syndrome is common for people in prisons or temporary detention centers, it often occurs within the first 24 hours of their last alcohol use. This complicates the provision of medical and psychiatric care. It is important to note that abolition can lead to suicidal acts, which are a significant cause of death in correctional facilities and that can be prevented [21]. Therefore, there may often be situations where it is necessary to provide emergency medical care without patient's consent. For example, the New Clinical Protocol "Emergency Care: Pre-hospital Stage" (2019), which is based on an attempt to adapt the best medical practice of European and North American countries, explicitly states that persons who tried to commit suicide, expressing suicidal intent or have other concomitant features that give emergency medical staff an ability to assume the patient's suicidal motives are considered to be incapable of making their own decisions [22].

Therefore, it is presumed that in the cases of the above patients' states do not raise the issue of adherence to the principle of voluntary treatment, because they require emergency medical care, which is emphasized in the Protocols of medical narcological care approved by the Ministry of Health of Ukraine. As for other conditions associated with alcohol addiction syndrome, their treatment is now possible only with the patient's consent.

It should be noted that this approach to solving an extremely serious medical and social problem is combined with some negative sides that need to be stated.

First, the untimely treatment of chronic alcoholism of convicts in penitentiary institutions creates a situation of further disintegration of alcoholics' personality and involvement of new unstable persons (especially young convicts) to such pernicious habit. Numerous facts of manufacturing of alcohol or its surrogates in penal institutions contribute to this process.

Secondly, chronic alcoholism is the cause of bad genetics for later generations born of such persons. This issue is known and will always be the focus of attention of geneticists and doctors worldwide [23; 24; 25].

Third, mental disorders that arise as a result of alcoholism can seriously affect a person's ability to make any decision including that of treatment necessity.

Fourth, evidence-based medical researches established that disorders of psyche and behavior due to psychoactive substances' use are chronic, recurrent disease that requires effective treatment with long-term support [21]. At the same time, this disease is the most important cause of both primary crime and recidivate illegal behavior and causes premature death [26; 27; 28].

All this gives reason to believe that existent principles of drug addicts' treatment (including alcoholics), which include the principles of voluntariness, maximum individualization and comprehensive approach to treatment, refusal to use psychoactive substances, etc. [13, 106; 29; 30], in penitentiary institutions will always be confronted with the principle of proportionality the essence of which can be expressed in the following way: "harm to society, in the case of voluntary treatment of chronic alcoholics vs harm to person's human dignity undergoing forced chronic alcoholism treatment".

Trying to solve this dilemma, one should look at the idea of introducing (at least in penitentiary institutions) a kind of substitute supportive therapy for chronic alcoholism treatment. As it is known, therapy-like treatment for drug addiction is similar in principle, on the one hand, is entirely based on voluntariness of a person to use an appropriate medicines in order to relieve him/her of suffering, and on the other, is carried out under society's control. In this way, the balance between fundamental human rights is most fully respected – voluntarily resorting to treatment and reducing the potential harm to society. This technique will undoubtedly have perspective in chronic alcoholism treatment. So, in any case, there will be a conflict between the public interest in limiting alcoholism spread and thus preserving nation's health and possibility of persons with certain health disorders to voluntarily receive medical care on principles of evidence-based medicine in accordance with clinical protocols developed using existing methods of national and / or professional medical as-

sociations of Member States of the European Union, the United States of America, Canada and the Australian Union.

CONCLUSIONS

Now in Ukraine there is an extremely dangerous situation with alcohol abuse. It is particularly acute amongst crime perpetrators and imprisoned persons. The penitentiary reforms undertaken in Ukraine since independence, including the transformation of approaches to treating chronic alcoholism in these institutions, have only exacerbated the situation. As a result, about 50% of prisoners in Ukrainian penitentiary institutions need treatment for chronic alcoholism, and the rest ones are active carriers of the "culture" of alcohol abuse. The unsatisfactory regulatory treatment of alcoholism contributes to the fact that these institutions become the focus of persons with alcoholism concentration whose' resocialization after their discharge is complicated by addiction. Thus, such persons become a catalyst for alcohol-related lifestyle spread among the population. This leads to further aggravation of social, medical and criminological situation in the country.

Treatment of chronic alcoholism should be considered as a special segment of work in penitentiary institutions, which should include at least several interconnected measures: a) continuous monitoring of the alcohol addiction situation in these institutions; b) introduction of progressive alternative methods of treatment of chronic alcoholism of convicts; c) allocation of material resources for implementation of such treatment; d) identification of specific measures aimed at reducing convicts' alcoholism; e) organizational work on implementation of such measures; e) continuous scientific support of existing problem and development of appropriate regulatory framework for its solution; g) immediate obtaining of licenses by those medical units of penitentiary institutions which do not have them.

Treatment of all manifestations of alcoholism (except for urgent conditions) of convicts in penitentiary institutions should, after appropriate diagnosis, take place solely based on voluntary consent. At the same time, in order to strike a balance between observance of one of the fundamental human rights, it is necessary to develop the idea of a peculiar substitution maintenance therapy and treatment of alcoholism in voluntary treatment and reduction of possible harm to society. Such an idea may prove to be promising for any country trying to address the problem of treating chronic alcoholism.

REFERENCES

1. Batyrgareieva V. S. Protidiya poshirennyu alkogolizmu – prioritetnij napryam derzhavnoï politiki u sferi borot'bi zi zlochinnistyu. [Combating the spread of alcoholism is a priority direction of state policy in the fight against crime.] Issues of crime prevention: collection of scientific works / V. I. Borisov ed:. Kharkiv: Pravo, 2013;25:5-44 (Ua)
2. Lins'kij, I. V., Golubchikov, M. V., Minko ta in. Aktual'ni tendencii poshirennya zalezhnosti vid psihoaktivnih rechovin v Ukraini: shchorichnij analitichnij oglyad. [Current Trends of the Spread of Substance Abuse in Ukraine: an Analytical Review.] Kharkov: Academy of Medical Sciences, 2007;4 Available from http://www.psychiatry.ua/articles/paper254.htm [reviewed 2019.09.09] (Ua)
3. Alkogol'na hvoroba pechinki: adaptovana klinichna nastanova, zasnovana na dokazah. Kiiv: Derzhavnij ekspertnij centr Ministerstva ohoroni zdorov'ya Ukraini, Ukrains'ka gastroerterologichna asociaciya, [Alcoholic Liver Disease: an Adapted, Evidence-based Clinical Setting. Kiev: State Expert Center of the Ministry of Health of Ukraine, Ukrainian Association gastroenterology]2014. 68 p. (Ua)
4. Slater M. Study: Media Rarely Notes When Alcohol Plays Role In Violent Crimes and Accidents. OSU EDU. Oct 22, 2006. Available from https://news.osu.edu/study-media-rarely-notes-when-alcohol-plays-role-in-violent-crimes-and-accidents [reviewed 2019.09.09].
5. Shocking Statistics and Facts about Alcohol-Related Crimes. Available from https://addictionresource.com/alcohol/effects/alcohol-related-crimes [reviewed 2019.09.09].
6. Zahalna kharakterystyka Derzhavnoi kryminalno-vykonavchoi sluzhby Ukrainy. [General Characteristics of the State Criminal Executive Service of Ukraine]. Available from https://kvs.gov.ua/2019/harakteristika/01.07.2019.pdf. [reviewed 2019.09.09] (Ua)
7. Kryminalno-vykonavche pravo: pidruchnyk [Penal Law: the Textbook] / V.V. Golina, A.H. Stepanyuk, O.V. Lysoded ed Harkiv: Pravo, 2011, 328 p. (Ua).
8. Yedynyi zvit pro kryminalni pravoporushennia za sichen-hruden 2017 roku [Unified Report on Criminal Offenses for January-December 2017] Prosecutor General's Office of Ukraine. Available from http://www.gp.gov.ua/ua/stst2011.html?dir_id=112173&libid=100820&c=edit&c=fo [reviewed 2019.09.09] (Ua).
9. Yedynyi zvit pro kryminalni pravoporushennia za sichen-hruden 2018 roku [Unified Report on Criminal Offenses for January-December 2018] Prosecutor General's Office of Ukraine. Available from https://www.gp.gov.ua/ua/stst2011.html?dir_id= 113653&libid=100820 &c=edit&_c=fo [reviewed 2019.09.09] (Ua)
10. Derzhavna penitenciarna sluzhba Ukraïni [State Penitentiary Service of Ukraine]. Available from: https://uk.wikipedia.org/wiki/Державна_пенітенціарна_служба_України [reviewed 2019.09.10] (Ua)
11. Shalashnij V. Reforma penitenciarnoï medicini [Reform of Penitentiary Medicine]. Available from http://ukrprison.org.ua/articles/1409735415 [reviewed 2019.09.11] (Ua)
12. Batyrgareieva V.S. Retsydivna zlochynnist v Ukraini: sotsialno-pravovi ta kryminolohichni problemy [Recurrent Crime in Ukraine: Socio-legal and Criminological problems]. Kharkiv: Pravo, 2009. 576 p. (Ua)
13. Malin D. I., Medvedev V. M. Klinicheskaya narkologiya v skhemah, tablicah i risunkah: ucheb. posob. 4-e izd. [Clinical Narcology in Diagrams, Tables and Figures: Textbook. 4th ed]. Moscow: University book, 2013. 172 p. (Ru)
14. Lechenie alkogolizma v raznyh stranah [Treatment of alcoholism in different countries]. Available from https://pohmelje.ru/lechenie-alkogolizma-v-razhyh-stranah [reviewed 2019.09.12] (Ru)
15. Eldar P. An Israeli experiement [sic] in the treatment of alcoholism: a demonstration project of an experimental programme for the treatment and rehabilitation of alcoholics within the family and community / edit. by Avraham Lavine. Jerusalem: State of Israel, Ministry of Social Welfare, Dept. of International Relations, 1976. 20 p.
16. Rukovodstvo po medicinskomu obespecheniyu lic, soderzhashchihsya v sledstvennyh izolyatorah i ispravitel'no-trudovyh uchrezhdeniyah MVD SSSR: utv. prikazom MVD SSSR № 285. ot 17 noyabrya 1989 g. [Guidelines for Medical Care of Persons Held in Pre-trial Detention Centers and Correctional Labor Institutions of the Ministry of Internal Affairs of the USSR: approved by order of the Ministry of Internal Affairs of the USSR № 285 of November 17, 1989]. Available from http://www.alppp.ru/law/zdravoohranenie--fizicheskaja-kultura-i-sport--turizm/zdravoohranenie/59/prikaz-mvd-sssr-ot-17-11-1989-285.html [reviewed 2019.09.10] (Ru)

17. Pro zatverdzhennia Nastanovy po medyko-sanitarnomu zabezpechenniu osib, yaki utrymuiutsia v slidchykh izoliatorakh ta ustanovakh vykonannia pokaran MVS Ukraïni: nakaz № 147 MVS Ukraïni vid 14 chervnya 1993 r. [On Approval of the Instructions on Health Care for Persons Held in Pre-trial Detention Centres and Penitentiary Institutions of the Ministry of Internal Affairs of Ukraine: order No. 147 of the Ministry of Internal Affairs of Ukraine of 14 June, 1993]. Available from https://zakon.rada.gov.ua/laws/show/z0147-93 [reviewed 2019.09.10] (Ua)
18. Pro zatverdzhennia normatyvno-pravovykh aktiv z pytanmedyko-sanitarnoho zabezpechennia osib, yaki utrymuiutsia v slidchykh izoliatorakh ta ustanovakh vykonannia pokaran Derzhavnoho departamentu Ukrainy z pytan vykonannia pokaran MOZ Ukraini №3/6 vid 18.01. 2000 [About the Approval of Normative Legal Acts Concerning Health Care of the Persons Containing in Pre-trial Detention Centers and Penitentiary Institutions of the State Department of Ukraine of Execution of Punishments: the order of the State Department of Ukraine of Execution of Punishments and Ministry of Health of Ukraine of 18 January, 2000 No. 3/6]. Available from https://zakon.rada.gov.ua/laws/show/z0143-00 [reviewed 2019.09.10] (Ua)
19. Pro zatverdzhennia Poriadku orhanizatsii nadannia medychnoi dopomohy zasudzhenym do pozbavlennia voli, zatverdzhenyi Ministerstvom yustytsii Ukrainy ta MOZ Ukrainy № 1348/5/572 vid 15.08.2014 r. [The Order of Organization of Medical Care for Persons Sentenced to Imprisonment: approved by the order of the Ministry of Justice of Ukraine and the Ministry of Health of Ukraine No. 1348/5/572 of 15 August, 2014] Available from https://zakon.rada.gov.ua/laws/show/z0990-14 [reviewed 2019.09.10] (Ua)
20. Protokoly nadannia medychnoi narkolohichnoi dopomohy Dodatok do nakazu MOZ «Pro zatverdzhennia klinichnykh protokoliv nadannia medychnoi dopomohy za spetsialnistiu« narkolohiia » № 681 vid 21.09.2009 r. [Protocols Medical Drug Treatment: Application to the Order of the Ministry of Health of Ukraine «On Approval of Clinical Protocols Providing Medical Aid on a Speciality «Narcology» No. 681 of September 21, 2009]. Available from http://medstandart.net/browse/3277 [reviewed 2019.09.10] (Ua)
21. SShA: novi pryntsypy povodzhennia z uviaznenymy z narkomaniieiu [USA: New Principles of Treatment of Prisoners with Addiction]. Available from http://www.uiphp.org.ua/uk/hromadske-zdorovia/podii-ta-anonsy/item/87-ssha-novi-pryntsypy-likuvannia-uviaznenykh-iz-zalezhnistiu [reviewed 2019.09.11] (Ua)
22. Ekstrena medychna dopomoha: dohospitalnyi etap. Novyi klinichnyi protokol– 2019: zatv. nakazom MOZ Ukrainy № 1269 vid 05.06.2019 r. [Emergency Medical Care: Prehospital Stage. New Clinical Protocol-2019: approved by the order of of the Ministry of Health of Ukraine of June 5, 2019. № 1269]. Available from https://moz.gov.ua/uploads/2/12737-dn_20190605_1269_dod.pdf [reviewed 2019.09.11] (Ua)
23. Browman K. E., Crabbe J. C. Alcoholism: Genetic Aspects. International Encyclopedia of the Social & Behavioral Sciences. Cambridge: Elsevier Press, 2001: 371-378.
24. Kumar R., Kumar K. J., Benegal V. Cognitive and behavioural dispositions in offspring at high risk for alcoholism. Asian Journal of Psychiatry. June 2018;35:38-44. doi: 10.1016/j.ajp.2018.05.006
25. Limosin F., Adès J., Gorwood P. Relationships between antisocial personality and alcoholism: genetic hypotheses. European Psychiatry. March 2000; 15 (2):123-128. doi: 10.1016/s0924-9338(00)00202-9
26. Binswanger, I. A., M. F. Stern, R. A. Deyo, P. J. Heagerty, A. Cheadle, J. G. Elmore, and T. D. Koepsell. Release from prison – a high risk of death for former inmates. New England Journal of Medicine. 2007. 356(2):157–165. doi:10.1056/NEJMsa064115
27. Bernstein M.H., McSheffrey S.N., van den Berg J.J., Vela J.E.; Stein L.A.R., Roberts M.B., Martin R.A., Clarke J.G. The association between impulsivity and alcohol/drug use among prison inmates. Addictive Behaviors. 2015 Mar;42:140-3. doi: 10.1016/j.addbeh.2014.11.016
28. Chen Kuan Yeo D., Singham T., Poremski D. The presence of alcohol consumption prior to homicide in Singapore. Asian Journal of Psychiatry. August 2019;44:80-85. doi:10.1016/j.ajp.2019.07.019
29. Klinicheskij protokol diagnostiki lecheniya: psihicheskie i povedencheskie rasstrojstva, vyzvannye upotrebleniem alkogolya (dlya vzroslyh) № 7: utv. Ministerstva zdravoohraneniya i social'nogo razvitiya Respubliki Kazahstan ot 27 avgusta 2015 goda [Clinical Protocol of Diagnosis of Treatment: Mental and Behavioral Disorders Caused by Alcohol Consumption (for Adults) № 7: approved by the Ministry of Health and Social Development of the Republic of Kazakhstan of August 27, 2015]. Available from http://www.rcrz.kz/docs/clinic_protocol/2015/Терапия/ Наркология.pdf [reviewed 2019.09.12] (Ru)
30. Klinicheskij protokol okazaniya medicinskoj pomoshchi pacientam s psihicheskimi i povedencheskimi rasstrojstvami: Prilozhenie k prikazu Ministerstva zdravoohraneniya Respubliki Belarus' 31 dekabrya 2010 g. [Clinical Protocol of Medical Care for Patients with Mental and Behavioral Disorders: Annex to the Order of the Ministry of Health of the Republic of Belarus of December 31, 2010. № 1387]. Minsk: State Institution «Republican Scientific and Practical Center of Mental Health», 2011. 374 p. Available from https://www.bsmu.by/downloads/vrachu/protokolu/p30.pdf [reviewed 2019.09.12] (Ru)

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REVIEW ARTICLE
PRACA POGLĄDOWA

LEGAL REGULATION OF IMPORTATION OF MEDICINAL PRODUCTS: EUROPEAN STANDARDS AND NATIONAL PRACTICE

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ABSTRACT

Introduction: The state policy in the field of medicinal products supply and import adjustment is aimed at steady assurance of quality throughout all stages of medicinal products circulation, starting with production and import to the stage of their medical application.

The aim:of the article is to study the existing permitting and restrictive legal mechanisms of importing medicinal products at international, regional and national levels.

Materials and methods: This research is based on empirical and analytical data from the WHO, EU, EU customs and medical legislation, national legislation of Ukraine and Republic of Poland, Eurostat statistics, European Court of Justice (hereinafter referred to as «ECJ») rulings.

Conclusions: Customs regime prohibitions and restrictions are of particular importance when it comes to importing medicinal products. That specificity is in the procedures of licensing, certification, quality control, packaging, marking etc. A proper mechanism for carrying out such procedures requires standardization at international and regional levels. At the level of regional cooperation the issue of parallel import of medicinal products is urgent. Associated risks should be minimized by means of the instruments of international, European law through the adaptation of the national licensing procedures of medicinal products import to the EU requirements, including those defined in the Association Agreements.

KEY WORDS: medicinal products, import, counterfeit medicinal products, parallel import, licensing

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INTRODUCTION

EU exports and imports of medicinal and pharmaceutical products grew almost every year between 2002 and 2017, reaching EUR 156 billion and EUR 77 billion respectively in 2017, in 2018 exports accounted already EUR 169 billion (this year, for example, Germany (USD 76,3 million) and France (USD 35,1 million) are the biggest importers of medicinal products for Ukraine), imports – EUR 78 billion [1].

The state policy in the field of medicinal products supply is aimed at steady assurance of quality throughout all stages of medicinal products circulation, starting with production and import to the stage of their medical application. The state is obliged to implement and constantly improve the mechanism of compliance with the legislation in the field of wholesale and retail trade in medicinal products.

The specified norm-principle testifies the importance of medicinal products, having, on the one hand, the characteristics of ordinary goods, and being, on the other hand, the subject of centralized public purchases (involving international organizations as intermediaries, such as UNDP, UNICEF etc. makes it possible to minimize elements of corruption and to save the state budget). A sufficient number of public purchases allowing the health care system to function and to promote the realization of the fundamental human values declared in the acts of international law, is a traditional subject of Humanitarian aid for victims of natural disasters or armed conflict, and their domestic and cross-border circulation is usually accompanied by strict requirements, restrictions and prohibitions etc.

Firstly, medicinal products are the goods, moved across the customs border in a limited way depending on their varieties, the subject of movement, the customs regime, etc., and secondly, counterfeit medicinal products (see the research published in this year's issue of Wiadomości Lekarskie [2, p.860]), may become contraband in case of their movement across the customs border [3, p.129]. For instance, in Ukraine under Article 305 of the Criminal Code importation of counterfeit medicinal products since 2011 [4], that is, immediately after the amendment of this Code in view of signing the MEDICRIME Convention (Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health [5]), entails criminal liability. At the same time, the above-mentioned Convention did not become widespread and became valid only for fifteen countries, three of which, namely Benin, Burkina Faso, Guinea, are not members of the Council of Europe [6]. European Union as a collective subject of international law, as well as the Republic of Poland, has not ratified the Convention. Currently, under Article 124 of Ustawy Prawo farmaceutyczne putting into circulation or holding in order to supply

medicinal products on the market without permission is punished by a fine, restriction of liberty or imprisonment up to 2 years [7].

The Council of Europe has long been concerned about the absence of harmonized international legislation, non-deterrent sanctions that were not proportional to the harm caused to patients, and the involvement of criminal organizations which operate across borders. Counterfeiting medical products and similar crimes threaten the right to life enshrined in the Article 2 of the European Convention on Human Rights and Fundamental Freedoms (ECHR) [8]. Incidences of counterfeit medical products and similar crimes undermine public trust in healthcare systems and authorities' surveillance thereof.

Thus, the steady increase in cross-border circulation of medicinal products, particularly on the European continent, on the one hand, contributes to the functioning of healthcare systems, on the other hand, - creates risks for the spread of substandard, spurious and counterfeit pharmaceuticals that can cause significant harm to human life and health. Taking into account an enormous risk of such wrongdoings, there is a need to create and implement an effective legal mechanism for importing medicinal products to the European Community. Accordingly, for the states having signed Association Agreements with the EU, the formed model of import should become a benchmark for gradual implementation into national practice.

MATERIALS AND METHODS

This research is based on empirical and analytical data from the WHO, EU, EU customs and medical legislation, national legislation of Ukraine and Republic of Poland, Eurostat statistics, European Court of Justice (hereinafter referred to as «ECJ») rulings. A total of 26 laws, 13 articles and court decisions have been analyzed. Dialectical, comparative, analytical, synthesis, system analysis have been used in this research.

REVIEW AND DISCUSSION

Article 35 "Health protection" of the Charter of Fundamental Rights of the European Union (hereinafter referred to as "the Charter") provides that everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the EU policies and activities [9].

A special article on health contained in the Charter justifies expectations [10, p.57]. Stating fundamental rights in the field of health protection is in fact traditional and repeatable not only at the national (constitutional) level, but also at the international level. As evidence there can be introduced the Universal Declaration of Human Rights (December 10, 1948), namely Article 25: "everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including food, clothing, housing, medical care and necessary social services" [11]. The Constitution of the World Health Organization also provides that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being" [12]. Paragraph 1 to the Article 12 of the International Covenant on Economic, Social and Cultural Rights of 16 December 1966 further secures "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health".

Although the right to health protection is not mentioned in the European Convention for the Protection of Human Rights and Fundamental Freedoms, at European regional level it is actually provided for by other European conventions. In particular, the European Social Charter in the Paragraph 11 of the Part I envisages that "everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable" [13].

In addition, the European Court of Human Rights has interpreted and, in our view, quite reasonably expanded the scope of certain conventional rights in the field of healthcare. For example, it is argued that Article 2 demands from states "to take appropriate steps to safeguard the lives of those within its jurisdiction" (para. 48), which should "apply in the public-health sphere too" (para. 49) [14]. The Court notes that "since a person's body is the most intimate aspect of private life, and medical intervention, even if it is of minor importance, constitutes an interference with this right" (para. 40) [15].

At the same time, it is worth agreeing that the historical, cultural and economic differences in EU countries are a kind of "brake" on the process of health care activities' standardization. Unfortunately, not all Member States are currently ready to adopt and follow the policies proposed by the European Union and international organizations [16, p. 31].

The EU Customs Code [17] does not regulate the import or export of medicinal products itself and does not use ore define such terms as "pharmaceuticals" or "medical products", "medicinal products". Instead, its authors use the concept of "goods", the content of which is disclosed in a kind of EU constitution – Treaty on the Functioning of EU. Thus, Article 28 of TFEU provides that the customs union between the Member States covers all trade of goods. The ECJ has defined "goods" as all products which have a monetary value and may be the object of commercial transactions.

This definition, as noted in the literature [19, p. 542], includes: Consumer goods including medical products (Case 215/87 Schumacher [1989] ECR 617) [20]).

In the EU there is a set of normative and legal acts elaborated to regulate the circulation of medicinal products, including imported ones. One of the main directives is Directive 2001/83/EU on the Community code relating to medicinal products for human use, as regards the prevention of the entry of falsified medicinal products into the legal supply chain [21]. Directive 2001/83/EU lays down the rules for, inter alia, manufacturing, importing, placing on the market, and the wholesale distribution of medicinal products in the Union as well as rules relating to active substances.

Awareness of the threats posed by counterfeit medicinal products has led to amending of the Directive 2001/83.

Therefore, the Directive 2011/62/EU of 8 June 2011 has come into force on 9 February 2019 [22]. It was named the Falsified Medicines Directive (FMD) and it aims to improve the safety of the manufacturing process and delivery of medicinal products across Europe in order to provide enhanced patient protection. It also introduces new rules for stricter supply chain regulation. Introduction of mandatory authentication (safety sign) on the outer packaging of medicines, stricter rules for control of source materials and active substances and fillers in medicines, stricter measures for controlling the wholesale distribution of medicines and brokerage activity, implementation of a single pan-European logo for the identification of legal online pharmacy, as well as message systems for organizations that offer medicines to the public via the Internet - all these provisions of the FMD - indicate that it is aimed at protecting public health by preventing the entry of falsified or counterfeit medicines into the supply chain of pharmaceuticals.

Fundamental rule in regulation of medicinal products' importation to the EU a is the requirement to provide the necessary controls in the exporting country. Following the establishment of the internal market, specific controls to guarantee the quality of medicinal products imported from the third countries can be waived only if appropriate arrangements have been made by the Community to ensure that the necessary controls are carried out in the exporting country.

Besides the issue of ensuring this type of control, the issue of compliance of Directive 2001/83 with the laws of the EU Member States inevitably arose. Thus, the inconsistency of the Law of the Republic of Poland «On Medicinal Products» with the provisions of the Directive has led to an action by the European Commission against the Republic of Poland of 13 April 2010. The claim is that the adoption and application by the Republic of Poland of Article 4 (1) and (3a) of the Law on Medicinal Products make it possible for medicinal products to be marketed in Poland when they do not possess a marketing authorization in Poland issued by the competent national authorities, a situation which is contrary to Article 6 (1) of the Directive 2001/83. In the applicant's submission, the Polish provision is not covered by Article 5 (1) and Article 126a of the Directive 2001/83, which provide for exceptions to the general requirement contained in Article 6 (1) of that directive that medicinal products must have a national authorization. Above all, Article 4 (3a) of the Law on Medicinal Products, according to which the condition for allowing imported medicinal products is their 'competitive price' compared with the price of medicinal products, already allowed on the national market, is based exclusively on an economic criterion. A criterion of that kind cannot, however, justify an exception to Article 6 (1) of the Directive 2001/83. Furthermore, the Polish provision concerns medicinal products with the same active substance, form and dosage as medicinal products already permitted on the national market, and it is therefore not possible to consider them to be unavailable on the national market, a situation which might justify the need for targeted import on the basis of Article 5 (1) of the Directive [23].

As the result, the Court found that the Republic of Poland has failed to fulfil its obligations under Article 6 of the Directive 2001/83/EU of the European Parliament and the Council of 6 November 2001 on the Community Code relating to medicinal products for human use, as amended by the Regulation No 1394/2007 of the European Parliament and the Council of 13 November 2007 [24].

However, the Court decision did not stop critics of the Directive 2001/83 in their desire to prove that the import of unlicensed medical products having competitive advantages in relation to those allowed on the national market, is a strong reason for non-compliance with the restrictions provided for by this Directive. For example, there was pointed at the "special need" of patients in unlicensed medicines, which should be taken into account considering the rules of Article 168 of the Treaty on the Functioning of the European Union, Article 8 of the European Convention on Human Rights. Finally it was suggested that in the argument "against" the supply of the cheaper unlicensed product the word "special" should be interpreted in the context and also remembered that the key objective of the Directive was to safeguard human health and nothing else [25]. The British licensing authority also stated that the unavailability of a licensed product does not in itself create a so-called "special need". Besides, there were exemplified legal provisions of Great Britain, where "The Medicines for Human Use (Marketing Authorizations Etc.) Regulations" [26] uses the same expression "special needs" as Article 5.1 of the Directive, without defining this concept. Instead, it should be noted that the stated act of national legislation proposed the definition of "parallel import".

It is worth remarking that under the conditions of legalization of parallel imports, there is a risk regarding a certain group of imported goods. First of all, they are medicinal and cosmetic products, as well as food. Unfair importers do not always adhere to the proper conditions for carriage of such goods, while official suppliers do their best. Owning to the parallel import, the quality of goods deteriorates and risks for a consumer appears because of importation of counterfeit and overdue goods, including medicines possibility. There is a also threat of reputational losses for a honest manufacturer.

Parallel import of medicinal products is ambiguously regulated in the EU Member States. The question of identifying it with the so-called "gray import" remains debatable.

Parallel imports are legitimately produced goods imported legally into a country without the authorization of a trademark, copyright or patent holder. In the European Union, so long as a pharmaceutical manufacturer has placed a good on the market voluntarily, the principle of free movement of goods allows individuals or firms within the EU to trade goods across borders without the consent of the producer [27].

In our opinion ECJ ruling in the case C-387/18 on 3 July 2019 Delfarma vs Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych was a crucial fact in this regard [28]. The ruling states that Articles 34 to 36 of the Treaty on the Functioning

of the European Union contradict the provisions, resulting from the definition in Article 2 Paragraph 7b Sub-paragraph b of the Pharmaceutical Law of the Republic of Poland of 6 September 2001, requiring certification of the registration category as a condition for granting consent for parallel import. This is the first time a Polish parallel importer has won a dispute in the EU Court of Justice. This ruling opens the possibility of registering a broad list of medicinal products for which license applications for parallel import have still been rejected. Therefore, there was a real opportunity to increase the number of cheaper goods in the Polish market and thus to save money for Polish patients.

Legalization of parallel imports can lead to increased competition, reduced retail prices and expansion of the product range. By forbidding parallel import the legislator will not prevent the flow of counterfeit goods to the country and will give the rightsholder a full control over the distribution of goods containing intellectual property rights, allowing them to independently identify the entities authorized to sell such goods. Such entities should comply with the requirements on their activity, including those related to pricing. Moreover, this situation can lead to abuse by distributors. Therefore, in our opinion, parallel import deserves to be legalized, taking into account the restriction of goods such as medical and cosmetic products. Such a decision is capable of increasing working efficiency of state authorities, whose task is to counteract the circulation of counterfeit goods.

The concept of counterfeit goods is defined in the EU Regulation No 608/2013 on customs control over the adherence to intellectual property rights [29]. Thus, it is important that national legislation acts with this concept, in particular, previously approved by the Ukrainian Parliament the draft law No 1230 of 2 September 2019 on amendments to the Customs Code of Ukraine on protection of intellectual property rights during the movement of goods across the customs border of Ukraine will be implemented [30]. That draft law was elaborated in order to approximate national customs legislation in the field of intellectual property protection to the EU standards and practices and increase the level of prevention and counteraction to the movement across the customs border of goods infringing intellectual property rights and, as a consequence, facilitate the cleansing of the internal market from counterfeit products that often do not meet the established security requirements. It actually regulates parallel imports, which implementation on medicinal products is one way to solve the problem of providing availability of medicinal products.

The World Health Organization is by far one of the "international organizations promoting customs regulation" at the global level. Adopted under the aegis of this organization the certification scheme is intended to allow importing countries to obtain from the regulating authorities of exporting countries the official confirmation of the imported pharmaceutical products licensed status. Confirmation that manufacturers are subject to regular inspections and that production conditions are in accordance with WHO recommended Good Manufacturing Practice (GMP) is also required [31]. The WHO Revises Guidance on Quality management system requirements for GMP Inspectorates on 25 July 2019 [32]: a draft of requirements for the Quality system for national GMP-inspectorates was recently presented for discussion [33] to bring them in line with international standards and principles of quality management system (QMS) operation and to expand the scope of the document.

An important tool in counteracting the cross-border circulation of counterfeit medicinal products is a created within the WHO International working group on struggling against counterfeit medicines – International Medical Products Anti-Counterfeiting Taskforce (IMPACT), an active member of which is the World Customs Organization as well. Its goal is to develop principles of the national legislation modification in order to combat counterfeit medicinal products.

The course of the Ukraine towards integrating into the European Community envisages the adaptation of national legislation to the requirements of the EU acts. This fully relates to the legal support for the import of medicinal products.

The authors of this article do not aim to fully disclose the norm and legal mechanism for importing medicinal products to Ukraine. It is worth focusing on some of the elements, especially on national custom's regulation new customs rules [34, p. 12], on the standards of the European legal space in general and the principles of the EU medical law in particular. Thus, arranging the procedure of their import into the customs territory of Ukraine is an integral element of reforming the healthcare system in general and the public health system in particular, which needs to be modernized due to a number of problems, which are emphasized in the approved Resolution of the Cabinet of Ministers of Ukraine of 30 November 2016 No 1002-p of the Concept of developing the public health system [35]. In particular, due to the ramifications and inconsistency of the public health system, the International medical and sanitary rules, the implementation of which into the country's healthcare system are a part of Ukraine's international obligations, are not properly implemented.

As the Preamble of the Concept points out, public health is one of the greatest values, necessary for the socio-economic development of a country; creating optimal conditions for realizing the potential of each person over a lifetime, achieving European standards of quality of life and well-being of the population are the part of the obligations under the Association Agreement between the Ukraine and the European Union, the European Atomic Energy Community and their member states, of the other part (hereinafter referred to as the "Association Agreement") [36].

The Association Agreement separately regulates in Article 222 issues relating to the protection of data submitted for the purpose of obtaining a marketing authorization of medicinal products: the Parties shall implement a comprehensive system to guarantee the confidentiality,

non-disclosure and non-reliance of data submitted for the purpose of obtaining an authorization to put a medicinal product on the market. In particular, Ukraine shall undertake to align its legislation concerning data protection for medicinal products with that of the EU at a date to be decided by the Trade Committee.

The provisions of Protocol 2 to the Association Agreement, named "On Mutual Administrative Customs Assistance", shall prevail with respect to the provisions of any bilateral mutual assistance agreement which have been or may be concluded between individual member states of the European Union and Ukraine in the field of the provisions of the latter which are incompatible with the provisions of this Protocol [36]. It would be correct to make greater use of the legal capacity of the Protocol and the Association Agreement to prevent and prohibit illegal import of medicinal products, including counterfeit ones.

The Article 220 of the Association Agreement introduces the so-called supplementary security certificate. Ukraine and the EU are obliged to provide for a supplementary period of medicinal product protection that is covered by patent and has been subject to the administrative authorization procedure.

Thus, the Association Agreement contains rules that can rightly be attributed to the key provisions of the medical reform implementation mechanism in Ukraine.

Since 23 January 2017 a system of compulsory licensing of manufacturing and export of patented medicinal products has been implemented according to the requirements of Annex to the Protocol of Amendment to the TRIPS Agreement of 6 December 2005 [37].

The European model of import licensing of medicinal products is implementing by stages. At first, economic activity on importing medicinal products began to be licensed. The further introduction of the European model of import licensing of medicines provided for the gradual implementation of GMP requirements to the approved by the Cabinet of Ministers of Ukraine Licensing conditions to economic activities on importing medicinal products, in particular, regarding self-inspection, contracting (technical or quality agreements) between importers, foreign manufacturers and holders of registration certificates; pharmaceutical quality system; study of medicine stability; control and archival samples of the authorized person of the importer [38].

The next stage of «Europeanization» of the mechanism of importing medicinal products to Ukraine is in implementation of the requirements for their marking. Consequently, according to the Resolution of the Cabinet of Ministers of Ukraine No 653 of 24 July 2019 [39], a pilot project on marking of control (identification) signs and monitoring of the circulation of medicinal products will be implemented in Ukraine under date of 1 September 2019, which will be in effect until 31 December 2020.

There has been set a goal to create a prototype of an informational and analytical system for controlling the circulation of medicinal products and there's been a draft Law of Ukraine «On Amendments to the Law of Ukraine «On medicinal products» proposed on the marking medicinal products with the identification number of international non-profit organization GS1 studying the issues of accounting of goods and services, bar coding of logistic units standardization, which is currently being comunucated with the Ministry of Health of Ukraine. In general, it is planned to adapt the licensing procedure for importing medicinal products in line with the EU requirements by amending the relevant licensing conditions in 2023 [40].

CONCLUSIONS

Prohibitions and restrictions peculiar to the customs regime are particularly important when it comes to importing medicinal products specifying in the procedures of licensing, certification, quality control, packaging, marking and etc. A proper mechanism for carrying out such procedures requires standardization at international and regional levels.

To ensure the effectiveness of this mechanism at the international level, it is worth supporting WHO's efforts to modernize national GMP inspectorates. The quality assessment system for their performance should indeed be compatible with international standards and current functioning principles of quality management system (QMS). It also makes sense to "prevent" introduction of the basic elements of an updated GMP in countries where it is not yet a mandatory part of the control mechanism for importing medicinal products.

The existence of criminal law mechanism alone to combat the spread of counterfeit medical products implemented internationally (through the MEDICRIME convention standards), regionally and nationally, is not enough to guarantee the implementation of health rights envisaged, in particular, by the EU directives. The Protocol 2 "On Mutual Administrative Customs Assistance" to the Association Agreement is subject to greater practical application.

The issue of parallel import of medicinal products is urgent at regional level of cooperation. The risks associated with them should be minimized (poor quality, counterfeit goods, weakening of customs control, displacement of domestic analogues from the market, curtailment of production by well-known pharmaceutical companies) by the instruments of international, European law (including precedents of the ECHR), capabilities of national regulatory authorities, in particular customs.

REFERENCES

1. EU-28 exports, imports and trade balance in medicinal and pharmaceutical products, 2002-2018 (EUR billion): Eurostat (online data code: DS-018995). Available from: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=International_trade_in_medicinal_and_pharmaceutical_products [reviewed 2019.08.24]
2. Gutorova N, Zhytnyi O, Soloviov O. Falsification of medical products: criminal law mechanism combating threats to public health. Wiadomości Lekarskie. 2019;5:856-861.
3. Zyma O.T. Likarski zasoby y mytna sprava [Medicinal products and customs affairs]. Comparative analytical law. 2017;3:128-131. (Ua).

4. Pro vnesennia zmin do deiakykh zakonodavchykh aktiv Ukrainy shchodo zapobihannia falsyfikatsii likarskykh zasobiv: Zakon Ukrainy vid 8 veresnia 2011 roku № 3718-VI. Vidomosti Verkhovnoi Rady Ukrainy. 2012. № 19-20. St. 168 [On Amendments to Some Legislative Acts of Ukraine on Preventing Falsification of Medicinal Products: Law of Ukraine of 8 October 2011 No 3718-VI. The official Bulletin of Verkhovna Rada of Ukraine. 2012. No 19-20. Art. 168] (Ua).
5. Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (Moscow, 28.X.2011, entry into force 01/01/2016). Available from: https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168008482f [reviewed 2019.08.24]
6. Chart of signatures and ratifications of MEDICRIME: status as of 15/08/2019. Available from: https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211/signatures [reviewed 2019.08.24]
7. Prawo farmaceutyczne: USTAWA z dnia 6 wrzesnia 2001 r. Available from: http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU20011261381/T/D20011381L.pdf [reviewed 2019.08.24]
8. Convention for the Protection of Human Rights and Fundamental Freedoms (Rome, 4.XI.1950). Available from: https://www.echr.coe.int/Documents/Convention_ENG.pdf [reviewed 2019.08.24]
9. Charter of Fundamental Rights of the EU. Official Journal of the European Union.2007;50. 2007/C303/01.
10. Charte des droits fondamentaux de l'Union européenne: Commentaire article par article / Fabrice Picod (ed.); Sébastien van Drooghenbroeck (ed.); Cécilia Rizcallah (other). Brussels: Bruylant; 2017. 1280 p. p.57
11. The Universal Declaration of Human Rights (UDHR), 10 December 1948. Available from: https://www.un.org/en/universal-declaration-human-rights/index.html [reviewed 2019.08.24]
12. The Constitution was adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States (Off. Rec. Wld Hlth Org.,2,100), and entered into force on 7 April 1948. Available from: https://www.who.int/governance/eb/who_constitution_en.pdf [reviewed 2019.08.24]
13. The European Social Charter. Collected texts (7th edition). Updated: 1st January 2015. Available from: https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168048b059 [reviewed 2019.08.24]
14. Case of Calvelli and Ciglio v. Italy, application no. 32967/96, judgment of 17 January 2002. Available from http://hudoc.echr.coe.int/eng?i=001-60329 [reviewed 2019.08.24]
15. Case of Konovalova v. Russia6, application no. 37873/04, judgment of 09 October 2014. Available from: http://hudoc.echr.coe.int/eng?i=001-146773 [reviewed 2019.08.24]
16. Hnatyk E., Sokova E. Osnovnye napravlenyia deiatelnosty Evropeiskoho Soiuza v oblasty zdravookhranenyia [The main activities of the European Union in the field of healthcare]. Law and management. XXI cent. 2015;3(36):28-32.
17. Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code. Official Journal of the European Union. 2013;269:1–101. Available from: http://data.europa.eu/eli/reg/2013/952/oj [reviewed 2019.08.24]
18. Consolidated version of the Treaty on the Functioning of the European Union (TFEU). Official Journal of the European Union. 2012;326:47–390. Available from: http://data.europa.eu/eli/treaty/tfeu_2012/oj [reviewed 2019.08.24]
19. Kaczorowska A.-I. European Union law. London and New York. Routledge. 2016. 1086 p.
20. Case of Schumacher v HZA (Hauptzollamt) Frankfurt am Main-Ost, № 215/87: 1989 ECR 617; 1990 2 CMLR 465. Available from https://eur-lex.europa.eu/legal-content/GA/TXT/?uri=CELEX:61987CJ0215 [reviewed 2019.08.24]
21. Directive 2001/83/ec of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Official Journal of the European Union.2001, p. 67. Available from https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf [reviewed 2019.08.24]
22. Directive 2011/62/eu of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. Official Journal of the European Union. 2011;174/74. Available from https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0074:0087:EN:PDF [reviewed 2019.10.24]
23. Action brought on 13 April 2010 — European Commission v Republic of Poland (Case C-185/10) (2010/C 209/16). Official Journal of the European Union. 2010;209/11. Available from https://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=uriserv%3AOJ.C_.2010.209.01.0011.01.ENG [reviewed 2019.10.24]
24. Judgment of the Court (Third Chamber), 29 March 2012. European Commission v Republic of Poland. Case C-185/10. Available from http://curia.europa.eu/juris/celex.jsf?celex=62010CJ0185&lang1=en&type=TXT&ancre= [reviewed 2019.10.24]
25. Walton B. The UK experience related to case C-185/10, Commission v Republic of Poland does a "special need" arise for an unlicensed medicine if the licensed equivalent. Available from: https://slideplayer.com/slide/7515584/ [reviewed 2019.10.24]
26. The Medicines for Human Use (Marketing Authorizations Etc.). Regulations No. 3144, 8th December 1994. Available from https://www.legislation.gov.uk/uksi/1994/3144/contents/made [reviewed 2019.10.24]
27. Ganslandt M., Maskus K. Parallel Imports of Pharmaceutical Products in the European Union. The World Bank Development Research Group; 2001. 28 pages. Available from: http://apps.who.int/medicinedocs/documents/s17518en/s17518en.pdf [reviewed 2019.08.24]
28. Case C-387/18: Request for a preliminary ruling from the Wojewódzki Sąd Administracyjny w Warszawie (Poland) lodged on 12 June 2018 – Delfarma Sp. z o.o. v Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych. Official Journal of the European Union.2018;294: 32.
29. Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003. Official Journal of the European Union.2013;181:15–34.
30. Proekt Zakonu №1230 vid 02.09.2019 pro vnesennia zmin do Mytnoho kodeksu Ukrainy shchodo zakhystu prav intelektualnoi vlasnosti pid chas peremishchennia tovariv cherez mytnyi kordon Ukrainy. [Draft Law No 1230 of 2 September 2019 on Amendments to the Customs Code of Ukraine on the Protection of Intellectual Property Rights during the Movement of Goods across the Customs Border of Ukraine]. Available from: http://w1.c1.rada.gov.ua/pls/zweb2/webproc34?id=&pf3511=66608&pf35401=496917 [reviewed 2019.08.24] (Ua).

31. WHO Certification Scheme: a timely assessment. Essential Drugs Monitor. 1995;19:5-6. Available from: https://apps.who.int/medicinedocs/documents/s21266en/s21266en.pdf [reviewed 2019.08.24]
32. WHO Revises Guidance on QMS Requirements for National Inspectorates (Posted 23 July 2019 By Zachary Brennan). Available from: https://www.raps.org/news-and-articles/news-articles/2019/7/who-revises-guidance-on-qms-requirements-for-natio?feed=Regulatory-Focus [reviewed 2019.08.24]
33. Quality management system requirements for national inspectorates: draft for comments (Working document QAS/19.811/Rev.1, July 2019). Available from: https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS_19_811_Rev1_Quality_Mgmt_System_Requirements.pdf?ua=1 [reviewed 2019.08.24]
34. Mazur A.V. Ponyattya mitnoyi spravi: ideya, zmist, zakonodavche zakriplennya [A concept of customs affairs: an idea, content, legislative recognition]. Customs business. 2008;5:8-12. (Ua).
35. Pro skhvalennia Kontseptsii rozvytku systemy hromadskoho zdorovia: rozporiadzhennia Kabinetu Ministriv Ukrainy vid 30 lystopada 2016 r. № 1002-r. [On Approving the Concept of Development of the Public Health System: Order of the Cabinet of Ministers of Ukraine of 30 November 2016 No 1002-p]. Available from: https://www.kmu.gov.ua/ua/npas/249618799 [reviewed 2019.08.24] (Ua).
36. Association Agreement between the European Union and its Member States, of the one part, and Ukraine, of the other part, Done at Brussels on 21 March 2014. Official Journal of the European Union. 2014;161/3. Available from: http://publications.europa.eu/resource/cellar/4589a50c-e6e3-11e3-8cd4-01aa75ed71a1.0006.03/DOC_1 [reviewed 2019.08.24]
37. TRIPS Agreement – Article 31bis. Available from: https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf [reviewed 2019.08.24]
38. Pro zatverdzhennia Litsenziinykh umov provadzhennia hospodarskoi diialnosti z vyrobnytstva likarskykh zasobiv, optovoi ta rozdribnoi torhivli likarskymy zasobamy, importu likarskykh zasobiv (krim aktyvnykh farmatsevtychnykh inhrediientiv): Postanova Kabinetu Ministriv Ukrainy vid 30 lystopada 2016 r. № 929. Uriadovyi kurier vid 20.12.2016. № 240. [On approval of the Licensing conditions for conducting economic activities in the production of medicinal products, wholesale and retail trade of medicinal products, imports of medicinal products (except for active pharmaceutical ingredients): Resolution of the Cabinet of Ministers of Ukraine of 30 November 2016 No 929. Government courier dated 20.12.2016. No 240.] (Ua).
39. Pro zaprovadzhennia pilotnoho proektu shchodo markuvannia kontrolnymy (identyfikatsiinymy) znakamy ta provedennia monitorynhu obihu likarskykh zasobiv: Postanova Kabinetu Ministriv Ukrainy №653 vid 24 lypnia 2019 r. Uriadovyi kurier vid 30.07.2019. № 143. [On the introduction of a pilot project on marking with control (identification) signs and monitoring circulation of medicinal products: Resolution of the Cabinet of Ministers of Ukraine No 653 of 24 July 2019. Government courier dated 30.07.2019 № 143]. (Ua).
40. Pro zatverdzhennia Derzhavnoi stratehii realizatsii derzhavnoi polityky zabezpechennia naselennia likarskymy zasobamy na period do 2025 roku: Postanova Kabinetu Ministriv Ukrainy vid 5 hrudnia 2018 r. №1022. Uriadovyi kurier. 11.12.2018. № 233. [On approving the State strategy for implementing the state policy of providing the population with medicinal products for the period until 2025: Resolution of the Cabinet of Ministers of Ukraine of 5 December 2018 No 1022. Government courier. 12.11.2018 No 233]. (Ua).

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SPECIAL FEATURES OF THE LEGAL STATUS OF THE RESEARCH SUBJECT IN CLINICAL TESTING OF MEDICINES

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ABSTRACT

Introduction: The issue of the content of the legal status of the research subject in clinical testing of medicines and its distinction from the patient's legal status is of practical importance, related to the observance of ethical standards in the field of clinical trials, as well as ensuring the balance of public and private interests in this field. Although the subject of this study and the patient being treated are usually united in the intention to overcome the disease, these processes have different essence. The regulation of the legal status of the research subject should be done by legal means that are relevant to the nature of such trials and ensure the effective protection and security of the interests of these subjects. Normative regulation of the legal status of the research subject, unlike the patient, is insufficiently structured and characterized by fragmentation thus requires the doctrinal elaboration.

The aim: The aim is to determine specific features of the legal status of the research subject and its difference from the patient's legal status being provided with medical care; to reason about the necessity and content of propositions to amend the current legislation of Ukraine in order to ensure the rights and legitimate interests of the research subjects.

Materials and methods: The authors used the judgements of the European Court of Human Rights (ECHR) on medical research, international and national regulatory acts, publications of scholars in the field of medical law. The research was carried out on the basis of the systematic approach using the methods of dialectical and formal logic, general scientific and specific legal methods of research.

Conclusions: With the aim to ensure the proper legal protection of the rights and legal interests of the subjects of clinical trials the authors provided arguments for the need to amend the current legislation of Ukraine in order to correspond the international legal acts and ethical standards.

KEY WORDS: a researcher, clinical testing, research subject, a patient, medicines

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INTRODUCTION

Clinical testing of medicines should be a matter of particular concern for the lawmaker, since they relate to the verification of the efficiency of medicines that have not been formally approved for the use in the provision of medical care. Such activities are accompanied by the risks to a human being involved in the clinical testing. The assessment of these risks and the establishment of an effective mechanism for the protection and security of the rights of the research subjects, based primarily on international ethical principles for ensuring protection of the rights, safety and well-being of the research subjects, depend on the state. Legal regulation of the research subjects and their guarantees should, primarily, take into account the nature of the clinical testing and also make it impossible to falsify the data of the clinical testing in order to provide effective medical help for future patients.

Analysis of national and international legislation and doctrine indicates that the research subject is often identified with the patient being treated. As a consequence, legal regulation of the research subject's rights uses legal means borrowed from the legal regulation of the patient's rights (without adaptation to the specifics of legal relations in the field of clinical testing); some aspects of such relations are left behind the attention of the lawmaker, or they are regulated by reference to normative acts, which provide medical care and do not take into account the specifics of the clinical testing. Because of the lack of legal protection, the research subjects become more vulnerable and receive no real legal protection, even having available legal means that do not work due to their incorrect perception by the subjects of legal enforcement. As a result, a person becomes even weaker subject of legal relations in the health care sector that affect the inalienable rights to life and health. These issues are not of the sufficient attention in the scientific literature. Considering this, the legal status of the research subject requires comprehensive doctrinal study.

THE AIM

The aim of the study is to determine specific features of the legal status of the research subject and its difference from

the patient's legal status being provided with medical help, to justify the necessity and content of proposals to amend the current legislation of Ukraine in order to ensure the rights and legal interests of the research subjects and legal certainty.

MATERIALS AND METHODS

To achieve the goals of the study, the authors have analyzed statistical data of clinical testing in Ukraine and have studied global and national tendencies in the field of such probations. The authors have analyzed the judgments of the European Court of Human Rights (hereinafter referred to as the ECHR) in cases pertaining to the topic of the study. Besides, the authors of the research have studied international and national legal acts regulating the procedure of clinical testing conducting.

The relevance of this research was determined by studying and analyzing of the publications of foreign and national researchers on the protection and security of the rights of the research subjects.

While studying the content of legal provisions and concepts contained in international and national regulatory acts and ethical standards, the authors of the paper have used the methods of theoretical analysis and synthesis. Certain issues required the use of systematic analysis method, first of all, in determining the balance between human rights and legitimate interests in the health care sector.

Formal and legal analysis of the international and national legislation provisions on the legal status of the research subject, its rights, as well as the legal means of its ensuring and differences from the legal status of the patient, allowed us to identify shortcomings in national legislation and to propose an improvements of legal regulation, in particular, on regulating specific features of keeping primary medical records during clinical testing, on specifying the definition of criminal illegal act in determining violation of the procedure for clinical testing conducting. The comparative and legal method was used in the analysis of specific features of regulating the issue of the access to the opportunity of using medicines that are being registered or undergoing clinical testing, as well as the peculiarities of ensuring the confidentiality of information about the research subjects.

In solving the objectives of the study, the authors have also used such methods as formal and logical (for distinguishing the rights of the research subject, delimitating the clinical testing from medical care), functional (in determining the impact of the clinical testing on the content of the rights of the subjects involved in the clinical testing), sociological (in analyzing the causes of the negative dynamics in the number of clinical testing in Ukraine) and others.

REVIEW AND DISCUSSION

Clinical testing of medicines is of considerable social and economic importance [1, 2]. Although, according to the statistics only 5% of all medicines under development actually reach the pharmaceutical market, but the costs of their clinical testing are annually increased by an average of 7.5%. Annual growth of the medicinal products' market is forecasted at 7.8%. If the participation in clinical testing for the research subjects is free of charge, the large amounts of money are spent on clinical trials each year. The range of costs on clinical testing at three stages is estimated between US $ 75 million and US $ 4 billion, depending on the country of conduction and the nature of the testing [3].

Having significant potential in the field of clinical testing, the annual number of such testing in Ukraine indicates negative tendency.

According to the World Clinical Trials Market Survey for 1999-2018, the number of trials in Ukraine is 0.75% (3 347 trials over the indicated period) of the total number of trials in the world, which is lower than, in particular, in Romania, Turkey, Mexico, Egypt, Greece, Bulgaria, New Zealand, Thailand, Hungary, Brazil. Among the leaders in the number of clinical testing is the United States, which conducts 26.53% of clinical trials in the world (120 654 trials), Japan ranks second with an indicator of 8.99% (40 895 trials), in the PRC this figure is 7.69% (34 954 trials), in Germany – 7.51% (34 143 trials) of the global clinical trial volume. Since 2015, the largest increase in clinical testing has been observed in the PRC and Japan [4].

Since 2017, there has been a decrease in the number of clinical testing in Ukraine, which is due to several reasons. For example, according to the survey conducted in January 2018 by the Ukrainian Association of Clinical Researchers (UACR) on the reasons that prevent Ukraine from becoming more attractive in the global clinical trial market, with 286 of clinical research representatives taking part in this survey, 35% of respondents consider such reasons in the insufficient legal normalization of the procedure of clinical testing conducting on the basis of state and municipal treatment-and-prophylactic institutions, 27% – in low education of the population, negative attitude to clinical testing, 10% – in undeveloped medical infrastructure, outdated logistics of health care facilities, 9% – in undeveloped research business environment (small number of Ukrainian CROs, SMOs, vendors, etc.), 7% – in imperfect work of regulatory agency, 6% – in a small number of physicians who are fluent in English, 5% – in the legal insecurity of researchers, 1% – in the low qualification of Ukrainian physicians [5].

This paper focuses on specific features of the legal status of the research subject in the clinical testing of medicinal products and its differences from the legal status of the patient.

A human being in the process of involving into clinical testing, as well as in the course of medical care, enters into legal relations with the health care facility, but the identity of the subject composition does not determine the same content and object of legal relations.

I. Ya. Seniuta believes that the participant of the experiment (the patient) has dual nature, is both the subject and quasi-object, because he acts as the research subject. The scholar offers to regulate the status of the subjects of legal relationship related to the conduction of medical experi-

ments by law act [6, p. 47-48].

The issue of legal provision for the protection and security of the rights and interests of the research subjects is relevant to many world countries and is addressed differently [7, 8]. The specific feature of legal regulation of these relations in Ukraine is to determine the detailed procedure for conducting clinical testing at the by-law level act, although at the level of law it is stated that clinical testing of medicines is conducted in accordance with the law [9]. Besides, the identification of a clinical testing subject with a patient (which is incorrect because the latter term means an individual seeking medical care and/or who is provided with such assistance [11]), is common in national law [10] and the scientific literature, namely a clinical testing is often considered as the provision of medical care using innovative medicines.

However, clinical testing of medicines is not the type of medical care. Such trials are primarily conducted to improve the effectiveness of medical care for future patients [12-14].

Clinical testing is the scientific study of an unregistered medicinal product for the purpose of establishing or confirming the efficiency and safety of a medicinal product [10, 15]. Medical care is the activity of professionally trained medical workers, directed on the prevention, diagnosis, treatment and rehabilitation of illnesses, injuries, poisonings and pathological conditions, as well as pregnancy and childbirth [11].

For example, the World Medical Association Declaration of Helsinki – "Ethical Principles for Medical Research Involving Human Subjects" [16] uses the term "medical research" that does not cover medical care. The paragraph 7 of the Declaration states the primary purpose of medical research involving human objects, which is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). The paragraph 16 of this Declaration states that research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.

The Article 2 of Regulation (EU) No. 536/2014 of the European Parliament and of the European Council of 16 April 2014 "On clinical trials on medicinal products for human use" [17] states that clinical study means investigation in relation to humans intended: to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products; to identify any adverse reactions to one or more medicinal products; or to study the absorption, distribution, metabolism and excretion of one or more medicinal products with the objective of ascertaining the safety and/or efficacy of those medicinal products. According to the Article 3 of the Regulation, a clinical testing is aimed to receive reliable and robust data.

Medical care is provided according to the medical evidence by professionally trained medical workers who are employed by the licensed healthcare institutions and individuals having appropriate license and able to stay in civil and legal relations with health care institutions [11].

Requirements for researchers and places for trials are different from the mentioned above. For example, it is obligatory to have the Ethics Committee that operates in the medical-preventive institution, to have the base for providing emergency medical care to patients at such institution, conditions for storage of medicinal products and documentation of clinical research, medical documentation in the archives for at least 15 years upon the testing completion, the ability to involve the required number of the research subjects according to the clinical trial minutes [10].

Despite the indicated differences in the scientific literature, the right to participate in a medical experiment refers to the rights of the patient [18, p. 93; 19], and legal relationship concerning the carrying out of medical experiments are considered as a component of legal relations in the field of providing medical care [6, p. 44].

Besides already made comments about the incorrectness of this approach, it should be noted that the patient is the person who addressed for medical care, whereas clinical testing should be conducted with the participation of a healthy patient.

It is advisably to note that international ethical rules and regulations, as well as the national law require researchers to obtain the informed consent of the subject involved in the clinical testing, or of the person authorized to make the relevant decision instead on behalf of that subject, explaining the research nature of the process, they are involved in (the Art. 7 of the International Covenant on Civil and Political Rights [20], paragraph 1 of the Nuremberg Code of 1947 [21], the Art. 4 of the European Charter of Patients' Rights [22], paragraph 30 of the Preamble and paragraph 21 of the Art. 2, of Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014, paragraph 4.8 of the Integrated Addendum to ICH E6 (R1) "Guideline on Good Clinical Practice E6 (R2)" of 09 November 2016 [23], paragraph 1.28, subparagraph 4.8.1 of the Instruction "Medicinal products. Appropriate clinical practice. ST-NMOZU 42-7.0: 2008" [24]).

The state is obliged to provide access to human beings for information about the risks to life and health connected with his participation in the experiment [19].

In view of the clinical testing and medical care are different activities undertaken by the medical-preventive institutions, then the legal status of the research subject cannot be determined on the basis of the provisions on the rights of the person as a patient in the provision of medical care. The research subject should not be considered as a patient or a quasi-patient.

Unlike the patient, the research subject is not entitled to choose a physician, since the candidate of a researcher is chosen by sponsors and is stated during the examination of the materials of the clinical testing. The researcher can be not only a full-time physician of a medical-preventive institution, but also an employee of the department of a higher medical educational institution, if there is a contract of cooperation between this higher medical educational

institution and the medical-preventive institution, where the trial is planned.

Besides, since clinical trials have predominantly "blind" nature (one or more parties to the trial do not know which medicine are intended for the research subject), some of the research subjects may also take registered medicines for the comparison purposes. The clinical testing itself must be carrying out according to the research protocol, so the research subject, unlike the patient, does not have the right to choose the methods of clinical testing applied to him.

The scientific literature argues that the appointment only of placebo for the patients in the control group within the clinical trial, may limit their right to receive the best treatment available today, and also contradicts the state guarantees for realizing citizens' rights in the health care sector by providing them guaranteed level of health care [25, p. 17].

At the same time clinical testing has the research nature that the researcher must explain to the subjects involved in such research. Therefore, the use of placebo or another medicine in allowed cases for research purposes according to the clinical testing protocol is not the violation of the individual's right to the best available treatment.

Any scientific study requires accurate data record and definitions of the used concepts. Clinical testing is not the exception, this requirement is crucial. It affects the life and health of not only the subject, but many people who may be offered medical care in the future with the use of medicines that shall undergo the appropriate probation.

Therefore, particular attention during the normative regulation of the clinical testing, as well as its conduction, is primarily paid to the initial documents filled in by the researcher, recording information about the results of the research. Although the clinical trial is not a medical aid, the researcher keeps primary medical records in regard to the subject.

The data provided in the individual registration forms should correspond to the original documents, they were transferred from; the differences should be explained [24].

Primary medical records include original documents, data and records, in particular, medical cards of hospital patients, medical cards of ambulant cases, laboratory records, service notes, diaries of the research subjects or questionnaires, journals of issuing medicinal products, etc. [10].

Normatively defined statutory forms of hospital patients' medical cards and medical cards of ambulant cases, as well as instructions for filling them in [26] do not provide the possibility of keeping relevant primary medical documents within the clinical trial, do not take into account the normatively defined features of storage and archiving of medical records of the research subjects, and therefore need to be modified in accordance with the specific features of clinical testing.

While determining an individual's legal status in the health care sector, we should take into account the diversity of legal options available in this sector.

For example, the European Charter of Patients' Rights provides, among other rights, the right to use modern technology that, in turn, provides the availability of medical care, including diagnostic and treatment procedures and medicinal products that meet international standards.

The realization of this right is ensured, in particular, through the use of Internet technologies, the introduction of innovative methods of treatment and new equipment, electronic histories of diseases, patients' personal cards on data medium, telemedicine [27, p.70-73].

Although the definition of this right does not textually refer to the possibility of participating in clinical testing, however, this right is interpreted more broadly in the scientific literature, and the term "right to innovation" is used to refer to it, which includes such components as: 1) the right to medical and biological experiment; 2) the right to reproductive technology; 3) the right to donate; 4) the right to therapeutic cloning; 5) the right to sex reversal [28, p. 145].

However, such right is not specified in national law [11] among citizens' rights in the health care sector.

The use of biomedical experiments on humans is permitted for public benefit, in terms that they are scientifically substantiated, the potential success benefit over the risk of causing serious health or life consequences, and the preservation of medical secrecy if necessary [11].

At the same time, the possibility of applying new methods of prevention, diagnostics, treatment, rehabilitation and medicines, which are under consideration but still not approved, is regulatory provided in the interests of cure of a person after receiving his/her written consent.

The right of the patient to access experimental treatment and medicinal products in different countries find their place in different laws.

For example, the European Court of Human Rights (ECHR) considered the case of "Hristozov and others v. Bulgaria" [29], where ten applicants with cancer complained that they were denied access to unauthorized experimental cancer medicines. The Bulgarian legislation provides the granting of an appropriate authorization only if the medicinal products are authorized in another state. Applicants asked to allow the use of medicinal products that were permitted in some states only for "charitable research use" and therefore, they were denied in the authorization. The ECHR in its decision of 13 November 2012 pointed out that there was no violation of the Art. 8 in this case, which provides the right to respect private and family life, the Convention for the Protection of Human Rights and Fundamental Freedoms [30] (hereinafter referred to as the Convention). The ECHR noted that there was a restriction on the right to respect the private life of the applicants, but provided the possibility of using unauthorized medicine under certain conditions. The ECHR stated that it could not be argued that the authorities denying applicants the access to the remedy, if it could potentially save their lives, which effectiveness is still dubious, thus increased the applicants' suffering. The Article 3 of the Convention does not oblige the Member States to eliminate differences in levels of health care in different countries.

In another case of "Durizotto v. Italy" [29], being considered in the ECHR, the Italian national courts refused to grant the

applicant's daughter permission to undergo charitable research for the treatment of her disease through the medicine treatment, which was under clinical trial, and had limited access to it, which the applicant regarded as discriminatory. The ECHR in its judgment of 6 May 2014 (admissibility decision), noted that the Scientific Committee set up by the Italian Ministry of Health had a negative attitude to the therapeutic method and the scientific value of the therapy. Therefore, the interference into the right to respect the private life of the applicant's daughter, which was to refuse to grant her request for such therapy, was necessary in a democratic society and pursued a legitimate aim of protecting the health and was consistent with that purpose.

Therefore, a person's right to being applied new methods of prevention, diagnosis, treatment, rehabilitation and medicines that have not been approved for use, is not absolute in the interests of the person's care.

The issues of the application of medical secrecy norms to clinical trial's subjects are of particular interest. The content of medical secrecy indicates that physicians both during medical care and clinical testing must respect it.

The right to secrecy about the state of health, the fact of seeking medical assistance, the diagnosis, as well as the information obtained during the medical examination is guaranteed in Ukraine [9]. During clinical testing, the information about the research subject is kept confidential and processed within the clinical trial in an impersonal form. Ensuring the confidentiality of documents that can identify the research subject is the necessary condition for protecting his or her rights [10].

These prescriptions of national law are important because, in case of the absence of such norms, the research subject may have been denied the confidentiality of the information about the trial, in particular on grounds of public interest in accessing the data on the safety and efficiency of medicines that were examined.

For example, the ECHR judgment in the case of Gillberg v. Sweden of 22 November 2010 and the Grand Chamber of 3 April 2012 [31] gave priority to public interests. The lawfulness of criminal prosecution of the researcher by the state for refusing to disclose information about clinical trials was considered in this case. The resolution of this case was primarily based on the inaccuracy of the clinical testing and medical care, which established the essence of confidentiality of clinical trial's information in this case for the ECHR. The applicant in this case, a professor of the University, was responsible for the research project on the syndrome of hyperactivity and attention deficit of children in 1977-1992. The University Ethics Committee determined the confidentiality of participant information as a precondition for this project that could only be accessed to the researcher and his staff, so he gave obligation to patients and their parents to keep this information. In 2002, a scholar from another university and a pediatrician asked for access to research materials, and the university refused them. The Administrative Court of Appeal, examining the complaint for this refusal, concluded that the applicants had demonstrated a legitimate interest and should have access to the material on terms that would include restrictions on its use and the prohibition on the removal of copies from the university premises. The applicant refused to disclose the material and he was sentenced for probation and ordered to pay a fine.

The ECHR noted in this case that, although, at first glance, it had posed serious ethical concerns regarding medical research, public access to information and the interests of children involved into the research, the only question that arises, is whether the applicant's conviction and sentence for failure to perform his duties were compatible with the Convention. Regardless of whether the applicant considered that the disclosure decisions were based on wrong or insufficient grounds, it was important that the applicant intentionally failed to fulfill the obligations imposed by the court decisions during the long period of time.

The Grand Chamber of the ECHR noted that the applicant was an official exercising public authority in a public institution. He was not a pediatrician or psychiatrist and did not represent children or parents. The materials which the applicant refused to provide belonged to the university and contained official documents that were subject to the principle of public access under the Law on Freedom of the Press and the Privacy Act. The legislation did not allow the agreement of a state agency or a third part, which in advance excludes the right of public access to official documents. The applicant, who was not empowered by the research participants with the powers of their physician, had no obligation to keep professional secrecy. The Grand Chamber of the ECHR emphasized that there was no breach of the confidentiality of the provided information, since it was a matter of research rather than treatment.

Having analyzed this judgement, Professor Erwin Deutsch criticized the ECHR judgement. E. Deutsch pointed out that the promise of keeping information secret is one of the fundamental tenets of European privacy law. If the subjects were aware that the promise could "fall back" under the Swedish Security Act, they would probably never have agreed to participate in the experiment. The right not to undergo the medical experiments without informed consent is one of the general rules of international law. The relation to a promise in such a delicate area was obvious to Gillberg, and he had the right to fulfill it, according to E. Deutsch. The ECHR had to rule in favor of the plaintiff, since the European law has the priority over the Swedish law, and the promise to keep information secret cannot be amended by national law [31].

Paragraph 2 of the Good Clinical Practice of the International Conference on the Harmonization of Technical Requirements for the Registration of Medicinal Products for Human Use (ICH GCP) "Guidelines for Proper Clinical Practice E6(R2)" provides that the rights, safety and prosperity of the research subject is of paramount importance and should prevail over the interests of science and society (subparagraph 2.3), the confidentiality of records allowing to identify the research subjects must be ensured with respect for the right to private life and the protection of privacy in accordance with the applicable regulatory requirements (subparagraph 2. 11).

The case covered above involved the criminal prosecution of the researcher for non-disclosure of information, including failure to provide access to clinical testing documents, which was qualified by national court as abuse of official position.

Criminal liability for the violation of the procedure for conducting clinical trials is established in Ukraine, which is defined in the Criminal Code separately from criminal liability for improper performance of professional duties by a medical or pharmaceutical employee. Besides, the criminal offense of the rights and legitimate interests of persons participating in a clinical testing (rather than patients receiving medical care) was called "Patient's Rights Violation". There is also a criminal liability for illegal conduction of medical, biological, psychological or other experiments on a person, if it poses a danger to the life or health of the last. Criminal offenses of failure to perform or improper performance of professional duties by a medical or pharmaceutical employee as a result of negligent or dishonest attitude, if it has caused grave consequences for the patient, as well as for conducting clinical testing of medicines without the written consent of the patient or his legal representative, or concerning a minor or incapable person, if these actions resulted in the death of the patient or other serious consequences, are related to criminal offenses against person's life and health [32].

Deliberate violation of the established procedure of pre-clinical study, clinical testing of medicinal products, falsification of their results, as well as violation of the established procedure of state registration of medicines belong to criminal offenses in the sphere of narcotic drugs circulation, psychotropic substances, their analogues or precursors and other criminal offenses against the health of the population of Ukraine. Sanction for such actions that did not cause the death of the victim or other grave consequences, is imprisonment for a term from three to five years with deprivation of the right to occupy certain positions or to be involved in certain activities for a term from one to three years. In case of these measures, imprisonment is for a term from eight to ten years with deprivation of the right to occupy certain positions or to be involved in certain activities for a term from two to three years [32]. The legislation of other European countries does not contain analogues of criminal liability for such actions. At the same time, the legislative definition of the mentioned criminal offense does not fully comply with the principle of legal security, which is an element of the rule of law and guarantees the subjects of legal relations the opportunity to predict the legal consequences of their behavior. Criminal liability for any deliberate violation of the clinical trial procedure (for example, breach of reporting deadlines for at least one day or reporting about certain circumstances), even if there are no grave consequences, does not coincide with the provided punishment.

As stated in the decision No. 15-rp / 2004 of November 2, 2004 of the Constitutional Court of Ukraine [33], the issue of fairness is conformity of punishment to the committed crime; the category of justice implies that the punishment for a crime must be reasonable to the crime arising from the rule of law principle, from the essence of the constitutional rights and freedoms of individuals and citizens, in particular the right to liberty.

The ECHR stated in its judgment in the case of "Soldatenko v. Ukraine" of 23 October 2008 [34] that, when it comes to deprivation of liberty, it is extremely important to ensure a general principle of legal security. In case if national law provides the possibility to deprive liberty, such law must be sufficiently accessible, clearly formulated and foreseeable in application to eliminate any risk of arbitrariness (paragraph 111).

Observance of the requirement of clarity and ambiguity of the norms establishing criminal liability, as stated by the Constitutional Court of Ukraine in its judgment of February 1, 2019 No. 1-r / 2019 [35], is especially important in regard to the specifics of the criminal law and the consequences of criminal prosecution related to possible significant restrictions on human rights and freedoms.

For example, clinical trials in Ukraine highlight the following: 1) violations that adversely affect the rights, safety or health of the subjects and (or) affect the quality and integrity of clinical testing data (inconsistency, falsification of data, lack of primary medical records, and numerous significant observations) that may be used to suspend or suspend a clinical testing; 2) defects that may adversely affect the rights, safety and health of the subjects and (or) the quality and integrity of the clinical trial data (deviations from the clinical trial protocol and / or numerical insignificant comments) and are subject to timely correction by providing written notification of their removal to the state enterprise "State Expert Center of the Ministry of Health of Ukraine"; 3) disadvantages that do not affect the rights, safety and health of the subjects and (or) cannot affect the quality and integrity of the clinical trial data and must be corrected [10].

For example, we would like to distinguish the following in accordance to clinical testing in Ukraine: 1) violations that adversely affect the rights, safety or health of the research subjects and (or) affect the quality and integrity of clinical trial data (inconsistency, falsification of data, lack of primary medical records, and numerous significant observations) that may be the reason for partial or complete stop of a clinical trial; 2) shortcomings that may adversely affect the rights, safety and health of the research subjects and (or) the quality and integrity of the clinical trial data (deviations from the clinical trial minutes and / or numerical insignificant comments) and are subject to timely correction by providing written notification of their removal to the state enterprise "State Expert Center of the Ministry of Health of Ukraine"; 3) disadvantages that do not affect the rights, safety and health of the research subjects and (or) can not affect the quality and integrity of the clinical trial data and must be corrected [10].

Therefore, it is inconsistent to provide criminal liability for the violation of the procedure for conducting clinical testing without determining the content of such violation in the definition of a criminal offense, whereas a special regulatory act distinguishes between violations and shortcomings [10]. The latter are also violations, misconduct, but by their nature and consequences they are not critical and should be corrected and taken into account in future medical and professional work.

The results of the research have proven that national

legislation and scientific doctrine are mistaken for treating clinical testing as medical care and defining the rights of the research subject as a kind of patient's rights. It has been substantiated that the legal status of the research subject should be determined separately from the legal status of the individual as a patient, by using special measures of legal protection of a human being as researched experimental medicinal product during the trial. Compulsory ground of the research of subject's rights is the state control over such activities and solution of safety issues of the research subject according to the principle of advantage of the potential success over the risk of serious harm to health or life, as well as in terms of maintaining the necessary privacy. The findings of the study can be used in further research on human rights in the health care sector, enforcement practice and while improving the current legislation.

CONCLUSIONS

Understanding the essence of clinical testing is the key to the proper legal protection and security of human rights and legitimate interests, as well as to the balance between public and private interests in the field of clinical testing of medicines, which directly affect the development of this vital area.

Human rights of the research subject differ from the human rights of the patient while providing medical care. Both groups of the rights belong to human rights in the health care sector.

The research subject shall have the right: 1) to participate voluntarily in the clinical testing, including to refuse to participate in the trial at any time, without explanation, without any sanctions or restrictions; 2) to obtain information on the nature and possible consequences of the trial, the properties of the medicinal product, its expected efficacy, the degree of risk, and other information to be provided for him under the legislation and agreed by the draft informed consent; 3) to privacy of the documents that can identify the person being examined; 4) to suspend the clinical testing or its separate stages in case of the threat to the health or life of such subject in relation to its conduction; 5) to the early termination of the clinical trial or its separate stages in case of the threat to the health or life of such subject in regard to its conduction, as well as in case of the absence or insufficient effectiveness of its action, violation of ethical standards; 6) to insure his life and health; 7) to address the sponsor, the state enterprise "State Expert Center of the Ministry of Health of Ukraine", the Commission on Ethics at the medical and preventive institution, the Ministry of Health and to court in case of the violation of the rights.

The forms of the medical card of the hospital patient and the medical card of the ambulant case and the instructions for filling them in need to be modified in order to determine the peculiarities of keeping the forms of primary medical documents during clinical testing.

While determining the objective aspect of the violation of the procedure of pre-clinical study, clinical testing and state registration of medicinal products in the criminal law, we must clearly state the action which implies criminal liability. Criminal liability should be provided for such violations that negatively affect the rights, safety or health of the subjects, the quality and integrity of the clinical trial data.

REFERENCES

1. Brown JN, Tillman F 3rd, Jacob S, Britnell SR. Economic outcomes associated with an investigational drug service within a Veterans Affairs health care system. Contemp Clin Trials Commun. 2019 Apr 6;14:100354. doi: 10.1016/j.conctc.2019.100354.
2. Kaló Z, Antal J, Pénzes M, Pozsgay C, Szepezdi Z, Nagyjánosi L. Contribution of clinical trials to gross domestic product in Hungary. Croat Med J. 2014 Oct;55(5):446-51. doi: 10.3325/cmj.2014.55.446
3. Mirovyie standartyi klinicheskih issledovaniy: sostoyalsya 1-y Kievskiy klinicheskiy forum [World Clinical Trials Standards: the 1st Kyiv Clinical Forum]. Apteka.Ua.2017;47(1118). Available from: https://www.apteka.ua/article/435992 [reviewed 2019.09.14] (Ua).
4. Number of clinical trials by year, country, WHO region and income group (1999-2018). Published: April 2019, Available from: https://www.who.int/research-observatory/monitoring/processes/clinical_trials_1/en/ [reviewed 2019.09.14]
5. Shcho zavazhaie Ukraini buty pryvablyvoiu na hlobalnomu rynku klinichnykh doslidzhen? [What does prevent Ukraine from being attractive in the global clinical trial market?], Available from: https://www.facebook.com/groups/UA.Clin.Research/permalink/1089532177867992/ [reviewed 2019.09.14] (Ua).
6. Senyuta I.Y. Tsyvilni pravovidnosyny u sferi provedennia medychnykh doslidiv [Civil legal relations in the field of medical experiments]. Medical Law Journal.2018;1(21):42–53 (Ua)
7. de Bijl N.P. The legal protection of test subjects in clinical trials of medicinal products for human use in the European Union. Med Law.2004;23(1):1-7.
8. Schott M. Medical research on humans: regulation in Switzerland, the European Union, and the United States. Food Drug Law J.2005;60(1):45-77.
9. Tsyvilnyi kodeks Ukrainy: Zakon Ukrainy [The Civil Code of Ukraine: Law of Ukraine] № 435-IV, of 16 January 2003 Available from: http://zakon3.rada.gov.ua/laws/show/435-15 [reviewed 2019.09.14] (Ua).
10. Pro zatverdzhennia Poriadku provedennia klinichnykh vyprobuvan likarskykh zasobiv ta ekspertyzy materialiv klinichnykh vyprobuvan i Typovoho polozhennia pro komisii z pytan etyky: Nakaz Ministerstva okhorony zdorovia Ukrainy [On Approval of the Procedure for Clinical Trials of Medicinal Products and Expertise of the Materials of Clinical Trials and Model Regulations on Ethics Commissions: Order of the Ministry of Health of Ukraine] № 690, of 23 September 2009 Available from: https://zakon.rada.gov.ua/laws/show/z1010-09 [reviewed 2019.09.14] (Ua).
11. Osnovy zakonodavstva Ukrainy pro okhoronu zdorovia: Zakon Ukrainy [Principles of Ukrainian Health Care Legislation: Law of Ukraine] № 2801-XII of 19 November 1992, Available from: https://zakon.rada.gov.ua/laws/show/2801-12 [reviewed 2019.09.14] (Ua).
12. Lemaire F. Patient care versus research: does clinical research provide individual benefit to patients enrolled in trials? Curr Opin Crit Care.2004 Dec;10(6):565-9. doi: 10.1097/01.ccx.0000144764.96410.e1
13. Kass N.E., Faden R.R., Goodman S.N., Pronovost P., Tunis S., Beauchamp T.L. The research-treatment distinction: a problematic approach for determining which activities should have ethical oversight. Hastings Cent Rep.2013 Jan-Feb;Spec №:4-15. doi: 10.1002/hast.133

14. Lewens T. Distinguishing treatment from research: a functional approach. J Med Ethics. 2006 Jul;32(7):424-9. doi: 10.1136/jme.2005.013078
15. Pro likarski zasoby: Zakon Ukrainy [On Medicinal Products: Law of Ukraine] № 123/96-VR of 04 April 1996, Available from: https://zakon.rada.gov.ua/laws/show/123/96-вр [reviewed 2019.09.14] (Ua).
16. Helsinska deklaratsiia Vsesvitnoi medychnoi asotsiatsii «Etychni pryntsypy medychnykh doslidzhen za uchastiu liudyny u yakosti obiekta doslidzhennia» [World Medical Association Declaration of Helsinki – «Ethical Principles for Medical Research Involving Human Subjects»], the new version of the Declaration as of October 2013, Available from: https://zakon.rada.gov.ua/laws/show/990_005 [reviewed 2019.09.14] (Ua).
17. Regulation (EU) № 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0536 [reviewed 2019.09.14]
18. Buletsa S. B. Prava ta oboviazky patsiienta ta likaria [Rights and obligations of a patient and a physician]. Uzhhorod Natsional University Bulletin. Series: Law.2016.41(1):93-95, Available from: http: http://nbuv.gov.ua/UJRN/nvuzhpr_2016_41(1)__24 [reviewed 2019.09.14] (Ua).
19. Viktor V. Horodovenko, Vitalii M. Pashkov, Larysa G. Udovyka. 2018. Protection of patients' rights in the european court of human rights. Wiadomości lekarskie. Czasopismo polskiego towarzystwa lekarskiego. 2018;Vol.71,6:1200-1206, Available from: http://wl.medlist.org/06-2018-13/ [reviewed 2019.09.14]
20. Mizhnarodnyi pakt pro hromadianski i politychni prava. [International Covenant of Civil and Political Rights] of 10 October 1973, Available from: http: https://zakon.rada.gov.ua/laws/show/995_043 [reviewed 2019.09.14] (Ua).
21. Nyurnbergskiy kodeks. Helsinskaya deklaratsiya [Nuremberg Code. Declaration of Helsinki], Available from: http: https://ulitka-kapusha.livejournal.com/51653.html [reviewed 2019.09.14] (Ua).
22. Evropeyskaya hartiya prav patsientov [European Charter of Patients' Rights], Available from: http://health-rights.org/index.php/cop/item/европейская-хартия-прав-пациентов-2 [reviewed 2019.09.14] (Ua).
23. Integrirovannoe dopolnenie k ICH E6(R1): Rukovodstvo po nadlezhaschey klinicheskoy praktike E6(R2) [Integrated addendum to ICH E6 (R1): guideline on Good Clinical Practice E6 (R2)] of 09 November 2016. Available from: URL:https://ichgcp.ru/ [reviewed 2019.09.14] (Ua).
24. Likarski zasoby. Nalezhna klinichna praktyka. ST-NMOZU 42-7.0:2008: Nastanova [Medicinal products. Appropriate clinical practice. ST-NMOZU 42-7.0:2008: Instruction], the new version of the Instruction as № 1169 of 26 October 2017. Available from: https://zakon.rada.gov.ua/rada/show/ru/v0095282-09#n3534 [reviewed 2019.09.14] (Ua).
25. Kornatskyi V. M., Talaieva T. V., Silantieva O.V. Pravovi problemy klinichnykh vyprobuvan likarskykh zasobiv v Ukraini [Legal problems of clinical trials of medicinal products in Ukraine]. Lawyer.2012;3 (138):15-18 (Ua).
26. Pro zatverdzhennia form pervynnoi oblikovoi dokumentatsii ta Instruktsii shchodo yikh zapovnennia, shcho vykorystovuiutsia u zakladakh okhorony zdorovia nezalezhno vid formy vlasnosti ta pidporiadkuvannia: Nakaz Ministerstva okhorony zdorovia Ukrainy [On Approval of Forms of Primary Accounting Documents and Instructions for their Completion, Used in Health Care Institutions Regardless of Ownership and Subordination: Order of the Ministry of Health of Ukraine] of 14 February 2012 № 110. Available from: https:// https://zakon.rada.gov.ua/laws/show/z0661-12 [reviewed 2019.09.14] (Ua).
27. Ukraina kriz pryzmu Yevropeiskoi khartii prav patsiientiv: rezultaty vykonannia v Ukraini druhoho etapu yevropeiskykh doslidzhen na vidpovidnist standartam YeS z prav patsiientiv [Ukraine through the prism of the European Charter of Patients' Rights: results of the implementation in Ukraine of the second stage of European research on compliance with EU standards of patients' rights]. Kyiv: Vydavnytstvo TOV «Dyzain i polihrafiia», 2012. 158 p, Available from: https://www.irf.ua/files/ukr/programs/euro/patients_brochure.pdf [reviewed 2019.09.14] (Ua).
28. Kovalenko O. O. Prava patsiienta u sferi okhorony zdorovia yak element derzhavnoho upravlinnia [Patients' rights in health care sector as an element of public administration. Public administration theory and practice]. Theory and practice of Public Administration.2018;2:140-148 [Online], available at: URL: http://nbuv.gov.ua/UJRN/Tpdu_2018_2_23 [reviewed 2019.09.14] (Ua).
29. Praktyka YeSPL: Faktychni dani – Zdorovia. Hruden 2015 roku [ECHR Practice : Actual data – health. December 2015]. Available from: https://unba.org.ua/publications/1262-praktika-espl-faktichni-dani-zdorovya.html (Accessed 14 September 2019) (in Ukrainian).
30. Konventsiia pro zakhyst prav liudyny i osnovopolozhnykh svobod [The Convention for the Protection of Human Rights and Fundamental Freedoms] of 1950, ratified by the Law of Ukraine of 17 July 1997 № 475/97-BP. Available from: http://zakon3.rada.gov.ua/laws/show/995_004 [reviewed 2019.09.14] (Ua).
31. Antoniuk El. Balans ynteresov v voprosakh ynformatsyy o medytsynskykh yssledovanyiakh (v kontekste reshenyia ESPCh po delu «Gillberg v. Sweden») [Balance of interests on the issues about information on medical experiments (in the context of the ECHR judgments in the case of «Gillberg v. Sweden»] of 07 December 2018. Available from: https://protocol.ua/ua/balans_interesov_v_voprosah_informatsii_o_meditsinskih_issledovaniyah_(v_kontekste_resheniya_espch_po_delu_gillberg_v_sweden_)/ [reviewed 2019.09.14] (Ua).
32. Kryminalnyi kodeks Ukrainy: Zakon Ukrainy [Criminal Code of Ukraine: Law of Ukraine], the new version of the Law as № 2617-VIII of 22 November 2018, Available from: https://zakon.rada.gov.ua/laws/show/2341-14 [reviewed 2019.09.14] (Ua).
33. Rishennia Konstytutsiinoho Sudu Ukrainy u spravi za konstytutsiinym podanniam Verkhovnoho Sudu Ukrainy shchodo vidpovidnosti Konstytutsii Ukrainy (konstytutsiinosti) polozhen statti 69 Kryminalnoho kodeksu Ukrainy (sprava pro pryznachennia sudom bilsh miakoho pokarannia) [Decision of the Constitutional Court of Ukraine in the case on the constitutional submission of the Supreme Court of Ukraine on the conformity of the Constitution of Ukraine (constitutionality) with the provisions of the Article 69 of the Criminal Code of Ukraine (case on imposing lesser sentence)] of 2 November 2004 № 15-rp/2004. Available from: https://zakon.rada.gov.ua/laws/show/v015p710-04 [reviewed 2019.09.14] (Ua).
34. Case of Soldatenko v. Ukraine, application no 2440/07, judgment of 23 October 2008 Available from: https://books.google.com.ua/books?id=qXsuD_W2ehUC&pg=PA281&lpg=PA281&dq=application+no+2440/07,+judgment+of+23+October+2008&source=bl&ots=NgDzYUfitw&sig=ACfU3U3cPGovQne8pe6Xi6HJYR18TvdU3Q&hl=ru&sa=X&ved=2ahUKEwi38JvZrenlAhWQxosKHVjfDL8Q6AEwAHoECAYQAQ#v=onepage&q=application%20no%202440%2F07%2C%20judgment%20of%2023%20October%202008&f=false [reviewed 2019.09.14] (Ua).

35. Rishennia Konstytutsiinoho Sudu Ukrainy u spravi za konstytutsiinym podanniam 59 narodnykh deputativ Ukrainy shchodo vidpovidnosti Konstytutsii Ukrainy (konstytutsiinosti) statti 368-2 Kryminalnoho kodeksu Ukrainy [Decision of the Constitutional Court of Ukraine in the case on the constitutional submission of 59 MPs of Ukraine on the conformity of the Constitution of Ukraine (constitutionality) with the Article 368-2 of the Criminal Code of Ukraine]. of 26 February 2019 № 1-r/2019. Available from: https://zakon.rada.gov.ua/laws/show/v001p710-19 [reviewed 2019.09.14] (Ua).

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REVIEW ARTICLE
PRACA POGLĄDOWA

SERIALIZATION AS NEW QUALITY CONTROL SYSTEM OF MEDICINAL PRODUCTS

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ABSTRACT

Introduction: medicinal products are special goods which the quality of life and health of the population directly depends on. Therefore, ensuring the quality of medicinal products is central to state policy of developed countries in the conditions of free movement of goods and services. High quality of medicinal products should be supported in the context of pharmaceutical market globalization by using exclusively a modern quality control system such as serialization.

The aim: the rationale for the need to use the serialization system of medicinal products by European countries which are not a part of the EU is the goal of our research.

Materials and methods: the research is based on EU law (Directive 2001/83/EC, Directive 2011/62/EU, Delegated Regulation (EU) 2016/161), Ukrainian legislation, statistics of WHO, General Prosecutor's Office, European Union Intellectual Property Office, Court judgment of the Ukrainian courts, legal doctrine in the field of medical law. The research is also based on general and special scientific research methods.

Conclusions: existing quality control mechanisms do not cope with the task of providing the people with access to high quality and safe medicinal products. The serialization of medicinal products provides an opportunity to raise the quality control of medicinal products to a new level in the process of globalization. Serialization of medicinal products is important for Ukraine and other country's not in EU, it will fill the internal pharmaceutical market with a qualitative product and will allow the export of medicinal products.

KEY WORDS: medicinal products, quality of medicinal products, falsified medicinal products, serialization

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INTRODUCTION

Globalization is a characteristic of the modern pharmaceutical market [1]. Globalization is aimed at creating a world, regional (European, American) pharmaceutical market. This market unites many countries. Thus, there are situations when medicinal products are produced in one country, packaged in others and sold in a third.

The term "medicinal products circulation" includes interrelated stages: clinical research, manufacturing (in pharmacies and/or industrial), storage, transportation, sale (wholesale, retail), utilization, and destruction of medicinal products. Thus, the circulation of medicinal products cannot be narrowed solely to their trading by business entities; this is a multi-element concept, which includes the entire chain of medicinal products from the moment of creation to the transferring to consumer.

Each stage of medicine products circulation can take place in the territory of different countries (these may be conflict areas, countries with ineffective system of criminal justice and high level of corruption, low level of quality control, etc.).

Due to this, the issue of the medicinal products quality control is relevant today, medicinal products are special goods, which the quality of life and health of the population directly depends on. Therefore, ensuring the quality of medicinal products is central to state policy of developed countries in the conditions of free movement of goods and services.

The national system of medicinal products quality control is considered efficient if the quantity of substandard and falsified pharmaceutical products does not exceed 1% rate (for countries high level of control over medicinal products circulation) or 10% rate (for low- and middle-income countries) [2].

There is an alarming increase of medicinal products detected in the European Union, which are falsified or substandard in terms of their identity, source etc. Those products usually contain substandard or falsified ingredients, no active ingredients or contain wrong dosage of ingredients, including active substances, thus posing a huge threat to public health. Former experience shows that such falsified medicinal products reach patients not only through illegal means, but also via legal supply chain. It poses an obvious threat to human health and may lead to a lack of patient's trust to legal supply chain [3].

The World Health Organization (WHO) also recognizes the threat to public health. WHO in 2017 estimates that 10.5% of medicines worldwide are substandard or falsified [4]. The substandard medicines increase the risks of morbidity and mortality by prolonging diseases and heighten the risk of treatment failure, poisoning, and adverse medicinal products interactions. Besides that, the substandard

medicinal products cause damages from $ 10 billion to $ 200 billion annually [5,6]. So, that is why it is impossible to solve the existing problems using an old methods of medicinal products' quality control.

So, the Medicrime Convention (The Medicrime Convention Combating counterfeiting of medical products and similar crimes) has been internationally adopted to ensure that the spread of illicit medicinal products in health care sector is properly prevented by the creation of a criminal law tool to criminalize any form of medicinal products tampering [7]. The Convention adoption is an important but not sufficient step for clearing the pharmaceutical market from falsified pharmaceutical products.

The development of modern technologies (e.g. blockchain [8], serialization, etc.) provides new opportunities in the field of quality control of medicinal products.

The latest technologies are actively introduced in the EU, USA field of health care. For example, the blockchain technology is already being used in five areas of the EU health care system [8].

High quality of medicinal products should be assured by modern quality control systems such as serialization. Thus, serialization of medicinal products starting to be used in the pharmaceutical market of the EU as a binding method of quality control of medicinal products. The EU uses new technological possibilities in the field of quality control of medicinal products, but their introduction causes a number of economic and organizational issues.

Therefore, the issue of serialization process of medicinal products researches is relevant for European countries which are not in the EU still but on their way of European integration and want to export pharmaceutical products to the EU market

THE AIM

The rationale for the need to use the serialization system of medicinal products by European countries which are not part of the EU is the goal of our research.

MATERIAL AND METHODS

The study is based on the theoretical and empirical data of WHO, statistic of European Union Intellectual Property Office, text of Directive 2001/83/EU of the European Parliament and of the Council on the Community code relating to medicinal products for human use, Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Europe Convention on the counterfeiting of medical products and similar crimes, criminal legislation and legislation about control quality medicines of Ukraine, date of General Prosecutor's Office data on the criminal liability of those who committed crimes of medicines falsification and the legal doctrine of medical law. Totally 15 laws and scientific papers, 20 court judgments were analyzed. The research also based on general and special scientific research methods (dialectical, comparative, analytic, synthetic and comprehensive).

REVIEW

Until 2019 there were no European regulation of the procedure of medicinal products quality control in circulation. The common issues of quality control of medicines contained in the directive 2001/83/EU of the European Parliament and the Council on the community code relating to medicinal products for human use [9].

The basis for legal regulation of preventing the spread of falsified medicines among EU territory is the Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, on the prevention of the entry into the legal supply chain of falsified medicinal products [3].

To date, legislation has focused on the control of deliberately falsified medicinal products, but substandard legitimate medicinal products, i.e. those that have gone through some sort of regulatory procedure, are more common and pose a greater threat to patient health, so both issues need to be tackled [10].

Substandard medicinal products can reach the market through substandard production of legitimate medicinal products due to inadequate quality-control processes during manufacture, as well as by deliberately fraudulent practices (falsified). The relative contribution of the two sources is unknown; however, genuine but substandard medicinal products are likely to account for the majority of cases. Falsified drugs are highly likely to be of substandard quality, possibly containing no active pharmaceutical ingredient. However, only a small proportion of substandard medicinal products are falsified; the rest reach the market as a result of poor manufacturing practices, inadequate quality-control processes, incorrect storage or inappropriate packaging, or a combination of these factors. This can affect both branded and generic medicinal products. In many cases, the reason why a medicinal product is substandard (i.e. deliberate falsification or poor manufacturing practice) is unknown. Whether a medicinal product is substandard because of criminal intent or because of failures in manufacturing, storage, etc. is immaterial to the patient because the impact on their health will be the same regardless of cause. We consider the term 'substandard' to apply both to legally approved but poor-quality medicinal products and to intentionally falsified medicinal products [10].

So, EU Member States use quite a severe authorization procedure on their territories, i.e. a procedure for admission to the common market of the EU. Key characteristics evaluated during the authorization procedure are the quality, safety and efficacy of a medicine. EU Member States expect to achieve such characteristics by using a number of measures [11]. Only using of the latest tracking technologies of the whole chain of the medicinal products is an effective way to prevent substandard or falsified medicinal products appearance at the pharmaceutical market. Drug serialization is such a latest tracking technology. Serialization will be done using the GS1 standard, the way the enhancement of requirements for the

labelling of medicinal products, i.e. the using of a unique identifier (2D code of the format GS1 ECC200) [11].

The EU is certainly not the first in its legislative push for serialization of pharmaceutical products. More than 40 countries worldwide have initiated similar legislative rules in response to the increase of falsified medicinal products and their illegal distribution. The difference is that starting from 9 February, 2019 every pharmaceutical product that is released or manufactured for the European market will have to comply with the Falsified Medicine Directive. This hard deadline approach forms a stark contrast with other legislations (outside the EU) that follow a gradual implementation. Furthermore, some of EU countries allowed for significant delays in the enforcement of their serialization legislation (the project implementation was postponed to 2025 due to economic, organizational, and technical reasons in Italy, Belgium and Greece). As the implementation of serialization over the entire pharmaceutical industry in such a short term seems to be challenging, arbitrary deadlines could make vital therapies inaccessible if stakeholders can't reach a workable solution by the due date [12].

Delegated Regulation (EU) 2016/161 regulates the procedure of automated medicinal products tracking system functioning. When a scan is performed, the product is decommissioned; that is, data on the medicinal products packet are transmitted to a national database where they are crosschecked with a database of known legitimate products, and is recorded as being dispensed. The information is then sent back to the terminal responsible for performing the scan. The terminal alerts the user to any warnings associated with that product. Warnings may include "medicinal products not found in the database," "medicinal products expired," "medicinal products will expire soon," "medicinal products recalled," "medicinal products have been falsified," or "medicinal products has been previously scanned elsewhere", which should prompt staff to quarantine the affected product [13].

So, organization area of serialization system includes creation of database on all stages of medicinal products circulation (at the state level and EU level), implementation a labeling of medicinal products packages and reading system that national controls bodies use. Instead, the quality control procedure of medicinal products is simplified and become less expensive. Therefore, the advantages of such quality control of medicinal products are obvious.

Databases will have all relevant information about supply chain, production, storage of medicinal products, its expiration date and the status of a batch of medicinal products. Technology databases is similar to the blockchain technology (like as USA), but it will use centralized databases.

Thus, the directive introduced a new form (method) of medicinal products quality control in the EU. This form is binding for EU member States. Fulfillment of this requirements provides the opportunity to get a pass to the European pharmaceutical market. Also, it provides better quality control of medicinal products. However, not all EU countries were able to implement it despite the imperative norms. It is postponed in several European countries due to considerable expenses, lack of time and organizational resources.

DISCUSSION

The issue of introducing a system of serialization of medicinal products was discussed by scientists for a long time.

Some scholars predicted the possibility of introducing a medicinal product tracking system into circulation. They believe that expanding the use of such labelling firstly into the territory of a subregion or region and subsequently worldwide would be reasonable. However, in their opinion such transition is costly and it is impossible today or in near future [11].

Serialization of medicinal products obviously has both advantages and disadvantages. Therefore, three scientific opinions are defined:

1) serialization of medicinal products is an effective measure of counteracting the ingress of substandard pharmaceutical products to the market. The advantages of such implementation are exceeding its disadvantages [11, 14].
2) it is necessary to adopt the system of serialization of medicinal products similar with that in the USA [15].

Adopting the USA-like system would have given the European Union broader advantages. Radio frequency identification technology has already become a useful and practical tool to reduce the risk of practitioner error. It is also proving to be a highly effective measure of contributing to the development of public health management systems. So, now is an ideal moment to build a global harmonized approach. It is, however, puzzling that all stakeholders have rejected radio frequency identification technology without conducting any tests. This was not the case for the data matrix system, which was evaluated and widely approved. Enforcement timeframes in the individual EU member states remain uncertain. It is unlikely that an all-embracing European Protection Network will be in place before 2025. Nor is it farfetched to predict that Europe will be in a position to effectively protect its pharmaceutical supply chain only around 2030 [15].

But the authors do not pay attention to the fact that some EU countries already have some experience in the functioning of such a system of medicinal products serialization. The difference between USA and EU systems is only about technological aspects. It means that the purpose of such technology will be achieved both in EU and USA – people will have access to high-quality and safe medicinal products.

3) third approach is based on inexpediency of the system of medicinal products serialization on the basis of the following disadvantages:

– high cost;
– considerable time frame;
– impossibility of technical equipping of all health care facilities [13].

So, opponents to serialization of medicinal products rise three main questions: Where? How much? When? [13].

We believe that the introduction of a system of medicinal products serialization is a necessary step in combating substandard or falsified medicinal products. We can find answers to all questions of the introduction of medicinal products serialization approach opponents.

Of course, the introduction of such a system of medicinal products serialization in the EU requires a lot of time and money. Since we believe that the protection of life and health is the primary responsibility of each country, introducing of the system of medicinal products serialization will become a blow in substandard and falsified medicinal products.

The advantages of such a system include:

- Unification of the quality control of medicinal products process;
- Simplicity and efficiency of the control process;
- Non-admission to the pharmaceutical market of low-quality products;
- Ensuring an absolute protection of life and health of the population.

The implementation of labelling and reading system will be financed at the expense of medicinal products' manufacturers and pharmacy owners.

The EU Falsified Medicines Directive states (art. 121, 121a) that manufacturers must pay for the medicines' authentication technology and national databases, but it will be the responsibility of the pharmacy itself to pay for staff education and hardware, such as scanners and additional computer terminals that may be required.

The only failing we have found is the refusal to use the blockchain system when forming a centralized database of pharmaceutical circulation stages. Database maintenance will require significant financial and organizational resources, and it would be much better to use a non-centralized database like in the United States.

Therefore, the introduction of serialization of medicinal products is a matter of time throughout the EU. Therefore, European countries which are not part of the EU but who export pharmaceuticals should also introduce such a system.

Ukraine has some successes in the issue of exporting medicinal products to the EU territory. However, the current legislation (the law of Ukraine on medicinal products, the basic principles of State supervision (control) in the sphere of economic activity, the fundamentals of the Ukrainian health legislation) does not provide for such a form (method) of control as serialization of medicinal products. However, Ukraine is interested in introducing a new method of control that will allow it to provide the internal pharmaceutical market with high-quality pharmaceutical products and also to increase efficiency of export [16].

Ukraine started a pilot project to create an automated medicinal product tracking system using labeling (codification) and identification in 24.10.2017 [17].

However, the project implementation was postponed to 2023 due to economic, organizational, and technical reasons (like as in Italy and Greece). This is due to that:

– all the project costs are planned from the budget (the project costs are planned from medicinal products manufacturers in EU);
– the national control body (State Service of Ukraine on medicinal products and Drug Control) is responsible for the implementation of the project, but it is overloaded with tasks (it exercises control over the drugs circulation, quality of medicinal products, licensing, etc.). This impacts the implementation process' timeframe;
– the database is centralized and does not use blockchain technologies.

Therefore, the quality control of medicinal products in Ukraine is carried out non-effectively by the use of an old control instruments.

Therefore, Ukraine should use EU experience on the issue of creating an automated medicinal product tracking system. There are some other reasons for introducing serialization of medicinal products in Ukraine.

A few examples of the practice of prosecution for falsification of medicines: group of persons in the garage produced falsified medicinal products "Gripstop", "Fermestal" and "Himesulide & Dicyclomine" in total number of 2.7 million of approximately 30 types of medicinal products, others made the mixture in the appropriate proportion of the medicinal products "Fluorard" and powdered sugar by the number of 50 thousand [18].

However, for five years it has been rendered 25 courts decisions for falsification of medicinal products [19], some of which are acquittals [18]. Although the number of cases of falsification are much more than that.

The system of serialization of medicinal products completely excludes the cases of falsification of medicinal products (they cannot be put into circulation in general), in addition, it will prevent the circulation of substandard medicinal products. A system of serialization of medicinal products excludes the use of unaccounted products because of changes on the manufacturing enterprises of medicinal products and wholesale warehouses, and therefore will strengthen the fiscal control in Ukraine.

CONCLUSIONS

A new system of quality control of medicinal products has been used in the EU since 2019. Its adoption has caused a lively debate among scientists, pharmacists, doctors.

The serialization of medicinal products provides an opportunity to raise the quality control of medicinal products to a new level in the age of globalization.

The serialization of medicinal products is expedient and necessary step as it has a number of advantages: 1) monitoring of the entire cycle of drug circulation; 2) simplification of procedure for quality control of medicinal products; 3) prevention of substandard and falsified medicinal products appearance at the pharmaceutical market; 4) ability to create a global or regional pharmaceutical market, etc.

Serialization of medicinal products is important for Ukraine and other country's not in EU. Serialization of medicinal products will fill the internal pharmaceutical market with qualitative products, and will allow export of medicinal products. It should be borne in mind that the new quality control system of medicinal products is complex also time is needed to create it. We disagree with the positions of scientists who think that it is inappropriate to introduce the system of medicinal products serialization due to its significant cost,

because protection of life and health is the primary task of each state. In addition, serialization is funded by manufacturers of medicinal products. The only disadvantage of such system is the rejection of the blockchain technology use.

Thus, the advantages of serialization of medicinal products are obvious, and the necessity of introduction is urgent because existing quality control mechanisms do not cope with the task of providing the people with access to high quality and safe medicinal products.

REFERENCES

1. Aleksandrov A. V. Chto takoe PIC/S? Kakovo ee vliyanie na dostup lekarstvennyh preparatov na drugie rynki [What is a PIC / S? It affects access to medicinal productss in other markets]. Pharmaceutical Review. 2013. Available from: http://www.vialek.ru/press/review/1389/. [reviewed 2019.08.23] (Ua)
2. Lawson G., Ogwu J., Tanna S. Quantitative screening of the pharmaceutical ingredient for the rapid identification of substandard and falsified medicines using reflectance infrared spectroscopy. 2018 Aug 10;13(8):e0202059. doi: 10.1371/journal.pone.0202059.
3. Directive 2011/62/EU of the European parliament and of the council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. Available from: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf [reviewed 2019.08.23]
4. A study on the public health and socioeconomic impact of substandard and falsified medical products/ Available from: https://www.who.int/medicines/regulation/ssffc/publications/SE_Study_EN.pdf. [reviewed 2019.08.23]
5. Ozawa S., Evans D.R., Bessias S., Haynie D.G., at al. Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries. 2018 Aug; 1 (4) 10. doi: 10.1001/jamanetworkopen.2018.1662
6. €10.2 billion lost every year across the EU due to fake medicines Available from: https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_lzibrary/observatory/resources/research-and-studies/ip_infringement/study9/Press_release-pharmaceutical_sector_en.pdf [reviewed 2019.08.23]
7. Counterfeiting of medical products (MEDICRIME) Available from: www.coe.int/medicrime. [reviewed 2019.08.23]
8. Prashant R. Top 5 Blockchain Use Cases in Pharma and Healthcare — that you should know about! Available from: https://medium.com/blockchainbistro/top-5-use-cases-of-blockchain-in-pharma-and-healthcare-that-you-should-know-about-77ccdd76369b. [reviewed 2019.08.23]
9. Directive 2001/83/EU of the European parliament and of the council of 6 November 2001 on the community code relating to medicinal products for human use. Available from: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2001_83_consol_2012/dir_2001_83_cons_2012_en.pdf. [reviewed 2019.08.23]
10. Johnston A., Holt D. Substandard drugs: a potential crisis for public health. British Journal of Clinical Pharmacology.2014; 78(2). 218–243. doi: 10.1111/bcp.12298.
11. Gutorova N., Zhytnyi O., Soloviov O. Falsification of medical products: criminal law mechanism combating threats to public health. Wiadomosci lekarskie, 2019; 5. 856-861.
12. Aroussi Y. L. Serialization in the EU can become a competitive advantage if you dare to innovate. Available from: https://qbd.eu/en/blog/serialization-in-the-eu-can-become-a-competitive-advantage-if-you-dare-to-innovate/. [reviewed 2019.08.23]
13. Bernard N. D. The EU Falsified Medicinal productss Directive: key implications for dispensers. Medicinal products Access@ Point of Care. 2017; 1. 155–159. doi: 10.5301/maapoc.0000024
14. Smith G., Brindley D., Smith J.. The Falsified Medicines Directive: How to secure your supply chain. Journal of Generic Medicines. 2014;11:169–172. doi: 10.1177/1741134315588986
15. Rampinelli P., Argenta G. Case Report Open Access Different Approaches and Timeframes in Anti-Counterfeiting Medicinal Products: Europe vs. United States. Available from: https://www.omicsonline.org/open-access/different-approaches-and-timeframes-in-anticounterfeiting-medicinalproducts-europe-vs-united-states-2167-7689-1000160.php?aid=69749#corr. [reviewed 2019.08.23]
16. Pidpysano Memorandum pro vzaiemoporozuminnia mizh Derzhliksluzhboiu Ukrainy ta EDQM [Memorandum on mutual understanding between derzhlikservice of Ukraine and EDQM] Available from: https://www.apteka.ua/article/233224. [reviewed 2019.08.23] (Ua)
17. Derzhliksluzhba informuie pro khid realizatsii pilotnoho proektu z vidstezhennia obihu likiv vid vyrobnyka do kintsevoho spozhyvacha [State Service informs about the progress of the pilot project on monitoring the circulation of medicines from the manufacturer to the end consumer] Available from: https://www.apteka.ua/article/439052. [reviewed 2019.08.23] (Ua)
18. Unified State Register of Court Decision. Available from: http://reyestr.court. gov.ua [reviewed 2019.08.23]
19. Prosecutor General's Office of Ukraine. Available from: https://www.gp.gov.ua/ ua/stst2011.html?dir_id=113281&libid=100820&c=edit&_c=fo#. [reviewed 2019.08.23]

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REVIEW ARTICLE
PRACA POGLĄDOWA

TENDENCIES FOR THE FALSIFICATION OF MEDICINAL PRODUCTS IN UKRAINE: GENERAL ANALYSIS AND AREAS OF COUNTERACTION

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ABSTRACT

Introduction: Ukrainian counterfeit pharmaceutical market affects pharmaceutical manufacturers' image and threatens citizens' lives and health.

The aim:of the article is to identify and systematize the causes and methods of pharmacy drugs' falsification, grounding the need for certain areas of counteraction.

Materials and methods: Empirical base includes Ukrainian legislation, international acts, statistical data of the WHO, State Register of Medicinal Products of Ukraine, General Prosecutor's Office of Ukraine, Unified State Register of Court Decisions, media materials, journalistic investigations. Methodological basis is a set of general and special research methods of scientific cognition.

Conclusions: Expired drugs' repackaging; production in non-licensed enterprises; replacement of drugs by non-pharmacological substances, etc. were established as the most common methods of falsifying pharmacy drugs in Ukraine. The authors systematized the reasons for uncontrolled production's growth, established distribution channels for pharmacy drugs in Ukraine and offered the most effective ways for counteracting drug falsification.

KEY WORDS: falsification, pharmacy drugs, methods of commission, causes, counteraction

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INTRODUCTION

The presence of a counterfeit pharmaceutical market in Ukraine both threatens the life and health of citizens of Ukraine, affects the image of the leading manufacturers of the Ukrainian pharmaceutical market [1], and creates a threat to the economic and political security of the state in the whole. Every civilized state has the duty to its citizens to create an effective health care system, a necessary component of which is the use of safe and high-quality medical products. This duty is based both on international law standards and national constitutional norms and principles [2].

According to the World Health Organization (hereinafter referred to as the WHO) for 2017 [3], every 10th medicinal product in states with low and medium-level economies (where Ukraine belongs) is counterfeit[1] [4]. Substandard drugs are "genuine medicines which have not passed the standards and quality testing protocols set for them" The WHO and International Pharmacopoeias have previously determined these standards and quality tests. Counterfeit medicines are a type of substandard drugs. There is no international consensus regarding the definition of counterfeit medicines, and the WHO defines them as "drugs that are deliberately and fraudulently mislabeled with respect to identity and/or source" [5].

Currently, it is estimated that 10–15% of the global drugs supplied are counterfeit. The prevalence is higher in developing countries in Africa and in some areas of Asia and Latin America where up to 30–60% of drugs on the market are counterfeit. India is a major supplier of poor-quality drugs whereby 35–75% of fake/counterfeit drugs globally originate from India [6].

Analysis of the data contained on the official website of the General Prosecutor's Office of Ukraine indicates a rather low level of revealing the facts of manufacture, purchase, transportation, shipping, storage for the purpose of sale or marketing of obviously falsified medicines, the commission of which there is criminal liability under the Art. 321-1 of the Criminal Code of Ukraine (the data in the Fig. 1 indicates about this). At the same time, 27 sentences were revealed in the Unified State Register of Judicial Decisions (hereinafter referred to as the USRJD), under this article of the Criminal Code of Ukraine (2013 – 6; 2014 – 3; 2015 – 6; 2016 – 5; 2017 – 3; 2018 – 2; 2019 – 2).

The current situation testifies to the latency of the manifestations of criminal activity associated with the

[1] As at April 18, 2019 the State Register of Medicinal Products of Ukraine has registered 13 311 of medicinal products, where, 4 054 are from national manufacturers, and 9 257 – from foreign ones [3].

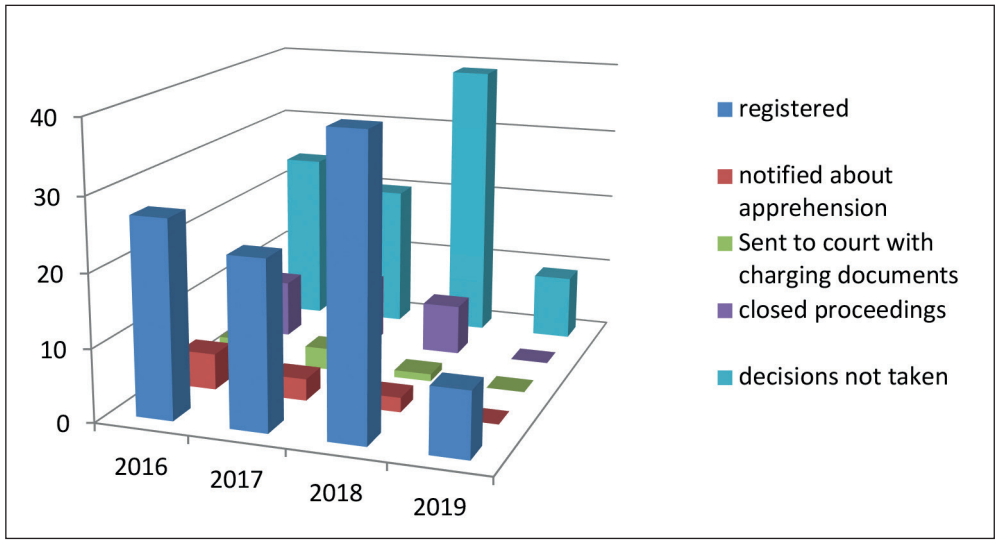

Fig. 1. Data of the General Prosecutor's Office of Ukraine for 2016-2019 in regard to criminal proceedings under the Article 321-1 of the Criminal Code of Ukraine.

falsification of medicinal products, the professional skills of criminals, as well as the insufficient effectiveness of the activities of state, law enforcement and judicial authorities. The aforementioned undermines the possibility of the proper implementation of the social and law enforcement functions of the state, since the state demonstrates powerlessness both in terms of controlling the quality of drugs and in terms of the criminal reaction to socially dangerous acts associated with their falsification.

THE AIM

The aim of this article is to determine and systematize the methods of falsification of medicinal products, the reasons of their commission, as well as to justify the need for some areas of counteraction to such a multifaceted phenomenon.

To achieve this aim, the following **main tasks** have been defined: 1) to study the existing methods of falsifying medicinal products taking into account current conditions in Ukraine; 2) to identify and systematize the reasons for their commission; 3) to suggest certain directions of counteraction to these phenomena.

MATERIALS AND METHODS

The materials for determining the causes, researching methods of falsification of medicinal products and possible areas of counteraction in Ukraine are Ukrainian legislation, international acts, statistics of the WHO, the State Register of Medicinal Products of Ukraine, the General Prosecutor's Office of Ukraine for 2016-2019, the USRJD (27 sentences), as well as media materials and the results of journalistic investigations. The methodological basis was the combination of general scientific and special scientific methods of scientific cognition, which were used in conjunction and ensured the comprehensiveness, completeness and objectivity of the study. The method of system analysis made it possible to formulate the reasons for the falsification of medicinal products. The formal and legal method was used in the analysis of legislative acts of Ukraine. The statistical method, logical methods, and comparative analysis method were used to analyze the data from the WHO, the State Register of Medicinal Products of Ukraine, the General Prosecutor's Office of Ukraine, and court decisions of the Unified State Register of Judicial Decisions, as well as own findings. The hermeneutic method was used to establish the essence of the concepts of "medicinal products" and "drugs".

REVIEW AND DISCUSSION

In accordance with paragraph. 1, Part 1 of the Article. 2 of the Law of Ukraine "On Medicinal Products" dated from April 4, 1996 (No. 123/96-VR) [7] a falsified medicinal product is a medicinal product deliberately labeled with not identical (not corresponding) data (one or more) about a medicinal product with the corresponding name entered in the State Register of Medicinal Products of Ukraine, as well as a medicinal product deliberately faked in another way that does not meet the data (one or more), including the composition, about a medicinal product with the appropriate name entered into the State Register of Medicinal products of Ukraine. At the same time, paragraph 4, Part 1 of the Art. 2 of the same Law contains the concept of "finished medicinal products", which means medicinal products, medicines, drugs, i.e., dosed medicinal products in the form and condition in which they are used, having passed all stages of production (manufacture), including final packaging.

We believe that the concept of "medicinal products" is not clear enough and is applied both to substances, whose use is aimed at treatment, prevention and diagnosis, and determines some special actions, techniques and methods of using such substances. Therefore, it would be more appropriate to use the term of "drugs", which more accurately

defines the technological readiness of a drug substance for consumption in the manner of a certain form having a brand name, and it is these drugs that are included in the State Register of Medicinal products of Ukraine.

According to the WHO data, "this issue affects all countries in all regions of the world from North America and Europe to the South from Sahara, Southeast Asia and Latin America. What used to be a problem for developing countries and low-income countries today concerns everyone" [8]. This is evidenced by the results of the research accomplished by international scholars [e.g.: 9; 10; 11 and others], as well as the effectiveness of law enforcement agencies of other states. In 2013, as a result of one of the largest operations in the last decade under the anti-counterfeit drug program, Chinese law enforcement agencies confiscated almost 9 tons of drugs and raw materials for them about 2.2 billion Yuan ($ 326,4 million) worth. Prescription of medicinal products – is varying from acute respiratory viral infections to heart diseases. Sales of drugs were carried out through the use of 140 websites, which were also blocked as a result of the operation. Besides, 149 US citizens died in 2008 as a result of the production of falsified drugs ("heparin") manufactured in China [12]. According to the results of an investigation conducted by the Food and Drug Administration of China in 2016, it became known that up to 80% of clinical trials in China were partially or fully falsified, on the basis of which decisions were made on the admission of new drugs to the market [13].

In accordance with the analysis of court decisions of the Unified State Register of Court Decisions, mass media and sociological research, the most spread methods of falsification of medicinal products in Ukraine are: repackaging of expired medicinal products [14; 15]; production at enterprises that do not have the license [16]; replacement of medicinal products with substances that are not pharmacological [14]; change in production technology in order to underestimate the amount of the pharmacological component [17; 18]; production of so-called drugs – simulators having a different therapeutic effect [19]. Detection of the organized criminal group in Kharkiv City in 2014 can be considered as one of the high-profile cases of the industrial production of counterfeit medicinal products, the activities of which included all of the above-mentioned methods. Joined parties of the organized criminal group launched a clandestine manufacture of flu and ARVI medication called "Pharmatsitron" and "Terafliu". Besides, they purchased 60 bags of expired drug called "Fliukold", which was mixed with powdered sugar and packaged in sachets. The manufacture was carried out in rented garages, and sales were carried out by mail in the cities of Kharkiv, Kyiv, Cherkasy, Mariupol. The total cost of seized counterfeit goods (without seized equipment) amounted to more than 204 thousand UAH. [15; 17; 18].

It is also worth noting that sometimes a manufacturer, in order to evade taxes, produces a full-fledged copy of a real drug that has not passed a special audit.

Analysis of modern methods of the medicinal products' falsification makes it possible to distinguish the mandatory stage of such a criminal activity as sale of medicinal products. We would like to note the tendency of selling counterfeit products through special Internet websites (which may be phishing ones) by creating an extensive distribution network based on network marketing (with the participation of medical personnel). At the same time, sales of counterfeit medicinal products are significantly increasing (according to the report from "Mark Monitor" for 2017, 67% of respondents trust online pharmacies, and 29% of consumers buy medicines online through mobile applications, social networks and online platforms [20]). There is also a "tossing" of business cards, price lists with unregistered medicinal products to medical institutions.

Attractive for the sale of counterfeit medicinal products is the pharmacy network existing in Ukraine (as of January 1, 2019, there are 16.4 thousand pharmacies and 4.2 thousand pharmacy points in Ukraine [21]). So, in 2017, the Security Service of Ukraine liquidated organized criminal group that launched a large-scale production of a wide range of medicinal products in one of the warehouse premises of Odessa City. To sell counterfeit products the criminals used their own network of pharmacies, as well as drugstore networks in other regions of Ukraine. The amount of counterfeit sold – is more than 30 million UAH, unsold drugs seized in the amount of more than 5 million UAH [22].

The channel of counterfeit medicinal products' sales are medical facilities. So, in 2018, the National Police of Ukraine together with the Security Service of Ukraine discovered in Kyiv an enterprise that produced counterfeit medicinal products (cases of injection into cylinders and the sale of technical oxygen through medical institutions in different cities of Ukraine were identified, which created a threat to the life and health of patients) [23]. Despite the detention of accomplices to the crime, there were issues about their corrupt relations with officials of medical institutions, where the specified counterfeit products were sold or used.

A separate area of criminal activity is the production and marketing of counterfeit steroids and so-called slimming drugs. Such counterfeit products are produced as in previous cases in artisanal conditions (in private houses, garages, unused production facilities, etc.). Sales are most often carried out through trainers of fitness centers or through Internet websites. So, in December 2018, the Security Service of Ukraine revealed in Kyiv region a local resident who ordered anabolic steroids in other countries for the manufacture of counterfeit medicines. The surreptitious workshop was organized in his own private house, sales were carried out through the website in different regions of Ukraine, as well as through the trainer of one of Kyiv fitness centers [24].

In Ukraine, there are cases of the production of counterfeit products for the purpose of marketing in other countries. So, in January 2019 law enforcement officers of Ukraine uncovered a resident of Khmelnitsky region, who sold home-made steroids and weight loss drugs through online store, designed for customers from Europe and Ukraine. The laboratory was equipped in his own apartment; the components of counterfeit drugs were purchased in China via the Internet [25].

Analysis of the methods and items of falsification of medicinal products indicates that they connected with the demand for certain types of medicinal products in a particular region. So, according to the research company "Grand View Research", the volume of the global biosimilar market will increase by an average of 34.2% annually till 2025 (2016 – $ 4.36 billion) [26] that indicates the possibility of these types of drugs' falsification increase. A similar situation may arise with the predictable growth of the global market for pneumococcal vaccines and oncologic drugs.

CONCLUSIONS

The results of the conducted study make it possible to argue that the reasons for the growth of uncontrolled production and the establishment of distribution channels for medicinal products in Ukraine are:

- low level of control by the state and law enforcement agencies over the implementation of existing laws;
- inefficient activities of organizations involved in establishing compliance of medicinal products, registered in Ukraine, with international requirements, as well as verification of the quality of drugs while their production and marketing, which leads to impunity for manufacturers of counterfeit products, and the high selling price (at low cost) makes it attractive for organized crime;
- insufficient level of the implementation of pharmaceutical practices [27] (GMP – Good Manufacturing Practice);
- lack of real copyright protection in Ukraine. The initiative of copyright holders for specific pharmaceutical products to ensure and protect them could increase the effectiveness of counteracting the production and marketing of counterfeit medicinal products;
- the availability of modern equipment to produce counterfeit medicinal products, which creates uncontrolled growth in the pharmaceutical market;
- the tendency of the population of Ukraine to self-diagnosis (out of 10 patients, only 3 visit physicians), self-medication, self-prescription of medicinal products based on advertising products, the advice of friends and pharmacists (sometimes participating in criminal sales schemes of counterfeit medicinal products), as well as a significantly lower cost of non-prescription medicinal products;
- a high level of corruption of state officials working in the pharmaceutical and healthcare sectors;
- the lack of drugs in an epidemic situation create shortage and the possibility of the distribution of counterfeit products.

The following areas are the most effective for countering the falsification of medicinal products:

- the reform of state public agencies of pharmaceutical industry (by reducing their amount, modifying powers and competences, etc.). It should be noted that the Cabinet of Ministers of Ukraine, in April 2019 has approved the Concept of state policy to prevent the falsification of medicinal products and a plan of measures aimed at its implementation [28]. However, this Concept is only a general plan of activities aimed at counteracting the falsification of drugs, without defining specific terms for the implementation of some activities [29]. Besides, to ensure the reality of the implementation of this Concept, it would be advisable to organize and conduct public hearings, where pharmaceutical market participants could determine the stages of suggested counteraction system implementation;
- with regard to the approval of this Concept, it is necessary to organize an automated system for tracking the turnover of medicinal products using a unique identifier. Starting from February 2019, two-dimensional barcodes ("cryptographic protection") are introduced in European countries instead of barcodes, which contain much more information about the medicinal product, as well as an indicator by which each specific medicinal product can be tracked (from manufacturer to a patient (consumer) [30]. Mandatory implementation of drug labeling has been envisaged since 2020 in the Russian Federation [31];
- the creation of specialized groups within the structure of the customs agencies of Ukraine, with the inclusion of specialists (experts) who could conduct expert research as soon as possible without causing material and moral damage to conscientious consignors or consignees. The main objective of the such groups' activity is to ensure inspections of imported drugs at import points of Ukraine, with the aim of identifying counterfeit medicinal products with their subsequent seizure from circulation (or confiscation);
- the introduction of electronic document management system in the pharmaceutical sector, including the electronic system for licensing the activities of business entities (this will ensure transparency in the activities of state agencies with the appropriate authority and will help to reduce corruption in this field). Besides that, an introduction of electronic prescriptions to purchase medicinal products outside the region, where the prescription was given (we can use the experience of Estonia and Finland as an example) can be considered as an integral part of such an electronic system. Using this form of prescription will reduce the frequency of the participation of medical employees in criminal schemes of production and marketing of counterfeit medicinal products;
- taking into account the experience of European countries, equipping drug packages with special protective "locks", which will ensure their integrity and the impossibility of replacing contents;
- in order to prevent falsification of medicinal products, it is necessary to increase the level of awareness of the population (not only patients), including by informing about the existing system of protection of medicinal products from falsification. This is especially due to the possibility of using the constantly updated mobile application "Medicines Control" launched in 2016 [32], which provides the ability to verify drugs registered in the List-register of the Ministry of Health of Ukraine;
- conduction of briefings, conferences and other joint events, joint development of strategic programs to combat the falsification of medicinal products in order to exchange

information and establish interaction between bona fide drug manufacturers, state agencies (including law enforcement agencies), media and public organizations.

REFERENCES

1. 13 grafikov, kotorye obieiasniaiut lekarstva v Ukraine. Atlas kompanii Top Lead, farmatsevticheskoi firmoi "Darnitsa", iuridicheskoi firmoi Aequo, Torgovo-promyshlennoi palatoi Ukrainy [13 figures that explain the medicines in Ukraine. Atlas of the company Top Lead, pharmaceutical company "Darnitsa", law company Aequo, Chamber of Commerce and Industry of Ukraine]. Business Views. 18.04.2018. Available from: https://businessviews.com.ua/ru/economy/id/13-grafikov-kotorye-objasnjajut-lekarstva-v-ukraine-1787/. [reviewed 2019.09.05] (Ru)
2. Gutorova, N., Zhytnyi, O., Soloviov, O. Falsification of Medical Products: Criminal Law Mechanism Combating Threats to Public Health. Wiadomości Lekarskie 2019;72(5 cz 1):856-861
3. Vsemirnaia organizatsiia zdravookhraneniia [The World Health Organization]. Globalnyi veb-sait. Available from: https://www.who.int/ru/home. [reviewed 2019.09.05] (Ru).
4. Derzhavnyi reiestr likarskykh zasobiv Ukrainy [The State Register of Medicinal Products of Ukraine]. Official site. Available from: http://www.drlz.com.ua. [reviewed 2019.09.05] (Ua).
5. Kelesidis, T., & Falagas, M. E. Substandard/Counterfeit Antimicrobial Drugs. Clinical Microbiology Reviews. 2015 Apr;28(2):443-64. doi: 10.1128/CMR.00072-14.
6. Mhando, L., Jande, M. B., Liwa, A., Mwita, S., & Marwa, K. J. Public Awareness and Identification of Counterfeit Drugs in Tanzania: A View on Antimalarial Drugs. Advances in Public Health, 2016:1-8. doi: 10.1155/2016/6254157
7. Pro likarski zasoby: zakon Ukrainy No 123/96-VR. vid 04.04.1996 r. [On medicinal products: Law of Ukraine] Available from: https://zakon.rada.gov.ua/laws/show/123/96-вр. [reviewed 2019.09.05] (Ua).
8. Nekonditsionnaia i falsifitsirovannaia meditsinskaia produktsiia [Substandard and falsified medical products]. World healthcare Organization 31.01.2018. Available from: https://www.who.int/ru/news-room/fact-sheets/detail/substandard-and-falsified-medical-products. [reviewed 2019.09.05] (Ru).
9. Janvier S, De Spiegeleer B, Vanhee C, Deconinck E Falsification of biotechnology drugs: current dangers and/or future disasters?/J Pharm Biomed Anal. 2018 Nov 30;161:175-191. Epub 2018 Aug 20. doi: 10.1016/j.jpba.2018.08.037
10. Philip E. Coyne, Jr. The World Health Organization Prequalification Programme— playing an essential role in assuring quality medical products/ Int Health 2019; 11: 79–80 Advance Access publication 14 December 2018 doi:10.1093/inthealth/ihy095
11. Rahman MS, Yoshida N, Tsuboi H, Tomizu N, Endo J, Miyu O, Akimoto Y, Kimura K. The health consequences of falsified medicines – A study of the published literature / Trop Med Int Health. 2018 Dec;23(12):1294-1303. Epub 2018 Oct 2. doi: 10.1111/tmi.13161
12. V Kytai politsiia zatrymala ponad 1300 osib za pidrobku likiv [Police of China apprehended more than 1 300 people for tampering medicines]. Available from: https://ua.112.ua/svit/u-kitayi-policiya-zatrimala-ponad-1300-osib-za-pidrobku-likiv-3616.html. [reviewed 2019.09.05] (Ua)
13. Ortega I. 80 protsentov vsekh klinicheskikh ispytanii lekarstv v Kitae byli poddelany [80 percent of all clinical trials of medicines in China were falsified]. Life. 03.10.2016 Available from: https://life.ru/t/наука/911560/80_protsientov_vsiekh_klinichieskikh_ispytanii_liekarstv_v_kitaie_byli_poddielany. [reviewed 2019.09.05] (Ru)
14. Vyrok Vasylkivskoho miskraionnoho sudu Kyivskoi oblasti vid 02.07.2013 roku u spravi № 362/3756/13-k. Yedynyi derzhavnyi reiestr sudovykh rishen [Judgement of Vasylkivskyi district court of Kyiv oblast dated from July 2, 2013 within the case No. 362/3756/13-k. Unified State Register of Court decisions]. Available from: http://reyestr.court.gov.ua/Review/32243528#. [reviewed 2019.09.05] (Ua)
15. Vyrok Moskovskoho raionnoho sudu m. Kharkova vid 27.01.2016 roku u spravi № 643/12970/15-k. Yedynyi derzhavnyi reiestr sudovykh rishen [Judgement of Moskovskyi district court of Kharkiv City dated from January 27, 2016 within the case No. 643/12970/15-k. Unified State Register of Court decisions]. Available from: http://reyestr.court.gov.ua/Review/55231709. [reviewed 2019.09.05] (Ua)
16. Ukhvala Holosiivskoho raionnoho sudu mista Kyieva vid 16.02.2018 roku u spravi № 752/2598/19. Yedynyi derzhavnyi reiestr sudovykh rishen [Court ruling of Holosiivskyi district court of Kyiv City dated from February 16, 2018 within the No. 752/2598/19. Unified State Register of Court decisions]. Available from: http://reyestr.court.gov.ua/Review/81965703. [reviewed 2019.09.05] (Ua)
17. Vyrok Moskovskoho raionnoho sudu m. Kharkova vid 16.09.2015 roku u spravi № 643/15936/15-k. Yedynyi derzhavnyi reiestr sudovykh rishen [Judgement of Moskovskyi district court of Kharkiv City dated from September 16, 2015 within the case No. 643/15936/15-k. Unified State Register of Court decisions]. Available from: http://reyestr.court.gov.ua/Review/50752895. [reviewed 2019.09.05] (Ua)
18. Vyrok Moskovskoho raionnoho sudu m. Kharkova vid 06.10.2016 roku u spravi № 643/17066/15-k. Yedynyi derzhavnyi reiestr sudovykh rishen [Judgement of Moskovskyi district court of Kharkiv City dated from October 6, 2016 within the case No. 643/17066/15-k. Unified State Register of Court decisions]. Available from: http://reyestr.court.gov.ua/Review/61819984. [reviewed 2019.09.05] (Ua)
19. Vyrok Liubenskoho miskraionnoho sudu Poltavskoi oblasti vid 21 liutoho 2018 roku u spravi № 539/1590/15-k. Yedynyi derzhavnyi reiestr sudovykh rishen [Judgement of Liubenskyi district court of Poltava oblast dated from February 21, 2018 within the case No. 539/1590/15-k. Unified State Register of Court decisions]. Available from: http://reyestr.court.gov.ua/Review/72368054. [reviewed 2019.09.05] (Ua)
20. Bondarchuk Iryna. Falsyfikatsiia likarskykh zasobiv ta perevirky aptek: holovne z praktyky mizhnarodnoi farmatsevtychnoi spilnoty [Falsification of medicinal products and inspection of drug-stores: basics from practice of the international pharmaceutical community]. Apteka.ua. 23.10.2017. Available from: https://www.apteka.ua/article/430840. [reviewed 2019.09.05] (Ua)
21. Dmitrik Ekaterina. Infrastruktura aptechnogo riteila: na poroge izmenenii [Retail pharmacy infrastructure: on the verge of change]. Apteka.ua. 04.02.2019. Available from: https://www.apteka.ua/article/487942. [reviewed 2019.09.05] (Ru)
22. SBU likviduvala vyrobnytstvo pidroblenykh likiv u Odesi [The Secret Service of Ukraine liquidated the production of fake medicines in Odessa]. Censor.NET. 01.04.2017 Available from: https://censor.net.ua/ua/photo_news/434480/sbu_likviduvala_vyrobnytstvo_pidroblenyh_likiv_u_odesi_fotoreportaj. [reviewed 2019.09.05] (Ua)
23. Natspolitsiia likviduvala pidpryiemstvo, yake vyhotovlialo u Kyievi falsyfikovani likarski zasoby [The National Police liquidated the enterprise that produced fake medicinal products in Kyiv]. Censor.NET. 25.01.2018. Available from: https://censor.net.ua/ua/photo_news/3046601/natspolitsiya_likviduvala_pidpryyemstvo_yake_vygotovlyalo_u_kyyevi_falsyfikovani_likarski_zasoby_fotoreportaj. [reviewed 2019.09.05] (Ua)

24. U pryvatnomu budynku pid Kyievom vlashtuvaly tsekh iz falsyfikatsii likiv [A workshop on falsification of medicines was launched in Kyiv in a private house]. Sohodni. 19.12.2018. Available from: https://ukr.segodnya.ua/kiev/kaccidents/v-chastnom-dome-pod-kievom-ustroili-ceh-po-falsifikacii-lekarstv-1199496.html. [reviewed 2019.09.05] (Ua)
25. Olha Lypych. Stalo vidomo, koho vbyly ukrainski liky dlia skhudnennia v Brytanii [It became known who was killed by Ukrainian medicines for weight loss in the UK]. Krapka.club. 24.01.2019. Available https://krapka.club/ua/stalo-vidomo-kogo-vbili-ukrayinski-liki-dlya-shudnennya-v-britaniyi/. [reviewed 2019.09.05] (Ua)
26. Mirovoi rynok biosimiliarov budet uvelichivatsia v srednem na 34,2% ezhegodno do 2025 g. Po materialam www.grandviewresearch.com [The global market for biosimilars will be increased by an average of 34.2% annually until 2025. According to www.grandviewresearch.com]. Apteka.ua. 02.10.2018. Available from: https://www.apteka.ua/article/474230. [reviewed 2019.09.05] (Ru)
27. Kazinov R. Chomu v Ukraini protsvitaiut "chorni farmatsevty" [Why "black pharmacists" are flourishing in Ukraine]. Biznes. 31.07.2018. Available from: https://biz.nv.ua/ukr/experts/chomu-v-ukrajini-protsvitajut-chorni-farmatsevti-2485564.html. [reviewed 2019.09.05] (Ua)
28. Ukraina pryiniala stratehichnyi dokument dlia borotby z pidroblenymy likamy. Yedynyi veb-portal orhaniv vykonavchoi vlady Ukrainy [Ukraine adopted the strategic document for combating fake medicines. Unified webportal of executive authorities of Ukraine]. Government portal. Official website. 03.04.2019. Available from: https://www.kmu.gov.ua/ua/news/ukrayina-prijnyala-strategichnij-dokument-dlya-borotbi-z-pidroblenimi-likami. [reviewed 2019.09.05] (Ua)
29. Sergienko N. Uchastniki rynka dolzhny priniat uchastie v obsuzhdenii realizatsii Kontseptsii predotvrashcheniia falsifitsirovaniia lekarstv [Market participants must take part in the discussion of the realization of the Concept for preventing the falsification of medicines]. Interfax-Ukraine. 09.04.2019. Available from: https://interfax.com.ua/news/pharmacy/579403.html. [reviewed 2019.09.05] (Ru)
30. Lekarstva v Evrosoiuze budut luchshe zashchishcheny ot poddelok [Medicines in the European Union will be better protected from tampering]. EvroPuls. 11.02.2019. Available from: https://euro-pulse.ru/news/lekarstva-v-evrosoyuze-budut-luchshe-zashhishhenyi-ot-poddelok. [reviewed 2019.09.05] (Ru)
31. Ushakova Mariia, Proskurina Olga i dr. Totalnaia kriptozashchita: Podorozhaet li za-za nee lekarstv i drugie tovary [Total crypto protection: Will it affect the increase of prices for medicines and other goods?]. The Village. 16.07.2018. Available from: https://www.the-village.ru/village/city/situation/318063-kriptozaschita-lekarstv. [reviewed 2019.09.05] (Ru)
32. V Ukraini yakist likiv mozhna pereviriaty za dopomohoiu smartfoniv [The quality of medicines in Ukraine can be verified with the assistance of smartphones]. TSN.ua. 30.08.2016. Available from: https://tsn.ua/ukrayina/v-ukrayini-yakist-likiv-mozhna-pereviryati-za-dopomogoyu-smartfoniv-736380.html?_ga=2.258213001.226708443.1567977471-716678083.1567977470. [reviewed 2019.09.05] (Ua)

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REVIEW ARTICLE
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LEGAL SECURITY OF AGRICULTURAL PRODUCTS AS A CONDITION PUBLIC HEALTH SYSTEM'S DEVELOPMENT

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ABSTRACT

Introduction: WHO (World Health Organization) considers food safety as one of the priorities of public health, therefore, it is important to comply with the safety parameters of agricultural products of both food and raw materials for their production. However, practice analysis shows that in order to achieve safety of agricultural products, in particular in Ukraine, it is necessary to resolve some issues associated with its legal support.

The aim:of the study is to analyze the state of legal security support for agricultural products as a mandatory component of Public Health system and justify the directions of its improvement.

Materials and methods: This research is based on the analysis of the norms of international and national legislation, the state of practice with the use of general and special methods of scientific knowledge: dialectical, systemic-structural, formal-logical, logical-legal, comparative-legal.

Conclusions: It has been proved that the safety parameters of agricultural products stipulated by the legislation of Ukraine mainly comply with the EU standards, but certain issues need to be improved. It is substantiated that the main directions of legal security improvement of agricultural products should include acceleration of the update of Ukrainian legislation in order to bring it in line with the EU acts and introduction of effective monitoring by involving the public to the field of agricultural product safety, implementation of which will contribute to the development of the Public Health system.

KEY WORDS: Public Health, agricultural products safety, safety parameters, state control, public control

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INTRODUCTION

Public health system aims at preventing, but not treating diseases. The development of this system will contribute to the achievement of such health goals as preservation and restoration of physiological and psychological functions, working capacity and social activity of a person. An important area of public health is healthy nutrition and creating opportunities for access to healthy nutrition. Among the key WHO recommendations for healthy nutrition are indicated seasonal fruits and vegetables, dairy and fermented milk products, meat and fish, which should be included in the daily diet of a person [1 Healthy diet. Key facts. World Health Organization. https://www.who.int/news-room/fact-sheets/detail/healthy-diet]. It is quite logical that the benefits of the use of these products can be expected if the agricultural market presents safe agricultural products in the form of food products or raw materials for their production. This is achieved with the compliance of the established safety parameters by all entities during the movement of these products: from production and sales in the agricultural market to the consumption by the consumers. At the same time the low level of agricultural product safety is one of the reasons of deterioration of population health conditions and limited access of Ukrainian agricultural products to the EU internal market, which necessitates the construction of a system for ensuring its safety in accordance with EU requirements.

THE AIM

The aimof the study is to analyze the state of legal support for safety of agricultural products as an obligatory component of the public health system and substantiate directions for its improvement.

MATERIALS AND METHODS

The main materials of the study are acts of international and Ukrainian legislation on ensuring safety of agricultural products. In particular, EU Regulation of the European Parliament and Council "On the Establishment of General Principles and Requirements of Legislation on Food Products, Establishment of European Food Safety Authority and Establishment of Procedures in Matters Related to Food Safety" No. 178/2002 of January 28, 2002 .. (hereinafter - Regulation No. 178/2002), Laws of Ukraine "On Basic Principles and Requirements for Food Safety and Quality" (hereinafter - Law No. 771/97-BP) "On Veterinary Medicine", "On state control over compliance with legislation on food products, feed, animal by-products, animal health and well-being" (hereinafter - Law No. 2042-VIII), the provisions of which form the basis of comparative analysis of agricultural product safety in Ukraine and the EU. The study was supported by WHO documents and information on food safety, Ukrainian reports on the fulfillment of the Associa-

tion Agreement between Ukraine and the EU regarding the implementation of food safety provisions, recent analytical materials of the Ukrainian state control authority.

The methodological basis of the study consisted of general and special methods of scientific knowledge: dialectical, systemic-structural, formal-logical, logical-legal, comparative-legal.

REVIEW AND DISCUSSION

The health of people is a prerequisite for successful development of any state. An important role in the prevention of diseases, improving health and increasing life expectancy is played by the public health system, the effective functioning of which nowadays is hindered by various challenges and threats. Thus F. Baum in the book "New Public Health" (2016) reviews global physical threats to the environment and public health, raises the issue of healthy societies and the environment [1].

Among the biggest public health issues with the reference to scientific developments could be named hazardous food products. Thus, the interconnection between diseased conditions and unhealthy diets, awareness of this by citizens was investigated by C. Wou and other authors [2, 3, 4, 5]; The issues of organic production influence on public health were repeatedly considered [6, 7]. According to cautious estimates by WHO every tenth person in the world is ill after eating contaminated foods, since food-borne risk factors include pathogenic bacteria, viruses, parasites, toxins and chemicals [8]. Subsequently the term "food-borne disease" becomes more and more common, which is due to the fact that the production, storage, transportation of agricultural products uses a significant arsenal of chemicals, veterinary drugs, GMOs, and other scientific achievements, which are mainly aimed at increasing agricultural productivity. The use of these substances becomes the basis for the appearance in the agricultural market of products which can constitute and/or cause a threat to health of citizens or carry out a hidden negative impact on future generations. The issue of aligning the priorities of nutrition and public health with agricultural production was directly or indirectly repeatedly addressed by various specialists [3, 9]. So, considering seven metrics of the food system for sustainable food safety, D. Gustafson names the first one as the sufficiency of food substances in food products, and the sixth's is food safety, noting that food products can cause intestinal diseases, parasitic diseases, contain chemicals and toxins beyond the established safety parameters [10]. So, safety of agricultural products (both food and raw materials for their production) is an equally important category for ensuring food security and public health. Awareness of the depth of the problem of agricultural and food safety is indicated by the fact that the United Nations General Assembly declared June 7, 2019 the first World Food Safety Day [11].

Each country has its own issues with ensuring safety of agricultural products, affecting food security and public health. In particular, Ukraine's rating according to Global Food Security Index in 2018 in the Quality and Safety category is 65.2 points (46th place out of 113 countries) [12]. At the same time in 2018, 27 577 measures were taken to monitor compliance with safety legislation and individual quality indicators [13], as a result of which 413.4 tons of dangerous and substandard products were identified in the agri-food markets as well as more than 30986.9 tons of dangerous meat and offal in the agricultural and food markets. According to the results of laboratory tests, measurements, research and examination 629,369.518 kg of dangerous food products were seized during monitoring [14]. Among the operators of the agricultural market the most common were violations of animal quarantine rules and other veterinary and sanitary requirements; violations during slaughter, utilization of non-identifiable and unregistered animals; implementation of unregistered objects of sanitary measures; unsuitable food products, etc. [15]. 3,000 regulations and 260 protocols were compiled for legislation violations on food and feed, which market operators held responsible for [16].

In Ukraine the issue of safety of agricultural and food products is primarily associated with imperfect legal support as pointed out by some Ukrainian researchers [17, 18, 13]. This gives reason to assert the need for further improvement of legal framework to ensure safety of agricultural products. Back in 2002 WHO, when introducing the Global Food Safety Strategy, convincingly disclosed issues related to global food safety and declared its readiness to contribute to the implementation of the concept called "from farm to fork," based on the need to consider each link of the food chain: from raw materials to the end consumer, since risk factors can appear and intensify in each link of this chain [19]. The growth of international trade complicated the situation with food safety, because in some cases different countries had completely different approaches to its provision. At the EU level this situation has been resolved by making a common decision to develop more unified rules for ensuring safety of agricultural products. This decision led to the approval in 2002 of Regulation No. 178/2002 [20], which established the European Food Safety Authority (hereinafter - EFSA) and laid down a new structure for food safety in the EU. As presented at the FAO / WHO Global Forum on Food Safety Regulation (Marrakesh, Morocco, January 28-30, 2002), this Regulation establishes principles, definitions and requirements on which all future European food legislation will be based, and reinforces the definition of food products, thereby reducing the differences which exist between some EU states [21].

From the analysis of Regulation No. 178/2002, it is evident that it lays down a model system for agricultural product safety, in which market operators and governments jointly participate. According to the provisions of Regulation No. 178/2002 norms of Ukrainian legislation and practice of its application, scientific literature implies that legal security of agricultural products offered for circulation in the agricultural market for the protection of human health in accordance with the requirements of the EU mechanism, among which the main components are: setting the parameters of agricultural product safety and introducing effective system of state control. The necessity to analyze these components is conditioned by Ukraine's European integration aspirations and the purpose of adaptation of Ukrainian legislation to the EU legislation in accordance with the National Program of Adaptation [22].

Establishment of agricultural safety parameters is based on Regulation No. 178/2002, Art. 3 of which gives a definition to the food products legislation, which means "laws

regulating rules and administrative provisions governing food in general and food safety in particular, either on the Community or national level; it covers any stage of the production, processing and distribution of food products as well as feed produced or fed to animals from which they produce food." In Ukraine food legislation is the law and other regulations that set requirements for food products at any stage of their production and circulation. Its analysis shows that more and more attention is being paid to the impact of agricultural products (food products produced from it) on the health of citizens (end consumers), the emphasis is being shifted from quality indicators to food safety parameters, and the awareness of the need for joint work of the authorities in public health and agriculture in the field of production, establishment and maintenance of agricultural safety parameters, development of legislation on food products, health and well-being of animals and feed.

The basis for such processes is the EU-developed general principles and approaches to ensuring the safety of agricultural products operating in the EU internal market, which underpin unconditional recognition of the impact of agricultural products on human health and next generations. At the same time, Ukraine shares the approach that can be traced in all EU acts (directives, regulations, ordinances, etc.) regarding aspirations to ensure the production and consumption of primarily safe and healthy food as a guarantee of preserving the health of the nation. This is indicated by the fact that Law No. 771/97-BP embodies the European approach to the definition of a food product, which is identical to Art. 2 of Regulation No. 178/2002 and Art. 1 of Law No. 771/97-BP. A clear orientation of Ukrainian legislation towards European values is also evident in determining a safe product, which is what scientists' attention is drawn to [23].

Analyzing provisions of the Ukrainian law on food products, we can conclude that Ukraine has implemented a European basic model of safety and quality regulations according to which compliance with the regulatory parameters of the safety of agricultural products is a primary responsibility of the market operator. In particular, the effectiveness of such a model is indicated by the fact that "the growth rate of Ukrainian organic production is 5.4 times higher than in European countries and almost 5 times higher than worldwide" [24]. At the same time, according to various experts, significant influence on the quality of products, the volume of production of safe food is carried out by consumers by providing consumer preferences for a particular product. According to EU practice, the parameters and rules are set for: 1) food hygiene, in particular of animal origin; 2) the presence of pesticides, veterinary drugs in agricultural products; 3) use of genetically modified organisms 4) food labeling; 5) control mechanisms to ensure compliance with the established requirements [25].The parameters and rules are set out in the relevant EU Regulations. From the reports on the implementation of the Association Agreement between Ukraine and the EU for 2015-2018, we can conclude that a number of EU acts on agricultural product safety have been adapted into Ukrainian legislation [26], in particular, Regulation of the European Parliament and Council of the EU No 854/2004 about the establishment of special rules for the organization of official control over products of animal origin intended for human consumption in food, which is included in the so-called "hygiene package"" [27]. They also include Regulation No 852/2004 of 29 April 2004, Regulation No 853 / 2004 of 29 April 2004 and Regulation No 882/2004 of 29 April 2004.

However, Ukraine still faces a big challenge in implementing European standards for setting safety parameters for agricultural products and implementing an effective system for monitoring compliance with them. So, in 2018, approximations of 64% of EU acts were ensured [13], and by the end of 2021 Ukraine should adapt more than 250 EU acts [28] to national legislation, that directly or indirectly relate to the mentioned parameters. At the same time, it requires special attention both to establish safety parameters for agricultural products, taking into account new and constantly changing safety conditions and requirements, and practice of introducing adapted regulatory legal acts. Timely completion of this work will be the next step in bringing Ukrainian and European agrarian markets closer, will create the basis for the realization of aspirations to increase agricultural exports to the EU countries and will contribute to the fulfillment of tasks by the public health system. An important component of legal support for the safety of agricultural products and improvement of the public health level is a proper control in this area. Reliability of control is reached by the appointed control bodies, they have the appropriate powers, control measures and control procedures, which should ensure prevention and admonition of negative effects on health of the end consumers of agricultural products. Obviously, to achieve a high level of protection of human life and health, control measures should be aimed at ensuring that dangerous products do not enter agricultural market, that dangerous agricultural products are not used as raw materials and are removed from the market as soon as possible. The analysis of the control system, founded in the EU, gives an understanding that it covers both food products and health of animals, plants, state of the environment, feed and drugs used for growing animals, plant protection products to the extent what their separate or complex effect can negatively affect the state of human health (consumer).

An assessment of the effectiveness of the agricultural product safety control system should be carried out precisely in terms of its effectiveness in achieving the goal of public health care. Comparing the functioning of the agrarian market allows us to state that, unlike the system for monitoring safety of agricultural products in the EU internal market, Ukrainian control system does not always keep pace with the development of production technologies and is more focused on solving problems of safety violation than on preventing them.

An important step in improving control is to implement it on HACCP principles, which is recognized as the most reliable system in the world that prevents the production of dangerous food products. At the same time, HACCP is focused not on combating the consequences of violations, but on preventing violations of food safety standards, and the market operator – not state control bodies, is responsible for the safety of products [29].

In Ukraine, fulfilling the requirements of adapting legislation to EU legislation and pursuant to the Comprehensive Implementation Strategy, the Law of Ukraine "On Feed Safety and

Hygiene" [30] has been adopted, amendments to the Law of Ukraine "On Veterinary Medicine" are being developed with the aim of implementing the provisions of Directive 91/496 / EEC and drafts of other regulatory legal acts in this area [31].

The importance of exercising proper control over the safety of agricultural products as a component of health care has led to the adoption of a separate law on this issue, which is the Law of Ukraine "On State Control of Compliance with Food, Feed, Animal By-Products, Animal Health and Welfare", which embodies all the key points of EU Regulation No 178/2002 on the control of agricultural product safety.

In general, according to BRDO, the adoption of Law No. 2042-VIII creates conditions for functioning of the effective food safety control system, however effective implementation of the law requires considerable state's financial resources, as well as the adoption of about 30 by-laws [32], some of which have already been adopted. At the same time, the process of the Ukraine-EU legislation adaptation is carried out considering constant update of EU acts in the field of food safety.

Summarizing the above, it can be argued that the existing legislative framework in Ukraine has fixed the requirements and the procedure for implementing state control in the field of ensuring safety of agricultural products, which meets the requirements of the EU. Today it is possible to carry out more effective control over ensuring the safety of agricultural products, identify offenses and take measures of accountability. However, Ukraine needs to implement the most successful practices of legal support to involve the public in the control over agricultural product safety. In the agricultural market, initiatives to meet the increased requirements for agricultural product safety may be implemented, or public control measures in this field may be applied. Such measures are possible in the organized agricultural market, wholesale markets for agricultural products or in public procurement of agricultural products.

CONCLUSIONS

Based on the above, we can conclude that in Ukraine there is an awareness that the EU food law is aimed at resolving common issues of high-level protection of human health and life, protection of consumers' interests. Important steps have been taken in recent years to update legal security of agricultural products, which is the key to improving the standard of living and preserving health of the nation and meeting the objectives of public health system. Improvements in legal security of agricultural products as a condition for the development of public health system should be accelerated by updating of national legislation in order to bring them in line with EU acts, taking into account new and constantly changing conditions, with further improvement of food standards, and introduction of food standards in the field of agricultural products safety.

REFERENCES:

1. Baum F. The new public health. Oxford. Oxford University Press, 2016. 700 p. Available from: https://global.oup.com/academaic/product/the-new-public-health-9780195588088?cc=ua&lang=en&# [reviewed 2019.09.09]
2. Wou C., Silarova B., Griffin S. et al, The associations between the response efficacy and objective and subjective change in physical activity and diet in the Information and Risk Modification trial. Public health. 2018 Dec; 165: 26–33.https://doi.org/10.1016/j.puhe.2018.09.006
3. John W Finley, Dennis Dimick, Elizabeth Marshall, Gerald Charles Nelson, Jonathan R Mein, David I Gustafson Nutritional Sustainability: Aligning Priorities in Nutrition and Public Health with Agricultural Production Advances in Nutrition, 2017Sept.;Volume 8(5):780–788. doi:0.3945/an.116.013995
4. Friel S., et al. 2009 Public health benefits of strategies to reduce greenhouse-gas emissions: food and agriculture. Lancet 2009 Dec 12;374(9706):2016-25 doi:10.1016/S0140-6736(09)61753-0
5. David W. Crowder, John P. Reganold Financial competitiveness of organic agriculture on a global scale. Proc Natl Acad Sci U S A. 2015 Jun; 112(24): 7611–7616. doi: 10.1073/pnas.1423674112
6. Muller A., Schader Ch., Scialabba N. El-Hage, Brüggemann J, and others Strategies for feeding the world more sustainably with organic agriculture. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5686079/ [reviewed 2019.09.09]
7. Reganold JP, Wachter JM. Organic agriculture in the twenty-first century. Nat. Plants. 2016;2:1–8. doi: 10.1038/NPLANTS.2015.221
8. The burden of foodborne diseases and the benefits of investing in safe food. Thematic Brochure the First FAO / WHO / AU International Food Safety Conference. Addis Ababa, 12-13 February 2019) Available from: http://www.fao.org/about/meetings/future-food-safety/international-food-safety-conference/ru/ [reviewed 2019.09.09]
9. What is Food Safety? Last updated: 19 August 2019 Dr Nina McGrath is Senior Manager for Food Safety, European Food Information Council (EUFIC) Available from: https://www.eufic.org/en/food-safety/article/what-is-food-safety [reviewed 2019.09.09]
10. Gustafson D., Gutman A., Leet Wh. et al. Seven Food System Metrics of Sustainable Nutrition Security. Sustainability 2016, 8(3): 196 doi: 10.3390/su8030196
11. Food safety, everybody's business' - the first World Food Safety Day 2019. Available from: https://www.efsa.europa.eu/en/press/news/190607-0 [reviewed 2019.09.09]
12. Global Food Security Index. – U. Available from: https://foodsecurityindex.eiu.com/ [reviewed 2019.09.09]
13. Brulevich V.V. Bezpechnist kharchovykh produktiv za zakonodavstvom Ukrainy ta Yevropeiskoho Soiuzu [Food safety under the legislation of Ukraine and the European Union]. Judicial appeal. 2016;2:75-83. Available from: http://nbuv.gov.ua/UJRN/Suap_2016_2_11 [reviewed 2019.09.09] (Ua)
14. Rezultaty za 2018 r. Derzhavna sluzhba Ukrainy z pytan bezpechnosti kharchovykh produktiv ta zakhystu spozhyvachiv [2018 performance results. State Service of Ukraine for Food Safety and Consumer Protection]. Available from: http://www.consumer.gov.ua [reviewed 2019.09.09] (Ua)
15. Planovi ta pozaplanovi zakhody (veterynariia) [Planned and unscheduled events (veterinary medicine)] State service site of Ukraine on food safety and consumer protection. Available from: http://www.consumer.gov.ua/ContentPages/Analitichna_Informatsiya/340/ [reviewed 2019.09.09] (Ua)
16. Planovi ta pozaplanovi zakhody (Zakon 2042) [Planned and unscheduled events (Law 2042)] State service site of Ukraine on food safety and consumer protection. Available from: http://www.consumer.gov.ua/ContentPages /Analitichna_Informatsiya/340/ [reviewed 2019.09.09] (Ua)

17. Kurman T.V. Ozelenennia tradytsiinoho silskohospodarskoho vyrobnytstva yak zasib zabezpechennia yoho staloho rozvytku: pravovi aspekty. [The greening of traditional agricultural production as a means of ensuring its sustainable development: legal aspects]. Actual problems of domestic jurisprudence. 2018;4: 95-99
18. Kulish I.M. Vplyv ostannikh tendentsii vyrobnytstva ta spozhyvannia produktiv kharchuvannia na konkurentni perevahy silskoi mistsevosti. [The influence of the latest trends in food production and consumption on the competitive advantages of rural areas] Regional economy. 2016; 2:112-120.
19. Global'naja strategija VOZ v oblasti bezopasnosti pishhevyh produktov [WHO global food safety strategy. Food Safety Program - 2002] Available from: https://apps.who.int/iris/bitstream/handle/10665/42559/9241545747_rus.pdf;jsessionid=C1CC4FD7CE2E5AC5E4D3D2B68434B03C?sequence=4 [reviewed 2019.09.09] (Ru)
20. Pro vstanovlennia zahalnykh pryntsypiv i vymoh zakonodavstva pro kharchovi produkty, stvorennia Yevropeiskoho orhanu z bezpeky kharchovykh produktiv i vstanovlennia protsedur u pytanniakh, pov'iazanykh iz bezpekoiu kharchovykh produktiv: Rehlament (IeS) Yevropeiskoho Parlamentu i Rady № 178/2002 vid 28.01.2002 [On establishment of general principles and requirements of food legislation, establishment of the European Food Safety Authority and establishment of procedures in matters related to food safety: Regulation (EU) of the European Parliament and of the Council № 178/2002 of 28.01.2002]. Available from: http:// old.vet.gov.ua/int-coop/EU_requirement. [reviewed 2019.09.09] (Ua)
21. Global'nyj forum FAO/VOZ po voprosam regulirovanija bezopasnosti pishhevyh produktov [FAO / WHO Global Food Safety Regulatory Forum Improving efficiency and transparency in food safety systems.] (Marrakesh, Morocco, January 28–30, 2002). Experience exchange. Application VIII. Available from: http://www.fao.org/3/Y3680R/Y3680R08.htm [reviewed 2019.09.09] (Ua)
22. Pro Natsionalnu prohramu adaptatsii zakonodavstva Ukrainy do zakonodavstva Yevropeiskoho Soiuzu: Zakon Ukrainy [On the National Program of the Legislation Adaptation of Ukraine to the Legislation of the European Union: Law of Ukraine] of March 18, 2004 No. 1629-IV. Verkhovna Rada of Ukraine News. 2004: 29. Art.367. (Ua)
23. Pravove rehuliuvannia zakhystu prav spozhyvachiv v Yevropeiskomu Soiuzi ta v Ukraini (vsebichne porivnialne pravove doslidzhennia) [Legal regulation of consumer protection in the European Union and in Ukraine (comprehensive comparative legal research)]/ Isichko A., Minin O., etc .; for headline I. Gritsyak. K .: Atika-N LLC". 2005. 656 p. Art. 41. (Ua)
24. Ukraina zaimaie 20-te mistse u sviti ta 11-te mistse v Yevropi za ploshcheiu silskohospodarskykh uhid, zainiatykh pid orhanichnym vyrobnytstvom [Ukraine takes the 20th place in the world and 11th place in Europe in terms of agricultural land occupied under organic production] The Ministry of Agrarian Policy and Food of Ukraine. Published July 2, 2019. Available from: https://minagro.gov.ua/ua/news/ukrayina-zajmaye-20-te-misce-u-sviti-ta-11-te-misce-v-yevropi-za-ploshcheyu-silskogospodarskih-ugid-zajnyatih-pid-organichnim-virobnictvom-olga-trofimceva
25. Analiz bar'erov dlja dostupa sel'skohozjajstvennoj produkcii na rynok stran Evrosojuza i Jugo-Vostochnoj Azii. Evrazijskaja jekonomicheskaja komissija [Analysis of barriers to access of agricultural products to the market of the European Union countries and Southeast Asia. Eurasian Economic Commission.] Moscow. 2017. 47 p. Available from: http://www.eurasiancommission.org/ru/act/prom _i_agroprom/dep_agroprom [reviewed 2019.09.09] (Ru)
26. Zvity pro vykonannia Uhody pro asotsiatsiiu mizh Ukrainoiu ta YeS [Reports on the implementation of the EU-Ukraine] Association Agreement. Government portal. Available from: https://www.kmu.gov.ua/ua/diyalnist/yevropejska-integraciya/vikonannya-ugodi-pro-asociaciyu/zviti-pro-vikonannya-ugodi-pro-asociaciyu [reviewed 2019.09.09] (Ua)
27. Pidstava dlia rozrobky novoho zakonodavstva pro prodovolstvo.[The basis for the development of new food legislation] Available from: http://zt-dpss.gov.ua/wp-content/uploads/HACCP_zak.pdf [reviewed 2019.09.09] (Ua)
28. Stan yevropeiskoi intehratsii u sferi silskoho hospodarstva ta SFZ [State of European integration in agriculture and SPS]. Ministry of Agrarian Policy and Food of Ukraine. Published March 2, 2019 Available from: https://minagro.gov.ua/ua/napryamki/mizhnarodne-spivrobitnictvo/yevrointegraciya/vikonannya-ugodi-pro-asociaciyu-mizh-ukrayinoyu-ta-yes/stan-yevropejskoyi-integraciyi-u-sferi-silskogo-gospodarstva-ta-sfz [reviewed 2019.09.09] (Ua)
29. Bezpeka produktiv. Yevropeiskyi Soiuz v Ukraini. [Product safety. The European Union in Ukraine]. Available from: https://medium.com/@euukrainecoop/%D0%B1%D [reviewed 2019.09.09] (Ua)
30. Pro bezpechnist ta hihiienu kormiv: Zakon Ukrainy [On the safety and hygiene of feed: Law of Ukraine] No. 2264-VIII. of 21.12.2017 Verkhovna Rada of Ukraine News. 2018. № 10. Art. 53.
31. Zvit pro vykonannia uhody Pro asotsiatsiiu mizh Ukrainoiu ta Yevropeiskym Soiuzom u 2017 rotsi [Association Agreement implementation report between Ukraine and the European Union of 2017.] Kiev. 2018. 23 p.. Available from: https://www.kmu.gov.ua/storage/app/media/uploaded-files/pro-vikonannya-ugodi-pro-asotsiatsiyu-mizh-ukrainoyu-ta-evropeyskim-soyuzom-za-2017-rik.pdf [reviewed 2019.09.09] (Ua)
32. Zakon pro kontrol za bezpechnistiu kharchovoi produktsii zapratsiuie lyshe za umovy nalezhnoho finansuvannia ta napratsiuvannia pidzakonnoi bazy [The Food Safety Control Act will only work if the by-laws are properly funded and developed.] Posted on 03-04-2018. Available from: http://brdo.com.ua/top/zakon-pro-kontrol-za-bezpechnistyu-harchovoyi-produktsiyi-zapratsyuye-lyshe-za-umovy-nalezhnogo-finansuvannya-ta-napratsyuvannya-pidzakonnoyi-bazy/ [reviewed 2019.09.09] (Ua)

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REVIEW ARTICLE
PRACA POGLĄDOWA

ENSURING THE ENVIRONMENTAL RIGHTS AS A PREREQUISITE FOR THE RIGHTS TO HEALTH IN UKRAINE AND THE EUROPEAN UNION

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ABSTRACT

Introduction: The present threats to public health and lives depend directly on environmental conditions of natural sites, their pollution and exhaustion degree. Accordingly, there is a need for proper legal enforcement of citizens' rights. Based on this, the relationship between citizens' environmental rights and the right to health is analyzed.

The aim:is to carry out a comparative analysis of legal support and correlation in the regulation of the right of citizens to a safe environment in Ukraine and the European Union, as well as to justify and formulate proposals for improving legislation on natural healing resources.

Materials and methods: The national and international legal instruments regulating the rights to health and a safe environment as well as their interrelations were examined by means of analytical expertise and analysis of the jurisprudence, in particular, the comparative legal, complex, formal and logical, structural and functional methods along with analytical and empirical research tools.

Conclusions: The environmental rights defined as the totality of the rights including the fundamental right to a safe environment and the right to natural resources (natural curative resources and natural resources for therapeutic and health-improving use) have to be proven a prerequisite for exercise of the human rights to health. The option proposed is for the adoption of a unified legal and regulatory instrument relating to the natural curative resources.

KEY WORDS: right to health, environmental rights, right to a safe environment, right to natural resources for therapeutic and health-improving use, natural therapeutic resources

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INTRODUCTION

The key provision of the Environment Law of Ukraine is that the government protects communities' health and safety from harmful environment impact (Article 1, Law of Ukraine "On Environment Protection").

In accordance with the Ukrainian legislative fundamentals on health protection the right to health provides, among other things, a safe to life and health environment. In this context, the state is obliged to provide the environment protection as an important prerequisite for human life and health. It is possible to accomplish the task by protecting the animate and inanimate nature, protecting people from harmful environment impact; achieving a harmonious interaction between a person, society and nature; rational use and reproduction of natural resources, etc. The environment protection relations are regulated by the special legislation of Ukraine and international treaties. The aforementioned is still relevant, since there is a direct interconnection between the human health status and the environmental conditions, the ecological safety of industrial and other objects, and real risks of technogenic incidents constituting potential threats to human life and health.

THE AIM

The aimof the research is to carry out a comparative analysis of the legal instruments in order to determine the legal regulation of the right to a safe environment in Ukraine and the European Union countries, to provide proposals for improving the laws related to natural curative resources.

MATERIALS AND METHODS

The national and international legal instruments regulating the right to safe environment and health as well as their interrelations were examined by means of analytical expertise and analysis of the jurisprudence, in particular, the comparative legal, complex, formal and logical, structural and functional methods along with analytical and empirical research tools.

REVIEW AND DISCUSSION

One of the main problems of health-care in Ukraine is an inadequate legal framework that hampers the efforts to improve the public health and efficient use of human and financial resources in the health system under market economy framework. Adaptation of the Ukrainian legislation to the EU legislation is a priority prerequisite Ukraine's' integrating into the European Union. One of the central components of this process is the legislation of Ukraine regulating human health and life protection, natural objects and the environment adaptation [1, p.12].

Most countries of the world, and Ukraine is not an exception, have entered into the 21st century with a set of global, regional and national challenges among which the most threatening to humanity are global environmental breaches, the depletion and degradation of natural resources [1, p.20].

The environmental legislation of Ukraine has a key provision in this regard: public health and human life are subject to public protection against the negative impact of adverse environmental conditions (Article 1 of the Law on Environmental Protection) [2]. Scientists are right to point out that these provisions are quite motivated, since there is a direct link between the state of human health and the state of the environment, the state of ecological safety, industrial and other economic objects and the level of real threat of man-made incidents dangerous for life and health of people [3, p. 45].

By the provisions of the Constitution of Ukraine the state assumes to protect the right to an environment that is safe for life and health, and to compensation for damages inflicted by the violation of this right. In fact, the present environmental situation is hardly contributing to the realization of the proclaimed rights [1, p. 17].

Meanwhile, it should be noted that at the international level the UN documents, in particular, "Environment and development. United Nations Terminology bulletin" contains the following terms relating to the right under research: an environment adequate for the health and well-being of individuals; healthy environment; enabling environment; sound, satisfactory and healthy environment [4]. However, the international legal instruments lack a single term or wording of the mentioned above.

Tretyakova G.A. rightly observes that "a number of universal and inter-regional international documents recognize the necessity for the environmental rights of citizens and the guarantees of their observance and protection to be consolidated on the legislative level. At the pan-European level, the directives have been adopted that enshrine the environmental rights of citizens and guarantees for their observance and protection. In the EU Member States, a process is underway to bring national legislation in line with the pan-European legal framework, including the legislation on environmental protection" [5].

The European Convention on Human Rights (ECHR) (formally – the Convention for the Protection of Human Rights and Fundamental Freedoms, 1950) [6] which established the European Court of Human Rights and the Law of Ukraine "On the implementation of decisions and application of the practice of the European Court of Human Rights" [7] play an important role in addressing the above-mentioned problems of the environmental rights' observance. The court decisions are binding to Ukraine.

After all effective domestic remedies have been exhausted everyone shall have the right to appeal for the protection of his rights and freedoms to the relevant international judicial institutions or to the relevant bodies of international organizations of which Ukraine is a member or participant (Article 55) [8]. This requirement is directly related to the possibility of recourse to protect the environmental rights. Therefore, it is necessary to study law enforcement practice relating to the issues which are in jurisdiction of the European Court of Human Rights.

At the international level a judicial precedent that occurs within the existing regime of the human rights protection is of increasing importance as it provides the mechanism for protecting and developing the institution of environmental human rights at the present stage [9]. Moreover, the Convention for the Protection of Human Rights and Fundamental Freedoms (Article 8) [6] does not contain an express provision for the right to a safe environment for human life and health and its protection.

The rights to life, health, an adequate standard of living and privacy are used to protect the environment. For example, in the case of Leon and Agnizhak Kania v. Poland [10], "the applicants complained that due to the cooperative's continuous activities they were subjected to serious noise and pollution for a number of years, which resulted in their sustaining very serious and long-term health problems" (Paragraph 93). The Court argues that there is no explicit right to a clean and quiet environment in the EU law, however, in cases where a person is directly seriously affected by noise or other pollution, an issue may arise under Article 8 of the European Convention on Human Rights. To raise an issue under of Article 8 of the Convention the interference must directly affect the applicant's home, family or private life, and the negative effects of environmental hazards must attain a certain minimum level of severity. The assessment of that minimum level is relative and depends on all the circumstances of the case, such as the intensity and duration of the nuisance, and its physical or mental effects (Paragraph 98, Paragraph 100).

In the case of Dzemiuk v. Ukraine (Application no. 42488/02) [11], the court found that Article 8 of the Convention had been violated and made the decision that the construction and use of the cemetery so close to the applicant's house with the consequent impact on the environment and the applicant's "quality of life" constituted an interference with the applicant's right to respect for his home, his private and family life and reached the minimum level of severity to trigger the application of Article 8 of the Convention.

The applications lodged with the European Court of Human Rights under the Articles for the protection of the environmental rights of citizens and the above-mentioned cases outcomes prove a close connection between the right to a safe and healthy environment guaranteed by the national environmental legislation of Ukraine and the right to respect for private and family life officially recognized in Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms [6]. It means that environmental pollution can impact the well-being of individuals and prevent them from using their homes with consequent adverse effects on their private and family life without serious danger to their health. This also establishes the recognition by the European Court of Human Rights of the right to safe environment for life and health as a

derivative right that is mainly inferred from the provisions of Article 8 of the aforementioned Convention [12].

There are very few court decisions on the environmental issues in the general array of documents generated by the judicial system of Ukraine. Among them are the cases which, in particular, deal with the protection of the right to a safe to life and health environment [13]. Another example is the court decision which became a landmark one as it was the first time in the history of Ukraine when the court ruled in favor of the victims of the environmental disaster [14]. The authors of this research fully support a practical initiative aimed at facilitating work and accelerating search for relevant judicial decisions of the Supreme Court of Ukraine, higher specialized courts, appellate and local courts. It is proposed to list all the decisions, orders, rulings rendered by the courts in civil, commercial and administrative cases initiated by the institutions of civil society, individuals or groups of individuals for the benefit of the environment and society in the relevant Register of court decisions on issues relating to the environment [15].

In theory and law, the environmental rights include all the rights of citizens and other entities in the field of "society-nature" [16, p. 83]. According to the level of legal regulation, these rights are classified into fundamental and other rights relating to environment protection. So, the fundamental constitutional right to private ownership of land, the right to a favorable environment, the right to free access to information about the environmental situation and the right to compensation for harm to individual's health or property, caused by environmental offenses and the right to health and medical care [17, p. 131-132].

The Constitution of Ukraine (1996) [8] specifies that human rights and freedoms as inalienable and inviolable. Thus, the fundamental law guarantees that no citizen shall be deprived of the human rights. These rights are birth-rights. The consolidation in the Constitution of Ukraine of the right to a safe to life and health environment and to compensation for harm, caused by the violation of that right, is based on the provisions of the important international human rights instruments, namely the Universal Declaration of Human Rights (1948) [18], the Convention on Protection of Human Rights and Fundamental Freedoms (1950) [6], the European Social Charter (1961) [19].

Human rights and environmental rights are a key area of attention at the international level. This is evident from the researches on the history of environmental rights, the relevance of environmental rights standards and international human rights covenants by such scholars as Stephen J. Turner, Sumudu Atapattu and others [20, pp.1-16, pp.17-40]. Alan Boyle, Professor of Public International Law, particularly studies the problems of human rights and international environmental law [21, 22].

The environmental legislation of Ukraine, namely the Law of Ukraine "On Environmental Protection" [2] defines a system of basic environmental rights of citizens, including the right to a safe to life and health environment; the right to natural resources for general and special use; the right to compensation for harm to health and property caused by the environment adversely impact etc.

There is no doubt that the right to a safe and healthy environment is an important fundamental environmental right. It is universally recognized that other environmental rights are derived from the aforementioned. For defining this important fundamental right, it is necessary to clarify the term "safety" in this context. The environmental legislation of Ukraine, in particular Article 50 of the Law of Ukraine "On Environmental Protection", provides for an appropriate wording of the concept of "environment safety" [2]. Thus, the environment safety is such a state of environment, in which the prevention of environment degradation and human health risks is enforced. The environment safety is guaranteed to citizens of Ukraine through implementing a wide range of interrelated political, economic, technical, public and legal, organizational, and other measures. The court is authorized to ban the activities of individuals and legal entities that harm the environment.

The experts define an important legal criterion of "favorable environment". First of all, these criteria are the system of environment protection standards and natural resource management limits, namely regulating maximum permissible concentrations of harmful substances; standards of sanitary and protective zones, etc. These standards reflect the qualitative characteristics of the environment state and are aimed primarily at improving and maintaining its cleanliness, which stands out as the only important characteristic of a favorable environment status though. The second important criterion concerns the intensity (inexhaustibility) of natural resources. The latter is ensured by limiting natural resources use (by establishment of the volume of natural resources use (utilization)). The third criterion is the ability to satisfy aesthetic and other human needs and to maintain species diversity [17, p. 142-143].

Based on the safe environment criteria described above, namely non-pollution clearness, inexhaustibility (intensity), etc., it is appropriate to analyze the current environment state in Ukraine. According to the environment experts, the amount of pollutants, especially in megalopolises, significantly exceeds permissible concentrations, and ultimately adversely affects public health. For example, water contamination by nitrates leads to various diseases and consequently to decreased body resistance and to increased morbidity, in particular, infectious and oncological diseases. Non-compliance of drinking water quality with the regulatory standards is one of the reasons for the spread of many infectious and non-communicable diseases. So, water is mainly misused in Ukraine. Unproductive water consumption is increasing while the volume of qualitative "usable" water resources is decreasing due to pollution and depletion [23].

The degree of danger to humans of air pollution remains a leading risk factor and the number of victims exceeds the value of water or soil pollution. This is due to the fact that a person consumes a lot more air than water and food. In addition, if the consumer can to some extent regulate the quality of food and drinking water, then the purity of

the air, the more atmospheric, at the individual level is almost impossible to control. In the issue of environmental hygiene, particular attention is paid to such dangerous chemical compounds as carcinogens. Thus, in general, the total carcinogenic risk to the health of the population of settlements created by the identified compounds in 2014 reached 1.8-7.3 cancer cases per 1 thousand people, which accounts for the annual increase of ecologically related oncological diseases to 10.4 cases per 100 thousand population. This level of risk significantly exceeds internationally acceptable risk indicators and requires measures to reduce it. The highest level of population carcinogenic risk falls on the residents of Kyiv, and the lowest - on the residents of Cherkasy [24, p. 30-31].

The interconnection between human rights and environmental protection was emphasized in the 1972 Stockholm Declaration on Environmental Issues [25], where human rights to a healthy environment were first mentioned. The absence in the international law of a strict definition (that is, the meaning of which is defined in accordance with the principles of general international law) the concept of "human right to a favorable environment" and also that the right to a favorable environment, although related to the rights of the new generation, by its structure is closely intertwined with the human rights system as a whole, leading to a different attitude to the right to a favorable environment at the level of national legislation, and as a consequence to the ambiguous assessment of its rights of this nature [26, p. 198-199].

It should be noted that the constitution guarantees this right in most countries. For example, at the national level Spain was the first country which constitutionalized the right to a favorable environment, and subsequently, Azerbaijan, Belarus, Belgium, Georgia, India, Spain, Mozambique, Moldova, Peru, Portugal, Finland, Ethiopia, South Africa, South Korea, to name a few, followed [26, p. 199], which should be recognized as positive, but the content of this right is defined differently.

In the context of the discussion of the human right to a healthy and favorable environment, which has been ongoing in Western Europe for 25 years, it is concluded that the wording of the basic right, which would give an individual citizen the opportunity to claim a clean and healthy environment in court, is impossible. Even those countries which provide for that wording by their Constitutions, experience difficulties in forming that right and putting it into effect [27, p. 126].

It should be emphasized that defining the right to a safe environment of Ukraine as a fundamental right, it is necessary to point out its relation to other environmental rights. Yes, Art. 3 of the Law of Ukraine "On Protection of Human Being from the Impact of Ionizing Radiation" [28] states that every person who resides or temporarily resides in the territory of Ukraine has the right to be protected from the influence of ionizing radiation. These are also the provisions of the Law of Ukraine "On ensuring the sanitary and epidemiological well-being of the population", in particular Art. 4, which defines the right of citizens to safe and healthy food, drinking water, working conditions, education, education, life, recreation and the environment. The Law also contains the concepts of environmental factors such as any biological, chemical, physical, social and other factors that influence or may affect human health or the health of future generations. The concept of harmful impact on human health is defined as the influence of environmental factors that threaten the health, life or ability of the person or the health of future generations (Article 1 of the Law of Ukraine "On Ensuring Sanitary and Epidemic Well-Being of the Population" [29]). In this case, the above concepts and list are well-grounded and take into account the current developments of environmental specialists.

Under the Fundamentals of the Legislation of Ukraine on Health Protection (Article 6) [30] the right to health protection consolidates, among other things, a safe environment for life and health. The state ensures the protection of environment as an important prerequisite for human life and health by protecting animate and inanimate nature, protecting people from negative environmental impacts, by achieving harmonious interaction between individuals, society and nature, rational use and reproduction of natural resources (Article 26).

The international legal instruments also place great emphasis on the connection between the environment state and human health. The General Assembly resolution emphasizes that continued deterioration of environment could jeopardize the very foundations of life. At the same time, it is recognized that all people have the right to live in an environment that is favorable for their health and well-being [31].

Article 11 of the European Social Charter [19] establishes the necessary measures designed for health protection. In this regard, it is pointed out that it is appropriate to eliminate as much as possible the cause of poor health and prevent the epidemic, endemic and other diseases, as well as accidents.

The environmental rights intended to meet a variety of needs (economic, recreational, health, aesthetic, cultural, and others) are universally recognized to have a special status in the system of environmental rights of citizens. Natural resources have numerous functions, but one of the most important is the possibility of their use as a means of maintaining or restoring human health. In Ukraine the legal framework has been developed to exercise these rights: the Land Code [32], the Water Code [33], the Forest Code [34], the Subsoil Code [35] and the Law "On the Plant World" [36], the Law "On the Animal World" [37], the Law "On the Nature Preserve Fund" [38], etc.

Taking into consideration the subject of this research, it is appropriate to highlight two types of citizens' environmental rights: the right to natural resources for recreational use and the right to medicinal natural resources. So, the former right covers the total free use of objects of the animal world to satisfy recreational needs; the use of natural plant resources for recreational purposes; the use of forests benefits for cultural and recreational purposes, etc.; the water use for recreational purposes, etc.

With regard to the latter, the Water Code of Ukraine specifies that places of water use for treatment, recreation and sports purposes are established by the relevant councils as prescribed by law [33]. Moreover, under Article 45 of the Water Code of Ukraine, in case of low water, the risk of epidemics and epizootics, as well as in other cases provided for by law (in conditions that could cause or have caused water pollution, etc.), the rights of water users can be restricted or the water use conditions can be changed to ensure public health and other public interests. Thus, the law justifiably gives priority to the use of water for drinking and housekeeping needs of the population. At that, harmonization of the Ukrainian legislation with the European Union law (EU Water Framework Directive) [39], in particular, bringing the quality standards of drinking water for personal use into conformity with the EU standards, is certainly a priority. It is also worth pointing out the importance of the Management of Bathing Water Quality and Repealing Directive adopted in the EU [40]. This document provides for the wording of the concept of these kinds of water, the acceptable norms for contamination and other pollutants which may not be exceeded.

Under Article 2 of the Law of Ukraine "On the Resorts" the relations arising in the use and protection of natural curative resources are subject to legal regulation and are aimed at identifying and accounting of these resources, ensuring their rational extraction, use and protection in order to create favorable conditions for treatment and prevention of diseases and recreation of people [41]. Article 6 of the Law classifies natural curative resources into mineral and thermal waters, therapeutic mud and ozokerite, brine of estuaries and lakes, sea water, natural objects and complexes with favorable climatic conditions for treatment, suitable for use for treatment, medical rehabilitation and disease prevention.

Articles 62 and 63 of the Water Code of Ukraine categorize water bodies of natural curatives properties as therapeutic, if they are specifically listed, and are used exclusively for therapeutic and recreational purposes. The list of water bodies therapeutic indicating the water reserves and their curative properties, as well as other conditions favorable for treatment and prevention, is approved by the Cabinet of Ministers of Ukraine upon the request of the relevant public authorities as stipulated by the law.

To monitor the possibilities of using water from water bodies for the needs of the population and economy sectors the standards are established to ensure the safe conditions of water use. Under Article 36 of the Water Code of Ukraine stricter environmental safety standards can be implemented as to waters of the water bodies used for medical, spa, recreational, rehabilitation and other purposes, if necessary [33]. The above provision is fully justified by the peculiar natural properties of these waters. These rights are widely exercised by citizens and guaranteed by the state.

The information system on the quantity, quality and other characteristics of all natural curative resources that are important in terms of treatment and prevention of human diseases are determined and calculated on the territory of Ukraine, as well as the possible volumes, methods and modes of their use totally comprises the State Cadaster of Natural Curative Resources of Ukraine, which is created and maintained in the accordance with procedure established by the central executive body tasked with public health policy [41]. The Cadaster data are also used to create favorable conditions for treatment, prevention of diseases and recreation of people [42].

So, in accordance with the legislation of Ukraine, citizens can use natural resources for health and medical purposes, in particular, natural curative resources, which, along with other natural resources, are one of the constituents of environment. Article 5 of the Law of Ukraine "On Environmental Protection" lists the latter [2]. Thus, the natural curative resources have a special legal status due to their natural properties, namely the ability to improve human health. Moreover, the above legal relations are aimed at maintaining a safe environment for human life and health.

In this regard, it is of great importance to determine the directions for improving the national environment legislative framework on ensuring the right to natural curative resources, as well as to reason and develop relevant proposals. It should be borne in mind that the current Subsoil [35], Water [33] and Forest [34] Codes of Ukraine, and the relevant laws of Ukraine contain separate provisions that can be applied to exercise this right if they will be improved and modified. It would be advisable to develop and adopt the Law of Ukraine "On Natural Curative Resources". This proposal should be considered quite appropriate as the legislative experience of EU member states proves the efforts of developing and adopting the relevant laws efficiency [43, 44].

The national program on the harmonization of Ukrainian legislation to European Union law establishes the mechanism for Ukraine to meet the third Copenhagen and Madrid criteria for the European Union membership. This mechanism includes the adaptation of legislation, the establishment of relevant institutions, and other additional measures necessary for effective lawmaking and law enforcement [1, p. 12].

CONCLUSIONS

The reform priority is the adaptation of the environmental legislation on environmental rights of Ukraine to the relevant European law. It is generally recognized that the goal is to bring the legal system of Ukraine in line with the basic European law, known as acquis Communautaire, taking into account the requirements established by the European Union to those states that want to join it. For this reason, the problems of legislative support of environmental rights should be solved based on the provisions of the relevant EU legislation.

Undoubtedly, the right to a safe environment is an important one in the system of environmental rights of our country, the implementation of which is crucial for

the health and life of citizens. Accordingly, being directly related to the right under discussion the derivative rights are of significance and include the right to natural resources (natural curative resources and natural resources for health and medical use). The latter should be recognized as a prerequisite for the realization of the right to health and life of a person.

The lack of proper legislative consolidation of the right to natural curative resources' main provisions necessitates the improvement of the legal framework to exercise this right be given utmost priority.

Proposals for improving the environmental legislation of Ukraine in the field of nature management by substantiating and adopting a new Law of Ukraine "On Natural Healing Resources", which would regulate relations in the field of use, protection and reproduction of natural healing resources and ensuring environmental safety, are substantiated and formulated. The drafting of this Law of Ukraine should take into account the existing positive experience of the Member States of the European Union.

REFERENCES

1. Ghubsjkyj S.M., Inshyn M.I., Mironenko T.Je. et al. Kompleksnyj porivnjaljno-pravovyj analiz vidpovidnosti zakonodavstva Ukrajiny zakonodavstvu JeS u sferi okhorony zdorov'ja ljudej, tvaryn, roslyn [Comprehensive Comparative Legal Analysis of Compliance of Ukrainian Legislation with EU Legislation in the Field of Human, Animal and Plant Health] Available from: https://minjust.gov.ua/files/general/2012/05/16/201205160000006884.pdf [reviewed 2019.09.10] (Ua)
2. Pro okhoronu navkolyshnjogho pryrodnogho seredovyshha: Zakon Ukrajiny vid 25 chervnja 1991 r. № 1264-XII [On Environmental Protection: Law of Ukraine of June 25, 1991 No. 1264-XII]. Bulletin of the Verkhovna Rada of Ukraine. 1991;41: art. 546. (Ua)
3. Malysheva N.R., Jerofjejev M.I. Naukovo-praktychnyj komentar do Zakonu Ukrajiny "Pro okhoronu navkolyshnjogho pryrodnogho seredovyshha" [Scientific and Practical Commentary to the Law of Ukraine "On Environmental Protection"]. Kharkiv: Pravo; 2017. (Ua)
4. Environment and Development. United Nations Terminology bulletin. 1992;344(1).
5. Tretyakova A.A. Ekologicheskie prava grazhdan v gosudarstvah-chlenah Evropejskogo Soyuza [Environmental Rights of Citizens in the Member States of the European Union] Dissertation for obtaining the Phd of Law. Moscow; 2001. (Ru)
6. Konvencija pro zakhyst prav ljudyny i osnovopolozhnykh svobod: vid 4 lystopada 1950 r. [Convention for the Protection of Human Rights and Fundamental Freedoms: of November 4, 1950]. Official Gazette of Ukraine. 2006;32: art. 2371. (Ua)
7. Pro vykonannja rishenj ta zastosuvannja praktyky Jevropejsjkogho sudu z prav ljudyny: Zakon Ukrajiny vid 23 ljutogho 2006 r. № 3477-IV [On the Enforcement of Decisions and the Application of the Case Law of the European Court of Human Rights: Law of Ukraine of February 23, 2006 No. 3477-IV]. Bulletin of the Verkhovna Rada of Ukraine. 2006;30: art. 260. (Ua)
8. Konstytucija Ukrajiny: vid 28 chervnja 1996 r. № 254k-96 VR [Constitution of Ukraine: of June 28, 1996 No. 254k-96 VR]. Bulletin of the Verkhovna Rada of Ukraine. 1996;307: art. 141. (Ua)
9. Voigt Ch., Makuch Z., eds. Courts and the environmen. Northampton: Massachusetts: Edward Elgar Publishing, Inc; 2018. doi: 10.4337/9781788114677.
10. Case of Leon and Agnieszak Kania v. Poland, application No. 12605/03, Judgement of the European Court of human rights of 21 July 2009, final 21/10/2009 Available from: http://hudoc.echr.coe.int/eng?i=001-93650 [reviewed 2019.09.10]
11. Case of Dzemyuk v. Ukraine, application No. 42488/02, Judgement of the European Court of human rights of 4 September 2014, final 04/12/2014 Available from: http://hudoc.echr.coe.int/eng?i=001-146357. [reviewed 2019.09.10]
12. Kalyshuk L.A. Osoblyvosti zastosuvannja st. 8 Konvenciji pro zakhyst prav ljudyny i osnovopolozhnykh svobod pry zakhysti ekologhichnykh prav ghromadjan [Peculiarities of Application of Article 8 of the European Convention of Human Rights for Protection of Environmental Rights of Citizens]. Scientific Bulletin of Uzhhorod National University (Series: Law). 2015;31,2:76–79. (Ua)
13. Zakhyst prava na bezpechne dlia zhyttia i zdorovia dovkillia [Protection of the Right to a Safe and Healthy Environment] Available from: http://epl.org.ua/law-tax/spravy/zahyst-prava-na-bezpechne-dlya-zhyttya-i-zdorovya-dovkillya. [reviewed 2019.09.10] (Ua)
14. Vpershe v istoriji Ukrajiny sud zadovoljnyv pozov postrazhdalykh vid ekologhichnogho lykha [For the First Time in the History of Ukraine, the Court Sustained the Claim of Victims of the Environmental Disaster] Available from: https://ecotown.com.ua/news/Vpershe-v-istoriyi-Ukrayiny-sud-zadovolnyv-pozov-postrazhdalykh-vid-ekolohichnoho-lykha. [reviewed 2019.09.10] (Ua)
15. Rejestr sudovykh rishenj z pytanj, shho stosujutjsja dovkillja [A Register of Court Decisions in the sphere of Environmental protection] Available from: http://caselawepl.org.ua. [reviewed 2019.09.10] (Ua)
16. Makarova T.I. Ekologo-pravovoj status grazhdan Respubliki Belarus [Environmental and Legal Status of Citizens of the Republic of Belarus]. Minsk: BGU; 2004. (Ua)
17. Brinchuk M.M. Ekologicheskoe pravo (pravo okruzhayushej sredy): uchebnik [Environmental Law: Textbook]. Moscow: Yurist; 2000. (Ru)
18. Zaghaljna deklaracija prav ljudyny: vid 10 ghrudnja 1948 r. (Dok. OON/PES/217 A) [Universal Declaration of Human Rights: December 10, 1948 (Doc UN/PES/217 A)] Available from: http://kr-admin.gov.ua/mol/molod/2.pdf. [reviewed 2019.09.10] (Ua)
19. Jevropejsjka socialjna khartija: vid 18 zhovtnja 1961 r. [European Social Charter: of October 18, 1961]. Bulletin of the Verkhovna Rada of Ukraine. 2007;51: art. 2096. (Ua)
20. Turner S.J., Shelton D.L., Razzaque J., McIntyre O., May J.R., eds. Environmental Rights: the Dvelopment of Standarts. Cambridge: Cambridge University Press; 2019. doi: 10.1017/9781108612500.
21. Boyle A. Human Rights and International Environmental Law: Some Current Poblems Available from: https://www.eui.eu/Documents/DepartmentsCentres/Law/ResearchTeaching/WorkingGroups/08-03-HumanRights.pdf. [reviewed 2019.09.10] (Ua)
22. Boyle A. Human Rights and the Environmental: Where Next? European Journal of International Law. 2012;23,3:613–642. doi: 10.1093/ejil/chs054.
23. Pro Osnovni zasady (strateghiju) derzhavnoji ekologhichnoji polityky Ukrajiny na period do 2020 roku: Zakon Ukrajiny vid 21 ghrudnja 2010 r. № 2818-VI [On the Main Principles (Strategy) of the National Environmental Policy of Ukraine for the Period until the Year 2020: Law of Ukraine of December 21, 2010 No. 2818-VI]. Bulletin of the Verkhovna Rada of Ukraine. 2011;26: art. 218. [reviewed 2019.09.10] (Ua)
24. Nacionaljna dopovidj pro stan navkolyshnjogho pryrodnogho seredovyshha v Ukrajini u 2014 roci [National Report on the State of Environment in Ukraine in 2014]. Kyiv: FOP Ghrinj D.S.; 2016. (Ua)

25. Deklaracija Konferenciji Orghanizaciji Ob'jednanykh Nacij z problem otochujuchogho ljudynu seredovyshha: vid 16 chervnja 1972 r. [Declaration of the United Nations Conference on the Human Environment: of June 16, 1972] Available from: https://zakon.rada.gov.ua/laws/show/995_454. [reviewed 2019.09.10] (Ua)
26. Evtushenko V.I. Sovremennye tendencii sovershenstvovaniya gosudarstvennogo regulirovaniya realizacii konstitucionnogo prava cheloveka i grazhdanina v Rossijskoj Federacii na blagopriyatnuyu okruzhayushuyu sredu [Current Trends in Improving State Regulation of the Implementation of the Constitutional Rights of Human and Citizen in the Russian Federation to a Favorable Environment]. Belgorod State University Scientific bulletin. Philosophy. Sociology. Law. 2010; 2(97),15:195–206. (Ru)
27. Dubovik O.L., Kremer L., Lyubbe-Volff G. Ekologicheskoe pravo: uchebnik [Environmental Law: Textbook]. Moscow: Eksmo; 2005. (Ru)
28. Pro zakhyst ljudyny vid vplyvu ionizujuchogho vyprominjuvannja: Zakon Ukrajiny vid 14 sichnja 1998 r. № 15/98-VR [On Human Protection from the Impact of Ionizing Radiation: the Law of Ukraine of January 14, 1998 No. 15/98-VR]. Bulletin of the Verkhovna Rada of Ukraine. 1998;22: art. 115. (Ua)
29. Pro zabezpechennja sanitarnogho ta epidemichnogho blaghopoluchchja naselennja: Zakon Ukrajiny vid 24 ljutogho 1994 r. № 4004-XII [On Ensuring Sanitary and Epidemic Safety of the Population: Law of Ukraine of February 24, 1994 No. 4004-XII]. Bulletin of the Verkhovna Rada of Ukraine. 1994;27: art. 218. (Ua)
30. Osnovy zakonodavstva Ukrajiny pro okhoronu zdorov'ja: Zakon Ukrajiny vid 19 lystopada 1992 r. № 2801-XII [Fundamentals of the Legislation of Ukraine on Health Care: Law of Ukraine of November 19, 1992 No. 2801-XII]. Bulletin of the Verkhovna Rada of Ukraine. 1993;4: art. 19. (Ua)
31. Need to ensure a healthy environment for the well-being of individuals: Resolution No. A/RES/45/94, 68th plenary meeting 14 December 1990. In: Resolutions and Decisions adopted by the General Assembly during its 45th session. Vol. 1. Resolutions and Decisions, 18 September – 21 December 1990: GAOR, 45th Session, Supplement No. 49 A (A/45/49). New York: United Nations; 1991, p. 178. Available from: https://undocs.org/en/A/RES/45/94. [reviewed 2019.09.10]
32. Zemeljnyj kodeks Ukrajiny: vid 25 zhovtnja 2001 r. № 2768-III [The Land Code of Ukraine: of October 25, 2001 No. 2768-III]. Bulletin of the Verkhovna Rada of Ukraine. 2002;3/4: art. 27. (Ua)
33. Vodnyj kodeks Ukrajiny № 213/95-VR vid 6 chervnja 1995 r. [The Water Code of Ukraine No. 213/95-VR of June 6, 1995]. Bulletin i of the Verkhovna Rada of Ukraine. 1995;24: art. 189. (Ua)
34. Lisovyj kodeks Ukrajiny № 3852-XII vid 21 sichnja 1994 r [The Forest Code of Ukraine No. 3852-XII of January 21, 1994]. Bulletin of the Verkhovna Rada of Ukraine. 1994;17: art. 99. (Ua)
35. Kodeks Ukrajiny pro nadra № 132/94-VR vid 27 lypnja 1994 r. [The Code of Ukraine about Subsoil No. 132/94-VR of July 27, 1994]. Bulletin of the Verkhovna Rada of Ukraine. 1994;36: art. 340. (Ua)
36. Pro roslynnij svit: Zakon Ukrajiny № 2026-III vid 5 zhovtnja 2000 r. [On Flora: Law of Ukraine No. 591-XIV of April 9, 1999]. Bulletin of the Verkhovna Rada of Ukraine. 1999;22/23: art. 198. (Ua)
37. Pro tvarynnyj svit: Zakon Ukrajiny № 2894-III vid 12 ghrudnja 2001 r. [On Animal World: Law of Ukraine No. 2894-III of December 13, 2001]. Bulletin i of the Verkhovna Rada of Ukraine. 2002;14: art. 97. (Ua)
38. Pro pryrodno-zapovidnyj fond Ukrajiny: Zakon Ukrajiny № 2456-XII vid 16 chervnja 1992 r. [On Nature Reserve Fund of Ukraine: Law of Ukraine No. 2456-XII of June 16, 1992]. Bulletin of the Verkhovna Rada of Ukraine. 1992;34: art. 502. (Ua)
39. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy Available from: http://eur-lex. europa.eu/legal-content/EN/TXT/?uri=CELEX:32000L0060. [reviewed 2019.09.10]
40. Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality and repealing Directive 76/160/EEC Available from: http://eur-lex.europa.eu/legalcontent/EN/TXT/?qid=1499762530430&uri=CELEX:32006L0007. [reviewed 2019.09.10]
41. Pro kurorty: Zakon Ukrajiny № 2026-III vid 5 zhovtnja 2000 r. [On Resorts: Law of Ukraine No. 2026-III of October 5, 2000]. Bulletin of the Verkhovna Rada of Ukraine. 2000;50: art. 435. (Ua)
42. Pro zatverdzhennja Instrukciji po stvorennju i vedennju Derzhavnogho kadastru pryrodnykh likuvaljnykh resursiv: nakaz MOZ Ukrajiny № 687 vid 23 veresnja 2009 r. [On approval of the Instruction on creation and maintenance of the State cadastre of natural medicinal resources: Order of the Ministry of Health of Ukraine No. 687of September 23, 2009]. Official Gazette of Ukraine. 2010;12: art. 586. (Ua)
43. EüM rendelet 74/1999. (XII. 25.) a természetes gyógytényezőkről Available from: https://net.jogtar.hu/getpdf?docid=99900074.EUM&targetdate=&printTitl. [reviewed 2019.09.10]
44. Zákon ze dne 13 dubna 2001 o přírodních léčivých zdrojích, zdrojích přírodních minerálních vod, přírodních léčebných lázních a lázeňských místech a o změně některých souvisejících zákonů (lázeňský zákon) Available from: https://www.zakonyprolidi.cz/cs/2001-164#cast2. [reviewed 2019.09.10]

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REVIEW ARTICLE
PRACA POGLĄDOWA

ALCOHOLISM AS A MEDICAL AND SOCIO-LEGAL PROBLEM AND WAYS TO SOLVE IT

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ABSTRACT

Introduction: Almost 3.3 million people die from alcohol abuse each year worldwide accounting for almost 5% of all deaths. In 20% of cases alcohol is a cause of death in traffic accidents with more than 250 million men and women suffering from health disorders due to alcohol consumption and the prospects for improving this situation are disappointing [1]. Alcohol abuse has a negative impact not only on the health of the population, but also on public relations in general. It is about causing physical, moral and material harm to the "healthy" part of the population, as well as financial burden related to social payments. Addressing and reducing the problem of alcoholism requires a coherent government policy.

The aim: To summarize the modern progressive experience of preventing alcoholism and to identify the most promising directions of this phenomenon limitation by medical and socio-legal measures.

Materials and methods: We've used statistics of the World Health Organization, open source analytical information, including law enforcement agencies of Ukraine and other countries data. Analyzes of scientific publications on the impact of alcohol on public health and the social and legal consequences of alcoholism in the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, PubMed systematic, using dialectical, comparative, general, and statistical methods of scientific research**.**

Conclusions: Alcoholism is a social problem, so its roots must be sought not only in the imperfection of medical therapies for the treatment of patients, but above all in the inefficiency of state social policy and the inconsistency of legislation. The most effective are the following governmental policies: reducing the number of places of sale of alcohol; increasing of prices on alcoholic beverages; regulation of sale hours of alcoholic beverages; increasing the age of alcohol purchase allowance. These policies will be effective, given the widespread promotion of healthy lifestyles, intolerance of excessive alcohol consumption, compliance with the laws entrusted to the entities in charge of controlling functions, the inevitability of liability for violations of anti-alcohol legislation in the form of fines and revocation of licenses.

KEY WORDS: alcoholism, health disorders, public health, alcohol policy, alcohol and crime

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INTRODUCTION

The modern period of mankind is characterized by increased alcoholization of the population. This problem is drawing attention not only to the scale of its worldwide spread, but also to its grave medical and social consequences. First, alcoholism is associated with the occurrence of more than 60 types of diseases, including: cirrhosis, high blood pressure, mental illness, congenital malformations [7, p. 1015]. Systematic alcohol abuse reduces the activity of the immune system, leading to infectious diseases. According to the World Health Organization (WHO) approximately 3.3 million people die each year as a result of alcohol abuse, accounting for almost 5% of all deaths. In 20% of cases alcohol is the cause of death during an accident. Worldwide more than 250 million men and women suffer from health disorders due to alcohol use and the prognosis for improving of this situation is negative [1]. Secondly, the uncontrolled consumption of alcoholic beverages threatens not only consumers but also the close environment of alcoholics and the whole society. After all, most drug addicts have problems with their families, their work, and usually they also have problems with law. Moreover, a significant number of them are at risk of falling victim to accidents and crimes due to alcohol intoxication, women and girls increase their chances of becoming a victim of rape because of drinking**.**

In 2018 WHO introduced to public a SAFER – a suite of proven measures to reduce alcohol-related harm. It outlines five highly effective strategies that can help governments of different countries to reduce harmful use of alcohol and its negative social and economic impact [2]. In other words, SAFER is one of the latest and most optimal strategies to support governments in taking practical steps to accelerate health progress, to overcome noncommunicable diseases by: 1) strengthening the restrictions on alcohol availability; 2) increasing measures to counteract drunk driving; 3) facilitating access to screening, short-term intervention and treatment; 4) ensuring complied with bans or comprehensive restrictions on advertising, sponsorship and promotion of alcohol; 5) raising prices on alcohol through excise taxes and pricing policy. According to WHO experts the implementation of these measures will reduce alcohol abuse by 10% till 2025 [2].

Thus, the problem of alcoholism in all its manifestations is solved mainly by the use of a whole complex of interrelated medical as well as social and legal measures.

THE AIM

To summarize the modern progressive experience of preventing alcoholism and to identify the most promising directions of limitation of this phenomenon by medical and socio-legal measures.

MATERIALS AND METHODS

We use statistics of the World Health Organization, open source analytical information, including law enforcement agencies in Ukraine, the US, UK, Australia and other. The scientific publications in the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, PubMed with systematic review of databases reflecting the results of researches on the impact of alcohol on public health, alcohol and crime interconnection, and analysis of national policies aimed on reducing of alcohol demand and their effectiveness.

The methodological basis of the article is the system of general and special methods of cognition. The dialectical method was used to analyze the essence of the phenomenon of alcoholism and its consequences for society, the comparative method allowed to establish the experience of implementing anti-alcohol policy in a number of countries of the world, the general method (analysis, synthesis, induction, deduction, abstraction, generalization) was useful in processing sources, the statistical method used to analyze information on alcohol and crime.

REVIEW AND DISCUSSION

Nowadays, there is a particular emphasis in the world on combating drug trafficking. At the same time, the problem of alcoholism, having no fewer negative effects than drug addiction, remains in the shadow of the latter. Alcohol is the most common and permissible drug, which harms the population on a large scale.

In general, the term "alcoholism" (in medical terminology - alcohol addiction syndrome) is used with regard to chronic drinking or periodic consumption of alcohol, characterized by impaired control over the amount of drinking, frequent episodes of intoxication (alcohol intoxication), narrowing the life interests to alcohol and drinking regardless their adverse effects [3, p. 5]. For example, the neurophysiologist J. Crystal identifies two states of alcoholism. The first is when a person is physically addicted to alcohol and consumes it daily, and when they stop drinking, they have symptoms of alcohol withdrawal syndrome: high blood pressure, anxiety, trembling, and changes in sensory perception. The second one is related to the non-systematic use of alcohol, but in a way that directly causes problematic situations for the individual. Thus, in a state of alcohol intoxication a person becomes aggressive, tend to drunk driving, is sexually risky, posing a threat of HIV or other diseases. Drunkenness also leads to job loss, deterioration of family relationships, the likelihood of becoming a victim of injury and crime [4]. So, even if alcohol use is moderate it can be a trigger for physical or mental health disorders. The WHO Global Alcohol and Health Report, released in 2018, states that alcohol consumption is a factor in more than 200 illnesses and injuries [1]. The short-term prospect of drunkenness causes memory loss, hangover, "shutdown". Longer term – threatens stomach problems, causes cancer, heart failure, brain damage, pancreatitis, high blood pressure, liver cirrhosis. Decrease in sexual function is observed in 1/3 of alcohol abusers and in patients with chronic alcoholism. Men have various functional disorders of the central nervous system (neuroses, reactive depression, etc.) due to "alcohol impotency"; pregnant women has the risk of harming the fetus [5]. Of particular concern is the use of alcohol in adolescence, as it affects brain development and a higher risk of damage to the internal organs. Researchers have found that drinking alcohol under the age of 15 is associated with a fourfold increase in the risk of alcohol addiction in adulthood, and reducing the likelihood of addiction by 14% every additional year [6]. And the list of negative impacts of alcoholism on human health is not exhaustive.

A team of researchers from the 2016 Global Disease, Injury and Risk Factor Survey on Alcohol and Alcohol-Related Deaths and Disability Adjusted Years (DALY) estimated data from 1990-2016 on 28 million people in both sexes in ages 15 to 95 and older from 195 settlements in the world. This study, published in The Lancet Medical Journal in 2018, confirmed a clear correlation between drinking and premature death, cancer, and cardiovascular disease. Only zero alcohol consumption minimizes the risk of health loss [7, p. 1015]. Also, the uncontrolled use of alcohol increases the risk of injury and premature death as a result of road accidents, poisoning, suicide and violence.

Inadequate alcohol use is medically diagnosed as "alcohol disorders caused by alcohol consumption" and is a chronic recurrent brain disorder characterized by compulsive alcohol consumption, loss of control over alcohol consumption, and a negative emotional state in case of misuse [8]. Alcohol disorders caused by alcohol are reasonably included in the International Classification of Diseases 10 (section F10 (F10.0 - F10.9)) "Mental and Behavioral Disorders Caused by Alcohol". Among them: a state of acute intoxication; harmful use; dependency syndrome; withdrawal syndrome or withdrawal syndrome; abstinence syndrome with delirium (with "white fever"); psychotic disorder (psychosis); amnestic syndrome and others.

Regarding Ukraine, the results of the evaluation "Transition Mental Health: Evaluation Results and Recommendations for Integration of Mental Health into Primary Health Care and Public Service Platforms", conducted jointly by the International Medical Corps, World Bank and the Swiss Cooperation Bureau shows that the problem of alcoholism is very acute in this country. In particular, experts estimate that 40% of deaths of working-age men and 22% of wom-

en aged 20-64 were due to alcohol. Suicide is most often the cause of death associated with mental disorders and alcohol use [9]. As for persons with mental and behavioral disorders due to alcohol use in syndromic-nosological forms, in the last five years in Ukraine such patients have been recorded from 450 to 480 thousand. Of these, 23% are persons aged 18 to 35 years [10].

Since alcoholism is considered a chronic brain disease it cannot be completely cured by medicine alone or prevented by vaccination according to relevant researches. Medications can be effective in reducing withdrawal symptoms and the possibility of relapse. Pharmacotherapy also helps to reduce the symptoms of other mental illnesses, such as anxiety and depression, which contribute to drug and alcohol use [11, p. 98-104]. In order to maintain control over the symptoms, such a disease requires constant and complicated medical treatment, as evidenced by medical practice. Recommendations for intervention for people with alcohol problems in primary care are limited to screening for alcohol use, brief interventions for more dangerous cases, and specialized treatment for people with alcohol addiction syndrome.

Despite the variety of therapeutic approaches to the treatment of alcohol addiction, there are basic principles that can improve the effectiveness of therapy. First and foremost is the voluntariness and continuity of the therapeutic process. Usually, patients suffering from such a disease are reluctant to acknowledge the existence of the problem and to agree on treatment, while constructive cooperation between the doctor and the patient is the main condition for successful treatment. The continuity of the therapeutic process means that complete treatment for alcohol addiction is impossible, it is only a question of sustained therapeutic remission [11, p. 98].

We have already paid attention to the fact that under the influence of alcohol a person becomes more aggressive and capable of unlawful, criminal, behavior. That is why the topic of constant focus in society is the link between alcohol and crime. According to the National Alcohol and Drug Addiction Council (NCAAD), for example, in the United States alcohol is the cause of 40% of violent crimes; of the 2 million people in prison 37% were arrested while intoxicated [12]. In New Zealand one third of all offenses are perpetrated by people who are intoxicated [13]. In the United Kingdom and Wales 12.4% of self-serving crimes and 21.5% of hate crimes were committed under the influence of alcohol, while in 35.8% of cases of sexual violence the offender was also under the influence of alcohol [14]. As for Ukraine, the average rate of identified criminals who have committed a criminal offense in state of alcohol intoxication over the past three years is 10.5%. Of these, 44.5% committed crimes against property; 37.9% are crimes against life and health; 8.8% are crimes against traffic safety and traffic operation [15].

Interestingly, according to the research team of the University of California at Davis, it turned out that alcohol abuse is a major predictor of violent crime in the use of firearms. It was found that one-third of firearms holders who were previously convicted of crimes of alcohol intoxication committed violent crimes using a firearm. Thus, it was concluded that an alcohol was a more important indicator of future violence than previous violent crimes [16].

The foregoing allows to argue that alcohol abuse has a negative impact not only on the state of health of the population, but also on public relations in general. It is about causing physical, moral and material harm to "healthy" part of the population as well as financial burden related to social payments. Addressing and reducing the problem of alcoholism requires a coherent government policy. The statistics on mortality, morbidity, other risks and alcohol-related crimes show an uncontrolled negative impact on society. By WHO's recommendation countries are encouraged to implement strategic measures, the key of which, in our opinion, are: regulating the availability of alcohol, reducing demand for it, short-term intervention and treatment.

Numerous observations indicate that a favorable factor in overall high consumption of alcoholic beverages is their availability. Researchers have found that in disadvantaged city areas there are 40% more places of alcohol sale compared to the more prosperous socially inhabited neighborhoods. In turn, in areas where there are large numbers of beer pubs, clubs and shops that sell alcohol the crime rate is almost eight times higher than in those areas where alcohol distribution is lowest [17]. Moreover, increasing the density of outlets for the sale of alcoholic beverages by 1% leads to an increase in the frequency of violent crimes by 0.62% [11, p. 86]. Hence, the availability of alcohol plays an important role in the link between alcohol and crime.[1]

In order to reduce the consumption and sale of alcoholic beverages, laws and local regulations are in place to regulate the density of their sales through zoning and licensing rules. We have already mentioned the link between alcohol availability and crime. In other studies, the thesis about the high level of injuries, car accidents, infectious diseases, sexually transmitted diseases and urgent hospitalization due to the effects of alcohol is fully confirmed. At the same time, an experiment on the interconnection between the closure of alcohol outlets and alcohol use and related violence was conducted by researchers in New York (Castillo-Carniglia A., Pear VA, Tracy M., Keyes KM, Cerdá M.), showed that the closure of such facilities does not significantly reduce the problems associated with alcohol. Alcohol was restricted from 90 to 50% of New York's population density and from 5 to 25% of outlets were closed. The result was as follows: the number of moderate users of alcohol decreased (42.2% at the beginning of the experiment versus 38.1% at the end); the intensity of alcohol consumption increased slightly (12.0% at the beginning of the experiment versus 12.5% at the end); cases of violence or murder remained unchanged [18, p. 694, 702]. Obviously, the results of the

[1] Note. We focus on the study of anti-alcohol policy and crime communication, since this is how it's efficiency can be traced.

mentioned study indicate the need for a comprehensive strategy to limit alcoholism. It is about taking different measures. Therefore, the ineffectiveness of, for example, medical treatment of alcoholism may be partially offset by the implementation of other (social, legal) directions of the harmonized limitation of this negative phenomenon.

Another measure to reduce the availability of alcohol is to regulate its timing. Studies have shown a reduction in the level of alcohol harm in the case of reduced hours of alcohol sale. For example, in Brazil as a result of the policy of restricting the hours of alcohol in bars to 23:00 instead of 24 hours the overall homicide rate was reduced by 44% [19]. A similar situation is observed in Australia. In particular, where pubs were open for two hours less there was a 37% reduction in police-reported attacks [20]. Norwegian scientists have substantiated the example of 18 cities that prolonging the time of closure of alcohol trading facilities for only one hour increases attacks by 16% [21].

Twenty-one alcohol policy experts in Australia agreed that pricing is a top national priority for reducing alcohol consumption with most agreeing that "something needs to be done" with alcohol advertising [22].

Increased taxation and minimum pricing are also considered as the most important pricing policies [22]. The issue of the impact of pricing on alcohol and violence was also not overlooked by scientists. Thus, it is estimated that 10% increase in beer tax leads to a decrease in the number of murders by 0.3%, rape - by 1.32%, assaults - by 0.3%, robberies - by 0.9% [23]. In addition, according to an international survey conducted in 16 countries the reduction of sexual and physical violence as well as cases of robbery can be linked to higher alcohol prices [24]. That is, the legal direction for restricting alcoholism cannot be underestimated.

Legislatively establishing a minimum legal age for the purchase of alcoholic beverages also helps to reduce alcohol consumption among young people. For example, in New Zealand reducing of the minimum age of allowance to buy alcoholic beverages from 20 to 18 years has led to an increase in road traffic injuries among adolescents aged 15-19 [25]. For an example, S. J. Hoffman, Ch. Tan in a review of systematic reports on public health effects of tobacco control, issued in 2015, concluded that the following policies were effective: bans and restrictions on smoking in public and workplaces; increase in prices for tobacco products; imposing a ban on the sale of tobacco products to minors subject to strict compliance with such a restriction [26].

CONCLUSIONS

Thus, the analysis and generalization of modern studies on alcoholism, the study of statistical information by law enforcement agencies of different countries gives grounds for some conclusions:

1) alcoholism is a modern medical and social problem that is actually transnational in nature because it is common to many countries worldwide;
2) alcoholism has a number of negative consequences not only for the health of alcohol users, but also for certain social groups, society, economic interests of states, and the gene pool of individual nations;
3) Alcoholism is a social problem. Therefore, its roots must be sought not only in the imperfection of medical and therapeutic treatment of patients, but above all in the inefficiency of state social policy and the inconsistency of legislation with the threats posed;
4) success in limiting alcoholism depends on applying a comprehensive strategy. It involves the application by various state and non-state actors of medical, social, legal and other organizational measures;
5) the most effective in view of limiting the spread of alcoholism and reducing the number of alcoholics are the directions for limiting the availability of alcohol through: increasing taxation on alcoholic beverages; setting a minimum price per unit; marketing regulation; reducing the number of places of alcohol sale; regulation of alcoholic beverages sale hours; increasing the age at which alcohol is allowed to be purchased;
6) in the light of the effectiveness of the social vector of preventing alcoholism, the positive foreign experience of certain measures implementation becomes particularly relevant: the sale of alcohol at special points of sale (Finland, Sweden); restriction of alcohol sales after 18-00 hrs. on Sundays and on dates of public holidays (Finland, Sweden); setting a curfew for minors regarding the prohibition to walk on their own without adults accompanying after 10 pm. (United Kingdom, USA, Poland, Brazil, Republic of Belarus); ban on the sale of alcoholic beverages to persons under the age of 21 (USA, some provinces of Canada, some states of India, Indonesia);
7) the most effective measures to reduce alcoholism are: issuing a license to sell alcohol to one nationwide trading network to facilitate control of its activities; a complete ban on the sale of alcoholic beverages near schools, sports facilities, and other locations frequented by adolescence; preventing the sale of alcohol to an adult accompanying minors; a complete ban on the sale of alcohol to persons under 18, and hard liquor - from 21 years; increasing of administrative liability for persons who have sold alcohol to under-aged persons.

REFERENCES

1. Global status report on alcohol and health 2018. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.
2. WHO launches SAFER alcohol control initiative to prevent and reduce alcohol-related death and disability. Available from: https://www.who.int/substance_abuse/safer/launch/en/ [reviewed: 2019.08.15]
3. Slovar terminov, otnosyaschihsya k alkogolyu, narkotikam i drugim psihoaktivnyim sredstvam. WHO, 1996. 80 p.
4. John Krystal Alcoholism. Available from: http://serious-science.org/alcoholism-7561. [reviewed: 2019.08.15]
5. Understanding Alcohol Use Disorder - the Basics. Available from: https://www.webmd.com/mental-health/addiction/understanding-alcohol-abuse-basics#1[reviewed: 2019.08.15]

6. Dawson DA et al. Age at first drink and the first incidence of adult-onset DSM-IV alcohol use disorders. Alcohol Clin Exp Res. 2008 Dec;32(12):2149-60. doi: 10.1111 / j.1530-0277.2008.00806.x
7. Alcohol use and burden for 195 countries and territories, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet, 2018; 392: P.1015–1035. doi: 10.1016/S0140-6736(18)31310-2
8. Alcohol & Your Health. Research-based information on drinking and its impact. Available from: https://www.niaaa.nih.gov/alcohol-health [reviewed: 2019.08.15]
9. Psykhichne zdorovia na perekhidnomu etapi: Rezultaty otsinky ta rekomendatsii dlia intehratsii okhorony psykhichnoho zdorovia v systemu pervynnoi medyko-sanitarnoi dopomohy ta hromadski platformy nadannia posluh [Mental health in transition: evaluation results and recommendations for integrating mental health care into the primary health and community service delivery platform]. World Bank Group. 2017. 146 p. (Ua)
10. Vidpovid na zapyt u Ministerstvo okhorony zdorovia. [Responding to a request from the Ministry of Health] Lyst vid 27.08.2019. (Ua)
11. Razvodovskiy Yu.E. Mediko-sotsialnyye problemy alkogolizma. [Medical and social problems of alcoholism] Grodno, 2005. 128 p. (Ru)
12. International statistics. Available from: https://www.drugfreeworld.org/drugfacts/alcohol/international-statistics.html [reviewed: 2019.08.15]
13. Alcohol and crime. Available from: https://www.alcohol.org.nz/resources-research/facts-and-statistics/nz-statistics/alcohol-and-crime. [reviewed: 2019.08.15]
14. Data on alcohol related incidents, years ending March 2011 to March 2017, Crime Survey for England and Wales. ONS (2018).
15. Yedynyi zvit pro kryminalni pravoporushennia za 2016–2018 roky (Forma 1)[The only report on criminal offenses for 2016-2018] / Upravlinnia orhanizatsii vedennia Yedynoho reiestru dosudovykh rozsliduvan ta statystychnoi informatsii Heneralnoi prokuratury Ukrainy [Office of the Organization of Maintaining a Unified Register of Pre-trial Investigations and Statistical Information of the Prosecutor General's Office of Ukraine]. Kyiv, 2018.(Ua)
16. Wintemute G.J, Kass P.H, Stewart S.L, et al Alcohol, drug and other prior crimes and risk of arrest in handgun purchasers: protocol for a controlled observational study. Injury Prevention. 2016; 22: 302-307. Available from: https://www.thetrace.org/2017/02/gun-owners-alcohol-abuse-crime/ [reviewed: 2019.08.15]
17. Higher crime' in areas where alcohol is most available, says study. Available from: https://www.bbc.com/news/uk-scotland-43809952. [reviewed: 2019.08.15]
18. Limiting Alcohol Outlet Density to Prevent Alcohol Use and Violence: Estimating Policy Interventions Through Agent-Based Modeling. American journal of epidemiology. 2019 Apr 1;188(4):694-702. doi: 10.1093/aje/kwy289
19. Duailibi S, Ponicki W, Grube J, Pinsky I, Laranjeira R, Raw M. The effect of restricting opening hours on alcohol-related violence. American Journal of Public Health. 2007; 97: 2276–2280. doi: 10.2105 / AJPH.2006.092684
20. Kypri K, Jones C, McElduff P, Barker D. Effects of restricting pub closing times on night-time assaults in an Australian city. Addiction. 2011 Feb; 106(2):303-10. doi: 10.1111 / j.1360-0443.2010.03125.x.
21. Rossow I, Norström T. The impact of small changes in bar closing hours on violence. The Norwegian experience from 18 cities. Addiction. 2012 Mar; 107(3):530-7. doi: 10.1111 / j.1360-0443.2011.03643.x
22. Fogarty A.S, Chapman S. What should be done about policy on alcohol pricing and promotions? Australian experts' views of policy priorities: a qualitative interview study. BMC Public Health. 2013 Jun 25;13:610. doi: 10.1186/1471-2458-13-610.
23. Kearns M.C., Reidy D. E., Valle L.-A. The Role of Alcohol Policies in Preventing Intimate Partner Violence: A Review of the Literature. J Stud Alcohol Drugs. 2015 Jan; 76(1): 21–30. doi.org/10.15288/jsad.2015.76.21
24. Markowitz S. Criminal violence and alcohol beverage control: Evidence from an international study. Cambridge, MA: National Bureau of Economic Research; 2000b. NBER working paper W7481. Available from: https://www.nber.org/papers/w7481.pdf. [reviewed: 2019.08.15]
25. Kypros Kypri, Robert B. Voas, John D. Langley, et al. Minimum Purchasing Age for Alcohol and Traffic Crash Injuries Among 15- to 19-Year-Olds in New Zealand. American Journal of Public Health. 2006 January; 96(1): 126–131. doi: 10.2105/AJPH.2005.073122.
26. Hoffman S. J., Tan Ch. Overview of systematic reviews on the health-related effects of government tobacco control policies. BMC Public Health. 2015 Aug 5;15:744. doi: 10.1186/s12889-015-2041-6.

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REVIEW ARTICLE
PRACA POGLĄDOWA

DISEASE AS INTERFERENCE FOR JUDGE'S PROFESSION

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ABSTRACT

Introduction: The judge's professional activity determines certain requirements for the health status of the person applying for this position or already performing his professional duties. Due to the specificity of professional activity, it could be cases of diseases that make it's impossible to perform professional functions effectively. It raises the question of the fairness of the dismissal procedure precisely for the health status that would exclude discrimination based on disability.

The aim: The purpose of the scientific article is to summarize the leading experience of European countries on the protection and prevention of occupational illnesses of judges in order to substantiate specific proposals for the creation of an optimal procedure for dismissing a judge due to health status.

Materials and methods: The subject under discussion has been considered based on the relevant sources (scientific publications, legal acts, decisions of judicial and quasi-judicial institutions), using the method of content analysis, comparative and contrastive, analytical and biblio-semantic methods.

Conclusions: An analysis of European practice, including judgments on appealing against violations of the right to work due to unlawful dismissal based on health status allowed us to formulate key elements of a fair procedure for dismissing a judge due to illness, which makes it impossible to perform professional functions. A vision on the list of diseases that may be interference to effective judicial activity is developed by the authors. It is substantiated that such list of diseases should be a legal filter to judges employment and dismission. Regular medical examination and prevention of the development of occupational illnesses of a judge should become an integral part of the court's labor protection system. In the event of an accident related to performing professional functions, the judge is entitled to compensation.

KEY WORDS: judge, health status, somatic illnesses, mental disorders, medical expert commissions, dissimulation, list of diseases

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INTRODUCTION

There is no need to prove the fact that the exercise of judge's authority is associated with considerable physical and mental impact. This profession requires a high stress resilience, that is, the ability to withstand psychological stress and overcome negative emotions. Empirical researches have recently paid considerable attention to the issue of judge's profession stress [1,2]. Therefore, it can be said that the specificity of the judicial profession requires a such health status in which the physical, physiological and psycho-emotional characteristics of a person will not interfere with the performance of the duties of a judge. Otherwise, the question of the judge's ability/inability to exercise his/her authority arises. We address the problem of the professional capacity of a person, which means the potential readiness and actual ability of a person to perform a certain type of activity at the required level of efficiency for quite a long time.

Working capacity of a person including a judge naturally depends on his/her physical and mental health, which is variable and depends among other things on working conditions. These conditions for the judge are determined by the specifics of the trial, which involves constant communication with a number of persons, including potentially ill; emotional tension and limiting in emotions expression; the tension of the organs of perception (eyesight and hearing) associated with studying and analysis of case files, the diversity and complexity of the tasks being decided by the judge; physical tension, which is associated with the variability and non-standard situations in conditions of limited time. After all, the judicial profession mainly involves working in a sitting position, which significantly influences the condition of the musculoskeletal system, cardiovascular and gastrointestinal system of the person.

The health status of a person admitted to the judicial profession is not only important to one's personally but also must be considered from an economic and social significance perspective. Failure to perform the duties of judge due to the health status (absence at work for a long time, prematurely dismissal from the judge's position due to the health status) leads to a redistribution of workload to other judges, resulting in their reduced productivity. This in turn leads to inefficient use of time and human resources, which is crucial for the effective judicial protection of the individuals' rights and interests. The factors of: (a) the judge's capacity to evaluate the cases as objectively as possible and to take a fair and lawful decision accordingly; (b) the adequate conduct of the judge, both in and out of court, through the lens of which the public authority of the judiciary is formed; - depend directly on the physical and mental health of the judge, his or her moral and emotional state.

There is limited (and virtually nonexistent in the post-Soviet space) information on medical indicators of the judge's ability to perform one's professional duties that would allow the development and unification of medical standards in the judicial profession. It is extremely difficult to find some empirical data on this, since information about human health in general and judges particularly is confidential and protected by law. However, there is an obvious need for a combination of medical and legal knowledge, which will allow for a discussion on the medical criteria for evaluating potential candidates for a judge, as well as for evaluation of the incumbent judges' health as a prerequisite for the effective exercise of judicial authority.

THE AIM

The study is aimed at clarifying the medical aspect of a person's suitability for the judicial profession and at determining the critical threshold for exercising of judge's authority according to the health status. The authors' aim is to initiate discussions on the compatibility of the judicial profession with the various pathological conditions of human health and on the ways of interaction between the health care system and the bodies responsible for the personnel policy of the judiciary. In particular, the establishment of a system of health and safety of judge's labor based on systematic interaction between health authorities and the judiciary.

MATERIALS AND METHODS

Through a sample analysis, we examined and compared legislative acts governing access to a judge's professional activity and regulatory acts of state health regulatory authorities in different countries (Ukraine, Russian Federation, Poland, Turkey, Spain, USA and others). We have used statistical, systemic, structural and analytical methods while analyzing court decisions and decisions of Labor Tribunals regarding disputes related to dismissal for health reasons. Content-analysis and biblio-semantic methods have been used in the systematization of scientific publications on occupational diseases and diseases as interferences to access to the judicial profession.

REVIEW AND DISCUSSION

An analysis of the existing rules in the legislation of different countries has shown that the medical indicators of health and the profession of judge overlap in the following cases: (a) while formulating requirements for judges candidates; (b) while referring to the grounds for the dismissal of a judge; (c) while referring to health care as a social guarantee. The latter concerns the issue of the proper organization and access to health care for judges in countries where it is guaranteed. This brings it outside of our study. At the same time, the first two cases require the identification and assessment of illness states for their effect on the specialist's ability to effectively perform the duties of a judge without endangering themselves and the health of others.

In most cases, a medical evaluation of an employee's ability to work without risks for one's own health or for others is defined as an assessment of suitability for a work [3]. To do this, one must have medical knowledge and an understanding of the judge's working conditions. As both "health" and "working conditions" are variable categories, suitability for work is a dynamic concept [4]. Suitability for judge's profession may be established both at the stage of the competition for the position of judge and throughout all the term of the judge's relevant powers. In most countries of the world it is regulated by general or specific legislation and is not unified.

Medical indicators of the judge's suitability for work., The laws of the majority of countries governing the status of judges provide, in varying interpretations, such a requirement for a candidate for judge that the person is able according to the health status perform the professional functions of a judge. This requirement is formulated in the form of (a) *direct authorization:* "a person has the ability to perform the duties of a judge according to health status" (Poland), "a judge may be a person not registered at a drug or psychoneurological dispensary in the alcoholism treatment, drug addiction, substance abuse, chronic and prolonged mental disorders and has no other illnesses that would interfere with the exercise of the judge's authority (Russian Federation) or (b) *direct prohibition*: " a person who has chronic psycho or other illnesses that interfere with the administration of justice cannot be appointed as judge"(Ukraine, Spain), "have no physical or mental health problems or disabilities that would interfere with the judge's duties or such an interference as unusual speech difficulties or controlling the movement of organs that others may regard as strangeness" (Turkey). Although in the latter case, the formulation is having the risk of unreasonable discrimination, the limited access to the profession of judge on medical grounds is generally justified and does not contradict to international standards in the field of judiciary organization.

At the same time, the ways of confirming the candidate's suitability for the position of judge differ. The most common is the passing of a medical examination by a candidate (Poland, Russian Federation, Turkey, USA), the binding nature of which is set directly in the law (Russian Federation) or in individual by-laws (Poland). In Ukraine, there is no medical examination for a judge candidate. However, such a person is a subject of special verification regarding the health status, namely, if the person is registered at a psychoneurological or narcological health care facility. To do this, the applicant for the position must submit a medical certificate for passing mandatory preliminary and periodic psychiatric examinations and a certificate of passing preventive narcological examination, the forms and the procedure of issuance of which are approved by the Ministry of Health Care of Ukraine.

The method of regulating the access to the judicial profession by the medical criteria existing in the Russian Fed-

eration is of interest. There is a list of diseases, which hinder the appointment of a judge. It has been developed by the Ministry of Health of the Russian Federation and approved by the Council of Judges of the Russian Federation. We have not found any such analogues in other countries to such practice. This list includes 32 types of diseases which interfere one of his/her right to apply for judge's position. Among them the first are the central nervous system diseases, which lead to the progressive disorders of the movement activity of all muscle groups, including breathing, disorders of the cerebral circulation, with the subsequent development of degenerative changes in the brain tissue. As a result of such changes, there is a decrease in the number of neurons and disconnections between them, which is clinically showed by the development of dementia (Alzheimer's, Pick's, Parkinson's, etc.). These diseases most often develop after the age of 40. In the second place there are mentioned diseases that significantly disturb the course of normal mental processes: epilepsy and epileptic seizures of another etiology, stroke (hemorrhagic or ischemic), in the event of which acute or chronic oxygen starvation of the brain tissue and their subsequent death is formed, signs of depression, dysphoria, amnesia, signs of progressive acquired dementia. The following are endocrine diseases, which are most often accompanied by intense headache, increased blood sugar levels, impaired regulatory influence of hormones on human homeostasis. Also, malignant tumors of the central nervous system and other neoplastic processes (hemoblastoses) are added, which lead to astheniaisation of the body, severe intoxication and impaired activity of all organs and systems, including the development of mental disorder. The list also includes diseases accompanied by various degrees of hemorrhagic diathesis. With hemorrhage, the number of erythrocytes is lost in the bloodstream, and therefore the amount of hemoglobin that transports oxygen to the tissues and cells. As a result, first neurons are suffered, which is accompanied by a decrease in concentration, inhibition of functions of all organs of perception, drowsiness, rapid physical and mental exhaustion. In the first place among the diseases worldwide are the diseases of the cardiovascular system in the various stages of compensation and decompensation, which are also mentioned in this list and are contraindications for the work of a judge. Systemic rheumatic diseases which are having a progressive course are also attributed to it (rheumatoid arthritis, systemic lupus erythematosus and systemic scleroderma) because in case of these disorders the vessels, heart muscle, kidneys, central and peripheral systems are always involved in the pathological process. The chronic course of hepatitis from this list includes intoxication syndrome, hemorrhage due to impaired blood coagulation, disorders of the central nervous system. Diseases of the gastrointestinal tract do not allow a person to be in a forced (fixed) position for a long time (family diffuse polyposis of the colon, Crohn's disease, nonspecific ulcerative colitis, etc.) and are accompanied by pronounced diarrheal and pain syndromes and bleeding. Chronic renal failure of varying degrees in the stage of decompensation greatly affects the function of the central nervous system due to uremic intoxication. Impairment of hearing function if it is impossible to improve by electro-acoustic correction to the level of perception of whispering language not less than six meters is an interference to the judge's profession. Complete blindness is also in this list. Mental illness with a prolonged or chronic course and frequent exacerbations of painful expressions is an absolute sign that a person is not fully aware of the consequences of his/her actions. Also, different types of addictions are mentioned: alcoholism, drug addiction, substance abuse.

According to a global study by The Lancet in 2016, alcohol abuse resulted in the death of 2.8 million people and became a leading risk factor for premature death and disability among people aged 15-49 [5]. Today, alcohol abuse most often depends on the causes embedded in society (historical, social, economic and socio-psychological) and lies in the anomalies of personality and characteristics of the body of the individual (hereditary, constitutional, exchange, psychological, etc.).

The incompatibility of alcoholism, drug addiction, substance abuse with the status of a judge is caused not only by clinical expressions (disorders of thinking, hypochondria, persecution mania, low self-esteem, anxiety, depression, impulsiveness, alcoholic degradation of personality) [6] which influence on doing any work. Each chemical addiction distorts the normal flexibility of an addict person's behavior toward the dehumanized compulsive behavior [7]. A person tends to live in a way of asocial lifestyle, thus ethical norms and moral values are losing their regulatory power. The influence of alcohol or drugs on the mental and physical health of a judge may raise a question on one's competence [8], which is unacceptable in this profession. In such case, the addicted must be dismissed.

Another indicator from the above list, which makes it impossible to occupy the position of a judge, namely the lack of a person's vision, which is perceived by experts ambiguously, also draws scientific attention. In the Russian Federation, this feature of human health is a direct interference to the appointment a person as a judge by the certain norms. At the same time, in 2014, by a decision of the General Council of the Judiciary, the blind Gabriel Perez could participate in the competition for the post of judge. In 2015, Richard Bernstein became the first blind judge of the Michigan Supreme Court. In general, the first blind judge in the twentieth century was the High Court of Justice of England and Wales, Sir John Wall, who was appointed in 1991 [9].

In Ukraine such possibility exists purely theoretically since the law obliges a person to submit only a medical certificate for the mandatory psychiatric examination and a certificate for passing a preventive narcological examination for participation in the competition. That is, there is no direct prohibition. However, this is practically impossible because the competitive procedure involves passing a written examination by an applicant (drafting a court decision). There is no technical ability to access for blind people at this stage.

We believe that a person's vision absence should not be an interference to the appointment of a judge, since: (a) the trial involves participating not only by a judge but also by the

auxiliary court staff (assistants, secretaries, advisers) whose aim is to assist and to help a judge (including dealing with case files); (b) the absence of vision deprives the prejudice caused by the appearance of the litigants that contributes to the impartiality of the judge; (c) long-term blindness develops other human organs of perception, in particular, hearing [10], which allows the judge to feel more intensely the intonation of the participants in the trial. No wonder that one of the attributes of the goddess of justice Themis is the blindfold, which symbolizes impartiality and justice.

A comprehensive approach to assessing a judge's suitability for work, considering a specific disease (level and quality of health defect) and conditions of judicial work, also requires existence of other ill conditions of a person that limits his physical capacity. Therefore, it is a very limited list of grounds since it is including diseases that in 100% of cases lead to disability. There are other ill conditions which are interfering professional activity, but do not lead to disability in the theoretical perspective. One of the dogmas of medicine is the "individual approach" to each patient, and this is because of one nosological unit cannot influence on two people equally - one person suffers more severely, the other one overcomes it easier, and in some case the person dies. The peculiarities of each organism are not studied well because they can be not only congenital and genetically determined, but also acquired as a result of other diseases or injuries of different genesis. That is why there is a pathological-anatomical and court-medical control over the quality of treatment worldwide.

The issue of psychodiagnostics is relevant for candidates to the position of a judge. It allows to assess the psychological readiness and suitability of a person to exercise justice, to identify among the candidates those who are neuro-psychological unstable and in a state of maladaptation, as well as persons with asocial settings and self-serving utilitarian. An important aspect of the psychodiagnosis of this group of individuals is to determine a person's stress resistance as an integrative quality, which characterizes a person's emotional stability, a low threshold of anxiety, a high level of self-regulation and psychological readiness for stress. Empirical studies show that stress, anxiety, burnout, and depression are inherent in legal practitioners to a much greater extent than in other professions (medics, teachers, scientists) [11]. Stress is associated with the development of virtually all diseases. It is the root cause of most pathologies, affecting both the genetic component and the body, stress accelerates the development of both somatic and mental illness [12]. It is known that stress is associated with an increased risk of heart attack (workplace stress increases the risk of heart attack by 23% and 9 times increases the likelihood of focal disorders of myocardial blood supply [13]). Therefore, it should not be forgotten that the assessment of a person's ability to work involves finding out whether he/she can perform professional tasks in terms of the risks to one's health.

Psychodiagnosis of the applicant for the position of judge allows to achieve more pragmatic goals in terms of the organization of judiciary. Based on the experience of Ukraine, where the psychodiagnosis of candidates for the post of judge has become a mandatory component of the competition only recently by using 4 methods. They include: Test of the candidate's overall abilities (thinking, intellectual abilities), MMPI-2 (diagnosis of general inconsistency in the personality system, accentuations, psychopathic traits, level of neuroticism, emotion, etc.), the BFQ-2 test (diagnosis of openness of experience, honesty, extraversion, benevolence and neuroticism), and the HCS Integrity Check,). They evaluate: (a) the individual competence (cognitive, emotional, motivational and volitional qualities of the individual); (b) social competence (communicativeness, organizational skills, managerial personality traits, moral personality traits); (c) professional ethics (defined in terms of "integrativeness" taking into account the following components: understanding and adherence of rules and norms, ability to defend one's own beliefs, discipline, respect for others); (d) good faith (determined by the "integrative" indicator, taking into account the following components: honesty and integrity, lack of counterproductive actions, lack of tendency to abuse). Although some of the techniques used in Ukraine (HCS Integrity Check) and the evaluation process itself have many complaints from experts, the introduction of psychodiagnostics as a mandatory procedure for assessing the suitability of candidates for judicial work is a progressive and necessary measure in this socially relevant profession and field.

Medical indicators for termination of judicial activity. Besides the medical filters for admission to the judicial profession, there should obviously be a system of monitoring of the physical and mental health of the judge. The health status of judges is of great social importance because exhaustion and mental stress increase the likelihood of judicial mistake. For example, in Ukraine, as in many other countries, a judge's illness is an independent ground for dismissal. In the United Kingdom, for example, the Lord Chief Judge after consultation with the Lord Chancellor may dismiss a judge for reasons of poor health and inability to perform judge's authority. It was first provided for by the Justice Act in 1973 and is now contained in the Law on the High Courts 1981. However, judges of higher courts evaluate such a rule as having the risk of extra-procedural pressure on them (given the specifics of the judicial career structure in this country, where the posts of judges in the high courts are of a sufficiently respectable age) and are discriminatory in nature, since such dismissal ground is not foreseen for lower-courts judges. Therefore, since 2005, requirements for such decision-making procedure have been formalized, including legal certainty and transparency [14].

The main issues of a judge's dismissal for health reasons are, first, that it may be compulsory when the person is not dismisse on his/her own will. The reasons may be different, in particular: (a) the person does not understand (in particular, due to the effect of the illness on his/her consciousness) that his/her health condition does not allow to perform judicial proceedings; (b) the person is self-confident or has a low social responsibility threshold; (c) the person hopes that his/her health will improve over time.

Secondly, a person can and does recognize that his or her health status does not allow him/her to exercise justice at the proper level, but wishes to be dismissed not at his/her own will (or in connection with the resignation or of the maximum allowable age on position), and it is because of a health status which, in one's opinion, has been damaged in connection with the performance of professional functions, and therefore one should have increased social guarantees and material compensation.

Mentioned above highlights the issue of ensuring a fair procedure for dismissing a judge from a position on the ground of health status, which ensures a reasonable balance of the human right to work and the interests of the state in the proper performance of one's functions (justice), since the judge in the classification of public positions belongs to the person "authorized to perform state function".

However, as noted above, in Ukraine there is no list of such diseases that give grounds to the conclusion on "the inability to perform justice functions" and, accordingly, the mechanism of establishing the presence or absence the judge's disease incompatible with the substitution of a judicial position, and guarantees for the reinstatement of the person whose health has been restored. Now in Ukraine there are only formal grounds for dismissal of a judge on health status basis. There is a general rule in Ukrainian labor law, according to which an employee is retained in the event of his temporary disability for no more than 4 consecutive months. That is, the employee's work at least for one day interrupts the progress of the prescribed period. But there is no deadline for a judge to be absent at work due to illness, which creates the risk of some manipulation by judges who may stay in hospital for a long time while maintaining the position (thus increasing the workload for other judges of this court), increasing the work experience and receiving social benefits. In this context, an interesting example is the legal regulation of this issue at the times of the Russian Empire, where it was assumed that a judge was obliged to be dismissed if "for less than two years in a row no more than half of all working days in each of these two years he was present at work." Today, the specifics of judicial profession (in particular, the principles of consistency of the court composition; reasonableness of the terms of trial; the calculation of full-time judicial positions, in particular, on the criteria of average workload; significant economic value of the judge's work) requires the development of more specific criteria for assessing the fairness of a judge's dismissal on the ground of health status. This issue becomes especially relevant when the judge does not admit his/her inability to perform justice precisely because of one's health status.

Obviously, the list of diseases that interfere a person from being a judge should be at least the same as when admitting to the profession. Attention to that issue was paid above. But unlike candidates for a judge who undergo at least some health assessment (opinion of a narcologist, psychiatrist, psychologist), no health control measures are provided for persons holding judicial positions (at least until they decide to compete for a vacancy in another court). In Ukraine, the activity of a judge is not included to the list of professions whose employees are subject of periodic medical examinations.

In many countries, employers seek dispensary examinations of their employees once a year, but if it is not free of charge for the employees, they may refuse to do so. Today, laboratory and instrumental examination is very expensive in Ukraine, but it is available to certain categories of workers. Therefore, in the case of the health control of a judge it is necessary to fix at the legislative level the passage through the medical expert commission not only of the applicant, but also of the acting specialist at least twice a year, provided that the composition of the commission should be new every time. Compulsory paid laboratory and instrumental testing – in such cases very modern equipment, high quality reagents and high resolution of the equipment are used. There is another unpleasant effect here – deliberate dissimulation (hiding an existing health disorder with either medication or deception). For this reason, these surveys should be conducted at least twice a year. There may also be a corruption component in the dispensary process because the financial status of the doctor and the judge's one cannot be compared today. Experts should include as many doctors of different specialization as possible, and in our opinion, it is possible to invite foreign specialists. It is not difficult to examine such a small group of professionals, because the state and social responsibility of judges is extremely high.

It should also be noted that a judge's health status can negatively influence not only the quality of performing one's professional function, but also contribute to the deterioration of the judge's health. A common example: a judge with type 1 diabetes requires periodic insulin injections, which should be followed in some cases by food. The court hearing may be delayed and the time for receiving the appropriate injection is over. Failure to receive a medication on time by a judge can have the most negative health effects. This should be provided by endocrinologists caring for such a patient and should be given prolonged insulin action if a dose is selected. But again, the problem is that dose selection is not a simple mathematical action. The patient should be examined in a stationary setting, blood glucose monitored while the use of prescribed doses of new insulin, and the body's reaction to be expected. These appointments can then be corrected, or generally returned to the primary doses of simple insulin. This process is a great stress for the body and requires a certain amount of time, during which it is very difficult and contraindicated to engage in intense professional workload.

The foregoing updates the issue of the introduction of a judge's health monitoring system in Ukraine, which, first, will provide for a list of diseases that negatively affect (or may affect) the quality of the judge's professional functions.

There may be several ways to resolve such issues. First, the periodic medical examination of the judges by a panel of doctors. We have already stated that. Provide that the judge periodically must undergo a medical examination and submit a certificate of his/her health status to the High

Council of Justice as the authority empowered to decide on the dismissal of the judge on the health status basis. Another way, when competing for position the judge provides information about his/her doctor and signs up the consent to the doctor's disclosure of the patient's health status at the request of the High Council of Justice (this path, in our opinion, is more promising because it eliminates risks of a formal approach and may be involved situationally when the person responsible for the staff of the court personnel has reasonable grounds for suspecting that the health of the judge interfere the performance of justice). But in this case the question arises: "What doctor? Is it that doctor, who the consent was signed with?" It is impossible to do this, because doctor's specialization should be narrow enough for a specialist to treat a certain disorder. There is no isolated disease of only one organ or one system. All other organs and systems are suffering to compensate an existing problem. How could a therapist give such messages if it is related to a surgical problem (blood vessels, gastrointestinal tract, urinary system, sexual disorders, etc.)? Then an agreement should be concluded with each specialist (otolaryngologist, ophthalmologist, neurologist, geneticist, surgeon, endocrinologist, infectious specialist, cardiologist, etc.). Again, the statement "expert medical commission and its conclusion" is arising. But in both the first and second cases there must be at least a formal list of diseases approved by the Ministry of Health, the presence of which testifies to the inability of the person to perform justice.

Judges in Ukraine today are not provided with adequate guarantees of protection, cases of assault on judges, causing them physical and mental injuries, even death, have increased. The law set that the life and health of judges are the subject of compulsory state insurance, which is provided at the expense of the Social Insurance Fund on accidents and occupational diseases. The occurrence of an insured event involves certain material payments and social services. Therefore, of course, a judge who has a chronic illness and wants to be dismissed is himself interested in finding his illness to be professional or injury (physically or mentally) to be professionally conditioned. However, due to the lack of clear criteria of understanding a professionally caused injury or occupational disease, a judge may be able to predict difficulties in law enforcement. Ukraine is not the only example of it. For instance, a Paris court categorized the death of an employee who had been on a business trip and died while having sex with a stranger as "an accident at work." The court referred to the rules of the law that made the employer liable for any situations that might occur with the employee during a business trip [15]. Manchester court has found a company guilty of dismissing an employee for over 97 days on sick leave due to a depression illness that resulted from one's work with a company troubled software. The court did not accept the employer's argument that the employee was offered other vacancies that did not require the use of problematic software, and the fact that to retain an employee who was seek leave for a long term is economically unprofitable [16]. However, this example demonstrates that deciding whether to dismiss for reasons of inability to perform professional functions due to the health status should be preceded by a set of measures to protect the human right to work, in particular finding the best balance between the interests of an employee who has certain health problems and an employer's interests.

In our view, the dismissal procedure in the ground of health status will be a fair enough if, first, *it is based on facts and not on presumptions*. It means that a qualified (medical) commission determines that (a) the person's illness does not allow one to perform professional functions effectively; (b) it is impossible to predict when a person is recovering (or at all if it is possible); (c) the employer has no other position that is appropriate for the employee's qualifications (see EAT Decision in Merseyside & North Wales Electricity Board v Taylor [1975] ICR 185).

Secondly, the procedure of dismissing a judge meets the criterion of *legal certainty*. In particular, the list of diseases/defects/injuries, the presence of which indicates the professional inability of a person to perform a certain type of activity. At the same time, these interferences should be objective, not subjective and without any risk of discrimination. For example, if a judge has been granted disability status, then he/she cannot be dismissed because the court building is not adapted for wheelchair use. Trauma, such as a leg one, is unlikely to interfere with the administration of justice, but a spinal injury may interfere if the person is bedridden, but the question of dismissal can only be raised after the responsible (medical) commission concludes that it is impossible to predict the terms for which recovery will take place. In other words, the nature of the illness, the prospect of recovery and the return of professionally important qualities (physical and mental capacity) to a judge should be considered (see SCIH 91 BS v Dundee City Council (2013).

The critical number of days of absence at the workplace to initiate a dismissal procedure should be clearly identified (see EAT Decision in Spencer v Paragon Wallpapers Ltd [1977] ICR 301). This authority is entirely at the discretion of the State as the employer of the judge. There is no universal term in world practice. For example, under the Fair Work Act an employee is protected from dismissal when temporarily absent due to illness or injury unless the employee's absence on unpaid personal/carer leave extends for more than 3 months, or total absences of 3 months within a 12-month period. Many State and Territory workers compensation laws also prohibit the termination of an employment by the employer within a specified period where the sole or primary reason for the dismissal is because of the employee's absence. The specified period can range from 6 months (under NSW law), to 12 months (under Queensland law), or indefinitely (under South Australian) [17]. We believe that in cases where it is difficult to determine the prospect of recovery for a judge, the alternative should be used: either dismissal for health reasons, or suspension a term of authorities for no more than one year. The right to choose the decision must be vested in the judge. If, after a prolonged illness, the judge receives the medical panel's conclusion that his/her health

is in line with the requirements of the profession, the judge's authority must be renewed (see EAT Decision in Cooper v Balfours Bakery Pty Ltd).

In addition, the procedure for establishing the grounds for dismissal of a judge for health reasons itself must be concrete, clear, and explicit. That is, the authorized entity entrusted such a decision making is identified, the method of obtaining information about the health of the judge (see Fair Work Commission (FWA) decision in Chetcuti v Coles Group Supply Chain Pty Ltd) and the entity, competent in determining a judge's suitability for justice due to the health status; the order of initiation (the subject of appealing to the High Council of Justice) and the order of studying the matter essentially; ensuring guarantees of the right to work and protection against discrimination on disability.

Third, the issue of *financial compensation* is analyzed. That is, the cause of illness/defect/trauma occurring is evaluated, which interfere him/her being a judge, which will confirm (refute) the nature of professional cause (and not, for example, heredity, genetic predisposition or development due to abuse) of illness or injury (physical or mental). If the nature of the illness or injury is determined to be professionally caused, additional guarantees of financial security and social protection should be applied. In addition, the employer (for judges the employer is the state) should have additional obligations to take measures in preventing occupational diseases and injuries, that is, to prevent the psychotraumatic effects of professional stress factors, as noted above.

Another problem is a situation in which damaging health is due to the performance of professional functions or, for example, inadequate working conditions. In addition, the profession of judge is associated with constant stressful situations, so the question on development of a program for the prevention of psychotraumatic impact of factors of professional stress.

So-called "occupational diseases" in legal profession have not been established yet. But there are already such health disorders that are quite common among lawyers who work as judges. Working as a judge is very difficult because the parties' competitiveness in any of the lawsuits is based on a conflict that creates certain types of emotions: anger, fear, excitement, disgust, anxiety - all of them cause stress. At the mental level, the most typical signs of prolonged stress and accumulated different emotions are unmotivated anxiety, depressed mood, which can lead to depression, mood swings, unreasonable irritability and conflict, emotional coldness, indifference and hostility with people. These processes are caused not mainly by external circumstances, but more by a disturbed internal psycho-emotional state. Traditionally, depression and hostility always coexist. When a person is in such a state, it is important what exactly will prevail: if one is depressed, that can develop into apathy or emotional dullness, and if hostility is taken place - dysphoria develops (profound disturbance of the emotional sphere of mental activity). Biochemically, in case of presence of such changes in the body there is an increase in the content of proteins in the blood, which are responsible for the inflammatory response and the increasing the amount of adrenaline and cortisol, which, in turn, is a very dangerous risk factor for the cardiovascular system, as well as smoking.

The most common somatic expression of stress are a sudden increase of blood pressure accompanied by a feeling of heat; pain of different intensity, which is most often felt in the head area (by the type of migraine, sometimes dizziness) and neck, in the heart (increased palpitations or arrhythmias) and in the abdomen (imitate pain in peptic ulcer); shortness of breath, foreign body sensation in the throat, sudden loss of voice; appetite disorders - from complete rejection of food to attacks of uncontrollable appetite; sleep disorders - insomnia or, conversely, drowsiness, and sleep becomes anxious and restless due to unpleasant dreams; various sexual problems. In regular life it is expressed by the loss of interest to work, the desire to fulfill one's duties formally, without interest in the outcome, and in some cases, the disgust to work. Because of it, judges have self-doubt, a decline in professional self-esteem, doubts and hesitation while making independent decisions.

In the Netherlands the research has been conducted not only on health risks such as professional burnout ("tension hypothesis"), but also on positive aspects of the judge's work, such as involvement in work ("motivational hypothesis"). Various studies in other countries show that judges are at a significantly higher risk of stress, burnout or secondary injury influence (more relevant to the criminal side of the legal field) or already suffer from them [18].

The work of a judge is one of the highly stressed ones, the consequences of which are alcohol or drug addiction in some cases. According to research by American scientists, lawyers are three times more likely to suffer from depression than representatives of other professions. One in four lawyers suffers from psychological stress, including feelings of inadequacy, inferiority, anxiety, isolation, and social alienation. As a result, the level of drug addiction among lawyers is twice as high as that of the entire US population, and male lawyers are twice as likely to commit suicide as men in the general population. In the legal profession of this country, alcohol abuse reaches 20%. Reports from help programs for US attorneys show that 50% -75% of discipline violation cases in legal practice are related to drug addiction [19].

In the light of the mentioned above, we consider it to be a fair practice to legally prescribe the powers of the High Council of Justice to require a judge to obtain an opinion from a narcologist and psychiatrist, but only in the context of a judge dismissal proceeding on the ground of his health status. Sometimes it is necessary to find out the fact of a judge's health deterioration due to his own actions, rather than the influence of negative factors of the profession. In our opinion, before visiting these specialists by the patient (judge), medics should be silently present at the trial of a judge and objectively determine the true mental state of the person beforehand, since there is again the possibility of deliberate stimulation when attending such specialized doctors.

Fourthly, there is a mechanism for appealing the decision of the competent authority on dismissal for health reasons

(see EAT judgment in Foster v Somerset County Council 2003, EAT / 0355/03 RN). In Ukraine judges can appeal to a court for dismissal because of their inability to fully exercise their authority due to the health status, it means that the judge's right to a court defense on this issue is unlimited (unlike dismissal on other grounds). Western jurisprudence has already developed a system of principles for dealing with such complaints [20] and the procedure for calculating compensation for unfair dismissal, as well as for legal protection against discrimination on disability [21].

In fact, European court practice has contributed to the fact that the legal procedure for dismissing a judge is similar to a disciplinary procedure: studying of a statement by a competent authority about the inability to perform justice for health reasons (filed by a judge, court administrator, third party) on a publicity basis (unless there are objections by a judge), the reasonableness of the terms, the proven fact of the unhealthiness of the judge which is incompatible with professional activity; examination of evidence (conclusion of medical commission); adopting a decision and granting the right to appeal that decision [22].

Thus, the interests of the judiciary require the specification of the criteria of mental and physical disease health of the judge, the term of one's absence at work in connection with temporary disability, which is the ground for the conclusion about the impossibility (inability) to perform his/her professional functions due to the health reasons, establishing a fair procedure for substantive review of the issue of the right to appeal the decision made, and increased financial compensation if health deterioration was caused as a result of performing professional functions.

It is advisable to legally prescribe the authority responsible for the court personnel the power to obtain timely and reliable information about a judge's health, including to prevent deterioration of one's condition due to the influence of professional factors.

CONCLUSIONS

Undoubtedly, to study within a single publication the question of a person's suitability for the judicial profession in the aspect of analyzing the whole spectrum of existing diseases for their compatibility with the professional activity of a judge is an unattainable task. But we didn't set it for ourselves. Within this section of our study, we can draw the following conclusions:

• candidates for the position of judge must undergo a medical examination for the purpose of assessing the suitability for exercising of judicial powers, which requires appropriate legal regulation;

• it is advisable to have a legally prescribed indicative, but not an exhaustive list of diseases, the presence of which interfere the person from performing professional functions. There are at least four arguments in favor of its existence: 1) persons with such illnesses will have some certainty about their career; 2) there will be legitimate grounds for denying persons with such diseases in access to the profession of a judge or in case of dismissal; 3) it will serve as a factor of population's confidence that justice is performed by adequate judges; 4) to protect from the deterioration of health through the work of a judge a person who already has certain diseases. Such a list must be developed jointly by medical and judicial professionals;

- psychodiagnosis should be a mandatory part of assessing a person's suitability for performing of judicial authority. Depending on the features of the appointment of a judge in the country, it may be part of a medical examination or a separate procedure in the competition process for a judicial position;
- the dismissal procedure of a judge on medical grounds must be in line with the following criteria of fairness: (a) to be based on indisputable facts about the judge's health status which is inappropriate for performing professional functions, as confirmed by the medical opinion of the expert medical commission; (b) to be legal, that is, the law defines the procedure for initiating the dismissal of a judge on medical grounds; the examination procedure is substantially ensured by guarantees of competitiveness, openness, reasonableness and protection against disability discrimination; a mechanism of appealing the decision on dismissal due to health status should be set; (c) financial compensation if the health status has become unsuitable for performing professional functions as a result of an occupational illness or injury is provided;
- implementation of the program of prevention of psychotraumatic influence of occupational stress factors on judges is relevant.

REFERENCES

1. Kirby M, Judicial stress: An update. The Australian Law Journal, 1997; 71: 774-784.
2. Schrever C, Judging stress. Law Institute Journal. 2015; September: 29-32.
3. Edgington K. Civil aviation. In: Cox R, Edwards F, Palmer K, eds. Fitness for work. 3rd edn. Oxford: Oxford University Press, 2000:534–8.
4. Serra C, Rodriguez M C, Delclos G L, Plana M, López L I G, Benavides F G. Criteria and methods used for the assessment of fitness for work: a systematic review. Occup Environ Med. 2007; May, 64(5): 304–312. doi:10.1136/oem.2006.029397
5. Alcohol use and burden for 195 countries and territories, 1990–2016: a systematic analysis for the Global Burden of Disease Study 2016. The Lancet. 2018; Vol. 392.: 1015-1035. doi: 10.1016/S0140-6736(18)31310-2.
6. Edwards, G. The alcohol dependence syndrome: A concept as stimulus to enquiry. British Journal of Addiction, 1986; 81(2): 171-183. doi:10.1111/j.1360-0443.1986.tb00313.x
7. Sellman, D. The 10 most important things known about addiction. Addiction, 2010; Vol. 105(1): 6-13. doi: 10.1111/j.1360-0443.2009.02673.x.
8. Commentary on The Bangalore Principles of Judicial Conduct. United Nations. Office on Drugs and Crime. 2007; September. Available from: https://www.unodc.org/documents/nigeria/publications/Otherpublications/Commentry_on_the_Bangalore_principles_of_Judicial_Conduct.pdf [reviewed 2019.08.23]
9. John Wall: first blind High Court judge of modern times. Obituaries. 2008; December 11 Available from: http://www.braillechess.org.uk/obituaries/johnwall.html [reviewed 2019.08.23]

10. Huber E, Chang K, Alvarez I, et al. Early Blindness Shapes Cortical Representations of Auditory Frequency within Auditory Cortex. Journal of Neuroscience. 2019; Vol. 39 (26): 5143-5152. doi: 10.1523/JNEUROSCI.2896-18.2019.
11. Chan J, Poynton S, Bruce J, Lawyering Stress and Work Culture: An Australian Study. University of New South Wales Law Journal. 2014; Vol. 37(3): 1062-1102.
12. Whiteman H Stress: its surprising implications for health. Medical News Today, 2015; Feb. 25 Available from: http://www.medicalnewstoday.com/articles/289969.php [reviewed 2019.08.23]
13. Kotikovich YU.S. Stress: vliyanie na sostoyanie zdorov'ya. [Stress: effects on health status.]. Ukrainian medical chronicle. 2015; Marth, 03: Available from: https://www.umj.com.ua/article/84911/stress-vliyanie-na-sostoyanie-zdorovya [reviewed 2019.08.23] (Ru)
14. The Dismissal of Judges Available from: https://lawaspect.com/the-dismissal-of-judges/ [reviewed 2019.08.23]
15. BBC news. Ukraine. 11.09.2019: Available from: https://www.google.com/url?q=https%3A%2F%2Fwww.bbc.com%2Fukrainian%2Fother-news-49665528&sa=D&sntz=1&usg=AFQjCNF638X5mBRBiRjWPfxP9sEgfzM-pg [reviewed 2019.08.23]
16. Calnan M. Depressed employee suffered unfair dismissal and disability discrimination, tribunal rules. 2017; Dec 5: Available from: https://www.peoplemanagement.co.uk/news/articles/depressed-employee-suffered-discrimination [reviewed 2019.08.23]
17. Clayer S. Australia: Dismissing an employee with long term medical issues. 2012; November 19: Available from: http://www.mondaq.com/australia/x/207080/Health+Safety/Dismissing+an+employee+with+long+term+medical+issues [reviewed 2019.08.23]
18. Hagen T., Bogaerts S. Work Pressure and Sickness Absenteeism Among Judges. Psychiatry, Psychology and Law. 2013; 22 May: 92-111. doi: 10.1080/13218719.2013.790003
19. Mauney C. Stuart, Chair, SC Bar HELP Task Force Member et al. The Lawyers' epidemic: depression, suicide and substance abuse: Available from: https://www.scbar.org/media/filer_public/3d/25/3d25d564-bc05-468b-9cc0-6317004adb38/outline_for_lawyers_epidemic.pdf [reviewed 2019.08.23]
20. Lloyd V. When is dismissal on the grounds of ill health fair? 2014; MARCH 10: Available from: https://www.thehrdirector.com/features/tribunals/when-is-dismissal-on-the-grounds-of-ill-health-fair/ [reviewed 2019.08.23]
21. Clayer S. Australia: Dismissing an employee with long term medical issues. 2012; November 19: Available from: http://www.mondaq.com/australia/x/207080/Health+Safety/Dismissing+an+employee+with+long+term+medical+issues [reviewed 2019.08.23]
22. Hannon J. Ill-health dismissals: Acas disciplinary code not applicable. 2016; Aug 11 Available from: https://www.personneltoday.com/hr/ill-health-dismissals-acas-disciplinary-code-applicable/ [reviewed 2019.08.23]

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REVIEW ARTICLE
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OVERVIEW AND ANALYSIS OF OCCUPATIONAL RISKS IN HEALTHCARE OF EASTERN EUROPE COUNTRIES

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ABSTRACT

Introduction: Occupational risks affecting each healthcare professional are diverse and significantly affect their physical and psychological condition. They can conditionally be divided into risks resulting from: 1) the impact of the work process and pose a risk to the life and health of healthcare professionals; 2) the activities of healthcare professionals and pose a potential risk to the patients lives and health. The latter group poses a threat of criminal liability for the healthcare professional. It is the task of each state to ensure safe working conditions for the effective performance of their duties by healthcare specialists. However, according to the study, the analyzed Eastern European countries lack accurate statistics on occupational diseases of healthcare professionals, while the latter often do not seek specialized care and are treated on their own.

The aim: to identify the types and causes of occupational risks for healthcare professionals working in the countries of Eastern Europe; to investigate the legislation of these countries under which medical professionals may be prosecuted/held guilty and, thus, criminally liable for causing harm to their patients.

Materials and methods: Legislation of the Republic of Belarus, Republic of Moldova, Russian Federation and Ukraine, international declarations and conventions, research papers, case law of the European Court of Human Rights, national court decisions of some East European countries.

Conclusions: Occupational risks to the healthcare professionals are risks to his or her life and health and risks of criminal liability for causing harm to the patient. The causes of the first type risk are: a significant prevalence proportion of infectious diseases; the use of faulty medical equipment; unregulated working day and low salaries; medical attendance of patients prone to aggression, etc. The healthcare professional shall be criminally responsible only if he/she is found guilty for infliction of harm to the life and health of the patient and the presence of the obligatory signs of a specific crime in his/her actions.

KEY WORDS: medical workers, professional risk, occupational disease, infectious disease, the responsibility

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INTRODUCTION

Professional risk is a multifaceted and complex phenomenon that has different aspects and levels of manifestation. Among the most occupational risky areas, medicine is rightly identified, noting that physicians 'are employed to diagnose our ills (take a risk, for they might be wrong), decide on treatments (e.g. particular pills and dosages) and make many other decisions (e.g. decide when it is appropriate to discharge patients)', as well as nurses, 'who have to make judgments, also known as 'risk decisions, irrespective of their specialty, level or experience' [1, p, 9]. Occupational (clinical) healthcare risks should be understood to mean risks arising directly from the delivery of medical care [2, p. 11]. By contacting infectious patients and their sometimes aggressive relatives on a daily basis, a healthcare professional is at risk not only of becoming ill, but also of being offended, beaten, etc. Harmful factors in the work process of a healthcare worker, which negatively affect his body, as well as the process of saving the life and health of another person, lead to the fact that healthcare is a 'double-edged sword', which poses risks for the life and health of both the patient and the healthcare professional. And if too much research is devoted to patient risk, the other topic is often overlooked.

THE AIM

The purpose of this study is to identify the types of occupational risks for healthcare professionals working in the countries of the Eastern Europe, the causes of their occurrence, the study of the legislative system of these countries, according to which healthcare professionals may be prosecuted/not prosecuted for harming their patients and court practice in this area.

MATERIALS AND METHODS

This research is based on Belarusian, Moldavian, Russian and Ukrainian regulations, ECHR decisions, research papers. In addition, the statistics of the World Health Organization (WHO), the National Institute for Occupational Safety and Health, the statistical data of the state institutions of Belarus, Moldova, Russia and Ukraine, 50 sentences from the national courts practice of Ukraine and

Russian Federation have been used, as well as doctrinal ideas and views on this issue.

The article is based on dialectical, comparative, analytical, synthetic, statistical and complex research methods.

REVIEW AND DISCUSSION

The field of healthcare assistance and medical services is extremely important to ensure the life activity of any person and society as a whole. At the same time, this area is associated with continuing professional risks. 'Healthcare workers face a wide range of occupational hazards, including sharps injuries, harmful exposures to chemicals and dangerous drugs, back injuries, latex allergy, violence, and stress. Although it is possible to prevent or reduce healthcare workers' exposure to these hazards, healthcare workers continue to experience injuries and illnesses at the workplace. Cases of healthcare workers' nonfatal occupational injury and illness are among the highest in any industry sector'[1] [3].

It should be noted that in the contemporary scientific literature, the concept of 'occupational risk' in healthcare is usually used in two meanings. Some researches attribute the occupational risk of a healthcare professional to circumstances that exclude crime. Other researchers view occupational risk as a detrimental effect of adverse labour conditions on the health of a healthcare professional, which sometimes leads to his/her disability or temporary disability [1; 4]. In other words, the causes of occupational diseases of physicians, their types and means of prevention are investigated. All risks encountered by healthcare professionals are also grouped by different criteria. Thus, N. Ulutasdemir, F. Tanir state: 'The health-related risks associated with health professionals can be grouped by psychosocial, physical, biological, chemical and ergonomic factors. The American National Institute for Occupational Safety and Health has reported 29 types of physical, 25 types of chemical, biological 24 varieties, 10 and six types of ergonomic and psycho social hazards and risks' [4]. There are other classifications of occupational health risks.

To achieve the goals of our article, we suggest subdividing risks into 2 main groups: 1 - occupational risks caused by the impact of the work process and posing a risk to the lives and health of healthcare professionals; 2 - the risks of criminal liability of a healthcare professional for causing harm to patient's life and health.

We will investigate the above mentioned risk groups in more detail in the territories of Eastern European countries such as the Republic of Belarus (hereinafter - the RB), the Republic of Moldova (hereinafter - the RM), the Russian Federation (hereinafter - the RF) and Ukraine.

1. *Occupational risks that are caused by the impact of the work process and posing a risk to healthcare professionals live and health.* This group of risks is nothing but healthcare professionals running the risks of occupational diseases and of violence by patients and other persons. In accordance with the Report of 2002 to the Occupational Safety and Health Convention, 22.06.1981, No. 155, the term 'occupational disease' covers any disease contracted as a result of an exposure to risk factors arising from work activity.

Subject to the nature of the working process conditions that adversely affect the life and health of a healthcare professional, we propose to subdivide these risks into: 1.1. Threats to infect an employee involved in care of patients with infectious diseases. 1.2. Threats of physical abuse by patients/their representatives or by third parties. 1.3. Threats to psychological health associated with working in conditions of increased responsibility and psycho-emotional stress. 1.4. 1.4. Health hazards for a healthcare professional due to both adverse working conditions and health equipment shortages. Our classification does not claim to be logically complete, because it is sufficiently conditional, as the risks often complement each other.

1.1. Threats of contracting an infectious disease by a healthcare professional involved in the care of patients with infectious diseases. The official statistics on the incidence of infectious diseases in the population of Eastern Europe, as noted by the absolute number of researchers, do not coincide with the real indicators for a number of reasons. Therefore, a healthcare professional is constantly at risk of contracting an infection.

Thus, according to the WHO official data, in 2017, 10 million people contracted tuberculosis (hereinafter TB) and 1.6 million died from the disease [5]. In the RM the global TB incidence in 2017 totaled 83.3 per 100 thousand population, in Ukraine - 63.9 per 100 thousand, in the Russian Federation - 48.3 per 100 thousand, while in the RB - 24.3 per 100 thousand [6; 7, p. 29; 8; 9, p. 182]. Thus, in Ukraine TB is consistently ranked 1st in the structure of occupational diseases among healthcare professionals (87.7% on average over 15 years) [10, p. 12]. A similar situation is observed in Russia, where respiratory TB is the main disease among medical professionals and its annual rate exceeds 80% [11, p. 158]. It is interesting to note that occupational TB incidence in the RB tends to decrease: in 2016 compared to 2010, the number of health workers who contracted this disease dropped from 94 to 56 people [12, 121]. Statistics show that there is no incidence of TB among medical workers in RM [13].[2] Although any healthcare professional working in general health care facilities runs a risk of occupational TB infection, healthcare professionals working at anti-TB facilities are referred to the highest

[1] Healthcare professionals face a wide range of hazards at work (injuries, chemicals, drugs, back injuries, latex allergy, violence and stress, etc.). Cases of occupational injuries and non-fatal illnesses among healthcare professionals are among the highest in any industry [3].

[2] This situation, according to Moldovan researchers, can be explained by the fact that in the RM they generally do not recognize such cases as occupational diseases. In addition, there is no possibility to recognize professional disease even through legal actions [14]. So we can talk about the lack of proper accounting.

risk group. For example, in Ukraine this group accounts for 70-95% of cases annually. Most often these are: nurses - 37.9%, doctors - 13.7%, paramedics - 5.6%, laboratory assistants and hospital attendants - 6.5%. There are also individual cases of infection among medical endoscopists, radiologists [10, pp. 8, 13; 15]. A medical worker may contract TB through contact with an infectious patients or infected materials.

An exceptional threat to human life and health are such viral infections like HIV/AIDS, B and C hepatitis. These nosological forms are next to the threat to human life and health. According to the WHO data as of 2017, approximately 325 million people worldwide are living with chronic B hepatitis (HBV) or C hepatitis (HCV) [16]. The prevalence of this infection in Eastern Europe is quite significant, although there is a tendency of its gradual reduction. As early as 2017, HBV/HCV incidence rates were as follows: in Belarus - 3.2 (overall); in Moldova - 0.57/1.32; in Russia - 9.57/34.63; in Ukraine - 3.54/122.7 per 100 thousand population [9, 180; 11, p. 132; 17; 18, p. 26; 19, p. 18]. However, these indicators are exceeding those of other European countries.

The risk of contracting these types of infections includes physicians who are in immediate contact with patients' blood: surgeons, dentists, resuscitators, obstetricians, physicians of hemodialysis units, laboratory assistants, operating and procedural nurses. Pathways for HBV and HCV contracting are hematogenic (through blood), using non-sterile needles or other carelessly disinfected medical tools, and contact one – during direct contact of the employee's mucous membranes with the fluids of patients or infected persons. It is interesting that the share of viral hepatitis in 2012–2017 in the Russian Federation accounted for 3.4–11.5% of health workers cases of occupational diseases (2017 - 9.86%) [11, p. 158]. However, one can claim there is statistical latency of this disease among physicians and nursing staff in all the countries studied which is due to the peculiarities of the clinical course of this infectious disease, which can be asymptomatic for a long time.

According to the WHO European Regional Office, 130,861 new HIV patients were identified in Eastern Europe in 2017, of which 104,402 were in Russia. According to experts, in the Russian Federation there are 71.1 HIV patients per 100 thousand people. Ukraine accounts for 37 cases, the Republic of Belarus – 26.1 and the Republic of Moldova – 20.6 [20, p. 42]. However, official data does not reflect the true scale of the epidemic, as information is available on the number of people who have been tested for HIV antibodies only and who have been detected as infected. In fact, the number of infected persons is much higher and they are not aware of their status, since for some time HIV infection may be asymptomatic [21, pp. 23–24]. That is, it is not difficult to imagine how often healthcare workers are exposed to the risk of infection, especially during occupational injuries (for example, when a health worker is injured with non-sterile needles after manipulation, with ampoules, cutting or piercing tools) or through direct contact of health workers with the mucous membranes of AIDS patients and HIV-infected individuals not receiving antiretroviral therapy. Nurses working in hospitals rendering assistance to HIV-infected individuals and in outpatient care units, as well as ambulance health workers are most often exposed to risk of occupational HIV disease. Surgeons, operating nurses and gynecologists also belong to higher risk group. However, official statistics operates with extremely low indexes. Thus, 'in Ukraine in 1987-2013, there were officially registered 3 cases of occupational HIV infection of healthcare workers (before 1997 – 1 case, in 2004 – 1, in 2005 – 1), which is 2.1 per 100 thousand of the relevant professional group' [22, p. 9]. The situation in other countries of Eastern Europe is even worse. For the period 2010-2017, there is no known case of recognition of health workers incidence working in Russia, Belarus or Moldova contracting HIV infection as an occupational disease. According to the researchers, this may be explained by the difficulties that arise in proving the fact that the contracting of HIV infection by a healthcare professional occurred as a result of their professional duties [22, p. 9], as well as the legal insecurity of such a worker by the state. A doctor with such a diagnosis is unlikely to remain at work. Employers do not take into account the fact that a significant number of patients who are treated daily by healthcare providers have a hidden HIV diagnosis. An HIV-infected doctor not receiving antiretroviral therapy is considered to be a threat to his patient, not the other way around.

Medical workers also suffer from hospital-acquired infections (pneumonia, purulent, acute intestinal infections, etc.). Thus, in the departments of purulent surgery, 63% of the medical staff each year suffer from purulent-inflammatory infections [23, p. 32]. They face daily (especially ambulances, therapists and pediatricians, otolaryngologists and dentists, etc.) and SARS, herpes, especially type I and II, staphylococcal and streptococcal infections, fungal lesions, etc. But there is no statistical accounting of medical personnel getting infected with these pathogens.

1.2. Threats of physical abuse by patients/their representatives or by third parties. In recent years, the Eastern European medical community has been concerned about the annual increase in the number of attacks on health workers. Thus, according to the official data of the Ministry of Health (hereinafter - the MOH) of Ukraine from 2013 to 2017, the total number of reported infringement on life and health of medical workers of the emergency medical care system alone, was 543 cases, 2 of them led to disability and 3 – to the fatal outcome [24]. In 2018 alone, 152 attacks on health workers were reported by the MOH press service in Ukraine [25]. The Ministry of Health of the Russian Federation also reported that in 2010-2016, there were registered about 1,226 attacks on health workers in the course of their duties. In 2016, a tendency of increase in the number of assaults was observed [26]. The situation in Belarus and Moldova is not much better, however,

official statistics of this type of offenses is not kept there [27]. In addition, there is every reason to believe that the figures are significantly underreported, as health professionals often do not turn to law enforcement authorities. Case law analysis shows that they are most often inflicted injuries of varying degrees of severity and they are subject to assaults with the purpose of drugs seizure [28]. Quite often, such acts are performed by patients who are prone to aggression (intoxicated [29], under the influence of drugs or other psychotropic substances, and persons who have already served their sentences in prisons or the mentally ill persons). Emergency medical team doctors and duty doctors in the reception units of medical institutions are at high risk. There are individual cases of harming nursing health. For example, a citizen of Ukraine was convicted for a set of crimes under Part 1 of Art. 122 of the Criminal Code of Ukraine (intentional moderate bodily harm) and Part 1 of Art. 296 of the Criminal Code of Ukraine (hooliganism), for being in the reception room of the children's clinical hospital, he broke the window of pediatric seat, causing the nurse slight bodily injury, and unreasonably struck a doctor in the face who ran out of the office on hearing the noise, inflicting him moderate bodily harm [30]. There is also a tendency of the increase in the number of attacks on emergency medical teams on the streets of Eastern Europe. In particular, conflicts over parking space, when entering/leaving an ambulance, are not uncommon. Owners of private cars can start a fight not only with the drivers of the ambulance, but also with its medical staff [31]. There are several reasons for the situation that has taken shape, in our opinion: 1) the decline of the authority of the health worker (the population begins to treat them as a staff, considers them to be corrupt, blames the inability to effectively and cheaply cure the patient). At the same time, not only patients but also their relatives or even outsiders behave aggressively; 2) understaffing of ambulance teams and as a consequence – their physical insecurity; 3) low salary level, unregulated working day, which makes it impossible to treat a patient in attentive and caring manner; 4) permanent impoverishment, loss of cultural values of the population increases its aggressiveness.

1.3. *Threats to psychological health associated with working in conditions of increased responsibility and psycho-emotional stress.* In Eastern Europe, the work of a healthcare professional is associated with constant stress. If we consider the unregulated working day, high physical activity and emotional exhaustion, low salaries, it is not surprising that the medical worker often has signs of a symptom of 'mental burnout'. The effects of the syndrome affect both mental and physical health as well as the quality of life and the effectiveness of a physician's work, which can cause a loss of professional competence. Alcohol abuse is often a way to overcome the stress. It is claimed that 5-7% of physicians have a severe form of alcoholism. According to the academician of the RAMS P. Sidorov, only 10-12% of doctors do not use strong drinks in the Russian Federation. And researchers at the Mayo Clinic (USA) found a link between educational level, occupation, and risk of Parkinson's disease: the average lifetime probability of the disease is 2%, but only 1% for people engaged in physical work. For physicians, the index is 4%! [32].

1.4. *Health hazards for the healthcare professional are associated both with adverse working conditions and health equipment shortages.* Among the diseases of healthcare professionals in Belarus, Ukraine and Russia, the 2nd and 3rd places share allergies, intoxication and diseases of the musculoskeletal system [10, p. 12; 33, p. 70]. We do not provide relevant percentages, as official statistics is not publicly available (except Russia). However, the literature sources note that 'occupational allergy accounts for 22.6% of the total number of diseases in healthcare professionals. One of its common manifestations is bronchial asthma. It is followed by allergies to medicines and skin diseases' [32].

Separately, it is worth to note that technologies used in medicine and increasing opportunities for diagnosticating and treatment are also dangerous. An example of this could be the accident that occurred in the intensive care unit of the city hospital in Lugansk city (Ukraine) caused by the explosion of an oxygen-air balloon which resulted in the death of 16 people, 4 of whom were health workers [34]. The health of medical staff in operating theaters and biochemical laboratories is adversely affected by chemicals (halothane, acetic acid, formaldehyde, phenol, ammonia, oxygen chloride), the concentration of which often exceeds the permissible limit. Ionizing radiation, which can cause leukemia, skin tumors in radiology laboratories, radiotherapy departments, surgeons of radiological teams, occupies a special place among the physical factors that pose a risk to the health of healthcare workers. On the background of contemporary knowledge about radiological protection it becomes especially hazardous when using malfunctioning equipment, or equipment with expired operation life, during emergency situations.

2. *The risks of criminal liability of a healthcare professional for causing harm to a patient's life and health.* Receiving medical care/services, despite all current protection measures, the patient is also exposed to risk. Many of them are inherent to therapeutic and diagnostic activities, and it is almost impossible to get rid of them. But at the same time, the risk-benefit ratio should be optimized, while minimizing the first one to provide the expected level of care (service). Usually, the likelihood of adverse effects increases with surgery, therapeutic treatment, blood transfusion or blood donation, during medical experiments and the like. As A.M. Serdyuk, states 'The magnitude of the harm to patients in the process of providing medical care is evidenced by the data given in the the Helsinki Declaration on

Patient Safety in Anesthesiology: annually around 230 million patients undergo anesthesia in major surgeries worldwide. These measures cause about 7 million severe postoperative complications, which in almost one million patients result in death (about 200,000 deaths in Europe)' [35, p. 18]. Researchers also note that according to the WHO, an average of 8.4% of patients record hospital-acquired infections, which often cause their death. In general, their mortality rate is 10 times higher than in individuals without such infection [23, p. 32].[3] A separate risk group relates to adverse (undesirable) drug response (hereinafter referred to as ADR). According to epidemiological studies conducted in many countries, there is a predominance of predictable (dose-dependent) responses (75–80% of all ADR). For example, in Ukraine, ADR B type ('bizarre', that is, unpredictable, dose-independent responses) occur in 40% of cases. 36–47% of all ADR cases report serious in-hospital reactions depending on the department profile, with 73% of incidents requiring hospitalization or its continuation (1.8–1.9% of ADR resulted in patient death) [36, p. 75-77]. Therefore, the most common negative consequences for a patient with medical intervention are infection, complication of the existing disease or/and his/her death. In such circumstances, the issue of criminal liability of a medical professional arises. That is, the negative consequences are borne by the both parties. But the opinion of those researchers who claim that healthcare workers are often criminally prosecuted seems to be groundless [37].

In particular, in order to prosecute a medical professional, it is necessary, at first, to exclude a possibility of the presence of a justifiable medical error, an extreme necessity, a risk related act (justifiable risk) and a casus (fortuitous event). And secondly, to establish and prove a number of mandatory signs of a specific crime, which is seen in the actions of a person.

So, let us consider the first part of the circumstances, which exclude the possibility of criminal prosecution. *A medical error is excusable* if a healthcare professional, due to his/her careful and conscientious attitude to the work, could not avoid the errors due to some objective and/or subjective reasons.[4]

Urgent need, based on criminal law, means of causing harm to the lawful interests in order to eliminate a danger directly threatening a person or a person's or other persons' rights protected by law, as well as public or national interests if this danger could not be eliminated by other means in these circumstances and if there was no exceeding the limits of extreme necessity herewith. [5] This circumstance, which eliminates the crime of action, occurs in the conditions of the ambulance (urgent medical care), when the actions of health workers are aimed at eliminating the danger that directly threatens the person at the moment. For example, in situations of anaphylactic, traumatic shock, hypertensive crisis, clinical death, snakebite, angioneurotic edema, etc. In particular, proper performance of indirect cardiac massage leads to fracture of the patient's ribs. A more difficult option is a situation when a pregnant woman is delivered unconscious to a physician but with great blood loss. In these circumstances, if the fetus threatens the life and health of the woman, a physician will save the latter, performing an induced pregnancy termination.

Therefore, in order to exclude the possibility of criminal prosecution, it is necessary that: 1) the danger should be real; 2) the situation should require emergency medical assistance, which would cause harm to a patient's health; 3) the non-infliction of this harm should threaten with more serious consequences for the patient's health or even life; 4) it should not possible to eliminate the danger under the conditions.

Risk-related action (justifiable risk) takes place in situations where socially dangerous consequences are the result of actions taken by a healthcare professional to achieve a meaningful socially beneficial purpose[6]. In this case, such actions will be considered valid only if the following conditions are met: 1) the harm was caused in order to achieve a significant socially beneficial purpose: for the sake of saving human life and health or developing medicine; 2) this goal cannot be achieved by traditional means. If help could be rendered in a traditional, non-risk-based way, then such actions are considered criminal; 3) the healthcare professional has taken all possible actions to prevent potential harm to the patient's life and health; 4) the patient is fully aware of the likelihood of adverse effects and voluntarily consented to the risky actions. The latter condition is particularly separately emphasized by Art. 5 of 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 (ETS-164) 1997 [39].[7] In addition, it also provides for a situation where the patient is unable to provide such consent due to being under age, incapacity or inability to give his/her consent for health reasons (Articles 6, 7 of the Convention, etc.). Although the said Convention does not contain a direct indication of the possibility of the protection of violated rights and freedoms

[3] Newborns are most affected by hospital-acquired infections. Thus, in 8 regions of the former CIS, the mortality from nosocomial infections at neonatal pathology units reaches 46.6% among the newly born babies. 21,9% of the operated children of the older age who stay in surgical hospitals, develop contracted intra-hospital infections. Also quite high rates are observed among adult patients (15-36% among women in labor and patients in surgical departments) [23, 32].

[4] See more in detail 'Medical Error and Liability for It in Some Post-Soviet Countries (Belarus, Kazakhstan, Moldova, Ukraine' [38].

[5] Art. 36 of the Criminal Code (hereinafter, the CC) of RB, Art. 39 of the CC of RF, Art. 38 of the CC of RM, Art. 39 of the CC of Ukraine.

[6] Art. 96 of the CC of RB, Art. 41 of the CC of RF, Art. 40 of the CC of RM, Art. 42 of the CC of Ukraine.

[7] As of February, 2019 The Convention on Biomedicine was signed and ratified by 29 states (including the Republic of Moldova), and 6 – signed it only (Ukraine among them). Belarus and Russia did not even sign it [39].

in the European Court of Human Rights (hereinafter referred to as ECHR), and the applicant cannot justify his/her claims by referring only directly to it, the Court itself has repeatedly referred to its rules in order to hear cases of violation of the Convention for the Protection of Human Rights and Fundamental Freedoms of 1950 or to protect biomedical human rights under Art. 2, 3, 6 and 8 of the 1950 Convention[8]. For example, in the case of 'Glass v. UK', the Court heard the case on the violation of the right to respect for privacy, namely consent to medical intervention. It stated that the decision to treat, when it contradicts the position of the patient (or his/her legal representative), indicates that there is an interference with the right to respect for his/her private life and his/her right to physical integrity. It was also noted that consent should be voluntary, clearly expressed and informed [40].

It should also be noted that the occupation of a physician is associated with the need to experiment at times. The ability to use new methods, treatments and diagnostics, new drugs without fear of criminal prosecution is an important factor for the healthcare system development. Nowadays, there are often reports on designing new devices, implants, performing new surgeries, etc.[9]. The world is changing rapidly, the dynamics of the development of science and the emergence of new inventions are very fast indeed. WHO, as well as individual states, often have lack of time for relevant response and checking everything for safety. A striking example of this could be a study conducted in Germany and Switzerland. According to the data obtained, 2/3 of the 40 tested nanoproduct manufacturing companies did not assess occupational risks for workers involved in production and the risks of causing potential harm to their consumers [41]. Instead, the legislation of the countries under analysis usually contains only outdated national programs that require intensive development of nanotechnology research and development. [10]

At the same time, reports of illegal medical studies (experiments) appear periodically in online publications, especially regarding trials of new medications [42]. However, only in the Criminal Code of Ukraine there is a special regulation (Art. 142) on the illegal conduct of experiments on a person, but according to the Unified State Register of Judgments of Ukraine, currently, there are no sentences passed and served for this crime.

It is also necessary to exclude the likelihood of a casus *(accident)* characterized by a lack of guilt of a healthcare professional. The most common causes of casus in healthcare are atypical disease due to individual features of the human body, unusual anatomical structure, congenital anomalies, allergic reactions to diagnostic manipulations and medications. The latter becomes more relevant and widespread, in particular, physicians witness a steady increase in allergic reactions, as described above.

Only after the exclusion of the existence of these circumstances, lawyers can raise the question of the liability of a healthcare professional for the so-called 'Medical crimes'[11].

Therefore, the risks that are caused by the activities of healthcare professionals and which pose a potential risk to the life and health of a patient, can lead to criminal liability of a healthcare professional. Therefore, adherence to the conditions put forward by the international community is not only able to protect the patient's life and health, but also to safeguard it.

CONCLUSIONS

Occupational healthcare risks should be considered as risks to the health and safety of a healthcare professional himself/herself, and as the risk of criminal liability for causing harm to a patient's life and health. The causes of occupational risks that cause harm to the life and health of a healthcare professional are: the high prevalence of infectious diseases; the use of faulty medical equipment or equipment whose service life has expired; unregulated working day, emotional exhaustion and low salaries; attending patients who are prone to aggression (including drug addicts, alcoholics, mentally ill persons) and dissatisfied with the scope of medical services, etc. The issue of criminal liability of a healthcare professional arises because of the negative consequences for the life and health of a patient and the presence of obligatory signs of a specific crime in a person's actions. In this case, a medical excuse should be excluded, a casus, an emergency condition, or a justified risk.

REFERENCES

1. Bain A., Carson D. Professional Risk and Working with People: Decision-Making in Health, Social Care, and Criminal Justice. London: J. Kingsley Publication; 2008: 256 p. Available from: https://books.google.com.ua/books?id=y3Gm0rvNJoMC&printsec=frontcover&hl=ru#v=onepage&q&f=false

[8] Examples include these decisions: 'Vo v. France' (Application No. 53924/00), 'Evans v. United Kingdom' (Application No.6339/05), 'Juhnke v. Turkey' (Application No. 52515/99), 'V.C. v. Slovakia' (Application No. 18968/07), 'Josef Prinz v. Austria' (Application No. 23867/94), 'Roche v. UK' (Application No. 32555/96) and other.

[9] The achievements of nanomedicine are particularly striking. It provides unique opportunities for penetration into cell membranes, allows to localize the use of a number of narcotic and toxic drugs in individual organs and systems, for more effective and safer treatment of HIV/AIDS, cancer and other diseases. A separate niche of opportunities – diagnosticating of diseases. The pace of research in nanocompatible drug delivery systems and diagnosticating tests is increasing, which will enhance physicians' capabilities greatly. Today, already, more than 10 names of nanomaterials that are part of medicines are actively used, in particular, for the treatment of cancer, osteoporosis and appetite suppression [41].

[10] In Ukraine, this is the State Target Scientific and Technical Program 'Nanotechnologies and Nanomaterials' for the period 2010-2014, in Russia – 'Program for Development of the Nanoindustry in the Russian Federation to 2015'). Only in Belarus, the President, on April 22, 2015, issued Decree No. 166 'On Priority Areas of Scientific and Technical Activity in the Republic of Belarus for the period 2016-2020'.

[11] In particular, these are Articles 156-158, 161-164, 178, 184, 335 of the Criminal Code of Belarus, Articles 144, 158-163, 169, 211-214 of the Criminal Code of Moldova, Articles 120-124, 128, 235 of the Criminal Code of Russia, Articles 131-134 , 138-145, 151 of the Criminal Code of Ukraine.

2. Metodychni rekomendatsii z orhanizatsii klinichnoho upravlinnia ryzykamy ta bezpeky medychnoi dopomohy v zakladakh okhorony zdorovia [Methodical recommendations on risks clinical management and medical assistance management in healthcare facilities] / general editorship by V.F. Moskalenko. Kyiv, 2012: 23 p.
3. CDC. Health Care Workers. Available from: http://www.cdc.gov/niosh/topics/healthcare/
4. Ulutasdemir N., Tanir F. Occupational risks of health professionals. 2017. DOI: 10.5772/67148. Available from: https://www.intechopen.com/books/occupational-health/occupational-risks-of-health-professionals
5. Tuberculosis. World Health Organization. Available from: https://www.who.int/news-room/fact-sheets/detail/tuberculosis
6. Se caută: lideri pentru o lume fără tuberculoză. [We are looking for: Leaders of the world not protected from tuberculosis]. Available from: https://msmps.gov.md/ro/content/se-cauta-lideri-pentru-o-lume-fara-tuberculoza
7. Tuberkuloz v Ukraini [TB disease in Ukraine (analytical and statistical reference)]. Kyiv, 2018: 105 p.
8. V 2017 hodu v Rossyiskoi Federatsyy nabliudalos snyzhenye zabolevaemosty tuberkulezom na 9,4% [Russian Federation sees 9.4% drop in TB cases in 2017]. Regional Office of Europe WHO. Available from: http://www.euro.who.int/ru/health-topics/communicable-diseases/tuberculosis/news/news/2018/4/russian-federation-sees-9.4-drop-in-tb-cases-in-2017
9. Statystycheskyi ezhehodnyk Respublyky Belarus 2018 [Statistical annual bulletin of the Republic of Belarus 2018] / Edited by I.V. Medvedeva. Minsk, 2018: 489 p.
10. Nagorna A.M., Sokolova M.P., Kononova I.G. Profesiina zakhvoriuvanist medychnykh pratsivnykiv v Ukraini yak medyko-sotsialna problema [Occupational morbidity of healthcare workers in Ukraine as a medico-social problem] // Ukrainian Journal of Occupational Health. 2016;2(47):3-16.
11. O sostoianyy sanytarno-эpydemyolohycheskoho blahopoluchyia naselenyia v Rossyiskoi Federatsyy v 2017 hodu: Hosudarstvennыi doklad [On the state of sanitary-epidemiological well-being of the Russian Federation population in 2017: Governmental report]. Moskov, 2018: 268 p. Available from: https://www.rospotrebnadzor.ru/upload/iblock/d9d/gd_2017_seb.pdf
12. Borodina G.L., Krivonos P.S., Krivosheeva Zh.I. et al. Mnozhestvenno lekarstvenno-ustoichyvыi tuberkulez y professyonalnaia zabolevaemost medytsynskykh rabotnykov [Multiple drug-resistant tuberculosis and occupational morbidity of medical workers] // Collection of scientific papers of the First Congress of TB Specialists and Pulmonologists of the Republic of Belarus, Minsk. 17-18/05/2018:118-121.
13. Vasiliu V. Angajații din sistemul medical se îmbolnăvesc mai des decât media pe economie. De câte ori au lipsit medicii, pe motiv de probleme de sănătate [Employees in the medical system get sick more often than the average on the economy. How many times doctors have been missing due to health problems]. 20/04/2018. Available from: http://sanatateinfo.md/News/Item/7617
14. Moldovanu I. Net proffesionalnykh zabolevanyi, tak kak otsutstvuet systema ykh ucheta [No occupational diseases because there is no system for recording them]. 14/11/2013. Available from: http://vocea.md/net-professional-ny-h-zabolevanij-tak-kak-otsutstvuet-sistema-ih-ucheta/?hilite=%27%D0%BF%D1%80%D0%BE%D1%84%D0%B5%D1%81%D1%81%D0%B8%D0%BE%D0%BD%D0%B0%D0%BB%D1%8C%D0%BD%D1%8B%D0%B5%27%2C%27%D0%B7%D0%B0%D0%B1%D0%BE%D0%BB%D0%B5%D0%B2%D0%B0%D0%BD%D0%B8%D1%8F%27
15. Astrovko A.P., Kalechits O.M., Klimuk D.A. et al. Profylaktyka professyonalnykh zabolevanyi rabotnykov zdravookhranenyia. PPO HU «RNPTs pulmonolohyy y ftyzyatryy» [Prevention of occupational diseases of health workers. PPO GU «RPPC Pulmonology and Phthisiology»]. 2013: 17 p. Available from: http://profmed.by/var/upload/file/ohrana_truda/2013/2013_04_26_den_ohrany_truda/profilaktika_professionalnyh_zabolevaniy.doc
16. New hepatitis data highlight need for urgent global response. WHO. 21/04/2017. Available from: https://www.who.int/news-room/detail/21-04-2017-new-hepatitis-data-highlight-need-for-urgent-global-response
17. Notă informativă cu privire la realizarea Programului Național de combatere a hepatitelor virale B, C și D pentru anii 2017-2021 [Informative note on the implementation of the National Program to combat viral hepatitis B, C and D for the years 2017-2021]. 2017: 9 p. Available from: https://msmps.gov.md/ro/content/nota-informativa-cu-privire-la-realizarea-programului-national-de-combatere-hepatitelor
18. Sergeyeva T.A., Ivanchuk I.O. Hepatyt V v Ukraini : epidemiolohichna kharakterystyka ta otsinka tiaharia (za rezultatamy analizu danykh z riznykh dzherel) [Hepatitis B in Ukraine: epidemiological characteristics and burden assessment (based on the analysis of data from different sources)]. Center for Public Health. Kyiv, 2017: 136 p.
19. Sergeyeva T.A., Ivanchuk I.O. Hepatyt S v Ukraini : epidemiolohichna kharakterystyka ta otsinka tiaharia (za rezultatamy analizu danykh z riznykh dzherel) [Hepatitis C in Ukraine: epidemiological characteristics and burden assessment (based on the analysis of data from different sources)]. Center for Public Health. Kyiv, 2018: 111 p.
20. HIV/AIDS surveillance in Europe. 2018: 134 p. Available from: https://ecdc.europa.eu/sites/portal/files/documents/hiv-aids-surveillance-in-europe-2018.pdf
21. Vorodyukhina A.K., Yareshko A.G., Boyko M.G. et al. Informovanist naselennia pro tuberkuloz ta VIL/SNID – odyn iz zasobiv profilaktyky [Population awareness of tuberculosis and HIV/AIDS as one of the prevention means]. The world of medicine and biology. 2014;2 (44):23-25.
22. Nagornaya A.M., Varivonchik D.V., Kalchenko A.M. et al. Otsinka profesiinykh ryzykiv VIL-infikuvannia pratsivnykiv likuvalno-profilaktychnykh zakladiv khirurhichnoho ta ftyziatrychnoho profiliv [Assessment of occupational risks of HIV-infection of of professionals of medical-preventive facilities of surgical and phthisiatric departments]. Ukrainian Journal of Occupational Health. 2012;4(33):3-10.
23. Serdyuk A.M., Surmasheva O.V. Profilaktyka ta borotba z vnutrishnolikarnianymy infektsiiamy [Prevention and control of hospital-acquired infections] // Patient safety is an urgent problem of the domestic system of health care: Internat. Scientific and Practical Conf. Dnipro, 6-7/06/2017: 32-34.
24. Martyshyn O.O. Zakhyst medychnykh pratsivnykiv pid chas vykonannia profesiinykh oboviazkiv: vid slova do dila [Protecting health care professionals in the performance of their duties, from word to case]. Ukrainian Medical Journal. 2018; 1(1). Available from: https://www.umj.com.ua/article/119989/zahist-medichnih-pratsivnikiv-pid-chas-vikonannya-profesijnih-obov-yazkiv-vid-slova-do-dila
25. See: http://www.ukrpress.info/2018/10/01/za-rik-152-napadiv-na-medpratsivnykiv/?fbclid=IwAR3TiOyDAce5nFHslSmsGxLNMgmEgrq9bpJ9CTMO0W0GUtE_vp32VszgbQA
26. See: https://www.interfax.ru/russia/550243
27. See: https://news.tut.by/society/155265.html

28. See: http://reyestr.court.gov.ua/; http://instante.justice.md/; http://www.gcourts.ru/
29. See: http://reyestr.court.gov.ua/Review/83380236; http://www.gcourts.ru/case/7930794; http://www.gcourts.ru/case/6951962
30. See: http://reyestr.court.gov.ua/Review/72140292
31. See: https://www.mosregtoday.ru/odincovo/voditel-range-rover-napal-na-skoruyu-pomosch-iz-za-parkovki-v-odincovskom-rayone/; https://www.fontanka.ru/2017/01/31/007/; https://nashkiev.ua/novosti/avtoham-s-orouzhiem-napal-na-skorouyu-pomosch-foto.html?in_parent=novosti
32. See: http://www.kiout.ru/info/publish/3702
33. Gatiyatullina L.L. Health condition of medical workers // Bulletin of contemporary clinical medicine. 2016; V. 9, Edition 3:69-75.
34. See: https://tyzhden.ua/News/86422
35. Serdyuk A.M. Medyko-sotsialni ta ekonomichni aspekty problemy bezpeky patsiientiv [Medical-social and economic aspects of patient safety] // Patient safety is an urgent problem of the domestic system of health care: Internat. Scientific and Practical Conf. Dnipro, 6-7/06/2017:18-20.
36. Khaitovich M.V., Golopikho L.I. Nebazhani pobichni reaktsii na likarski zasoby: suchasnyi stan problemy [Adverse drug response: contemporary state of the issue] // Patient safety is an urgent problem of the domestic system of health care: Internat. Scientific and Practical Conf. Dnipro, 6-7/06/2017:75-77.
37. Franchuk V.V., Trach-Rosolovska S.V., Selskyy P.R. et al. Analysis of Final Judgments in Cases of Medical Negligence Occurred in Ukraine. Wiadomości Lekarskie. 2018;3:757-760. Yuryst: Medykov v Rossyy ne staly sudyt chashche, эto edynychnыe sluchay [Lawyer: Healthcare professionals are not prosecuted more often, these are individual cases]. «Rosbalt» Informational Agency. 16/07/2018. Available from: http://www.rosbalt.ru/russia/2018/07/16/1717620.html
38. Gornostay A., Ivantsova A., Mykhailichenko T. Medical Error and Liability for it in some Post-Soviet Countries (Belarus, Kazakhstan, Moldova, Ukraine). Wiadomości Lekarskie. 2019;5:877-883.
39. 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: Details of Treaty №.164. Available from: https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/164
40. «Glass v. United Kingdom». Application № 61827/00, 09/03/2004. Available from: https://hudoc.echr.coe.int/eng#{%22fulltext%22:[%22Glass%20v.%20the%20United%20Kingdom%22],%22itemid%22:[%22001-23115%22]}
41. See: http://www.kiout.ru/info/publish/206; Nanosafety in Europe 2015-2025:Towards Safe and Sustainable Nanomaterials and Nanotechnology Innovation, 2013: 212 p. Available from: https://www.eu-vri.eu/filehandler.ashx?file=12392
42. Proverkoi faktov nezakonnykh klynycheskykh yssledovanyi na volhohradskykh mladentsakh zanialas Henprokuratura [The Prosecutor General's Office checked the facts of illegal clinical trials on Volgograd babies]. «Vysota 102» Informational Agency. 14/02/2008. Available from: https://v102.ru/news/4017.html; Kak peterburhskye vrachy nazhyvaiutsia, yspytyvaia lekarstva na svoykh patsyentakh [How Petersburg physicians capitalize by testing medications on their patients]. Social and political web-portal «Online812.ru». 30/01/2013. Available from: http://www.online812.ru/2013/01/30/009/

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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 axe 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.

REFERENCES

1. Pashkov VM. Immunoprophylaxis in Healthcare: Human Rights Context. Socrates; 2(11):9–18.
2. Pashkov V, Udovyka L, Dichko H. International medical law and its impact on the Ukrainian healthcare legislation. Wiadomości Lekarskie. 2018; 1(II):201–205.
3. Tatsiy V, Gutorova N, PashkovV. Legal aspects of cancer diseases prophylactics: patients' rights context. Wiadomości Lekarskie. 2017;6(I):1108–1113.
4. Unicef. For every child. 20 million children missed out on lifesaving measles, diphtheria and tetanus vaccines in 2018. Available from: https://www.unicef.org/press-releases/20-million-children-missed-out-lifesaving-measles-diphtheria-and-tetanus-vaccines [reviewed 2019.08.17]
5. World Health Organization. .Global Health Observatory visualizations Immunization coverage country punchcards. Available from: http://apps.who.int/gho/data/node.wrapper.immunization-cov?x-country=UKR. [reviewed 2019.08.17]
6. Smiianov V.A., Zaitseva H.S., Kurganskaya V.A .et al. Vaccination coverage rates and the incidence of vaccine preventable diseases among children in sumy region of Ukraine. Wiadomości lekarskie. 2019;2(72):255–260.
7. Suk JE, Lopalco P, Celentano LP. Hesitancy, Trust and Individualism in Vaccination Decision-Making. PLOS Currents Outbreaks. 2015;7. doi: 10.1371/currents.outbreaks.49dba84ad4146de33706b1f131d7caa3
8. Kovalenko O.O. Prava patsiienta u sferi okhorony zdorovia yak element derzhavnoho upravlinnia. [Patient rights in the field of health activities as a public government] Theory and Practice of Public Administration 2018;2(61):1–9 (Ua)
9. United Nations. Universal Declaration of Human Rights. General Assembly resolution 217 A, Paris on 10 December 1948. Available from: https://www.un.org/en/universal-declaration-human-rights/. [reviewed 2019.08.17]
10. United Nations. International Covenant on Civil and Political Rights Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of December 16 1966. Available from: https://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx. [reviewed 2019.08.17]
11. Konventsiia pro zakhyst prav i hidnosti liudyny schodo zastosuvannia biolohii ta medytsyny: Konventsiia pro prava liudyny na biomedytsynu, pryjniata Radoiu Yevropy 4 kvitnia 1997 [Convention for the Protection of Human Rights and Dignity in the Application of Biology and Medicine: Convention on Human Rights for Biomedicine, adopted by the Council of Europe on April 4, 1997]. Available from: https://zakon.rada.gov.ua/laws/show/994_334 [reviewed 2019.08.17] (Ua)

12. Polozhenye o zaschyte prav i konfedentsyal'nosty patsyenta, pryniatoe 45-j Vsemyrnoj medytsynskoj assambleej 1 zhovtnia 1993 [Patient Rights and Privacy Statement, adopted by the 45th World Medical Assembly on October 1, 1993.]. Available from: https://zakon.rada.gov.ua/laws/show/990_056 [reviewed 2019.08.17] (Ru)
13. Lyssabonskaia deklaratsyia otnosytelno prav patsyenta. Pryniata 34-y Vsemyrnoi medytsynskoi assambleei, Lyssabon, Portuhalyia, sentiabr/oktiabr 1981 h. [Lysabonskaya declaratsyia otnosytel'no prav patsiienta, pryniata 34-j Vsemyrnoj medytsynskoj assambleej, sentiabr/oktiabr' 1981]. Available from: https://zakon.rada.gov.ua/laws/show/990_016 [reviewed 2019.08.17] (Ua)
14. World Health Organization. Declaration on the promotion of patiens rights in Europe. Europen consultationon on the rights of patients, Amsterdam, March 28–30 1994. Available from: https://www.who.int/genomics/public/eu_declaration1994.pdf. [reviewed 2019.08.17]
15. Ukraina krytykuie pryzmu Yevropeiskoi khartii prav patsiientiv: rezultaty vprovadzhennia druhoho etapu yevropeiskykh doslidzhen shchodo vidpovidnosti standartam YeS shchodo prav patsiientiv v Ukraini. [Ukraine crises the prism of the European Charter of Patients' Rights: results of the implementation of the second stage of European research on compliance with EU patient rights standards in Ukraine. Kiev: Design and printing].2012: 1– 158 (Ua)
16. European Charter of patients rights. Rome, November 2002. Available from: https://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co108_en.pdf. [reviewed 2019.08.17]
17. Case of Jacobson v. Massachusetts, application no. 197 U.S. 11, U.S. Supreme Court Judgement of 20 February 1905. Available from: https://supreme.justia.com/cases/federal/us/197/11/. [reviewed 2019.08.17]
18. Pierik. R. Mandatory vaccination: an unqualified defence. Journal of Applied Philosophy. 2018;Vol. 35;2. doi: 10.1111/japp.12215/
19. Pejin L.S. Tightening measures for compliance with vaccination in Serbia/ESPN Flash Report. 2016/46. Available from: https://ec.europa.eu/social/BlobServlet?docId=16078&langId=en/. [reviewed 2019.08.17]
20. Zagaja A., Patryn R., Pawlikowski J., et al. Informed Consent in Obligatory Vaccinations? Med Sci Monit. 2018;24:8506–8509. doi: 10.12659/MSM.910393.
21. Thousands of people in Warsaw protest against compulsory vaccinations. EURONEMS, updated: June 2, 2018. Available from: http://www.euronews.com/2018/06/02/thousands-of-people-in-warsaw-protested-against-compulsory-vaccctions. [reviewed 2019.08.17]
22. Donald ND, Harmon S, Dube E et al. Mandatory infant & childhood immunization: Rationales, issues and knowledge gaps. Vaccine. 2018; Vol. 36;39:5811–5818. doi.org/10.1016/.
23. Ricciardi W., Boccia S., Siliquini R.B. Moving towards compulsory vaccination: the Italian experience . European Journal of Public Health, 2018;Vol. 28:2–3. doi: 10.1093/eurpub/ckx214.
24. Wolfe E. Federal vaccine court quietly pays out billions. Salon. Available from: https://www.salon.com/2018/12/23/federal-vaccine-court-quietyly-pays-out-billins_partner/. [reviewed 2019.08.17]
25. Case of Solomakhin v. Ukraine, application no. 24429/0315, Judgement of March 2012. Available from: http://hudoc.echr.coe.int/eng?i=001-109565. [reviewed 2019.08.17]
26. Jeffrey R.H. Vaccination and the law. Mental illness. 2015;Vol. 44;11: 769–864
27. Postanova Vinnytskoho apeliatsiinoho sudu, sprava № 128/2994/15-ts, vid 12.06.2019 [Resolution of the Vinnytsia Court of Appeal, no. 128/2994/15-c, of February 12, 2019]. Available from: http://reyestr.court.gov.ua/Review/79859824 [reviewed 2019.08.17] (Ua)
28. Postanova Verkhovnoho Sudu, sprava № 128/2994/15-ts, vid 22.05.2019 [Resolutionof the Supreme Court, Case No. 128/2994/15-c, of May 22, 2019]. Available from: http://reyestr.court.gov.ua/Review/82419652 [reviewed 2019.08.17] (Ua)

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REVIEW ARTICLE
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PROBLEMS OF ASSISTED REPRODUCTIVE TECHNOLOGY'S APPLICATION

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ABSTRACT

Introduction: Application of assisted reproductive technology facilitates the solution of any nation's reproductive health problems.

The aim: is to identify the issues of legal regulation of assisted reproductive technology applying, to analyze legal practice in this area and to determine the ways of overcoming these problems.

Materials and methods: The authors have studied and analyzed international legal acts, national legislation, decisions of the European Court of Human Rights, sentences and rulings of the courts of Ukraine in the field of assisted reproductive technology's application with the use of philosophical, general and specialized scientific methods.

Conclusions: The imperfection of legal regulation of relations in applying of assisted reproductive technology leads to the criminal prosecution of persons trying to take away children born with the use of such technology from their native countries. The authors have offered to provide general provisions for determining the origin of the child from the mother and father, without requiring the existence of the document about the child's genetic relationship with one of the parents in those countries, where surrogate maternity is permitted.

KEY WORDS: child's origin, assisted reproductive technology, surrogate maternity, a visiting mother, child trafficking

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INTRODUCTION

In terms of current demographic challenges, the issue of maintaining reproductive health of population remains one of the priorities of any country worldwide. Ukraine also seeks to focus efforts on the preservation of family reproductive health, which is fully in line with the European Action Plan for Sexual and Reproductive Health and Reproductive Rights for 2017-2021 of the World Health Organization (WHO) [1].

Application of assisted reproductive technology (ART) facilitates the solution of demographic and reproductive health problems of any nation. There are many problems of medical, moral and legal nature in application of ART, which are in the focus of both physicians and lawyers. Despite considerable scientific interest to the problems of legal regulation of applying assisted reproductive technology [2-3], problematic issues of surrogate maternity as a form of its use [4], protection in the field of the application of ART [5], the issue of determining the origin of a child born with the use of ART, the legal status (regime) of embryos, have been researched fragmentarily by scholars and are relevant nowadays, considering the significant migration processes among the population and existing artificial resettlement from countries with prohibitions and restrictions for conducting ART to other countries, where its permitted by law.

THE AIM

The aim:of this research is to identify the problematic of legal regulation of assisted reproductive technology application, to analyze legal practice in this area and to determine the ways of overcoming these problems.

MATERIALS AND METHODS

The authors have studied and analyzed eight international and national legislative acts, in particular acts of France, Switzerland, Ukraine in the field of assisted reproductive technology, four decisions of the European Court of Human Rights, the judgements and rulings of district courts of Ukraine on the resolution of disputes on the origin of a child in the application of assisted reproductive technology and prosecution of perpetrators committed offenses in the field of applying assisted reproductive technology. The conclusions have been made on the basis of the analysis of scientific researches of well-known specialists in the field of medicine and medical law, statistics published by the World Health Organization and the Ministry of Social Policy of Ukraine.

In this research, the authors have used a set of philosophical, general and special scientific methods of research. In particular, the method of analysis and synthesis helped to clarify problematic issues of determining the origin of a

child born with the use of assisted reproductive technology within the practice of the European Court of Human Rights and national courts. Comparative and legal method provided an opportunity to compare the experience of different foreign countries in the field of legal regulation of relations in the application of assisted reproductive technology.

REVIEW AND DISCUSSION

The issues of reproductive health of the population, increase of birth rates and the use of assisted reproductive technology are interrelated. There is a lowering of birth rate since 2013 in Ukraine after a prolonged period of its raise (2002-2012). It was particularly noticeable in 2015, when the number of births was reduced for more than 54 thousand (or 11.6%) compared to previous year, and the number of births per 1,000 was decreased from 10.8 to 9.6. According to the national demographic forecast, the number of women of fertility age (15-49 years old) in 2020 will be decreased by 6% compared to 2015, and up to 2025 this reduction will reach almost 11%. Recognizing the strategic importance of reproductive health for the sustainable development of society, Ukraine approved the Action Program of the International Conference on Population and Development Issues (Cairo, 1994), the UN Millennium Development Goals (2000-2015), the Plan and the Sustainable Development Goals (2016-2030) [6].

Reproductive health strategy to accelerate progress towards the attainment of international development goals and targets, adopted by the 57th World Health Assembly (2004), states that there are approximately 60-80 million married couples in the world suffering from infertility [7]. In particular, there are about 1 million couples in Ukraine. It is believed that the reason of infertility of the spouses in 55-65% of cases is the state of woman's health, in 45-55% of cases – of a man's health, and in some cases, there are disorders of the reproductive function of both partners [1].

Researchers note that the overall prevalence of infertility in developing countries is 3.5-16.7%, and in developed countries – 6.9-9.3% of the population. Moreover, in some regions of Africa to the South from Sahara, the rate of infertility is between 30 and 40% of the population [8].

The WHO report on "Women and health: today's evidence, tomorrow's agenda" (2009) provides data from 47 developing countries (excluding China), which demonstrates that 187 million couples were affected by infertility, as of 2004 – approximately 18 million in primary infertility and the remaining 169 million in secondary infertility. The percentage of infertility couples was the highest in South Africa (30%) compared to Central Asian countries (28%), Southeast Asia (24%), and Latin America and the Caribbean (16%) [9, p. 46].

Infertility has traditionally been a field of medicine for a long time, where physicians had limited resources to help their patients. However, things have dramatically changed since the announcement of the birth of Louise Brown on July 25, 1978 through in vitro fertilization. She is called the world's first IVF baby [10] and since her birth more than 1 million children have been born with the use of this procedure [11].

In the current state of medicine's development, the following assisted reproductive technology has become widespread: 1) surrogate maternity; 2) intracytoplasmic sperm injection; 3) intra-uterine insemination; 4) donation of gametes; 5) donation of embryos [5, p. 475.].

In vitro fertilization and intracytoplasmic sperm injection are legal almost worldwide. However, there are different legal restrictions in most countries on the availability of these treatment methods for older women, unmarried couples, single persons, gays and transgender patients. As a result, thousands of infertile patients go abroad for in vitro fertilization. Due to higher success rates and fewer number of regulatory norms, such countries as the US, Spain, Czech Republic, Denmark, Belgium and Israel are destinations for medical tourism. There are restrictions on the number of embryos for in vitro fertilization in some European countries. Many women from Germany, Italy and the UK travel abroad to treat infertility and use an unlimited number of embryos. The most common European destinations for such women are Spain, Czech Republic and Belgium [12]. Ukraine is also the country of destination, where assisted reproductive technology techniques are used, where surrogate maternity, in vitro fertilization techniques, etc. are permitted.

Different countries have various approaches to legal regulation of surrogate maternity. The laws of some countries allow the use of assisted reproductive technology through the application of surrogate maternity methods (Ukraine, some US states, United Kingdom, Greece), and surrogate maternity is prohibited in such countries as France, Switzerland, Germany, Italy. Thus, according to the Art. 16-7 of the Civil Code of France (1804), any agreement that provides the impregnation or bearing of a fetus for another person is void [13]. According to Swiss law, anyone who uses in vitro fertilization with medical assistance of a surrogate mother is punished with up to three years of imprisonment or a fine. The same punishment is provided for those who act as mediators (the Art. 31 of the Law of Switzerland of 18 December 1998 "On Reproductive Medicine") [14].

While applying in vitro infertility treatment to adult women in Ukraine, the issue of determining the origin of the baby from the mother and father is sufficiently regulated. So, if a baby is born as a result of in vitro technique to a married woman, then she is indicated as the mother of the child, and a man who gave written consent for the use of ART is recorded as the child's father. If the baby is born using in vitro technique to a non-married woman, then she is indicated as the child's mother.

Issues of a child's origin often arise when the child was born by a surrogate mother. The legislation of Ukraine regulates the procedure for determining the origin of a child using such a method of infertility treatment as surrogate maternity, only if there is a genetic relationship between the born child and one of the parents (mother or father), that is, when a human embryo was transferred to

the body of the surrogate mother, conceived by a couple (a man and a woman), or a human embryo conceived by her husband and another woman was transferred to the body of the wife. In these cases, the establishment of maternity is not allowed.

Therefore, in the application of such infertility treatment techniques known to modern medicine, there are problems of determining the origin of the child from the mother and father in legal precedents of Ukraine, when an embryo of a person conceived using donor material from a relative of spouses (wife and (or) husband) is transferred to the body of another woman (surrogate mother), or an embryo conceived using donor material, when donors are not relatives of the client (s) under the surrogacy agreement. It is alleged that there is a genetic relationship of the spouses – parents (mother or father) with the fetus, but we do not talk about a human embryo conceived by a couple, or a human embryo conceived by a husband and another woman.

In accordance with the Art. 311-19 of the Civil Code of France (1804), in case of assisted reproduction of a child with the participation of a third donor, no related relationship between the donor and the child born of that reproduction is to be established. No claim for prosecuting the donor is allowed. The Article 311-20 of the Civil Code of France (1804) provides that spouses or cohabitants who want to conceive a child, seeking for medical assistance involving the participation of a third party – the donor, must, in advance, complying with the conditions of secrecy express their consent to a judge or notary, who informs them of the consequences of their actions regarding the child's origin. The consent granted for assisted reproduction is an impediment to any claim to dispute the child's origin or establishment of ancestral relationship, unless it is proven that the child was not born as a result of assisted reproduction or that the consent was invalid. The consent is invalid in case of death, filing the application for divorce, or the establishment of a separate spousal residence regime or in case of the termination of cohabitation that took place prior to assisted reproduction. Equally, the consent is not valid if a man or woman calls it off, stating in writing about this to a physician responsible for the surgery and prior to the assisted reproduction. Anyone who does not recognize a child born as a result of that reproduction, and prior provided the consent to assisted reproduction, shall be liable to the mother and the child. Besides, the person who has provided the consent to assisted reproduction does not recognize the child born as a result of this reproduction is recognized as the father of the child by a court order [13].

France non-recognition of relationship between a child born by a surrogate mother and customers under surrogacy agreement results in a violation of the child's right to respect for privacy, although there is no violation of the right of customer-parents to respect for family life proclaimed under the Art. 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms (1950) [15].

Disputes about the application of assisted reproductive technology and the use of embryos have been the subject matter of consideration by the European Court of Human Rights (ECHR) in the context of protecting the right to respect private and family life, proclaimed in the Art. 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms (1950). Thus, the judgment of the European Court of Human Rights in Mennesson v. France (2014) (application No. 65192/11) established the violation of the applicants' right to respect private life, which was to refuse France in recognizing relationship in the French law legally established in the United States between children born from surrogate reproduction and spouses who addressed to such reproduction method. The applicants in the case were the spouses Mennesson, French citizens, and twins Mennesson, US citizens, born in 2000. Because of Mrs. Mennesson's infertility, the parents decided to go to the United States for surrogate reproduction with Mr. Mennesson's gametes, and the fertilized embryo had to be implanted in another woman's uterus. This is how the Mennesson twins (the applicant's children) were born. Court rulings in California noted that the Mennesson spouses are twin parents. Suspecting the case of a surrogate reproduction, the French state authorities refused to submit birth certificates to the French civil registers. In the *Mennesson* case, the record was made at the behest of the prosecutor's office, which subsequently filed a suit for annulment against the couple. The applicants were finally dismissed by the Court of Cassation on April 6, 2011 on the ground that such a record would have the legal effects of a surrogate reproduction, which according to the French Civil Code is null and void. The European Court of Human Rights noted that there was no consensus in Europe on either the legality of the surrogate reproduction or the legal recognition of the relationship of legal parents and children legally conceived abroad. This lack of consensus is explained by the fact that the use of surrogate reproduction raises sensitive ethical issues. In fact, countries should have considerable discretion in matters of surrogate reproduction. However, the possibility of discretion should be limited when it comes to relationship, since it is a cornerstone of an individual's identity. Therefore, the Court has to determine whether there is a fair balance between the interests of the state and the interests of a person directly affected by the decision, in particular, in regard to the fundamental principle, when the overriding priority of a child should be a priority in each case concerning the child's status. [16].

Italy does not recognize the relationship between a child born by a surrogate mother and clients in accordance with surrogacy agreement, which also leads to litigation and, in some cases, criminal liability of the contracting parents under the surrogacy agreement. For example, the judgment of the European Court of Human Rights in the case of "Paradiso and Campanelli v. Italy" (2017) states that Mrs. Paradiso and Mr. Campanelli decided in 2006 to have a newborn baby. The Italian authorities have issued a permit, but given the age limit of "parents", which prohibits to adopt a newborn. The couple had long waited for the opportunity to adopt a child, and in 2010 applied to a Moscow company and concluded a contract on surrogate maternity with this company. The applicant acknowledged

in Italian court that the child had been born by a surrogate mother. On May 25, 2011, she told the carabinieri that the applicant was the child's father, but this was refuted by the DNA analysis. At the same time, the documents on surrogate maternity stated that the Russian physicians had examined both applicants, but this did not correspond to the real facts, since the applicant did not come to the Russian Federation. The Court concluded that the only known fact is that the child was born and was transferred to the applicant in exchange for the payment of almost EUR 50,000. In the court's opinion, it is reasonable to assume that the applicants acted unlawfully in order to obtain inclusion in the register of civil status the records of the child's birth certificate and to bypass Italian law. The child was outcasted and placed under supervision and care of another family. In its ruling of 24 January 2017, the Grand Chamber of the ECHR explained that there had been no violation of the Art. 8 of the Convention, and the child was not harmed by the negative effects of weaning, since she was not with the applicants for a very long time and had no biological connection with them [17].

The world center for surrogate maternity is the state of California, where international services of surrogate mothers are provided. In 1992, the California legislature decided that surrogacy maternity service agreements were not against the public interest. The same year, they adopted a bill to legalize the use of surrogate maternity on commercial basis. However, the state governor vetoed it. In 1993, the California Supreme Court ruled that spouses entered into a contract to bear the child by a surrogate mother are legal parents of a child born by the method of surrogate maternity. Thus, in California they started to apply the statutory principle according to which all rights to a child born with the help of a surrogate mother belong to the genetic parents. In some other US states, including Virginia, only commercial surrogate maternity is prohibited starting from July 1, 1993 [18, p. 317].

There are some problematic issues in the US, in determining the origin of a child born with the use of assisted reproductive technology, as evidenced by the case law, in particular, the lawsuit that took place in 1987-1988. Despite the concluded contract, surrogate mother Mary Whitehead refused to give the child to Sterns spouses (the egg belonged to Elizabeth Stern, and the sperm to her husband William Stern). The first court of justice deprived M. Whitehead of motherhood and transferred the parental rights to Sterns. However, after 10 months, the New Jersey Supreme Court resolved this case differently: it retained Sterns' rights to guardianship and granted M. Whitehead the rights of a visiting mother [19, p. 420-421]. The current legislation of Ukraine does not provide the legal status of a "visiting mother" for a surrogate mother. Establishing such a status is considered inappropriate, given that the child must have one mother, which is completely natural.

Situations when citizens of a foreign country cannot be recognized as the parents of a child born by a surrogate mother in another country are enormous within law-enforcement activities. According to the legislation of this country they, as participants in the assisted reproductive technology program, were considered the child's parents. The imperfection of legal regulation of relations in determining the origin of a child in the application of assisted reproductive technology also leads to the commission of criminal offenses in this area.

Thus, two French citizens were prosecuted according to Part 2 of the Art. 332 of the Criminal Code of Ukraine "Illegal transfer of persons across the state border of Ukraine" for organizing the illegal transfer of children across the state border of Ukraine, committed by prior conspiracy by a group of persons. At the trial, the defendant fully admitted his guilt stating that he and his wife could not bear a child for a long time. Kyiv company "Viotekhsom" provided him and his wife assistance in the treatment of infertility, the representatives of which took them to a specialized medical clinic in Kyiv City – LLC "Institute of Reproduction Genetics", which subsequently dealt with the issue of fertilization, carrying of a pregnancy and birth of children by a surrogate mother. On January 23, 2011, two girls were born by a surrogate mother in one of the maternity hospitals in Kyiv. After the birth of the children they were issued birth certificates and after that he and his wife applied to the French Embassy in Ukraine to issue the necessary documents for taking the children to France and to grant them French citizenship. The Embassy refused them because surrogate maternity in France was forbidden. According to this fact, he had no other option of taking his children from the territory of Ukraine, he decided to take the children from Ukraine illegally, hiding them from passport and customs control in his father's car-house. However, he did not inform his wife about the illegal nature of his own actions, because he believed that she would be against this. On March 20, 2011, his father arrived in Mukachevo on his "Daimler Chrysler Caravans Inter" car, and in the morning of March 21, 2011, he, his father and his children went to the "Luzhanka" checkpoint. Before reaching the checkpoint, they hide the children in the car's furniture chest so that they could not be identified during visual inspection. However, at the checkpoint, their car was taken out of the general flow of vehicles and sent to the observation deck to undergo an in-depth inspection, during which a customs officer discovered two children hidden from transport control [20].

From the analysis of court cases entered in the Unified State Register of Court Decisions of Ukraine, we can conclude that the Unified Register of Pre-Trial Investigations includes criminal proceedings on the basis of the offense provided in the Art. 149 of the Criminal Code of Ukraine (2001) "Trafficking in Human Beings".

Thus, the ruling of Shevchenkivskyi district court of Kyiv City dated from June 29, 2018 (court case No. 761/22218/18) stated that pre-trial investigation agency established that a criminal group organized by citizens of the Republic of Moldova and the Federal Republic of Germany illegally acted on the territory of Ukraine, in particular, in the cities of Kyiv, Kropyvnytskyi, Lviv, Donetsk and Mariupol during 2011-2018. That group included officials of

the LLC "VIOTEKHSOM" and other related enterprises, who in the course of their business activities eliminate to pay taxes in extremely large amounts and pretending to carry out assisted reproductive technology programs using surrogate maternity for cash in the amount of about 50,000 euros, assist foreign citizens in the implementation of illegal agreements on minors (Ukrainian citizens), thereby accomplishing children trafficking for money reward. In particular, officials of the LLC "VIOTEKHSOM" contribute to unreasonable submission of false information about foreign citizens as parents of newborn citizens of Ukraine into certificates on the genetic relationship. After that foreign citizens illegally register newborn citizens of Ukraine as foreign nationals and take them abroad forever. The actual parents of such children are unknown persons, as the treatment program for assisted reproductive technology uses eggs and sperm from donors' banks that have nothing to do with foreigners, who are entered as parents in the genetic relationship certificates. As a result, foreign citizens illegally take children (Ukrainian citizens) abroad on the basis of forged documents. During the pre-trial investigation the fact of export of a Ukrainian citizen born in Vinnytsia City to the Italian Republic on the basis of a fake birth certificate was revealed. The parents of the child in this certificate are recorded citizens of the Italian Republic whose genetic relationship is excluded by the results of the genetic examination. Taking this child from the territory of Ukraine was carried out by the citizens of the Italian Republic, accompanied by the officials of the LLC "VIOTEKHSOM", who assisted to the mentioned citizens of the Italian Republic for a sum of about 50 thousand euros in the falsification of the act of civil status, namely the birth certificate of the child, who was born in Vinnytsia City. Besides, it was established that the citizens of the Republic of Poland, acting on prior agreement with the officials of the LLC "VIOTEKHSOM", concluded illegal agreement with respect to minors born on the territory of Ukraine, having previously obtained the birth certificates of children from the Civil Registry Office with deliberately false information, on the basis of which they tried to take them abroad from Ukraine [21].

The determination of the origin of a child born with the use of assisted reproductive technology is closely linked to the determination of the legal status (legal regime) of the embryo. Ukraine has signed the Convention on the Protection of Human Rights and Dignity for the Use of Biology and Medicine (1997), where the Article 18 provides, if the legislation allows for embryo research in vitro, it guarantees adequate protection for the embryo. Growing human embryos for research purposes is prohibited [22]. The Parties to this Convention are Bulgaria, Greece, Spain, Lithuania, Romania, Slovakia, Slovenia, Hungary and other countries.

Appendix Rules of the Council of Europe, Parliamentary Assembly Recommendation 1046 on the use of human embryos and fetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes (1986) state that no intervention for diagnostic purposes, other than those already authorized under national law, on the living embryo in vitro or in utero or on the foetus whether inside or outside the uterus shall be permitted, unless its object is the well-being of the child to be born and the promotion of its development. No intervention on the living embryo in vitro or in utero or on the foetus whether inside or outside the uterus shall be permitted, unless its object is the well-being of the child to be born, that is, to facilitate its development and birth [23].

Council of Europe Parliamentary Assembly Recommendation No. 1100 on the Use of Human Embryos and Foetuses in Scientific Research (1989) provides the intentional creation and / or keeping alive of embryos or foetuses whether *in vitro* or *in utero* for any scientific research purpose, for instance to obtain genetic material, cells, tissues or organs therefrom, shall be prohibited [24].

In particular, the judgment of the European Court of Human Rights (2011) in the case of "S.H. and others v. Austria" (application No. 57813/00) did not establish the violation of the Art. 8 of the Convention (1950) and stated that the applicants were two married couples. Because of infertility, they would like to apply medical techniques of assisted reproduction. Only fertilization in vitro (FIV) with the use of donor sperm (in case of the first couple) or eggs (in case of the second couple) would allow them to have children for whom one of the spouses could be a genetic father or mother. These two methods are prohibited in Austria by the law on assisted reproduction, the law does not allow the use of donor sperm for the purpose of FIV and egg donation in general. However, this law allows other methods of assisted reproduction, such as FIV using the exchange of eggs and sperm between married persons or those who have stable unregistered relationship (homologous techniques of impregnation) and, in exceptional cases, sperm donation for the purpose of impregnation in utero. … The Court has noted that the use of fertilization in vitro techniques still causes controversy that affected and continues to affect the delicate moral and ethical aspects; moreover, these disputes occur in the context of the rapid evolution of science and medicine [25].

There were also no violations of the Art. 8 of the Convention (1950) found in the judgment of the European Court of Human Rights (2015) in Parrillo v. Italy case (application No. 46470/11). The Court established that the applicant in 2002 had used assisted reproductive technology – in vitro fertilization with her partner in the Center for Reproductive Medicine at the European Hospital (Center) in Rome. Five embryos were obtained from in vitro fertilization and frozen by cryopreservation method. Before the embryos could be implanted, the applicant's partner died on November 12, 2003 during an explosion in Nasiriyah (Iraq). Deciding not to implant the embryos, the applicant tried to donate them for scientific research and thus to contribute to the treatment of serious diseases. The director of the Center refused her request, since this type of research was banned and prosecuted in Italy. The Court admitted that "the protection of the embryo's potential life", in the sense of this notion provided to it by the Government, might be linked to the protection of the morals and rights

and freedoms of other persons. However, this does not imply any assessment by the Court of whether the words "other persons" extend to human embryos... However, some countries (Andorra, Latvia, Malta and Croatia) have enacted legislation that directly prohibits any research on embryonic cells. Other countries allow this type of research, but only under harsh conditions, requiring, for example, with the purpose of protecting the health of the embryo or using cells imported from abroad (Austria, Italy, Germany and Slovakia). Therefore, Italy is not the only State Member of the Council of Europe that forbids the transfer of human embryos for research… However, the Court believes, that there is no need to consider the sensitive and contradictory issue of the moment, when human life begins, since this case is not related to the Art. 2 of the Convention. With regard to the Art. 1 of Protocol No. 1, the Court considers that it is not applied to this case. Taking into account the economic and property subject matter of this Article, human embryos cannot be reduced to "property" in the sense of this provision. Since the Art. 1 of Protocol No. 1 to the Convention is not applied in this case, this part of the application must be rejected as incompatible ratione materiae with the provisions of the Convention in accordance with §§ 3 and 4 of the Art. 35 of the latter [26].

CONCLUSIONS

The use of ART raises many issues of medical, legal, moral and ethical nature, in particular, there are problems in determining the origin of a child. According to the laws of some countries, there are restrictions on the procedure of assisted reproduction, surrogate maternity, which facilitates the forced departure of potential parents to other countries. Ukraine is a country often visited by foreigners for the use of such infertility treatment methodology as surrogate maternity, since surrogate maternity is prohibited in some countries (for example, France, Italy) or restricted by law. The imperfection of legal regulation of relations in this area leads to the criminal prosecution of persons trying to take such children outside the country, where surrogate maternity is allowed, to those countries, where it is prohibited.

The European Court of Human Rights recognizes the broad boundaries of certain countries' discretion in legal regulation of relations in applying assisted reproductive technology, but in regard of determining a child's origin it supports the position of guaranteeing the best interests of a child. It would be advisable to provide general provisions for determining a child's origin from the mother and father without requiring a document on the genetic relationship of the child with one of the parents in those countries, where surrogate maternity is allowed at the level of legal regulation of determining the origin of a child born by a surrogate mother. It would help to guarantee the best interests of the child.

A surrogate mother in some U.S. states may have the legal status of a visiting mother. This approach is rather controversial, considering that a child naturally has one mother and one father.

Research on embryos is often the subject matter of disputes considered by the European Court of Human Rights in the context of protecting the right to respect private and family life. The European Court of Human Rights does not consider as a violation of the right to respect private and family life, if there are legal restrictions and prohibitions on embryo research in the country; embryos also cannot be considered as certain "property", "possession".

REFERENCES

1. Derzhavna dopovid pro stan simei ta shliakhy realizatsii derzhavnoi polityky z pytan sim'i za pidsumkamy 2014-2015 rokiv. 2016 [State report on the families and ways of implementing the state policy on family issues by the results of 2014-2015]. Kyiv: Ministerstvo sotsialnoi polityky Ukrainy, Instytut demohrafii ta sotsialnykh doslidzhen imeni M. V. Ptukhy NAN Ukrainy. Available from: http://www.msp.gov.ua/timeline/?t=17&from=&till=&g=154#tagpanel [reviewed 2019.09.11] (Ua).
2. Vitalii Pashkov, Anna Lyfar. Assisted reproductive technologies: the problems of legal enforcement. Wiadomości lekarskie. Czasopismo polskiego towarzystwa lekarskiego. 2018. 71(5):1066-1070. Available from: http://wl.medlist.org/05-2018-23/ [reviewed 2019.08.27]
3. Seniuta I. Ya. Tsyvilno-pravove rehuliuvannia vidnosyn u sferi nadannia medychnoi dopomohy: pytannia teorii i praktyky: monohrafiia. [Civil and legal regulation of relations in the field of medical care: issues of theory and practice: monograph]. Lviv : Vydavnytstvo LOBF «Medytsyna i pravo» 2018. (Ua).
4. Korenha Yu. V. Dohovir surohatnoho materynstva v simeinomu pravi Ukrainy : monohrafiia. [Surrogate maternity agreement within family law of Ukraine : monograph]. Lutsk : Vezha druk 2015 (Ua).
5. Pashkov V., Gutorova N., Noha P. Reproductive function: the protection of the rights of the people which are sent to the area of the fighting. Wiadomości lekarskie. Czasopismo polskiego towarzystwa lekarskiego. 2018; 71 (2 pt 2):403-407. Available from: http://wl.medlist.org/02b-2018-27/ [reviewed 2019.08.27]
6. Proekt rozporiadzhennia Kabinetu Ministriv Ukrainy «Pro Kontseptsiiu Zahalnoderzhavnoi prohramy «Reproduktyvne ta stateve zdorov'ia natsii na period do 2021 roku». [Draft Regulation of the Cabinet of Ministers of Ukraine "On the Concept of Nation-Wide Program "Reproductive and Gamic Health of the Nation for the period until 2021"]. Available from: http://old.moz.gov.ua/ua/portal/Pro_20170316_0.html#2 [reviewed 2019.09.01] (Ua).
7. Reproductive health strategy to accelerate progress towards the attainment of international development goals and targets (2004). World Health Organization, Geneva. Available from: https://apps.who.int/iris/bitstream/handle/10665/68754/WHO_RHR_04.8.pdf?sequence=1 [reviewed 2019.09.09]
8. Luis Bahamondes, Maria Y Makuch. Infertility care and the introduction of new reproductive technologies in poor resource settings. Reproductive Biology and Endocrinology. 2014; vol. 12: 87. doi:10.1186/1477-7827-12-87
9. Women and health: today's evidence tomorrow's agenda World Health Organization. 2009. 91 p. Available from: https://apps.who.int/iris/bitstream/handle/10665/44168/9789241563857_eng.pdf?sequence=1 [reviewed 2019.09.09]
10. Paul R. Brezina, Yulian Zhao. The Ethical, Legal, and Social Issues Impacted by Modern Assisted Reproductive Technologies. Obstetrics and Gynecology International. 2012: 686253. doi: 10.1155/2012/686253.

11. Sudhaa Sharma, Neelam Aggarwal. In vitro fertilization in older mothers: By choice or by law? J Midlife Health. 2016 Jul-Sep; 7(3): 103–104. doi: 10.4103/0976-7800.191018.
12. Mahmoud Salama, Vladimir Isachenko, Evgenia Isachenko et al. Cross border reproductive care (CBRC): a growing global phenomenon with multidimensional implications (a systematic and critical review). Journal of Assisted Reproduction and Genetics. 2018 Jul; 35(7): 1277–1288. doi: 10.1007/s10815-018-1181-x.
13. Code civil. Version consolidée au 21 juillet 2019. Available from: https://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006070721[reviewed 2019.09.07]
14. Loi fédérale sur la procréation médicalement assistée du 18 décembre 1998 (Etat le 1er septembre 2017). Available from: https://www.admin.ch/opc/fr/classified-compilation/20001938/index.html [reviewed 2019.09.07]
15. Konventsiia pro zakhyst prav liudyny i osnovopolozhnykh svobod vid 4 lystopada 1950 r. [Convention for the Protection of Human Rights and Fundamental Freedoms dated from November 4, 1950]. Available from: https://zakon.rada.gov.ua/laws/show/995_004 [reviewed 2019.09.07] (Ua).
16. Case of Mennesson v.France, aplication No. 65192/11, judgment of 26 June 2014. Available from: https://hudoc.echr.coe.int/eng#{%22itemid%22:[%22002-9781%22]} [reviewed 2019.09.09]
17. Case of Paradiso and Campanelli v. Italy, application No. 25358/12, judgment of 24 January 2017. Available from: http://hudoc.echr.coe.int/eng?i=001-170359 [reviewed 2019.09.09]
18. Sopel M. V. Pravovi aspekty surohatnoho materynstva: Ukraina ta SShA. [Legal aspects of surrogate maternity: Ukraine and the USA.]. Medychne pravo: pravovyi status patsiientiv v Ukraini ta yoho zakonodavche zabezpechennia (henezys, rozvytok, problemy i perspektyvy vdoskonalennia) : materialy II Vseukr. naukovo-prakt. konf., m. Lviv, 17–18 kvit. 2008 r. [Medical law: the legal status of patients in Ukraine and its legislative guaranteeing (genesis, development, problems and perspectives of improvement) : materials of the II All-Ukrainian scientific and practical conference, Lviv City, April 17-18, 2008], Lviv, 2008: 314–318 (Ua).
19. Stetsenko S. H., Stetsenko V. Yu. and Seniuta I. Ya. (2008), Medychne pravo Ukrainy: pidruchnyk [Medical law of Ukraine: textbook]. Kyiv: Pravova yednist (Ua)
20. Vyrok Berehivskoho raionnoho sudu Zakarpatskoi oblasti vid 17 travnia 2011 r., sudova sprava № 1-131/11 [Sentence of Berehivskyi district court of Zakarpatska oblast dated from May 17, 2011, court case No. 1-131 / 11]. Available from: http://reyestr.court.gov.ua/Review/15625789 [reviewed 2019.09.05] (Ua)
21. Ukhvala Shevchenkivskoho raionnoho sudu m. Kyieva vid 29 chervnia 2018 r., sudova sprava № 761/22218/18 [Ruling of Shevchenkivskyi district court of Kyiv City dated from June 29, 2018, court case No. 761 / 22218 / 18]. Available from: http://reyestr.court.gov.ua/Review/75186008 [reviewed 2019.09.05] (Ua)
22. Konventsiia pro zakhyst prav i hidnosti liudyny shchodo zastosuvannia biolohii ta medytsyny vid 4 kvitnia 1997 r. [Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, dated from April 4, 1997]. Available from: https://zakon.rada.gov.ua/laws/show/994_334 [reviewed 2019.09.06] (Ua)
23. Recommendation 1046 Use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes, dated from September 24, 1986. Available from: https://assembly.coe.int/nw/xml/XRef/Xref-DocDetails-EN.asp?FileID=15080&lang=EN [reviewed 2019.09.06]
24. Recommendation 1100 on the use of human embryos and fetuses in scientific research 1989. Available from: http://assembly.coe.int/nw/xml/xref/xref-xml2html-en.asp?fileid=15134&lang=en [reviewed 2019.09.06]
25. Case of S.H. and Others v. Austria, application No. 57813/00, judgment of 03 November 2011. Available from: http://hudoc.echr.coe.int/eng?i=001-118062 [reviewed 2019.09.06]
26. Case of Parrillo v. Italy, application No. 46470/11, judgment of 27 August 2015. Available from: http://hudoc.echr.coe.int/eng?i=001-157263 [reviewed 2019.09.06]

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REVIEW ARTICLE
PRACA POGLĄDOWA

INTERNATIONAL COOPERATION IN CRIMINAL PROCEEDINGS INVOLVING ASSISTED REPRODUCTIVE TECHNOLOGIES

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ABSTRACT

Introduction: The fact that Ukrainian legislation in the field of reproductive medicine is the most liberal in Europe leads plenty of foreigners to come to Ukraine for using surrogacy as a method of treatment and in such a way to avoid certain prohibitions of their domestic legislation. Subsequently, they face legal issues during the border-crossing with a newborn. Additionally, there are several problems with acquiring a nationality for child in its parents' country. Moreover, it could lead to initialization of criminal proceedings in Ukraine and other countries as during pre-qualification these actions formally are similar to human trafficking.

International cooperation in criminal proceedings in cases involving assisted reproductive technologies is a way of resolving the moral and legal dispute of countries with different legal regulations on assisted reproductive technologies.

The aim: To establish the optimal ways of solving problems arising from the use of assisted reproductive technologies by foreign citizens, who come to Ukraine from countries, where surrogacy is prohibited. Thus, the use of it in Ukraine triggered the urgent need for international cooperation in criminal proceedings.

Materials and methods: This study has been conducted in 2019. In this research as an empirical basis 2 decisions of the European Court of Human Rights (ECHR), 1 press-release of the ECHR, 4 cases› materials, and additionally 2 regulatory documents have been used.

Methods of general science (synthesis, induction, system method) and specific scientific methods (legal comparative method, special-legal method) have been applied.

Conclusions: According to the mentioned above, it follows that the problematics of the international cooperation in criminal proceedings involving ART application also lie outside the scope of criminal proceedings alone, resulting in waste of time, funds and human resources in some countries' proceedings. Moreover, European countries have accepted a unified approach, according to which ART is a method of treatment, and newborns are full-fledged citizens according to «jus sanguinis". However, it is essentially important to admit that material law is primary here. The optimal way to solve the issues of foreigners opting for surrogacy in Ukraine for the sake of avoiding criminal proceedings in Ukraine and abroad is to provide for all countries a unified approach to understanding that ART technology is a method of treatment. And that countries of Europe, where surrogate motherhood is prohibited, should freely recognize parental rights of individuals, who have used or applied method of surrogate motherhood, and the rights of newborns to adopt the citizenship of their parents.

KEY WORDS: human rights, surrogate motherhood, surrogacy, assisted reproductive technologies, general principles of international cooperation in criminal proceedings, reproductive tourism

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INTRODUCTION

The fact that Ukrainian legislation in the field of reproductive medicine is the most liberal in Europe leads foreigners to come to Ukraine in order to use surrogacy as a method of treatment and in such a way to avoid certain prohibitions of their domestic legislation. Subsequently, they face legal issues during the border-crossing with a newborn. Additionally, there are several problems with acquiring a nationality for child in its parents' country. Moreover, it could lead to initialization of criminal proceedings in Ukraine and other countries as during pre-qualification these actions formally are similar to human trafficking.

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REVIEW AND DISCUSSION

Surrogacy is treated as the systematical complex of actions: artificial (instrumental) fertilization of an ovum with the subsequent placement of an embryo in a cavity of the uterus of another woman (substitute or surrogate mother). Surrogate motherhood is a method of treatment of infertility at which the embryo received from genetic parents is transferred to a cavity of the uterus of another woman. It is necessary to pay attention to Article 123 of the Family Code of Ukraine, which states that genetic relation with at least one parent is required [1].

In the case of surrogate motherhood using according to Ukrainian legislation motherhood establishment is not subject to dispute. The child's biological parents are spouses (married couples). This rule protects potential parents from abuse and speculation by a surrogate mother. The analysis of the legislative provisions of Ukrainian legislation shows the legal authorization of the use of surrogate motherhood rights by foreigners, and consequently the phenomenon of reproductive tourism in Ukraine. However, this phenomenon still has many problems in the realization by people (parents) of their reproductive rights through a cross-border nature of relations, including a criminal law nature, that provides relevance of research of the international cooperation in criminal proceedings involving using ART treatment method.

The phenomenon of reproductive tourism with the realization of the rights to surrogate motherhood has its reasons, in general, those that cause further crossing of the states' border by parents with a newborn child, and the emergence of grounds for criminal proceedings, such as 1) countries may prohibit a specific service because of religious or moral purpose; 2) the service may not be available as it is not considered sufficiently and originally safe or the risks of its use are unknown, thus, countries which create preventing measures, may prohibit procedures available elsewhere; 3) some categories of people may not receive services based on age, marital status, or sexual orientation. The reasons, which had an extensive impact on reproductive tourism development, including through surrogacy, are described and revealed in researches of Inhorn MC [2, p.88], Ferraretti AP, Pennings G, Gianaroli L, Natali F, Magli MC [3, p.261], Marcia C. Inhorn, Pasquale Patrizio [4, p.904], Sun Chia-Ting [5, p. 38-39], Britta van Beers [6, p. 105] and others.

All of the abovementioned factors that affect reproductive tourism in Ukraine, according to the authors, are mainly due to the direct limitation in some countries on the use of such reproductive technologies, or by granting permission to use surrogacy free of charge and/or from a close relative. Thus, surrogate motherhood is totally and completely prohibited in France, Germany, Italy [7, p. 291], Norway, partially allowed in Great Britain, Australia (other than Tasmania) [7, p. 297], Canada, New Zealand [7, p. 291], China's administrative region - Hong Kong [8, p. 79], Brazil [9, p. 33], Lebanon and Iran [2, p. 98-99], allowed in India, Ukraine, some states of the United States, South Africa, Japan and Saudi Arabia [7, p.2 97].

According to Van Beers B, despite the fact that many national European governments remain critical towards the growing commercialization of human reproduction, the rise of reproductive tourism has made it clear that simply prohibiting of reproductive markets is not the panacea. Instead, new regulatory dilemmas have emerged [6, p.105]. At the same time, such a regulatory dilemma also include the fact that spouses who will return to the country of their citizenship with a newborn child, where the surrogate motherhood is completely prohibited or prohibited on a commercial basis, criminal proceedings will be initiated while crossing border of Ukraine or border of countries of parents' citizenship, which cause both issues of the parental rights and newborn child's rights realization, as well as criminal proceedings initiation and execution of international cooperation in criminal proceedings.

Such practice of people's realization of their rights to use surrogate (substitute) motherhood as a method of treatment and following conflicts of two countries' national legislation are not uncommon. Thus, the European Court of Human Rights (hereinafter referred to as ECHR, Court) in the case of Mennesson v. France pointed out, that there is no consensus in Europe neither on the legality of surrogate conception, nor on the legal recognition of the affinity between parents and child who was legally conceived in other country. The Court found that the difference between the applicants' right to respect for family life on the one hand and the rights of children born by surrogacy to respect for their privacy – on the other. At the same time, The Court found a violation of the children's' rights to privacy [10]. A similar decision was taken by the court in Labasse v. France [11].

According to these decisions, the ECHR determined that, regardless of the country of origin of the newborn child and the prohibition of surrogate motherhood in the parents' country, children are protected. This approach is also supported by Nila Bala [12, p.13-16, 19]. However, the ECHR did not solve the problem, which is repeatedly mentioned in complaints to the ECHR.

The Court's similar position has been shown in a press release of another case of D. and Others v. Belgium (application no. 29176/13). The case concerned the Belgian authorities' initial refusal to authorize the arrival on its national territory of a child who had been born in Ukraine from a surrogate pregnancy, as resorted to by the applicants, two Belgian nationals. But the Court concluded that the Belgian authorities did not breach the Convention in carrying out checks before allowing a child, who had been born in Ukraine by a surrogate mother, to enter Belgium [13]. Similar positions are used in cases of Braun v. France

(no. 1462/18) [14], Saenz and Saenz Cortes v. France (no. 11288/18) [15], Maillard and Others v. France (no. 17348/18) [16], Schlittner-Hay v. Poland (nos. 56846/15 and 56849/15) [17].

In all these cases surrogacy is illegal in the country of parents' citizenship. The Public Prosecution Services pointed out that in cases where it was the ECHR's decision about respect for privacy of newborns, they have to be retained in the country of their parent's citizenship.

In such situations, there is a need to apply international legal assistance. There are plenty of cases according to which foreign country's diplomatic mission embraces petitions to the legal authorities of Ukraine for the illegitimacy of the actions of married couple. These petitions are also provided because of that country's surrogacy prohibition, full or partial. Then, on the basis of such claims the information on the commission of an offense under the preliminary qualification "human trafficking" is including to the Unified Register of Pre-trial Proceedings. At the same time, international cooperation in criminal proceedings ground on taking the necessary measures to provide international legal assistance through the transfer of documents, the execution of separate proceedings, the extradition of people, who have committed a criminal offense, the temporary transfer of humans, the prosecution, the transfer of convicted people and the enforcement of sentences. An international treaty of Ukraine may provide for forms of cooperation in criminal proceedings other than The Criminal Procedural Code of Ukraine (hereinafter referred to as CPC of Ukraine) (art. 542 of the CPC of Ukraine) prescribes [18]. The application of international cooperation in such criminal proceedings is the only correct way to provide documents as appropriate and admissible sources of evidence to establish the truth in the case.

However, it should be stated that the issue is more complicated and is not based on criminal procedural rules alone, or simply on unification and standardization of the surrogacy rules, citizenship, borders-crossing by biological parents with a child born by implementing surrogate motherhood technologies. A lot of problems are also related to differences in the legal regulation of the reproductive rights of parents, in particular, queer- and transgender people. Leibetseder, Doris and Griffi Gabriele stated, that changes in the legal access to ART for queer and transgender people in different countries have created both challenges and possibilities for reproduction for LGBTQI+-people. Some queer and transgender people circumvent restrictive laws (not only concerning LGBTQI+ access to ART, but also limiting access by age, relationship status, and class) in their own country and make use of fertility border crossing. Nonetheless, in many cases, those either traveling or using local ARTs experience legal and administrative problems with birth and parental certificates [19, p. 3]. Ferraretti AP, Pennings G, Gianaroli L et al pointed out, that single women, post-menopausal women, homosexual couples and, in some European countries, unmarried couples are also not eligible for infertility treatments. The exclusion is based on the belief that only a heterosexual (married) couple of normal reproductive age can fit the model of a 'normal and ideal family'[3, p. 263].

According to materials of Deonandan R, Green S, Van Beinum A, we find as the global ART industry expands, it is incumbent upon all parties, government, and civil society included, to explore options for mitigating the many ethical challenges with which the phenomenon presents us [20, p. 745]. Whittaker A has similar ideas. The author stated that some countries leave all decision-making concerning ARTs to the discretion of the physician and patient with minimal governmental oversight, as is currently the case in Thailand (although regulations are currently under discussion). Only a few countries have legal sanctions for the violation of regulatory requirements regarding reproductive technologies. There appears to be no country with specific guidelines on the provision of reproductive services to foreign patients [21, p. 400].

Thus, the problems which are faced by Ukraine in the context of European integration and the use of ART by foreign citizens in order to avoid criminal proceedings for "human trafficking" since of crossing the border and registering a newborn child in a country where surrogate citizenship is prohibited it is inevitably are as follows: 1. Ukrainian legislation does not directly permit or a prohibit the use of ART (including surrogate (substitute) motherhood by foreigners), which in turn stimulates reproductive tourism development in Ukraine. 2. Partial limitations on commercial surrogate motherhood, or a complete prohibition on surrogate (substitute) motherhood in European countries raise the issues of legalizing a status of a newborn child in countries of this prohibition, beginning from the moment of crossing state's border and initiating of criminal proceedings both in Ukraine and their domestic countries. At the same time, before the study and synthesis of statistics, it was a belief that a significant percentage of surrogate mothers are relatives or friends of women who cannot give birth to the child on their own. However, these women are less than one percent from total, and the rest are strangers that are acting on the basis of civil contracts. This creates obstacles in the realization of the rights of those foreign citizens whose countries permit the practice of surrogacy not based on commercial agreements. Also, it provides a necessity for consular and diplomatic institutions of foreign states and their law enforcement agencies or legal authorities to apply for international cooperation in criminal proceedings and vice versa: domestic law enforcement agencies or legal authorities to communicate with the competent authorities of other states.

All of the abovementioned arguments lead to the necessity of searching for ways of solving the issue. All countries in the world, including European countries, should pay attention to the fact that surrogate (substitute) motherhood is a treatment in which there must be no discrimination, as it was stated by Ferraretti A, Pennings G., Gianaroli L., Natali F., Magli M., health care cannot be treated as any other product [3, p. 265].

Pennings G. established that it is much easier to move from permission to prohibition when controversial issues are considered than vice versa [22, p. 2692] and promotion of the trade-in health services need to ensure that it does

not inadvertently promote unethical or exploitative trade such as may occur if regulatory mechanisms are not present and enforced [21, p. 407].

Ergas Y. admits, that states have tried to address individual dramas through ad hoc solutions – issuing emergency entry documents for children caught at borders or compelling administrative authorities to recognize birth certificates related to surrogacy arrangements that run counter to domestic public policies, and judges have attempted to craft doctrines that inevitably – and necessarily – correspond to the specificities of the cases before and their legal systems. But the inadequacy of such approaches has become increasingly evident. As a result, states have developed national legislation and, together with international institutions and civil society networks, begun to seek international agreements. Indeed, international coordination represents the only viable solution to the individual dramas and diplomatic crises that have characterized the market in international commercial surrogacy [23, p. 117].

However, there are controversial thoughts with which is hard or even impossible to agree with. Thus, Abdullah, F.M. suggests that to preserve uniformity with the principles in international and European law, particularly the Convention on the Rights of the Child and its second protocol, and the decisions of the European Court of Human Rights, we recommend the legislators all over the world who's didn't have specific laws for surrogacy to follow the same track of other European countries by prohibiting surrogacy. As well, on the local stage, the rejection to permit the registration of the child born from surrogacy will terminate this issue since it would work effectively as an obstacle and would radically terminate the surrogacy business and exploitation against women and children [24, p.5].

CONCLUSIONS

The experience of surrogate motherhood legal support in Ukraine is considerable. In most European countries surrogate motherhood is prohibited as one that is contradict with the moral principles of society. This, in turn, creates situations of conflict, when foreigners, that have used ART, becomes subject of criminal prosecution while taking their newborn child to motherland, which leads to the engagement of international cooperation in criminal proceedings.

Taking into account extensive experience of surrogacy in Ukraine (18 years), it is possible to state that such phenomenon gives rise to controversial moral and legal discussions on the foreigners' use of Ukraine as a "facility" for surrogacy. This controversy is also confirmed by the practice of the ECHR in cases of Saenz and Saenz Cortes v. France and D. and Others v. Belgium. However, if we will look at this problem from the reproductive rights' perspective, we can conclude that surrogate motherhood often is the only opportunity to realize the right to have a genetically native child. This is the main argument and moral basis for the parents' appeal to the ECHR.

According to the mentioned above, it follows that the problematics of the international cooperation in criminal proceedings involving ART application also lie outside the scope of criminal proceedings alone, resulting in waste of time, funds and human resources in some countries' proceedings. Moreover, European countries have accepted a unified approach, according to which ART is a method of treatment, and newborns are full-fledged citizens according to "jus sanguinis". However, it is essentially important to admit that material law is primary here. The optimal way to solve the issues of foreigners opting for surrogacy in Ukraine for the sake of avoiding criminal proceedings in Ukraine and abroad is to provide for all countries a unified approach to understanding that ART technology is a method of treatment. And that countries of Europe, where surrogate motherhood is prohibited, should freely recognize parental rights of individuals, who have used or applied method of surrogate motherhood, and the rights of newborns to adopt the citizenship of their parents.

REFERENCES:

1. Simeinyi kodeks Ukrainy: Zakon Ukrainy [Family Code of Ukraine: Law of Ukraine] № 2947-III. vid 10.01.2002 Available from: https://zakon.rada.gov.ua/laws/show/2947-14#n594 [reviewed 2019.09.10] (Ua)
2. Inhorn MC. Globalization and gametes: reproductive 'tourism,' Islamic bioethics, and Middle Eastern modernity. Anthropology & Medicine.2011; 1(18): 87–103 doi: 10.1080/13648470.2010.525876
3. Ferraretti AP, Pennings G, Gianaroli L et al. Cross-border reproductive care: a phenomenon expressing the controversial aspects of reproductive technologies. Reprod Biomed Online. 2010; Feb;20(2):261-266. doi: 10.1016/j.rbmo.2009.11.009.
4. Inhorn MC, Patrizio P. Rethinking reproductive "tourism" as reproductive "exile". Fertility and Sterility. 2009; 3 (92):904–906 doi:10.1016/j.fertnstert.2009.01.055
5. Chia-Ting S. Reconsider contemporary capitalism through reproductive tourism. Vestnik of Saint Petersburg University. Sociology, 2019; 1 (12): 36–50. doi:10.21638/spbu12.2019.103
6. Van Beers B. Is Europe `giving in to baby markets?` reproductive tourism in Europe and the gradual erosion of existing legal limits to reproductive markets. Medical Law Review. 2015; 1(23):103–134. doi:10.1093/medlaw/fwu016
7. Yadav R, Anand S. Commercial surrogacy: legal, social, ethical issues. Journal of Legal Studies and Research. 2018; 5 (4): 290-300. Available from: https://jlsr.thelawbrigade.com/wp-content/uploads/2018/10/Richa-Sonali.pdf [reviewed 2019.09.10]
8. Qiu R-Z. Sociocultural dimensions of infertility and assisted reproduction in the Far East. In: Medical, Ethical and Social Aspects of Assisted Reproduction (2001: Geneva, Switzerland) Current practices and controversies in assisted reproduction : report of a WHO meeting / editors, Effy Vayena, Patrick J. Rowe and P. David Griffin. p. 75-80.
9. Luna F. Assisted reproductive technology in Latin America: some ethical and sociocultural issues. In: Medical, Ethical and Social Aspects of Assisted Reproduction (2001: Geneva, Switzerland) Current practices and controversies in assisted reproduction : report of a WHO meeting / editors, Effy Vayena, Patrick J. Rowe and P. David Griffin. P. 31-40.
10. Case of Mennesson v. France, application no 65192/11, judgment 26 June 2014 Available from: https://hudoc.echr.coe.int/eng?i=001-145389 [reviewed 2019.09.10]
11. Case of Labassee v. France application no 65941/11, judgment 26 September 2014 Available from: https://hudoc.echr.coe.int/eng?i=001-145180 [reviewed 2019.09.10] (Fr)

12. Bala N. The Hidden Costs of the European Court of Human Rights' Surrogacy Decision. The Yale Journal of International Law 2016; 40: 11-19. Available from: https://cpb-us-w2.wpmucdn.com/campuspress.yale.edu/dist/8/1581/files/2016/09/bala-proof-v-1-pdf-xqn5h2.pdf [reviewed 2019.09.10]
13. The Belgian authorities did not breach the Convention in carrying out checks before allowing a child who had been born in Ukraine to a surrogate mother to enter Belgium. Press Release issued by the Registrar of the Court. ECHR 252 (2014) 11.09.2014. Available from: https://hudoc.echr.coe.int › app › conversion › pdf [reviewed 2019.09.10]
14. Case of Braun v. France, application no. 1462/18, judgment of 4 January 2018 Available from: http://hudoc.echr.coe.int/fre?i=001-182515 [reviewed 2019.09.10]
15. Case of Saenz and Saenz Cortes v. France application no. 11288/18 judgment of 2 March 2018 Available from: http://hudoc.echr.coe.int/fre?i=001-182516 [reviewed 2019.09.10]
16. Case of Maillard and Others v. France application no. 17348/18 judgment of 10 April 2018 Available from: http://hudoc.echr.coe.int/fre?i=001-183942 [reviewed 2019.09.10]
17. Case of Schlittner-Hay v. Poland application nos. 56846/15 and 56849/15 Available from: http://hudoc.echr.coe.int/fre?i=002-12393 [reviewed 2019.09.10]
18. Kryminalnyi protsesualnyi kodeks Ukrainy: Zakon Ukrainy [The Criminal Procedure Code of Ukraine: Law of Ukraine] № 4651-VI vid 13.04.2012 Available from: https://zakon.rada.gov.ua/laws/show/4651-17#n4211 [reviewed 2019.09.10] (Ua).
19. Leibetseder D, тGriffi G. Queer and Trans Reproduction with Assisted Reproductive Technologies (ART), in Europe. Journal of International Women's Studies. 2018; 20(1): 1-9. Available from: htts://vc.bridgew.edu/jiws/vol20/iss1/1 [reviewed 2019.09.10]
20. Deonandan R, Green S, Van Beinum A. Ethical concerns for maternal surrogacy and reproductive tourism. Journal of Medical Ethics. 2012; 38:742-745 doi:10.1136/medethics-2012-100551
21. Whittaker A. Challenges of medical travel to global regulation: A case study of reproductive travel in Asia. Global Social Policy. 2010; 10(3): 396–415 doi: 10.1177/1468018110379981
22. Pennings G. Legal harmonization and reproductive tourism in Europe. Human Reproduction. 2004; 12 (19): 2689–2694. doi:10.1093/humrep/deh486
23. Ergas Y. Babies without borders: human rights, human dignity, and the regulation of international commercial surrogacy. Emory International Law Review. 2013; Vol. 27: 117-188. Available from: http://law.emory.edu/eilr/content/volume-27/issue-1/articles/babies-without-borders.html [reviewed 2019.09.10]
24. Abdullah F.M. Legal and Ethical Aspects beyond Commercial Surrogacy: Modern Form of Human Trafficking. Journal of Legal, Ethical and Regulatory Issues. 2019; 22 (S1): 1-7. Available from: https://www.abacademies.org/articles/legal-and-ethical-aspects-beyond-commercial-surrogacy-modern-form-of-human-trafficking-7858.html [reviewed 2019.09.10]

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REVIEW ARTICLE
PRACA POGLĄDOWA

REPRODUCTIVE RIGHTS VIOLATIONS: FORCED STERILIZATION AND RESTRICTION OF VOLUNTARY STERILIZATION

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ABSTRACT

Introduction: realization of reproductive rights is a relevant medical, social and legal problem in modern society. It is due to unfavorable demographic situation in almost all European countries, overcrowding problems in Asian countries, religious and moral oppression against persons, who do not wish to realize their right to reproduction.

The aim: To define problems related to the protection of the right to reproduction and to develop propositions to improve the prevention and fight against forced sterilization and restrictions on voluntary sterilization.

Materials and methods: The research is based on theoretical basis, which includes scientific articles, legislation reviews, reports of non-governmental organizations, as well as empirical basis – 3 judgements of the ECHR, international legal acts and directives, based on the analytical data of the World Health Organization. Systematic, structural, functional and legal comparative methods, as well as systematization, analysis and synthesis, were crucial in the research process.

Conclusions: Nowadays, it is possible to distinguish such types of sterilization in the world as voluntary and forced ones. Forced deprivation of the right to reproduction is a serious criminal offense that still takes place in modern society. Violations in the form of restricting voluntary sterilization have more latent nature and are not sufficiently regulated by legislation. Forced sterilization requires greater effectiveness in combating both at the national, and at the international level. Voluntary sterilization, as a method of contraception, requires clear regulation at the legislative level and the development of uniform principles and standards, both in national and in international law, in order to preclude restrictions in freely disposing reproduction function.

KEY WORDS: reproductive rights, reproductive rights violations, forced sterilization, voluntary sterilization

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INTRODUCTION

Human rights and freedoms in modern civilized society must have the highest and most reliable level of protection. A human being, his life and health, honor, dignity and safety are the most important social values in any democratic state. One of the inherent natural human rights that he has since the birth is the right to reproduction of his kind. Non-interference with human reproductive activity is guaranteed by constitutional regulations, provisions of international legal acts and belongs to the sphere of his private life.

The issue of sterilization, both voluntary and violent, is one of the most difficult issues in the realization of human reproductive functions. If a person consciously and freely chose medical intervention that makes it impossible to exercise the reproductive function in the future, he may need protection from religious and moral condemnation and oppression. In case if a person is sterilized by force – there is the most serious violation of his constitutional inalienable rights to life and health in accordance with the general rule.

Violations of civil rights to freely use the function of reproduction of own kind, are primarily related to the lack of efficiency, inconsistency of legal acts regulating the sphere of human sterilization, to the presence of many gaps. Overcoming these negative phenomena will make it possible to fill the reproductive rights with real content, but not to have profanity.

THE AIM

The aim:of this article is: (1) to distinguish the types of sterilization, 2) to determine the status of legal regulation of voluntary and forced sterilization at national and international levels, 3) to study the issues of legal regulation of sterilization worldwide.

MATERIALS AND METHODS

The issues of the reproductive human rights' realization are covered in the researches of Pashkov V. [1], Gutorova N. [2], Horodovenko V. [3], Lyfar A. [4], Semeniuk L. [5], Bakun O. [6], Biletska E. [7] and others. However, some aspects of legal regulation of sterilization, distinguishing of its types, grounds and problematic issue have not been the subject of thorough research. Theoretical foundations of the study include scientific articles, legislation reviews, doctrinal ideas, and views on the subject. The empirical basis of the research includes 3 judgements of the European Court of Human Rights (ECHR) and health legislation acts

of Ukraine, Belarus, Armenia, Kazakhstan, Kyrgyzstan, Moldova, Azerbaijan and others. International legal acts of the United Nations, WHO, Congressional Executive Commission on China, Open Society Foundations and others have been also used in this paper. The methodological basis of the research consists of general and special scientific methods. The dialectical method was used to define the terms of "sterilization", "forced", "voluntary" has been used in the paper. The statistical method has been applied to statistics. The formal method has been used to analyze the experience of such foreign countries as Ukraine, Armenia, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Azerbaijan, USA, China, Spain, Egypt, Japan, Australia and others. The comparative and generalization methods have been used while studying the laws of different countries and ECHR judgements. Through the use of historical and logical methods, the authors have achieved deeper understanding of the essence of the problematic, and there is an opportunity to provide more valuable recommendations for their resolution.

REVIEW AND DISCUSSION

The United Nations Conference on Population and Development was held in Cairo in 1994, focusing on the need for governments to increase their attention to human rights to reproduction of own kind. It has been emphasized that married couples as well as single (unmarried) persons have the right to resolve issues relating to their reproductive rights and behavior in terms of not using discriminatory, coercive and violent methods for them [8].

The key topic of medical ethics, which is reflected in human rights law, is the principle of autonomous, full, free and informed decision-making by an individual. Guaranteeing the ability to make independent decisions about one's reproductive rights is one of the manifestations of respect for dignity and respect for the physical and mental integrity of individuals. The very fact of legal regulation of the issues of freedom to reproduce own kind at the international level indicate on its importance and the need to improve the mechanisms of its protection.

Sterilization (defertilization) is the most radical solution for refusing from reproduction. It can be voluntary and forced.

Sterilization is a medical operation that is aimed at the loss of fertility which could be achieved by: 1) surgically removing or profoundly inhibiting the function by other methods (e.g., irradiation) of genital glands (testes) in men (castration) and ovaries in women (ovariectomies); 2) by ligation or removal of the tracts, through which man's sperm moves (vasectomies) and woman's uterine tubes (salpingectomies).

Any person has the possibility to choose whether to be sterilized or to refuse from sterilization. Nowadays, voluntary sterilization becomes more widespread and is one of the methods of family planning.

Sterilization, in general, can be divided into types depending on the will of an individual, to whom it is applied.

Forced sterilization is a medical operation that is carried out without the will (with its disregard) of an individual. These are intentional actions of one person against another one, which violate the rights and freedoms of the victim, causing him physical, moral or mental harm.

In turn, forced sterilization can be divided into the types according to the range of persons, to whom it is applied (sterilization of national minorities, sterilization of persons having mental or physical disabilities and prisoners, sterilization of the poorest segments of population in overcrowding countries).

Forced sterilization of national minorities is the most common type of deprivation of fertility caused by the purpose of genocide of a particular nationality.

The law on forced sterilization as the method that prevents the transmission of hereditary features to future generations was for the first time adopted in Indiana (USA) in 1907. There was forced sterilization of the indigenous population – the Indians in America until the 1970s. It was performed by physicians on behalf of the Indian Health Service. Sterilization of the Indians was carried out without their consent. For example, Jean Whitehorse of the Navaho tribe was sterilized during the surgery for appendicitis. She found out that she would no longer be able to give birth in a few years. According to Professor Brightman's research, 10% of men and 42% of women indigenous persons in the US were forcibly sterilized [9].

The ECHR in 2009 has heard the case of K.H. and others v. Slovakia. Eight Slovak Roma women found that they could not become pregnant after caesarean operation. Suspecting that they had been sterilized without their consent, they filed a complaint for two Slovak hospitals [10]. In 2011, the ECHR heard the case of V.S. v. Slovakia, where it established the fact of forced sterilization because of the applicant's belonging to ethnic minorities – the Roma. The applicant was forced to sign an agreement for sterilization during the second childbearing, threatening that the next child or she would die during the third pregnancy, without explaining that the procedure was irreversible. After sterilization, she was expelled from the Roma society and divorced for her infertility [11].

Nowadays, mass forced sterilization of Uighurs – ethnic Turkic-speaking minorities, is now being applied in China under the auspices of the government. An Uighur woman, Mehrigul Tursun, testified in November 2018 at the Congressional Executive Commission on China about the tortures that had been committed against her. In 2019 she called for the international community to draw attention to forced sterilization at the Amnesty International conference in Tokyo. She testified that she and other Uighur women were forced to use unknown drugs. After that the victims did not have menstruation for a long time or forever. Those drugs also caused some women to have severe bleeding as a result of which they died. Mehrigul Tursun, after arriving to the United States, has undergone a full medical examination, which confirmed that she could never have children as a result of sterilization [12].

This type of forced sterilization in criminal legislation of different countries is envisaged as the most serious crime that has severe punishment. But if some instances of forced sterilization have the liability and punishment of certain individuals, then mass government-sanctioned sterilizations are still unpunished.

Sterilization of persons with mental or physical disabilities and prisoners is a form of deprivation of the reproduction possibility that is tried to be justified by the interests of both those indi-

viduals and the whole society. For example, surgeries in Japan were conducted for persons with disabilities, according to the law that was in force until 1996. The Ministry of Health and Welfare (MHW) issued guidelines in 1953, which stipulated that a surgery could be performed against the patient's own will: it was allowed to restrict the patient's movements, to inject the anesthetic, or deceive a patient, if deemed necessary by the commission. These provisions in the early 1950s allowed forcible and fraudulent sterilization, which was a common practice. These sterilizations were often performed not by fixation of the fallopian tube, but by hysterectomy, because the purpose of the surgery was not only to sterilize, but also to stop menstruation to facilitate the care of women in prisons and hospitals. According to statistics, 16,520 sterilizations were performed from 1949 to 1994 without patients' consent. 11 356 of them were conducted to women and 5 164 to men. The youngest known patients were only 9 or 10 years old. About 70% of cases were related to women or girls [13]. In 2019, Japanese Prime Minister Shinzō Abe apologized to victims of forced sterilization and promised to pay compensation for them.

The laws of different countries (e.g. Spain) allow the sterilization of minors with serious intellectual disabilities [14, p. 64]. The Egyptian Parliament does not prohibit the use of sterilization as a "treatment" for psychiatric illness [15]. On October 23, 2012 a case was sent to the ECHR concerning the sterilization of five young women with mental illness for contraception who worked at the local vocational center. They stated that sterilization without their consent resulted in interference with their physical integrity, and claimed that their right to respect the privacy and their right to family had been violated [16].

There is the world practice, when decisions about sterilization of minors and incapable adults are commonly made by parents or guardians. Guardianship is abused in many countries. Wards are extremely vulnerable to the threat of forced sterilization since they are deprived from the right to refuse medical procedures.

This type of forced sterilization is characterized by the presence of a number of legal acts of a medical nature that allow such restriction of patients' reproductive rights. Although, the existence of such norms in today's world seems to be unethical and immoral. At the same time, criminal norms do not have a clear mechanism for regulating and protecting the impartial and unhelpful consent of guardians and parents to sterilize persons with immaturity.

Sterilization of the poorest population in the overcrowding countries is a violent contraceptive measure applied more to women and allows authoritarian governments to control the population rate in the country.

Women living in India, Peru, South Africa and other underdeveloped countries are sterilized without their consent to implement government programs to control population rate. They are sterilized during other obstetrics and gynecology procedures, in particular caesarean operation. These women are either not informed at all about what was done to them, or misinterpret after surgery that the procedure was mandatory, "it saved the life".

The Report (Policy Report for Open Society Foundations) found out that physicians in the East, in autocratic Uzbekistan, sterilized a lot of women without their consent, usually during caesarean operations, to implement a family planning government program. Women returned to consciousness after caesarean operations in many of these cases and found out that they had been sterilized and had not even been asked about that. For example, a 34-year-old mother of two children in Bukhara, has undergone a routine examination, when her gynecologist suggested her to ligate fallopian tubes. The physician told her that the procedure was reversible and that he would be able to loose the "fallopian tube" at any time. The woman signed the consent form and underwent the procedure. In one year, both of her children died in a car crash. A few years later, she got married again, returned to her gynecologist and asked him to "loose the tubes" so she could give birth. The physician told her that it was impossible. The woman's second husband left her because she was infertile. Four months after their divorce, she committed suicide [17].

Because of these consequences the UN Committee on Human Rights recognizes forced sterilization as a violation of the right not to be subjected to torture, cruel, inhuman or degrading treatment or punishment, and calls on countries to take specific measures in combating such practices. Forced sterilization is so severe and discriminatory that it falls under the international legal definition of torture. The UN Special Rapporteur on the Right to Health notes that regulations and legislation that authorize treatment types without patient's consent ... including sterilization ... violate the right to physical and mental integrity and may constitute an act of torture and ill-treatment [18].

The opposite concept of forced sterilization is *voluntary sterilization,* which is a medical operation that is carried out on a voluntary, informed and volitional initiative or with the consent of the person.

First of all, a type of voluntary sterilization is *therapeutic or healing* sterilization. In case of surgical treatment of tumors or other pathological conditions that are not amenable to other treatment, sterilization can be a side effect. However, the main aim is to save lives and health, but not to deprive a person of fertility. Such sterilization will be voluntary only if a patient is fully aware of the possible treatment options and their consequences, as well as his or her consent.

Another type of voluntary sterilization is *sterilization for the purpose of contraception*. Many young people in today's world use sterilization for this purpose.

Amy Blackstone, professor of sociology at the University of Maine, distinguishes the specific reasons for refusing from reproductive rights. For example, the increase of costs for childbirth and child support, striving of independence and spontaneity, the freedom to travel, many childfree couples want to focus solely on the relationships they already have, etc. [19].

Besides, sterilization is attractive to many couples as a family planning event. After the birth of the desired number of children, one parent or both are sterilized.

Taking into account the complex moral and ethical aspect, this type of voluntary sterilization is criticized in many countries around the world. Contraceptive sterilization is called immoral because it permanently deprives a person of reproductive function. There is negative attitude towards voluntary contraceptive

sterilization by the representatives of religion. Pope Francis said in 2015 that choosing not to have children is selfish.

The Catholic and Orthodox churches have a negative attitude towards voluntary sterilization, considering it a loss to the integrity of the human personality. In terms of religion, any law that allows sterilization is objectively and morally criminal and morally perverted [20, p.277]. According to the Catholic doctrines enshrined in official documents, sterilization is absolutely forbidden by the Catholic Church. Protestantism does not contain such radical prescriptions and notes that it is a matter of married couple and, even, of a woman, when it comes to female sterilization. Jewish religious morality also allows only female sterilization. Islam permits sterilization with the mutual consent of the married couple and if such a measure is psychologically beneficial to them. The attitude towards voluntary sterilization may be different at the state level. For example, sterilization is illegal in Iran. The right to voluntary sterilization in Australia has emerged relatively recently. The Australian Medical Association (AMA) until 1971 recognized this procedure as being contrary to law and ethics. Although facts demonstrate that some physicians have secretly conducted such surgeries since 1930s. Only following the example of Britain, voluntary contraceptive sterilization has been officially authorized in Australia since 1972. Voluntary contraceptive sterilization was illegal in France until 2001.

There are some restrictions on voluntary sterilization in many countries.

According to the venue: it is allowed only in state institutions (in legislation of Moldova [21], Armenia [22], Belarus [23]); it is allowed both in state and non-state medical institutions (in the legislation of Azerbaijan [24]); it is allowed even to individuals who are involved in private medical practice, having the license to carry out this activity (in the legislation of Kazakhstan [25]).

According to the patient's age: voluntary sterilization is allowed only for adults (legislation of Armenia [22] and Kirghizia [26]); voluntary sterilization is only permitted to persons at the age of at least 35 years or who have at least 2 children (in the legislation of Belarus [23] and Kazakhstan [25]).

Besides, a married woman in Tajikistan must obtain her husband's consent for sterilization [27]. Kirgizia and Tajikistan require compulsory medical and social counseling [26] and mandatory prior notification of the irreversibility of this surgery [27].

At the same time, the legal status of voluntary sterilization is still unclear in dozens of countries. For example, the Article 281 of the Civil Code of Ukraine states that the application of sterilization is performed for adults at their request, and the Article 49 of the Basics of Ukrainian Legislation on Health Care specifies that it is performed only under medical indications. In fact, voluntary sterilization as a mean of contraception is not legally envisaged in Ukraine [28]. On the contrary, some countries such as Uzbekistan, grant citizens with an unlimited right to make independent and responsible decisions about the number, time and mode of birth of their children, and to deal independently with their sexual and reproductive rights [29].

CONCLUSIONS

In modern world the right to freely dispose own reproductive rights must be based on fundamental constitutional principles and must be protected by the regulations of the relevant branches of law, in particular, criminal law. The lack of uniform principles and standards for the realization of the right to reproduction at the international level causes absolute insecurity of subjects who are either limited or deprived of the opportunity to choose the desired option of realizing their own reproductive rights. The current legislation does not fully ensure the conditions and opportunities for realizing person's right to reproduction in various countries.

Forced sterilization is introduced in many criminal codes and laws as a criminal offense. It imposes a duty for States to combat such a phenomenon. Recognition of forced sterilization as tortures, obliges the international community to intensify the fight against it both at international and national levels.

Instead, voluntary sterilization, as a measure of contraception is either not regulated at all or regulated only partially in many countries. Besides, legislation's regulations of different countries provide certain restrictions or prohibitions on voluntary sterilization. Voluntary sterilization as a method of contraception requires a clear regulation at the legislative level and development of uniform principles and standards, both within national and international law in order to eliminate the restrictions to freely use the reproduction function.

It is appropriate to use the legislation experience of those countries, where the regulations contain progressive approaches in guaranteeing the person's freedom of choice to exercise his or her own reproduction function. First of all, to entrench mandatory consultation before the sterilization procedure at the legislative level, which may highlight the advantages and disadvantages of the procedure, its risks and side effects. The person's age and level of education must be also taken into account. The information should be provided in a language understandable to the patient, either verbally or in writing. If persons have hearing or visual defects, they must be provided with hand language or Braille script. Reaching of particular age, preferably 25 years, should be also a mandatory prerequisite for voluntary sterilization as a mean of contraception. Any other restrictions must be regarded as a restriction of the right to free choice while realizing the right to reproduction. Persons guilty of forced sterilization should be also prosecuted for this grave crime against human health.

REFERENCES

1. Pashkov V., Olefir A. Protection of children's rights in the health care: problems and legal issues. Wiad. Lek. 2017;70(6 pt 1):1122-1132.
2. Pashkov V., Hutorova N., Noha P. Reproductive function: the protection of the rightsof the people wich are sent to the area of the fighting. Wiad. Lek. 2018; LXXI (2):403–407
3. Horodovenko V., Pashkov V., Udovyka L.: Protection of patients' rights in the European Court of Human Rights. Wiad. Lek. 2018;6:1200–1206.
4. Pashkov V., Lyfar A. Assisted reproductive technologies: the problems of legal enforcement. Wiad. Lek. 2018;5: 1066-1070.
5. Semeniuk L., Likhachov V. et al. Risk markers of reproductive loss in women with hyperandrogenism. Wiad. Lek. 2018;71(8):1550-1553.

6. Bakun O., Yurkiv O. et al. The level of some hormones in the blood women with endometriosis which associated with infertility. Wiad. Lek. 2019;72(4):654-656.
7. Biletska E., Onul N. et al. Current tendencies in the nutrition of women and pregnant women of industrial region of Ukraine and their influence on microelements supply. Wiad. Lek. 2018;71(4):843-848.
8. International conference on population and development (ICPD) Cairo, Egypt 5/13/1994. Available from: https://www.unfpa.org/sites/default/files/pub-pdf/icpd_rus.pdf [reviewed 2019.09.11]
9. 18th UN Permanent Forum on Indigenous Issues (UNPFII 18) Intervention by Jean Whitehorse on the forced sterilisation of Indigenous women. Available from: https://papersmart.unmeetings.org/media2/21491534/aimw.pdf [reviewed 2019.09.11]
10. Case of K.H. and others v. Slovakia, application no. 32881/04, judgment of 06 November 2009 Available from: http://hudoc.echr.coe.int/eng?i=001-92418 [reviewed 2019.09.11]
11. Case of V.C. v. Slovakia, application no. 18968/07 Available from: https://www.refworld.org/cases,ECHR,4a648cb42.html [reviewed 2019.09.11]
12. China's Forced Sterilisation of Uighur Women Is Cultural Genocide. The Heritage Foundation 2019. Available from: https://www.heritage.org/asia/commentary/chinas-forced-sterilisation-uighur-women-cultural-genocide [reviewed 2019.09.11]
13. Eugenic Sterilisations in Japan and Recent Demands for Apology: A Report Takashi Suchiya, M.A. Lecturer Department of PhilosophyOsaka City University. Available from: https://www.lit.osaka-cu.ac.jp/user/tsuchiya/gyoseki/paper/JPN_Eugenics.html [reviewed 2019.09.11]
14. Peláez Narváez A., Martínez Ríos B., and Leonhardt Gallego M. Maternidad y Discapacidad (Comité Representante de Personas con Descapacidad, Barclays Fundación, Ediciones Cinca, 2009), 64 p.. Available from: http://sid.usal.es/idocs/F8/FDO21028/maternidad_discap.pdf [reviewed 2019.09.11]
15. Mental Disability Advocacy Center, "New Mental Health Law for Egypt," May 18, 2009. Available from: http://www.mdac.info/node/185 [reviewed 2019.09.11]
16. Reproduktivni prava. YeSPL: Ukrainskyi aspect [Reproductive rights ECHR: Ukrainian Aspect] 2018 Available from: https://www.echr.com.ua/publication/reproduktivni-prava/ [reviewed 2019.09.11] (Ua)
17. Forced Sterilisation of Women in Uzbekistan. Policy Report Open Society Foundations. 2013. Available from: http://www.opensocietyfoundations.org/sites/default/files/sterilisation-uzbek-20131212.pdf [reviewed 2019.09.11]
18. Against her will. Forced and coerced sterilisation of women worldwide. Open Society Foundations. Available from: https://www.opensocietyfoundations.org/uploads/62505651-2c58-4c12-a610-46499e645a2c/against-her-will-20111003.pdf [reviewed 2019.09.11]
19. Dr. Amy Blackstone. Childfree by Choice: The Movement Redefining Family and Creating a New Age of Independence. - Hardcover., 2019
20. Sgrechcha E., Tambone V. Bioetika. Bibleysko-bogoslovskiy institut sv. apostola Andreya [Bible and Theological Institute of St. Andrew]. Moscow. 2002. 434 p. (Ru)
21. Ob ohrane zdorov'ya: Zakon respubliky Moldova [About health care: Law of the Republic of Moldova] №411-XIII ot 28/03/1995 Available from: http://base.spinform.ru/show_doc.fwx?rgn=3461 [reviewed 2019.09.11] (Ru)
22. :O reproduktivnom zdorov'e i reproduktivnyh pravah cheloveka: Zakon respubliki Armeniya [On Reproductive Health and Human Reproductive Rights: Law of the Republic of Armenia] 11/12/2002. Available from: https://www.arlis.am/documentview.aspx?docid=63870 [reviewed 2019.09.11] (Ru)
23. O zdravoohranenii: Zakon respubliki Belarus [On healthcare: the law of the Republic of Belarus] № 2435-XII 18/06/93 Available from: http://pravo.by/document/?guid=3871&p0=v19302435 [reviewed 2019.09.11] (Ru)
24. Ob ohrane zdorov'ya: Zakon Azerbaidzhanskoy respubliky [About Health Protection: Law of the Republic of Azerbaijan] 26/06/1997 №360-IQ.. Available from: http://base.spinform.ru/show_doc.fwx?rgn=5809 [reviewed 2019.09.11] (Ru)
25. O zdorov'e naroda i sisteme zdravoohraneniya: .Kodeks Respubliky Kazahstan [on people's health and healthcare system: code of the Republic of Kazakhstan] 1/09/2009 №193-IV Available from: https://www.pavlodar.com/zakon/?dok=04444&all=010002 [reviewed 2019.09.11] (Ru)
26. O reproduktivnyh pravah grazhdan I garantiyah ih realizatcii: Zakon Kirkizskoy respubliki [On Reproductive Rights of Citizens: Law of the Kyrgyz Republic] 4/06/2015 № 148. Available from: http://cbd.minjust.gov.kg/act/view/ru-ru/111191 [reviewed 2019.09.11] (Ru)
27. Ob ohrane zdorov'ya naseleniya: Zakon respubliky Tadzhikistan [On public health: the law of the Republic of Tajikistan] № 41915/05/1997. Available from: http://base.spinform.ru/show_doc.fwx?rgn=2296 [reviewed 2019.09.11] (Ru)
28. Osnovy zakonodavstva Ukrainy pro ohoronu zdorov'ya: Zakon Ukrainy. [Fundamentals of Ukrainian legislation on health care: the law of Ukraine] №2801-XII. 19/11/1992. Available from: https://zakon.rada.gov.ua/laws/show/2801-12 [reviewed 2019.09.11] (Ua)
29. Ob ohrane reproduktivnogo zdorov'ya grazhdan: Zakon respubliky Uzbekistan № ЗРУ-528, 11/03/2019, Available from: https://regulation.gov.uz/ru/document/9 [reviewed 2019.09.11] (Ru)

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REVIEW ARTICLE
PRACA POGLĄDOWA

PRESUMPTION OF CONSENT IN THE ECHR PRACTICE AND LEGAL SYSTEMS: LEGAL MODELS FOR ORGAN REMOVAL FOR TRANSPLANTATION

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ABSTRACT

Introduction: Post-mortem organ donation is widely used and poses a problem for transplant specialists and lawyers, whose task is to provide legal support for the removal of organs of the deceased.
The aim: of the article is the scientific search for the optimal legal model of organ removal for transplantation.
Materials and methods: The theoretical base of the research consists of the works of Bonnie F., Dakhno I.N., Erin C., Evans R., Kevorkian J.A., Price D., Richardson R., Reriht A.A. The empirical base includes the results of the opinion poll and the analysis of the ECHR practice. Formal-logical (dogmatic) method, comparative legal method, logical-semantic method, generalization and modelling techniques are used.
Conclusions: To improve the legal regulation of transplantation it is necessary to improve the legal literacy; create effective mechanisms to protect the patients' and doctors' rights; increase the information and scientific support of transplantation.

KEYWORDS: transplantation, organ transplantation, «presumption of consent»

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INTRODUCTION

Post-mortem organ donation covers 90-95% of transplant services demands in different countries and thus poses a problem not only for transplant specialists but also for lawyers, whose task is to provide legal support for the removal of organs of the deceased. The development of the law governing posthumous organ donation puts the legislator in a difficult position. On the one hand, it is necessary to ensure human rights to the autonomy of the body and its respect after death, on the other – to create an effective legal model of the system of removal of cadaverous organs. Thus, the legislator must pass between the wall of the accusations of "pseudo-Democrats" and so-called "human rights" in the lack of respect for "universal values" and the sick, the dying an agonizing death from an incurable disease without a possibility to be saved by donors' organs [1, p. 21]. All the above-mentioned factors determine the relevance of the research topic.

THE AIM

The purpose of the article is the scientific search for the optimal legal model of organ removal for transplantation, considering the practice of the ECHR and the legislation of countries with different legal systems.

MATERIALS AND METHODS

Research methods are chosen according to the aim of the article. Both general and special scientific methods are used.

The formal-logical (dogmatic) method was used to interpret certain provisions of current Ukrainian legislation, foreign legislation and international legal acts. The comparative legal method was applied in foreign experience studying of the legal regulation in the field of transplantation. The logical-semantic method was applied to interpret and distinguish basic concepts and some scientific categories. Generalization and modelling techniques have been used to examine existing regulation practices in the field of transplantation.

The theoretical base of the research is papers of Bonnie F., Dakhno I.N., Dubovik O.L., Erin C., Evans R., Kevorkian J.A., Price D., Richardson R., Reriht A.A. The empirical base includes the results of the opinion poll and the analysis of the ECHR practice.

REVIEW AND DISCUSSION

A serious obstacle to postmortem organ donation is people's lack of confidence that death will be diagnosed accurately and will not be accelerated specifically to obtain the necessary organ.

Thus, one of the most important tasks faced by the legislators of many countries is to consolidate the rules of law to regulate the necessary actions and conditions for the accurate diagnosis of human death, taking into account the latest achievements in Biomedicine. In search of the optimal legal model it is necessary to refer to the existing

experience. The analysis gives us the basis to allocate four main approaches to removal of bodies of the dead for transplantation regulation:
1) routine transplantation;
2) forcible removal from persons sentenced to death;
3) the removal of organs based on "consent" (the "presumption of disagreement") of the deceased during his life (partial agreement – no doubt agreement) or his next of kin after the donor's death (full consent procured (simplified) consent»;
4) removal of organs based on the" presumption of consent " of the deceased, that is, his alleged consent.
So, what is the meaning of routine transplantation as a method of organ removal?
According to experts, this method is the most beneficial in terms of ensuring the needs of transplantology, but at the same time from a legal point of view has significant gaps, since the removal of the organs of the deceased only the permission of the medical administration and, in criminal cases, the forensic expert and the Prosecutor is required. This does not take into account the will of the deceased or his relatives, which grossly violates the human rights to autonomy and integrity of his body and respect for him after death. The basis of the ideology of this organs removal system is the belief that the corpse belongs to society. The legal basis of this system is usually not laws, but by-laws as it was, for example, in the USSR before its collapse and in several countries of the "socialist camp".

Advanced democracies have rejected the method of routine organ removal for transplantation purpose because a person has the right to express his or her will about his or her body after death, or the right is transferred to the relatives of the deceased (the so-called "next of kin").

Only in China, through the use of this method, there is a systematic removal of kidneys from sentenced criminals. However, the state authorities of China claim that the permission of the criminals themselves and their relatives for the removal of organs as compensation for the harm caused to people was obtained in advance.

In the Syrian Arab Republic according to the law this method is allows to take organs for transplantation from criminals that are convicted to the penalty. Similar approaches are used in Egypt and Taiwan [2, p. 83].

The author (A.O.) considers that this method should be legally prescribed for convicts, who have committed grave crimes in case of an them diagnosis of deadly disease, except for contraindications to this procedure.

At the same time, the review allows us to conclude that described approaches to the removal of deceased organs for transplantation are currently being used very limited and rejected by all democratic states, where there are two principal Legal models of "expressed consent" or "presumption of consent".

Each of these "models" from a legal point of view is both "strong" and "weak" depending on the will of deceased's relatives.

The "strong" model does not require any mandatory approvals of relatives of the potential donor, if there is a formal confirmation of the will of the deceased to donate their organs (for example, the so-called "donor card"), or none of the relatives of the deceased did not inform about the refusal to remove organs.

A "weak" model requires, in any case, the obligatory alignment of this procedure with of the deceased's relatives, even if there is a notarized volition of the deceased on the donation of organs.

The essence of the withdrawal system on the basis of "expressed" or "concerned" consent is that it is necessary to obtain a "pronounced" consent, issued by the deceased during the life, or the obligatory consent of relatives of the deceased on the removal of organs for transplantation (concerned consent). Under such approach one of the so-called "cards" of the donor could be used, where he expresses his willingness to donate of their organs for transplantation after the death (UK) or categorically abandon this (Denmark, Holland, Spain, Portugal, Sweden). In Belgium and Sweden these data are logged in the central computer database.

However, as a practice shows, the effectiveness of such consolidation volition was low. In particular, in 2013 in the United States the staff of the centre Gellop found that 69% of Americans are willing to donate their organs after death, but only a small part of them has a "card" of donor [3].

In the UK, 27% of the individuals has such a card, but only 1 of 5 carry it constantly with them, in the US – only 1 of 4 [4].

Even in the early 80s, many countries abandoned the system of "expressed consent" and switched to the "presumption of consent" system. For example, according to F. Stewart (1981) of 28 countries in 13 a legal model for the removal of organ transplants based on "presumption of consent" was introduced at that time. A review conducted by the Council of Europe in 1987 testified the implementation of a system based on "presumption of consent", in 21 states of the Council of Europe and also in Finland.

At the same time, it should be noted that in almost all countries with the legalized system of "expressed consent" its "strong" version implemented (Argentina, Australia, Denmark, Norway, the Philippines, Romania, Slovenia, Venezuela, Zimbabwe), "weak" version took place in United Kingdom, Japan, and Lebanon [5, p. 92].

Practically, as the literature review shows, the case went differently. According to the law in countries with a "strong" version of "expressed consent", relatives had no right to change the volition of the deceased, but the medical staff had such an opportunity (Great Britain, the USA, Australia). Thus, in most countries with the legalized "pronounced consent", the practice of the permission to relieve relative's authority, which was subsequently enshrined in the legislation of several states, was developed. Thus, for example, by the law of Germany in 1997 [6, p. 2363]. Seizure of the organ for transplantation is permitted provided that:
1) There is consent provided for life by the donor;
2) In case of absence of any written official volition of the deceased there is the consent of the close ("next kin") relative.

Similar provisions were enshrined in the legislation of Venezuela, Algeria, Sri Lanka and Turkey.

It should be noted that although the law was supposed to get the consent of relatives, but in most regulations there are no any clear instructions that would oblige someone to purposefully seek these relatives. Therefore, in some countries, these requirements have appeared in the laws much later.

The additions made to these laws partially eliminated this gap by putting the responsibility of the medical official to allow the removal of organs in the absence of volition of the deceased and the consent of relatives only in cases when they are convinced that necessary, and provided reasonable efforts of the staff were made to establish a valid will of the deceased and to search for his relatives.

Under Danish and Dutch law, the lack of direct consent of relatives prohibits the removal of organs for transplantation.

Of great interest is the law of Germany "on donation, withdrawal and transplantation of organs." The essence of this law is manifested in the fact that, acting on the basis of the model of "Express consent" doctors, in the absence of an express will of the deceased, will agree to the request of relatives, who have a certain period of time to decide whether they agree to the removal of organs of the deceased for transplantation. Relatives in such cases are formally warned that the absence of any response will be regarded as consent (although this reservation is characteristic of the presumption of the consent). Therefore, relatives, by law, must confirm their awareness. In this case, the following is of interest:" silence "of relatives can be considered as a consent by prior agreement of the parties since without a preliminary explanatory conversation, the assessment of" silence" as consent is contrary to the general rule of law.

The differentiated approach to the consideration of the above systems leads to the disclosure of the legal nature of the model of withdrawal based on the "presumption of consent".

In foreign literature, it is noted that the "presumption of the consent" approach is the "weakest link" in the legislation on transplantation of human organs of many States and serves as an occasion for discussion and well-reasoned objections. Systems based on the "presumption of consent" are often compared to routine organ removal. John. Kevorkian even expressed the view that the removal of organs based on "presumption of consent" is simply a state system of organ theft [7, p. 48].

Some authors and, in particular prof. Richardson believe that society paid dearly for failing to recognize the need of consent and that the "presumption of consent" is essentially a denial of this necessity [8, p. 78].

Erinn S., Harris J. (1999) consider the "presumption of consent" to be a legal fiction, and that without "Express" consent can be considered that it does not exist at all [9, p. 366].

At the same time, many supporters of the "presumption of consent" believe that a significant number of medical manipulations are based on the "presumption of consent" and therefore it is not a fiction, but a real consent.

Despite the revealed differences among specialists, it can be concluded that with "expressed consent" there is a real consent to the removal of organs for transplantation, and with "presumption of consent" – there are simply no identified objections.

"Strong "versions of legal models based on the "presumption of consent" legalized in Austria, France, Luxembourg, Poland, Portugal, Slovak Republic, Spain, Peru, Brazil, Singapore," weak " – in Belgium, Finland, Russia.

To date, there has been some debate as to which system of "expressed" or "implied" consent is better. No one doubts the superiority of the first in terms of moral and ethical and the second in terms of much greater opportunities to provide patients with donor organs.

Only a few authors believe that there is no correlation between the legal model of organ removal in the country and the number of organs seized.

It is very interesting that recently there has been a clear trend towards convergence of both legal models due to the fact that although "de jure" medical personnel should not actively "ask" for the consent of relatives in the presence of a "strong" version of the "presumption of consent", "de facto" this happens in almost all cases.

For example, in Spain, which has the world's most effective post-mortem organ donation system, there has been provided more than 1,500 kidney transplants in 2017.

The same trend can be seen by comparing transplantation legislation in the UK ("expressed consent") and Norway ("presumption of consent"). In the legislation of both countries for the removal of the organs of the deceased the requirements are: the "express consent" of the deceased; the absence of objections of relatives, subject to the expression of consent of the deceased.

None of these laws contain a provision on the mandatory receipt of the consent of the deceased after his death – his relatives, and in Croatia, Sweden, Norway need a mandatory family permit for transplantation. Rules for the harmonization of medical manipulation with the family or other community are adopted by States within the framework of the so-called "principle of family autonomy".

It should be noted that there are cases where both criteria are applied at the same time to establish death. For example, in accordance with Art. 2 and 15 of the Venezuelan Law "on transplantation of organs and anatomical materials of the person" receiving of donor's organs is possible from a person whose death is established on the basis of traditional criteria of clinical death (cardiac and respiratory arrest, lack of reactions to external stimuli) or complete cessation of electrical activity of the brain within 30 minutes (in persons whose vital functions are maintained artificially). You should pay attention to the fact that the Law expressly stipulates the condition that should be equated with death: it is reversible toxic, and metabolic changes caused by hypothermia [10, p. 73].

The European Convention on Human Rights (ECHR) (formally the Convention for the Protection of Human Rights and Fundamental Freedoms) is one of the basic European legal acts in many spheres, including transplantation.

Thanks to the European Court of Human Rights the Convention [11] is a "living document". The European Court in its case law concretizes, clarifies and expands the normative content of the ECHR. Examples of such solutions are used in the field of transplantation and organ donation. The study of the practice of the European Court in the field of transplantation and donation is limited to two cases.

The judgment in the first case "Petrov against the Republic of Latvia" (Petrov v. Latvia, complaint No. 4605/05) was issued in June 2014 [12]. The judgment in the second case "Alberta (Elberte v. Latvia, complaint No. 61243/08) against the Republic of Latvia" was issued in January 2015 [13]. The plots of these cases are similar in factual circumstances.

In Petrov v. Republic of Latvia, the applicant's son suffered serious injuries as a result of a traffic accident, after which he was taken to the hospital, where he underwent a craniotomy, and it was decided by doctors to remove the kidney and spleen for further organ transplantation.

The Complainant was reported to have deteriorated in her son's condition but was not approached with the consent of an organ transplant. About what happened, the applicant learned nine months later during the consideration of the criminal case on the fact of a traffic accident. Following the Complainant's complaint, the police concluded that the transplantation of her son's organs was legal under the national law and refused to initiate criminal proceedings [12].

According to the Law of the Republic of Latvia "On the protection of the body of a deceased person and use of human organs and tissues in medicine" (as of January 1, 2002), it was assumed that every person in life has the right to inform the institution in writing that he/she agrees to further removal of their organs after death. Such information is entered in the internal passport of a particular person on his consent or disagreement to the removal of organs during transplantation, this information is as well recorded in special registers. Article 11 of this Law provided that "the removal of organs and tissues from the deceased donor for further transplantation is allowed if during his lifetime he did not object to this and if his next of kin did not prohibit this removal" [14].

In her application to the European Court of justice, the applicant claimed that the case involved a violation of article 8 of the Convention concerning the removal of organs from her son without his prior consent and the prior consent of the applicant herself. The European Court concluded that in the applicant's situation there had been a violation of the right to private and family life (article 8 of the Convention). That is, the European Court recognized that interference with the right to respect for private life was not provided by law, as required by article 8 of the Convention, because Latvian law, formally granting close relatives of the deceased the right to object to the removal of his organs, which were not formulated clearly and did not provide effective protection against arbitrariness [12].

The legislation of Latvia does not provide proper notification of relatives of the deceased on the transplantation of its organs so that they could argue against it, as well as did not forbid the removal of organs without obtaining consent from the relatives if the deceased had not expressed their will. The applicant, formally having the right to object to the removal of her son's organs, was not informed of how and when she could implement it, let alone to obtain proper explanations [12].

It should be noted that in response to this situation, the Law of the Republic of Latvia "on the protection of the body of a deceased person and the use of human organs and tissues in medicine" was amended. The amendments were aimed at a clearer definition of "consent", including by close relatives. Thus, article 11 this Law establishes that "the Removal of organs and tissues from the body of a deceased person for transplantation is allowed in cases when the register of citizens of the Republic of Latvia has no information concerning the refusal of the deceased person from the post-mortem use of organs or tissues, or its consent to the procedure, and the nearest relatives of the deceased before the transplant not reported medical institution in writing of its objections to post-mortem use of organs and tissues of his body made during his lifetime. The removal of organs and tissues from a deceased child for further transplantation is prohibited unless one of his parents or his legal representative has given written consent to it" [15].

In the second case, Elberte v. Latvia, the applicant's man died in a car accident. During the autopsy at the forensic center his tissues were seized and transferred to a pharmaceutical company in Germany for the manufacture of bio implants under an approved state contract.

The Complainant alleged, inter alia, that without her consent and notification, tissue samples were taken from her deceased husband and that her husband was buried with his legs tied. The applicant learned about the seizure of tissues two years later during the consideration of the criminal case on the fact of large-scale illegal seizure of organs and tissues from the corpses [13].

The Complainant claimed that there had been a violation of article 8 of the Convention in the case, in particular, that the removal of her husband's tissues had conducted without his and her consent. She complained that in the absence of such consent his dignity his individual integrity had been violated and his body had been treated with disrespect. The Complainant also claimed that there had been a violation of article 3 of the Convention in this situation because the removal of tissue from the man's body had been carried out without her prior consent or notice, and that she had been forced to bury him with his legs tied.

Violation of the Law "on the protection of the body of a deceased person and the use of human organs and tissues in medicine" in two ECHR cases are the same.

The European Court found that the Latvian authorities had not created the legal and practical conditions that would have allowed the applicant to Express her opinion on the removal of her deceased husband's tissue and thus allowed interference in the exercise of her right to respect for private life [13].

The Latvian authorities differed on the significance of the applicable domestic legislation. The forensic medical

examination center and the Latvian police assumed that there was a system of "presumed consent", whereas the investigators believed that the Latvian legal system was based on the principle of "informed consent", and the removal of organs and tissues was possible only with the consent of the donor (during his lifetime) or his relatives. At the time when the Latvian police agreed with the interpretation proposed by the Prosecutor's office and decided that it was necessary to obtain the consent of the applicant, the Statute of limitations for criminal prosecution had already expired. Such disagreements between the authority's point to the lack of clarity of the provisions of the legislation of Latvia [13].

Concerning to compliance with article 3 of the Convention, the European Court found that apart from the grief caused by the death of a close family member, the applicant suffered without knowing why the man's legs were tied when the body was returned to her for burial. In fact, she became aware of what fabrics were seized and in what quantity only during the proceedings in the European Court.

Thus, the applicant was denied the negative consequences of the violation of her personal rights, concerning a very painful aspect of her private life, namely the right to consent to or object to the removal of her deceased husband's tissues.

Although in the highly specialized field of organ and tissue transplantation, it is generally accepted that the human body should be treated with respect even after death. Indeed, there are many international treaties, including the Convention on human rights and Biomedicine and its Additional Protocol, aimed at protecting the rights of living or dead organ and tissue donors. Moreover, respect for human dignity is one of the " trunks" of the Convention [13].

Analyzing the Ukrainian legislation in our opinion there is a substitution of "presumption of disagreement" of "presumption of consent". Currently, Ukraine has a presumption of disagreement, which is reflected in article 17 of the Law of Ukraine "on the use of transplantation of human anatomical materials" 2018 (hereinafter – the Law) [16]. " It is forbidden to remove anatomical materials for transplantation and / or production of bioimplants from a deceased person in the case of: the existence in the Unified State Information System of Transplantation of the information about the life-giving written consent for the death donation provided by such person". A logical question arises: "The absence of written disagreement is the basis for the transplantation of human anatomical materials?". The subparagraphs of this article are contradictory and may lead to conflict and abuse of law. For example, another case of a ban on the removal of anatomical materials for transplantation and/or the manufacture of bio-implants from a deceased person is the lack of consent of relatives.

If the donor-corpse has no legal representatives the deceased may be a subject of law, but not of legal relations. In this case, in our opinion, it would be logical if the interests of such a subject of law would be represented by the state, provided that there is no expressed disagreement on organ transplantation.

In case of formation in the future of judicial practice in part of Art. 17 p. 3 PP.1 of the Law there should be a mandatory procedure for informing relatives about their right to informed consent.

As for the recipients, that in article 13 [16] the Law clearly stipulates that the withdrawal of anatomic materials for transplantation and/or manufacture of bio implantation is carried out with the consent objectively proposed by capable person. In the absence of consent to the operation, the specified medical intervention is prohibited. But article 13 p. 5 of the Law provides for the case of a real threat to life (but what is meant by a real threat to life is not clear, because medical practice knows many "journal" cases of patients coming out of conditions that threaten their lives), which implies the lack of consent of the recipient to medical intervention.

It is necessary to pay attention to one more issue which will lead to the inhibition of the development of transplantation. This contradiction between the Law "fundamentals of legislation of Ukraine on health protection (article 47, 52) [17], where for the first time the definition of the concept "the moment of irreversible death" – the moment of brain death or biological death, and the Order of the MOH of Ukraine No. 821 dated 23.09.2013 "About establishment of the diagnostic criteria of brain death and the procedure of finding the death of the person" [18], changes to which had not been made. The reference rules of the order are based on the old law on transplantation and contain outdated provisions, which is unacceptable. This in turn leads to the incorrect execution of procedural actions during transplantation.

The law did not provide specifics about the order of obtaining consent from relatives and family members of the donor in case there is a list of persons defined by law or in the case of radically different views on the removal of anatomical materials. The main task of the Ukrainian legislator is to solve these conflicts. In our opinion, this is especially aggravated in cases that concern the future recipient. Regarding this, we consider it appropriate to conduct the procedure of listening to both sides in terms of validity, objectivity, the impartiality of the judge in the field of the main question: "what would be better for the life and health of the recipient?"

CONCLUSIONS

Taking into account the practice of the ECHR and the experience of other legal systems, it is necessary first of all to focus on improving the legal literacy of the population and on the peculiarities of accepting consent to the removal of human anatomical materials. This is the first point. The second point is that the improvement of legal culture is not possible without the creation of effective mechanisms to protect the rights of patients and doctors. The third one is the necessity to increase the information and scientific support of this sphere.

Despite the mixed nature of the system of removal of anatomical materials, the Ukrainian legislator prefers the

presumption of disagreement. This system requires a complex process of debugging. And the presumption of consent may be the next stage when the pyramid "Transplantation in Ukraine" will be competently and harmoniously built, will be based on the trust and law.

REFERENCES

1. Bonnie F. Medical law and Ethics. – 3rd ed., USA. 2008: 21.
2. Dakhno I.N. Istoriia krain svitu: dovidnyk [World History: A Handbook]. Kyiv: Center for Educational Literature. 2017: 816. (Ua)
3. Council on Ethical and Judicial Affairs of the American Medical Association. Strategies for Cadaveric Organ Procurement. –Joumal of the American Medical Association. 2018; 27: 821.
4. Evans R., Manninen D. US Public Opinion Concerning the Procurement and Distribution of Donor Organs. Transplantation Proceedings. 2015; 20: 791.
5. Price D. Legal and Ethical Aspects of Organ Transplantation. – Cambridge : Cambridge University Press, 2000: 118.
6. Dubovik O.L., Reriht A.A. Chelovek i medicina: pravovye, eticheskie i filosofskie aspekty [Human and medicine: legal, ethical and philosophical aspects]. Pravo I Politika [Law and Politics]. 2009;11:2361-2366. (Ru)
7. Kevorkian J.A. Controlled Auction Market us a Practical Solution to the Shortage of Transplantable Organs. Medicine and Law. 2012; 11: 51.
8. Richardson R. Fearful Symmetry in Jounger. Organ Transplantation. Meanings and Realities. University of Wisconsin Press, Madison. 2016: 74-79.
9. Erin C., Harris J. Presumed Consent or Contracting Out. Journal of Medical Ethics. 2015; 25: 393. doi: 10.1136/jme.25.5.365
10. Ley sobre trasplante de organos y materiales anatymicos en seres humanos. Gaceta Oficial. № 4.497. Extraordinario, Caracas jueves 3 de diciembre de, 2017: 79.
11. Convention for the Protection of Human Rights and Fundamental Freedoms ETS No. 005 dated 04.11.1950. Available from: https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/005. [reviewed 2019.09.15]
12. Case of Petrova v. Latvia, application no. 4605/05, judgment of 24 June 2014. Available from: http://hudoc.echr.coe.int/eng?i=001-144997. [reviewed 2019.09.15]
13. Case of Elberte v. Latvia, application no. 61243/08, judgment of 13 January 2015. Available from: http://hudoc.echr.coe.int/eng?i=001-150234. [reviewed 2019.09.15]
14. Zakon Latvijskoj Respubliki o zashite tela skonchavshegosya cheloveka [The Law of the Republic of Latvia on the Protection of the Body of a Deceased Person] dated 01.01.2002. Available from: http://www.pravo.lv/kdks_z. html. [reviewed 2019.09.15] (Ru)
15. Zakon Latvijskoj Respubliki o zashite tela skonchavshegosya cheloveka [The Law of the Republic of Latvia on the protection of the body of a deceased person] dated 30.06. 2004. Available from: http://www.pravo.lv/kdks_z.html. [reviewed 2019.09.15] (Ru)
16. Pro zastosuvannya transplantaciyi anatomichnih materialiv lyudiny: Zakon Ukrayiny [On the Application of Transplantation of Anatomical Materials to Man: the Law of Ukraine] № 2427-VIII dated 17.05.2018.. Holos Ukrayini [The Voice of Ukraine]. 2018;115. (Ua)
17. Osnovy zakonodavstva Ukrayiny pro ohoronu zdorovya: Zakon Ukrayiny [Fundamentals of Ukrainian Healthcare Legislation: the Law of Ukraine] № 2801-XII dated 19.11.1992.. Vidomosti Verhovnoyi Rady Ukrayiny [Information of the Verkhovna Rada of Ukraine]. 1993;4:19. (Ua)
18. Pro vstanovlennya diagnostichnih kriteriyiv smerti mozku ta procedury konstataciyi momentu smerti lyudiny: nakaz Ministerstva ohoroni zdorov'ya Ukrayiny [On Establishing Diagnostic Criteria for Brain Death and Procedures for Finding the Moment of Death: the Order from the Ministry of Health of Ukraine] № 821 dated 23.09.2013. http://zakon.rada.gov.ua/laws/show/z1757-13. (Ua)

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HEALTHCARE FOR MIGRANT WORKERS: HUMAN RIGHTS' ASPECT

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"Often, we mistake stability, in terms of security and economic activity, to mean a country is doing well. We forget the third and important pillar: rule of law and respect for human rights".
Kofi Annan, UN Secretary-General 1997-2006

ABSTRACT
Labor migration in a modern world is regarded as a positive and beneficial phenomenon for the growth of economic well-being[1]. However, migrant workers often find themselves vulnerable and unprotected, especially when it comes to protecting their health. The aim of the article is to clarify the role of a human rights-based approach in protecting the migrant workers' health. The basis of the study constitutes: acts of international law, expert reports and research studies, case law, scientific literature on the problem. It was found a human rights-based approach is the most applicable in the light of this problem.

KEY WORDS: migrant workers, human rights, migration, right to health, international law

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INTRODUCTION

In 2015 it was a significant event in the development of mankind – the leaders of states around the world agreed on 17 new goals, the achievement of which has become crucial for the balanced and prudent development of present and future generations. Actually, these goals are called the Sustainable Development Goals or SDGs [1]. In fact, the idea of sustainable development has taken on the mainstreaming character and is now pervading almost all spheres of public life.

Labor migration has become one of the priority areas in the achievement of the SDGs, that is absolutely obvious and justified, because in the modern world people's mobility, regardless of the cause and scale, is no longer evaluated as "background context for development, or even worse, as a by-product of lack of development". Migration, including labor, is now regarded as "a core, cross-cutting issue and an important contributor to sustainable development" and migrant workers are a "key target group for the achievement of the SDGs" [2].

THE AIM

The aim of this article is to identify the challenges that migrant workers face in terms of their health care and to analyze current approaches to understanding the right to health of migrants seeking work outside their own country.

MATERIALS AND METHODS

International migration and human rights issues discussed in the article determine the choice of the following general philosophical and legal methods. Through the use of a dialectical approach and a historical method, we have been able to understand the patterns of formation and development of perceptions of the international community and states about migration and the protection of the rights of labor migrants. The formal legal method was used while studying legal documents, and comparative legal method enabled comparing different approaches to the protection of labor migrants` human rights that are embodied in different international human rights mechanisms.

The study is mainly based on international law (6 universal and regional instruments), interpretation and explanation of human rights' treaty bodies (Committee on Economic, Social and Economic Rights, UN Committee on Labor Migrants, UN Refugee Council), expert reports and research studies, case law (3 European Court of Human Rights judgements, advisory opinion of the Inter-Amer-

[1] Relevant methods of estimating labor migration in the world are not always able to take into account migrant workers who do not have the necessary documents or permits, i.e. undocumented migrant workers. In this regard, the issue of developing and improving existing data collection mechanisms for undocumented migrant workers is urgent.

ican Court of Human Rights, decision of the European Committee of Social Rights (Council of Europe), relevant scientific literature.

REVIEW AND DISCUSSIONS

The problem of people migrating worldwide in order to find better work and higher pay has been under the scrutiny of the international community since the beginning of the twentieth century, namely – since the creation of the International Labor Organization (ILO) in 1919, the priority area of which is the promotion of equality of working migrants. Thus, Migration for Employment Convention (Revised), 1949 (No. 97) [3] established the obligation of each ratifying State to provide for immigrants lawfully within its territory the same conditions that are no less favorable than that applied to its own nationals, without discrimination in respect of nationality, race, religion or sex (Art. 6). In its Art. 5 Convention pays particular attention to the protection of the health of migrant workers: states are under a duty to assert, that migrant workers and their families, who are allowed to accompany or join them, are in reasonable health state; states are also obliged to provide them with the necessary adequate medical care and appropriate hygienic conditions at the time of their departure, during the journey and after arrival at their destination.

State obligation to respect migrant workers` human rights is the main idea of the first provision of another ILO Convention, No. 143, adopted in 1973, that particularly prohibit abuses in the field of clandestine movements of migrants for employment and illegal employment of migrant [4]. This ILO Convention No. 143 further demonstrated the need for equal protection of all migrant workers, especially since that creation of this Convention was already based on established human rights standards.

As to the United Nations level, in 1990 International Convention for the Protection of the Rights of All Migrant Workers and Members of Their Families (ICRMW) was adopted, which together with the ILO Conventions No. 47 and No. 143, mentioned above, constitutes the *international charter on migration*. ICRMW provides a broad understanding of the term "migrant worker", meaning a person who will be engaged, is engaged in, or has been engaged in remunerated activities in a country of which he or she is not a national. In this case, ICRMW distinguishes between the *regular migrant workers* (so-called "documented" migrants), who are authorized to enter, to stay and to engage in a remunerated activity in the State of employment pursuant to the law of that State and to international agreements, to which that State is a party, and *irregular migrants,* who don`t comply with these conditions (have either entered the country of employment without authorization, or have not been entitled to stay, reside and work in that country, or have an expired permit or visa, or have tourist visas, but they are engaged in remunerated activities in the country and so on). Both regular and irregular migrants enjoy all the rights, provided for in Part III of the ICRMW, which is essentially consonant with widely recognized human rights catalogue, but at the same time, irregular migrant workers are excluded from the scope of rights grouped under Part IV of the ICRMW that are primarily social-economic. For instance, with regard to healthcare Part III of ICRMW (Article 28) guarantees all migrant workers, irrespective of their legal status of residence or employment, the right to receive urgent medical assistance if their life or health are under threat.

According to Part IV of the ICRMW only regular migrant workers have: the right to social and health services (Article 45); freedom to leave the country freely without prejudice to future return (Article 38); freedom to form associations and trade unions (Article 40); the right to participate in the public and political life of the country of employment (Article 41); the right to consultation from public bodies of local communities (Article 42); access to housing (Article 43); the right to protection of the unity of the family life (Art. 44) and others. It seems that the inability of these migrant workers to enjoy their rights poses risks to their right to health. Once European Court of Human Rights (ECtHR), known for its evolutionary interpretation of human rights, in the interstate case Cyprus v. Turkey (2001)[2] [4] noted that sometimes "the authorities of a Contracting State put an individual's life at risk through the denial of health care, which they have undertaken to make available to the population generally" (para. 219). In this connection, the Court notes that paragraph 1 of Art. 2 of the Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) obliges states not only to refrain from the intentional and unlawful taking of life, but also to take appropriate steps to safeguard the lives of those within its jurisdiction.

There is almost 20 years' discussion among experts and human rights` treaty bodies about the expanding the range of rights for irregular migrant workers and about more decisive overcoming the discrimination and inequality treatment of States. The texts of international agreements on the migrant workers` status indicate that the "employment states" are the main actors in establishing the rules and determining the status of migrant workers, and that is why these "undocumented" migrant workers are placed in a potentially vulnerable light [7; 258]. They usually find themselves in situation of a "legal limbo": as human beings they are bearers of human rights, but they have limited access to enjoying of rights and remedies [7; 258]. Such situation often combined with a feeling of uncertainty that further transforms into a feeling of real danger and restriction of freedom. Moreover, often the motives for labor migration – searching for better jobs and higher wages are reinforced by other reasons that make this displacement truly forced. For instance, one of the key reasons for the labor migration of Ukrainians abroad during the last 5 years is annexation of Crimea, occupation of some regions

[2] This case concerned the issues of internal displacement as a result of military occupation of Cyprus by Turkey and armed conflict.

of Donetsk and Luhansk regions, armed conflict there and providing of anti-terrorist operation at the contact line.

Freedom from fear, freedom from want and freedom to live in dignity are the basic elements that underpin current understanding of human security. But it becomes more obvious that in the global era, promotion of human security with traditional public policies and concepts of national, military and state security are no longer effective [7; 253]. And here the human rights-based approach "may come in handy": it says that each state has three levels of positive obligations towards all human beings within its` jurisdictions – obligations to respect, obligations to protect and obligations to fulfill [8, 9]. What is the right to health from this prospect? What positive obligations do states bear in the sphere of health care? What labor migrants can count on from the point of view of human rights` positive obligations as a whole and as to the health in particular?

It is well-known that according to the Constitution of the World Health Organization, "health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" [10]. In terms of a human rights-based approach, this definition is non-informative. Today it is customary to consider one`s health not only as a desire for well-being, but also as a human right that is structurally composed of freedoms and rights (for rights bearers – natural and legal persons), as well as obligations – for obligation bearers (states and non-state actors). Everyone has the freedom to control his or her health and body, including sexual and reproductive freedom, freedom from intervention (from torture, unfair medical treatment and experimentation); at the same time, the entitlements include the right to a system of health protection, which provides equality of opportunity for people to enjoy the highest attainable level of health [11]. One should note, there are a number of human health issues as to which the regulative potential of law is limited.

After all, no country in the world can be obliged to achieve any certain result, because of objective reasons that impact on fulfilling state`s obligations, regardless of its good faith and will. [12, p. 74]. Any state can hardly promise to protect a person from any illness, to guarantee a perfect health, but it is obliged to respect the right of every person to health and to protect it against the interference of other private and state actors. Nor should we underestimate the fact that social health policy is more dependent on, and should be adequate to, the economy, but at the same time ignoring social problems can lead to significant economic losses in the future. [13; p. 49]. In this connection, according to Art. 2 (par. 1) of the International Covenant on Economic, Social and Cultural Rights of 1966 (ICESCR) all states undertake steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures. At the same time, par. 2 of Art. 2 allows "developing countries, with due regard to human rights and their national economy" to "determine to what extent they would guarantee the economic rights recognized in the present Covenant to non-nationals".

The prohibition of discrimination in the enjoyment of human rights is one of the basic principles of the human rights-based approach and is a direct and inclusive duty of any state. In its Advisory Opinion on the "Juridical Condition and Rights of Undocumented Migrants", the Inter-American Court of Human Rights (IACHR) stated unequivocally that the principle of equality and non-discrimination has entered the domain of *jus cogens*, since the whole system of "national and international law is based on this principle" (para. 101) [14]. As IACHR mentions, "the situation of vulnerability has an ideological dimension and occurs in a historical context that is distinct for each State and is maintained by de jure (inequalities between nationals and aliens in the laws) and de facto (structural inequalities) situations" (para. 112) [14]. Regarding the latter, it should be noted that states can often be constrained in their efforts to overcome discrimination by the fact that society discriminates against a particular group, which is quite often the case with migrant workers. This can be enhanced by cultural prejudices, ethnic rivalries and xenophobia, violence of distinct forms, personal insecurity [14]. However, this means that the state should be more deliberate about the implementation of the principle of non-discrimination in the horizontal dimension, i.e. between private actors [15; p. 23].

Art. 12 of ICESCR proclaims the right to the highest attainable standard of physical and mental health for all without limitation. The same approach is enshrined in the 1981 UN Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) and the 1989 UN Convention on the Rights of the Child (CRC). On the same ground the European system of protection of social rights is based, namely, the European Social Charter of 1996 (revised) (ESC). The European Committee of Social Rights (ECSR), which monitors fulfilling the provisions of ESC by states by adjudicating collective complaints, found in one of the cases the lack of access to medical assistance for children of "undocumented" migrants as a violation of social, economic and social rights of children and young people, that are protected by means of Article 17 of ESC [16].

As the UN Committee on Economic, Social and Cultural Rights (UN CESCR) explained, Art. 12 ICESCR obliges states to ensure that all migrant workers and their families, regardless of their migration status, have effective access to primary care, as well as to preventive, curative and palliative care services[11], as far as such care is urgent to preserve their life or to avoid irreparable harm to their health; here the CESCR addresses the issues of immunization of migrant children against major infectious diseases, as well as the access of women-migrant workers to safe reproductive health and abortion services, where they are at risk or after being raped, and to emergency obstetric care [11].

Consolidating all abovementioned and taking into account human rights` -based approach, in the field of health

care the state is obliged : 1) *to respect*, which requires states to refrain from direct or indirect interference with the right to health (to refrain from denying or limiting access to health-care services; withholding, censoring or misrepresenting health information and violating the right to privacy (e.g. of persons living with HIV / AIDS); 2) *to protect* – to pass legislation or take other reasonable measures in order to ensure private individuals` right to health in interfered with: for example, preventing women from being subjected to harmful practices or establishing liability for forcing them to do so (prohibition of female genital mutilation); to guarantee people's access to information and services related to health, including environmental protection; and to provide medical assistance to persons with disabilities, with their free and informed consent [17]; this duty also means to control the marketing of medical equipment and medicines by individuals; states also should prevent third parties from violating the right to health in other countries, as well as exercise human rights due diligence when negotiating international or multilateral agreements with other states, that means assessing their potential impact on human rights and taking measures to prevent them 3) *to fulfil the right to health* – to adopt appropriate legislative , administrative, budgetary, judicial and other measures to fully assure one`s the right to health [17].

Within the ECtHR case law there are several prominent judgements which found states failing to fulfill a positive obligation to ban slavery and forced labor (Article 4 ECHR). One of the first such is *Siliadin v France (2006)*[20]. In this case, a 15-year-old African migrant who arrived in France on a tourist visa and worked as unpaid servant, actually became a "house slave". The ECtHR has decided that States have positive obligations to adopt criminal-law provisions that penalize of forced labor and to apply these criminal sanctions to violators (para. 89). In case of *Chowdury and others v. Greece (2017)* [21] ECtHR awarded to applicants — a group Bangladesh agricultural irregular migrant workers – a just satisfaction of EUR 588,000. The applicants, who protested against the non-payment of their wages for a considerable period of time, were injured by the employer's armed guards. The ECtHR found of the applicants in the situation of vulnerability, taking into account their undocumented status and the risk of being arrested, detained and expelled. The fear of not receiving pay was compounded by a greater feeling of threat – a threat to life, since the applicants worked under the supervision of armed guards. The ECtHR found Greece to fail to fulfil its positive obligations under that provision, namely the obligations to prevent the impugned situation of human trafficking, to protect the victims, to conduct an effective investigation of the offences and to punish those responsible for the trafficking (par. 128).

Human rights treaty bodies, as well as non-governmental organizations in their reviews and reports repeatedly noted the discriminatory treatment towards migrant workers while providing health services: collecting excessive charges from irregular migrants for medical services, practices of demanding immediate payment, or paying for services before providing them [18].

In this regard, implementation of national policies of encouraging the health professionals working with vulnerable groups is urgent. It may mean promotion of specific trainings and exercises on anti-discrimination rules, creation of mechanisms for evaluating health care professionals in the context of equal treatment of all patients (e.g. medical questionnaires) assuring patients that responding to questionnaires will not harm further treatment [19; p. 89].

Quantitative and qualitative researches fix the major challenges and threats faced by migrants, especially undocumented migrants, as to their right to health: they are usually excluded from public health systems and cannot afford medical insurance. For example, ICRMW does not provide for irregular migrant workers access to national health programs (Art. 45); migrants have difficulties in accessing to health information and available services; often information is not properly provided by the state (ICRMW also provides that access to public information of irregular migrant workers is limited); female domestic workers are particularly vulnerable to sexual abuse and violence; dangerous, unecological and unhealthy working conditions; migrant workers may be more at risk of sexual intercourse, thus contributing to the rapid spread of sexually transmitted diseases; migrant workers are more vulnerable to such cruel practices as human trafficking, forced labor, slavery, as a result of which they are physically abused and ill-treated, and face threats to their reproductive health (sexually transmitted diseases, unwanted pregnancies, dangerous abortions) [11].

A serious obstacle to getting proper medical assistance by undocumented migrant workers is their fear of being reported about to immigration authorities by health workers or employers. Some countries have implemented specific policies that *in certain circumstances* protect such migrant workers from deportation when they seeking medical care: if proper treatment is not guaranteed in the country of origin (Austria, Belgium, Greece, Italy, Norway); if it is demonstrated the serious harm to health, if service is not provided (Luxembourg); in case of pregnancy, when a temporary authorization for medical assistance should be provided (France, the Netherlands); emergency aid in the case of threat to life (Norway); in case of progressively developing diseases (Hungary) [22]. Language and cultural barriers as well as the political climate in the country are also recognized as barriers to the implementation of migrant workers' rights [23].

But it is exactly workplaces, where migrant workers are more often exposed to various health threats. Migrant workers, especially irregular ones in most cases are engaged in so called *"3d" jobs* – dirty, dangerous and demanding jobs. Migrant workers are often at risk of performing work without adequate training or protective equipment, and are not able to challenge dangerous working conditions, and that increases the risks of injuries, occupational diseases and deaths at work. For example, agriculture is dangerous sphere because of high temperatures and toxic effects of pesticides; construction and hotel business are physically exhausting [23].

It seems that the only way out in this case is human rights-

based approach. As IACHR rightly notes, the "labor rights necessarily arise from the circumstance of being a worker, understood in the broadest sense. A person who is to be engaged, is engaged or has been engaged in a remunerated activity, immediately becomes a worker and, consequently, acquires the rights inherent in that condition. The right to work, whether regulated at the national or international level, is a protective system for workers; that is, it regulates the rights and obligations of the employee and the employer, regardless of any other consideration of an economic and social nature. A person who enters a State and assumes an employment relationship, acquires his labor human rights in the State of employment, irrespective of his migratory status, because respect and guarantee of the enjoyment and exercise of those rights must be made without any discrimination." [14]. That means that every person, regardless of status, should be protected in the meaning of security of workplace and conditions by all accessible remedies.

It worth to mention, that promoting a safe working environment for migrant workers, eliminating of modern slavery and human trafficking, the worst forms of child labor, including the recruitment and use of child soldiers, are goals that have taken their place in the 2025 Sustainable Development Agenda. Incidentally, the latter, as well as much of what has been stated in the text above, raises the issue of non-state actors' obligations in the field of human rights, and business corporations are on the first place here. Human rights due diligence of business is a common standard of expected behavior for all enterprises, wherever they operate and regardless of their size. It is important to understand that these obligations exist irrespectively of the ability and/or willingness of states to fulfill their human rights obligations, but does not diminish the role of states` obligations; human rights responsibility is also separate from the obligation to comply with national laws and regulations protecting human rights [25]. In August 2019, 181 CEOs of the world (Amazon, Apple, Google, Mastercard) made a joint commitment to sustainable practices, including investing in their employees, providing them with honest remuneration and caring for their rights and the rights of stakeholders, i.e. others on which they have some influence. Particularly, they decided to pay much more attention to working conditions and protection of workers from discriminative treatment [26].

CONCLUSIONS

The major challenges facing by migrant workers in the modern world require new approaches to public policy. This particularly concerns their health care. Despite an extensive system of international human rights instruments, discriminatory practices and treatment of migrant workers are still widespread in the world. It is mostly agreed within the expert and scientific community that human rights-based approach is able to counter these threats.

There are also an unequivocal understanding that natural and inalienable human rights must be accessible to migrant workers and protected by their states of residence, that complies with current perceptions of the positive obligations of states in the sphere of human rights. Often, the health care of migrants is directly dependent on the access to enjoyment of human rights (the right to access to information, the right to freedom of association, the right to freedom of movement) or the degree of protection of freedoms (freedom from torture and torture, freedom from forced labor). The more dangerous link is opposite, when health insecurity and lack of access to medical care results in the loss of life, that is the biggest value ever.

REFERENCES

1. Transforming our world: the 2030 Agenda for Sustainable Development. UN Resolution adopted by the General Assembly on 25 September 2015. Available from: https://www.un.org/ga/search/view_doc.asp?symbol=A/RES/70/1&Lang=E [reviewed 2019.09.03]
2. Tsili staloho rozvytku ta mihratsiia v Ukraini [Sustainable development goals and migration in Ukraine]. International Organization of Migratio, August 20, 2019. Available from: http://iom.org.ua/sites/default/files/sdgs-ukrainian-context_ukr.pdf [reviewed 2019.09.03] (Ua)
3. Convention concerning Migration for Employment (Revised), 1949 (No. 97). Available from: https://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:12100:0::NO::P12100_INSTRUMENT_ID:312242 [reviewed 2019.09.03]
4. Migrant Workers (Supplementary Provisions) Convention, 1975 (No. 143). Available from: https://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:12100:0::NO:12100:P12100_INSTRUMENT_ID:312288:NO [reviewed 2019.09.03]
5. International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families, adopted by General Assembly resolution 45/158 of 18 December 1990. Available from: https://www.ohchr.org/EN/ProfessionalInterest/Pages/CMW.aspx [reviewed 2019.09.03]
6. Case Cyprus v. Turkey, application no. 25781/94, Judgment of 10 May 2001 Available from: https://hudoc.echr.coe.int/eng#{"fulltext":["Cyprus%20v.%20Turkey"],"documentcollectionid2":["GRANDCHAMBER","CHAMBER"],"itemid":["001-59454"]}[reviewed 2019.09.03]
7. Estrada-Tanck D. E. Human Security and Human Rights of Labour Migrants in the Americas. In: Panizzon M., Zürcher G., Fornalé E., eds. The Palgrave Handbook of International Labour Migration Law and Policy Perspectives. Basingstoke Palgrave Macmillan, 2015. 613 p.
8. Circle of Right: Economic, Social and Cultural Rights Activism: A Training Resource. Module 9. Obligations of States and Nonstate Actors Available from: http://hrlibrary.umn.edu/edumat/IHRIP/circle/modules/module9.htm [reviewed 2019.09.03]
9. The Human Rights-Based Approach to Development Cooperation Towards a Common Understanding Among UN Agencies. UNDG, 2003. Available from: https://undg.org/document/the-human-rights-based-approach-to-development-cooperation-towards-a-common-understanding-among-un-agencies/ [reviewed 2019.09.03]
10. Constitution of World Health Organization. Adopted by the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by the representatives of 61 States Available from: http://apps.who.int/gb/bd/PDF/bd48/basic-documents-48th-edition-en.pdf#page=7 [reviewed 2019.09.03]
11. CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12). Adopted at the Twenty-second Session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000 (Contained in Document E/C.12/2000/4). Available from: https://www.refworld.org/pdfid/4538838d0.pdf [reviewed 2019.09.03]

12. Khrystova H. Pozytyvni zoboviazannia derzhavy u sferi prav liudyny: suchasni vyklyky [Positive commitments of the state in the field of human rights: current challenges] Kharkiv, 2018. 680 p. (Ua)
13. Inter-American Court of Human Rights, Juridical Condition and Rights of Undocumented Migrants, Advisory Opinion OC-18/03 requested by the United Mexican States, 17 September 2003 (AO 18/03). Available from: http://www.corteidh.or.cr/docs/opiniones/seriea_18_ing.pdf [reviewed 2019.09.03]
14. Non-Discrimination in International Law. A Handbook for Practitioners. Interights. The international centre for the Legal Protection of Human rights. London, 2011. 260 p.
15. International Federation of Human Rights Leagues (FIDH) v. France, compl. № 14/2003, Decision of 8 September 2004 Available from: https://www.escr-net.org/caselaw/2006/international-federation-human-rights-leagues-fidh-v-france-complaint-no-142003 [reviewed 2019.09.03]
16. UN Office of the High Commissioner for Human Rights (OHCHR), Fact Sheet No. 31, The Right to Health, June 2008, № 31. Available from: https://www.refworld.org/docid/48625a742.html [reviewed 2019.09.03]
17. UN Committee on RMW, Draft General Comment No. 2 on the rights of migrant workers in an irregular situation and members of their families, December 2012, point 2, Available from: http://www2.ohchr.org/english/bodies/cmw/GC2.htm . [reviewed 2019.09.03]
18. Pashkov V., Olefir A.. Problem of Patient Discrimination in Sphere of Health Protection. Socrates. 2018; 1 (10): 76 – 93.
19. Case of Siliadin v. France, application no. 73316/01, Judgment 26 July 2005 final 26 October 2005 (merits and just satisfaction). HUDOC. Available from: https://hudoc.echr.coe.int/rus#{"fulltext":["\"CASE%20OF%20SILIADIN%20v.%20FRANCE\""],"documentcollectionid2":["GRANDCHAMBER","CHAMBER"],"itemid":["001-69891"]}[reviewed 2019.09.03]
20. Case of Chowdury and others v. Greece, application no. 21884/15, Judgment 30 March 2017. HUDOC. Available from: http://hudoc.echr.coe.int/eng?i=001-172701 [reviewed 2019.09.03]
21. Public health aspects of migrant health: a review of the evidence on health status for labour migrants in the European Region. Health evidence report 43/. J Simon J., Kiss N., Łaszewska A., Mayer S. Eds. WHO, 2015. Available from: http://www.epgencms.europarl.europa.eu/cmsdata/upload/114f16b6-1667-44ab-802b-a5a83dd50af0/WHO-HEN6o-Report-A5-1-Labour-FINAL_EN.pdf [reviewed 2019.09.03]
22. Migrant Workers and Their Occupational Health and Safety. Eds. Sally C. Moyce and Schenker M. Annual Review of Public Health 2018 39:1, 351-365. doi: 10.1146/annurev-publhealth-040617-013714.
23. Sustainable development goals. Knowledge platform. Available from: https://sustainabledevelopment.un.org [reviewed 2019.09.03]
24. Kerivni pryntsypy shchodo biznesu i prav liudyny: Realizatsiia Ramkovoi prohramy Orhanizatsii Obiednanykh Natsii «Zakhyst, povaha I zasoby zakhystu» [Business and Human Rights Guidelines: Implementation of the United Nations Framework Program on Respect and Protection]/ per. K.Buriakovska, Yu.Razmietaieva, O. Uvarova, D. Filipskyi/ za zah. red. O. Uvarovoii. Kharkiv: Pravo, 2018.
25. Business Roundtable Redefines the Purpose of a Corporation to Promote 'An Economy That Serves All Americans'. 19 August 2019. Available from: https://www.businessroundtable.org/business-roundtable-redefines-the-purpose-of-a-corporation-to-promote-an-economy-that-serves-all-americans [reviewed 2019.09.03]

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REVIEW ARTICLE
PRACA POGLĄDOWA

ENFORCEMENT OF THE RIGHT TO MEDICAL CARE FOR PATIENTS STAYING ABROAD

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ABSTRACT

Introduction: The right to health care is one of the fundamental human rights, at the same time the right to medical care is the main component of such right. The issue of medical care obtaining while staying in the territory of a foreign country is relevant for all categories of foreign nationals – those who during a temporary being outside their own country have a need to receive unplanned or planned medical care.

The aim: To study the peculiarities of enforcement of the right to medical care for patients staying abroad and to formulate proposals on legislation improvements on the basis of the analysis of the international law and national legislation of the European Union countries.

Materials and methods: International acts and practice of the European Union legislation application in the field of patients' rights protection abroad were used in the study. The methodology of the study is based on a combination of philosophical approaches, general scientific and special legal research methods.

Conclusions: On the basis of the international treaties, the practice of application of the European Union legislation analysis we can conclude that in the EU the right of an insured person (patient) while receiving unplanned medical care in another EU Member State is ensured by a number of regulatory requirements and confirmed by the European Medical Insurance Card.

KEY WORDS: patient, medical care, right to health care, implementation, foreign nationals

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INTRODUCTION

The deepening of integration has led to a significant increase in the influence of international organizations on all spheres of public life, and on people's mobility in particular. Health care in a globalized environment is not confined by national borders, and as a result of increased mobility of people more and more issues of social security and medicine are arising. One of such an issue is the right to access to medical care for citizens while they are outside their home country. This problem is derived from two criteria: the need for access to unplanned medical care during temporary staying abroad, as well as the availability of the right to access to planned medical care, that is, when a person insured in one country has the need to obtain some medical services outside of that country. The question naturally arises as to the grounds, guaranteed scope and conditions for receiving medical care by such patient – a national of a foreign country. The issue of receiving medical care staying in the territory of a foreign country is relevant for all categories of foreign nationals – those who, during a temporary being abroad, have the need to receive unplanned or planned medical care.

The international legal regulation of the right to receive medical care is not perfect; the existing interstate agreements contain only general provisions in the field of the health care Law. At the same time, the acts of the national legislation of the states have provisions that fragmentarily regulate the rights of foreign patients to medical care.

Despite the fact that Ukraine is not a member of the European Union, our country clearly defined the integration vector of its development, so the reforms of the health care system should be based on the European values and standards of medical care. Thus, the creation of an effective mechanism for ensuring the citizens with rights that are equal to European Union citizens' ones in terms of accessibility and quality of healthcare should be a strategic aim.

THE AIM

To study the peculiarities of enforcement of the right to medical care for patients staying abroad and to formulate proposals on legislation improvements on the basis of the analysis of the international law and national legislation of the European Union (EU) countries.

MATERIALS AND METHODS

International acts in the field of protection of the rights of the patients staying abroad, in particular, legislative acts

of the EU states, court decisions of the European Union, national legislation of foreign countries, scientific publications of the leading experts in the field of medical law, legislation of Ukraine in the field of protection of patients' rights to medical care were used in the study. Access to court decisions and legislative acts was obtained via official websites of the Court of Justice of the European Union, the Supreme Court, the Verkhovna Rada of Ukraine, the Ministry of Justice of Ukraine and the Ministry of Health of Ukraine. The analysis and comparison of the medical laws' provisions of the EU states and Ukraine were done in the course of the study. In addition, scientific publications of the leading experts in medical law, current international and national legislation were used.

The methodology of the study is based on a combination of philosophical approaches, general scientific and special legal methods of research. In particular, the systematic method was used to carry out a systematic analysis of the current EU legislation on the procedure for receiving medical care by the patients abroad. The structural-and-functional method allowed us to examine the main aspects of proceedings of the EU court. The comparative-and-legal method has made it possible to compare EU legislation on access of patients to medical care with Ukrainian national health legislation. The legal modeling method was used to formulate proposals for improving current legislation.

Problems of enforcement of the right to medical care for patients were studied in science, however, due attention was not paid to the issues of enforcement of the right to medical care for patients staying abroad. Therefore, the chosen topic is obviously relevant.

REVIEW AND DISCUSSION

Provision on the human right to health is contained in the Preamble to the Charter of the World Health Organization (hereinafter - WHO), according to which: "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition" [1]. The Universal Declaration of Human Rights, although it does not include a direct reference to the right to health care, points to the human right to the standard of living that is necessary for maintaining health (and for medical care) [12]. Also, the human right to health is enshrined in Article 12 of the International Covenant on Economic, Social and Cultural Rights, 1966, which emphasizes "the recognition by States of the right of every person to the highest attainable level of physical and mental health" [3]. At the same time, Article 7 of the International Covenant on Civil and Political Rights, 1966, contains the provisions on the right not to be subjected to the medical and scientific experiments without consent [4]. The studied provisions allows to conclude that the right to health care is inextricably connected with other social-and-economic, civil-and-political rights and other factors, such as living conditions, infringement of physical or mental inviolability, which can directly affect the level of health, and therefore, the right to health care itself.

According to V.V. Sokurenko, the imperative link to the state and its institutions concerning recognition, respect and protection of the rights and freedoms of a human and citizen is formed in a society that perceives the human, his internal freedom and rights as a manifestation of that freedom, as the most important social value [5].

The implementation of the human right to health care by the state is a mechanism of creating the conditions for equal access to medical care based on the resources of each individual state. As the scientific literature indicates, ensuring of equal access to medical care does not mean providing the same amount of medical services for all categories of patients. Each state, first of all, ensures the enforcement of the rights of its citizens, and the regime for providing of medical care to non-citizens is regulated by the national legislation [6]. Despite the proclamation of the general right to health care, there are no provisions of the international acts that disclose the content, the mechanism of providing guarantees and the enforcement of such a right. Of course, the right to health care is a set of rights that make up one whole: the right to access to medical care, the right to be informed about the condition of providing of such care, and also the right to safe environment.

However, the enforcement of the human right to health care is impossible without the mutual cooperation of states [7], since state borders are not an obstacle for the spread of epidemics and infectious diseases. In addition, many international legal acts contain the direct obligation of the states concerning establishing of international cooperation in a wide variety of fields including health care. Thus, Article 56 of the Charter of the United Nations (hereinafter - "UN") of 1945 contains a provision under which Member States are required to undertake both independent and collective actions in coordination with the United Nations on the issues of medical care [8]. These include ensuring of equal access to medical care.

A particular problem is presented by the situation in which non-nationals of the states apply for receiving of such care. States may not restrict the right to access to medical care on the basis of the patient's nationality. This follows from the provisions of the United Nations International Convention on the Elimination of All Forms of Racial Discrimination of 1965 concerning removing of administrative restrictions on using of social and economic rights by non-nationals. The above acts proclaim the human right to health care, but do not contain specific provisions on the mechanisms for proving of such a right.

The Council of Europe adopted the European Convention on Social and Medical Assistance in 1953 [9]. The Convention's provisions specify providing of medical and social care to the nationals of the contracting states when staying outside of their own country on an equal basis with the nationals of the country where they stay, as well as to stateless persons in case of legality of their staying in the territory of the contracting state. However, the Convention norms apply only to those who do not have sufficient livelihood.

The European Social Charter of 1996 [10] in Article 13 regulates the right to social and medical care, which should

be provided to any person who does not have sufficient livelihood or is unable to obtain it through his own efforts or from other sources. The ratification of the Charter on the basis of the Law of Ukraine "On Ratification of the European Social Charter (Revised)" gave a qualitatively new impetus to the social democratic changes in Ukraine [11].

One way or another, the main volume of the enforcement of the right to health care, including medical care, is governed by the national legislation. A person who is in the territory of another state falls under the jurisdiction of that state, in the case of providing medical care to a foreign person, the provisions of domestic law usually considering the provisions of international law is applied. However, depending on the country the legal status of such a patient may vary: it depends on the existence of international agreements in the field of medicine and health care between the country of stay and the country of citizenship, on participation in conventions governing the right to medical care, and state participation in the international intergovernmental organizations, integration projects, etc. In addition, there is a social and health insurance system in some Member States of the European Union, a nationally funded public health system in others. In both cases it is possible to conclude on the "medical-and-social state security" or "health care system".

The Treaty on European Union, signed on 7 February 1992 in Maastricht (hereinafter TEU) and the Treaty on the Functioning of the European Union [13] (hereinafter - TFEU), signed in Rome on 25 March 1957 are the main sources of European Union law [12] which are of supreme legal force.

The Preamble to the Treaty on European Union emphasizes the direct link between Member States and the fundamental social rights set out in the European Social Charter of 1961 [14], which also include the right to health care. Therefore, the right to health care is one of the fundamental provisions on which the European Union is built. Moreover, the objectives of the Union as defined in the Treaties are the well-being of the peoples of Europe, the promotion of social justice and social protection, the fight against discrimination and social marginalization, as well as the achievement of a high level of health care of the citizens.

Receiving of medical care in another country is always determined by different reasons. If medical care in another country can be provided without delay, by highly qualified specialists, will meet all the requirements of quality and safety, as well as the possibility of providing the most effective treatment, not available in the territory of their own country, then the patients will be motivated to receive such care in another country.

Since 1998, the Court of Justice of the European Union (hereinafter - the Court of EU) has begun to study the practice in this field based on the provisions of the EU treaties, such as the freedom of movement of persons, capitals and services principle. As a consequence, this raised a question in the context of the right to compulsory health insurance in an EU Member State in which the patient is not insured. In this regard EU Member States are adjusting their national health systems in accordance with the regulations and norms established by the European Union.

The European Commission, as the EU's executive body, held many consultations on health care issues. These actions resulted in the adoption, in particular, of Directive 2011/24/EU of the European Parliament and of the Council of the European Union of 9 March 2011 "On application of the patients' rights to cross-border health care services" [15] (hereinafter - Directive 2011/24/EU).

According to Article 3 (e) of Directive 2011/24/EU, cross-border medical care is understood as medical care provided or received in other Member State of EU than the country of the insured person. This definition is rather narrow, since the sphere of its application is the issue of providing or receiving medical care within the territory of the European Union. At the same time, the tendency of providing cross-border medical care is only increasing every year, and it is possible to talk about the development of cross-border medical care not only within the EU but also within other international organizations. Within the EU cross-border medical care is governed by Directive 2011/24/EU and the European Economic Community (hereinafter - EEC) Regulations No.3/58 on social security for migrant workers (entered into force on 1 January 1959), No.1408/71, EU Regulations No.883/2004 [16] and No.987/2009 [17], which the social security system of the EU Member States is coordinated by.

Coordinating Regulations No.883/2004 and No.987/2009 regulate the procedure for receiving both planned and unplanned medical care. In this case, medical care to the patients from other EU countries is provided only in public health care institutions. At the same time, Directive 2011/24/EU does not contain provisions on their application in cases of unplanned medical care. The provisions of the Directive regulate the rights of the patients traveling outside the country for the purpose of receiving medical care. As a conclusion, the Directive applies only in cases of planned medical care. However, the Administrative Commission of the European Commission in its decision explained that the provisions of Directive 2011/24/EU are also applied to the cases of unplanned medical care. This leads to the need to amend Article 1 of Directive 2011/24/EU on patients' rights to cross-border services in the field of health care, stating that the provisions of Directive 2011/24/EU are expanded to the situations of providing both planned and unplanned medical care.

Thus, the EU in accordance with the ordinary legislative procedure, determines the volume of the rights of third-country nationals legally residing in the territory of the Union, including conditions regulating freedom of movement and residence in other EU Member States (other than the country of residence). These provisions are important because Article 63 p.4 of the Treaty on European Union (equivalent to Article 79 p.2 of the Treaty on the Functioning of the European Union) was used to extend the scope of implementation of regulations of the EU (and, accordingly, regulation of cross-border health care) to third-country nationals.

The patient has the right to free emergency medical care when temporarily staying abroad in the territory of another EU Member State, in such cases the patient does not have to pay in advance for provided medical services. That is, a foreign patient is subject to the same conditions as local patients who are covered by the state social security system upon presentation of a European Health Insurance Card (hereinafter - EHIC). Thus, if local patients do not have to pay for the provided medical services, then the foreign patient also does not have to pay [18, 19]. However, this rule does not apply to the persons residing abroad permanently.

In addition to the restrictions laid down by the TFEU, there are restrictions created by the case law of the EU Court. In some cases, restrictions on the freedom to provide care may be a matter of national interests for Member States. For example, limiting the amount of social security treatment received abroad as a way to maintain a financial balance in the national health care system. However, as stated in doctrine, the principle of proportionality must be applied in all cases even when it comes to the protection of national interests [20].

The specificity of the right to medical care enforcement in Ukraine by the foreigners stems from the provisions of the Law of Ukraine "On the Legal Status of Foreigners and Stateless Persons", according to which the foreigners and stateless persons residing permanently in Ukraine, as well as those foreigners who have been granted refugee status in Ukraine, receive medical care on an equal basis with the Ukrainian citizens [21]. Other foreigners and stateless persons receive medical care in accordance with the procedure approved by the Decree of the Cabinet of Ministers of Ukraine No.121 of 19 March 2014. This procedure defines three categories of the foreigners and stateless persons: who resides or stays temporarily in the territory of Ukraine; who lives permanently in the territory of Ukraine; who is recognized as refugees or persons in need of additional protection.

The procedure of providing medical care also differs depending on the legal status of foreigners and stateless persons. In particular, medical care is provided to the foreigners and stateless persons who reside or stay temporarily in the territory of Ukraine on a paid basis, unless otherwise provided by the international treaties or laws of Ukraine. Medical care is provided at the expense of budgetary funds provided for this purpose in the state and local budgets to the foreigners and stateless persons permanently residing in the territory of Ukraine, to the foreigners and stateless persons recognized as refugees or persons in need of additional protection. The above provisions of the national legislation differ significantly from the provisions of the EU legislation on the rights of the foreigners to medical care.

Thus, relevant measures on the changes of the national legislation in the field of enforcement of the right to medical care by the foreigners in Ukraine have not been taken despite the declared intentions for an association between Ukraine and the European Union, which determines the perspectives for the further study of this issue and related legislative activity.

CONCLUSIONS

One can conclude that the right of an insured person (patient) in the EU to receive unplanned medical care in the territory of another EU Member State is ensured by a number of regulatory requirements and confirmed by the European Medical Insurance Card while analyzing the international treaties, the practice of applying the legislation of the European Union. However, there is a legal gap in the provision of unplanned medical care in the between two legal instruments (coordinating Regulations and Directive 2011/24/EU) governing patients' rights on cross-border health care. Coordinating Regulations No.883/2004 and No.987/2009 regulate the procedure for receiving both planned and unplanned medical care. In this case, medical care to the patients from other EU countries is provided only in public health care institutions. At the same time, Directive 2011/24/EU does not contain provisions on their application in cases of unplanned medical care. The provisions of the Directive regulate the rights of the patients traveling outside the country for the purpose of receiving medical care. It follows that the Directive applies only to the cases of planned medical care. However, the Administrative Commission of the European Commission in its decision explained that the provisions of Directive 2011/24/EU are also applied to the cases of unplanned medical care. This leads to the necessity to amend Article 1 of Directive 2011/24/EU on patients' rights to cross-border services in the field of health care, stating that the provisions of that Directive are expanded for providing both planned and unplanned medical care.

There is a need to develop and adopt a unified domestic legislative act on the rights of the patients receiving medical care abroad and to make corresponding changes to the legal acts on health care in accordance with the provisions of the Association Agreement between Ukraine and the European Union, under which the Contracting Parties should develop cooperation in the field of health care in order to improve its safety and protection of human health as a prerequisite for sustainable development and economic growth; which in turn determines the perspectives for further study of this issue.

REFERENCES

1. Valeev R, Vseobshchej deklaracii prav cheloveka – 60 let [Universal Declaration of Human Rights - 60 Years] European Law Journal. 2008;3:11–16 (Ru)
2. Universal Declaration of Human Rights from 10.12.1948 Available from: https://www.un.org/en/universal-declaration-human-rights/ [reviewed 2019.09.10]
3. International Covenant on Economic, Social and Cultural Rights from 19.12.1966 Available from: https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx [reviewed 2019.09.10]
4. International Covenant on Civil and Political Rights from 19.12.1966 Available from:http://www.un.org.ua/images/International_Covenant_on_Civil_and_Political_Rights_CCPR_eng1.pdf [reviewed 2019.09.10]
5. Sokurenko V. Prava liudyny yak fundamentalna tsinnist [Human Rights as Fundamental Value] National and international mechanisms for the protection of human rights: Abstracts of the All-Ukrainian Round Table (Harkiv KhNUVS 2016); 7-9 (Ua)

6. Bogdanova D. Sotrudnichestvo gosudarstv po obespecheniyu prava cheloveka na poluchenie medicinskoj pomoshchi pri nahozhdenii za predelami sobstvennogo gosudarstva' [Cooperation of States in Ensuring the Human Right to Receive Medical Assistance While Outside Their Own State] thesis abstract for obtaining the degree of Candidate of Law. 2013:15–16 (Ru)
7. Kapustin A. Pravo na ohranu zdorov'ya v mezhdunarodnom prave [The right to health care in international law] Modern problems of medical law and the right to health protection: materials of the international scientific-practical conference Moskou 2003;138–141 (Ru)
8. Charter of the United Nations from 26.06.1945. Available from: https://www.un.org/en/charter-united-nations/index.html [reviewed 2019.09.10]
9. European Convention on Medical and Social Services from 11.12.1953. Available from: https://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/014 [reviewed 2019.09.10]
10. European Social Charter (Revised): Council of Europe Charter from 03.05.1996. Available from: https://www.coe.int/ru/web/conventions/full-list/-/conventions/treaty/163 [reviewed 2019.09.10]
11. Pro ratyfikatsiiu Yevropeiskoi sotsialnoi khartii (perehlianutoi): Zakon Ukrainy [About the ratification of the European Social Charter (revised): Law of Ukraine] №137-V vid 14 veresnya 2006 roku Available from: https://zakon.rada.gov.ua/laws/show/137-16 [reviewed 2019.09.10] (Ua)
12. Law of the European Union: a Textbook for Master Students. Voronezh, 2016:78–100.
13. Treaty on the Functioning of the European Union from 26.10.2012. Available from: https://www.refworld.org/docid/52303e8d4.html [reviewed 2019.09.10]
14. Churchill R., Khaliq U. The Collective Complaints System of the European Social Charter: An Effective Mechanism for Ensuring Compliance with Economic and Social Rights? European Journal of International Law. 2004;Vol. 15(3):417–456.
15. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (2011) OJ L88/45. Available from: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF [reviewed 2019.09.10]
16. Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (Text with relevance for the EEA and for Switzerland) Available from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32004R0883 [reviewed 2019.09.10]
17. Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems (Text with relevance for the EEA and for Switzerland) Available from: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R0987 [reviewed 2019.09.10]
18. Case C-211/08 european Comission v Kingdom of spain 2010 ECR-I-5627 paras 45-50 Available from: http://www.brugesgroup.com/eu/the-yvonne-watts-case-the-eu-and-health-care.htm?xp=media [reviewed 2019.09.10]
19. Case C-208/07 Petra von Chamier v Deutsche Angestellen-Krankenkasse 2009 ECR I-6095 para 75, relating to reliance on care Available from: http://www.brugesgroup.com/eu/the-yvonne-watts-case-the-eu-and-health-care.htm?xp=media [reviewed 2019.09.10]
20. Lenaerts K., Nuffel P., Bray R. European Union Law. London, 2011:280–284.
21. Pro pravovij status inozemciv ta osib bez gromadyanstva: Zakon Ukrainy [About the Legal Status of Foreigners and Stateless Persons: The Law of Ukraine] № 3773-VI vid 22.09. 2011 Available from: https://zakon.rada.gov.ua/laws/show/3773-17 [reviewed 2019.09.10] (Ua)

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REVIEW ARTICLE
PRACA POGLĄDOWA

THE ROLE OF SMART TECHNOLOGY IN PROMOTING THE RIGHT TO HEALTH OF OLDER PERSONS

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ABSTRACT

Introduction: The right to health is one of the fundamental human rights. Due to the fact that older persons are requiring special treatment in medical care international law pays particular attention to the issue of securing their specified right. Nowadays new forms of health-care are being established, in particular, by using the latest technologies that facilitate access to healthcare services. However, there is a number of barriers related to the implementation of these rules. In view of this, the practical implementation of the international agreement's provisions in this field into national legal system is obviously important.

The aim: of the article is to study the organizational and legal aspects of the provision of medical services to older persons through the use of information and communication technology; to create recommendations aimed at improving the health-care system with regard to older persons.

Materials and methods: The following research is based on the analysis of the international legal acts and scientific researches in this field. The methodological basis of the study is a set of general and special methods of scientific knowledge.

Conclusions: Smart technologies are becoming an important tool in health-care system. The introduction of digital health solutions can increase the quality of life for older persons who may need medical care for aging. Important when using ICT is: keeping patients' confidential medical information; training of medical staff; ensuring transparent legal support at all stages of implementation. Given the fact that the problem of aging is a common problem for modern states of the world, it is important to share the latest developments in the field of healthcare.

KEY WORDS: older persons, health-care, smart technologies, right to health, tele-medicine

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INTRODUCTION

The article focuses on the health-care for older persons using smart technologies. Emphasis is placed on the legal basis for regulating the issues related to "digitization" of health-care for older persons within the European Union, stressing that these acts are based on generally recognized standards adopted by specialized universal international organization – World Health Organization, the Council of Europe, since the aging of the population is an urgent issue nowadays and crucial for most countries of the world, in particular the European region. Special attention was paid to the activities of the European Innovation Partnership on Active and Healthy Aging, the e-Health Action Plan, Communication from the Commission COM (2008)689 final, Directive on the application of patients' rights at cross-border health-care, and others. Considering the fact that maintaining confidential patient information in accordance with their right to privacy is important in the application of information and communication technologies, the provisions of the acts adopted by the EU in this area of legal regulation are examined (the EU Charter of Fundamental Rights of 2000, Regulation (EU) 2016/679, Directive 2011/24/EU).

Practical experience of the European states on the introduction of innovative technologies in health-care of older persons (Flemish Region of Belgium and the municipal district of Prague, Czech Republic, were taken as an example) is analyzed.

The abovementioned indicates the relevance of the topic, its importance for the protection of human rights in the field of health-care.

THE AIM

The purpose of the article is to investigate the organizational and legal aspects of the healthcare provision to the older persons through the use of information and communication technology; to create and evaluate the recommendations aimed at improving the system of healthcare for older persons.

MATERIALS AND METHODS

The following research is based on the analysis of the international legal acts, scientific researches. The methodological basis of the study is a set of general and special methods of scientific knowledge, the use of which allowed to achieve the goal and to ensure the scientific reliability and clarity of the obtained theoretical results. All methods are applied in conjunction, which ultimately contributed

to the comprehensiveness, completeness and objectivity of the scientific findings obtained.

The research was based on dialectical method, which made it possible to understand objectively and thoroughly the international legal reality, determine the nature of the studied international legal phenomena in their development and the unity of their substantive content and legal form. The axiological approach made it possible to comprehend the value orientation of the right to healthcare for older persons and to consolidate it in international acts. The formal-logical method was used to identify existing gaps and contradictions in current international instruments and to develop proposals for their improvement. The formal (dogmatic) method facilitated a detailed analysis of the provisions for the protection of the right to healthcare for older persons, including the classification and systematization of barriers related to the exercise of this right.

REVIEW AND DISCUSSION

Population aging is one of the dominant trends of the 21st century. It has important and far-reaching consequences for all aspects of society [1]. The provisions of the European Commission staff working document "Progress of the European Innovation Partnership on Active and Healthy Aging" also confirm that aging is one of the major social problems today in the Union and beyond, affecting labor markets and the stability of health and social care systems. Aging is associated with an increase in chronical diseases that affect the quality of life of millions of people. Worldwide, Europe has the largest burden of chronical disease in the world, accounting for 86% of all deaths and 77% of healthcare and long-term care costs [2]. In its communication COM (2018) 233 final, the European Commission also stated that healthcare systems in Europe are facing serious problems, including aging… [3].

In many European countries, there is an increase in the average age of the population and an increase in the proportion of the older persons as a result of the progress made in medicine and health-care technology, improving the environment in which people live (improving hygiene practices, access to food, living and working conditions), as well as fertility decline. Only in 25 EU Member States the proportion of people aged 65 and over is projected to increase from 17% in 2007 to 21% by 2020 and to 28% by 2040 [4].

It should be noted that population aging is taking place in a context of technological changes that create opportunities that have never existed before. These important social and technological changes mean that the policy should not be based on outdated social models of aging, but on using of available opportunities, including access to information technologies [5].

Such developments require a new integrated approach to health and social care. Assistance professionals should work side-by-side with representatives of different sectors, one team, with common goals and resources, in order to take concerted action in response to emerging needs for assistance to each individual. Advanced information and communication technology (hereinafter – ICT) offer broad opportunities for implementation of measures to positively impact on particular health threats [4].

In order to exercise their right to enjoy the highest attainable standard of mental and physical health, the older people must have access to affordable and age-friendly health-care information and services to meet their special needs. This includes, namely, preventive, curative and long-term medical care [1].

Changing the health paradigm means investing in active aging through preventative measures, rather than focusing solely on curing medicine [6]. The ability to monitor from anywhere the condition of patients with chronical diseases of low complexity, which typically include older persons, may contribute to their active aging.

Great attention within the EU is paid to the issue of healthy aging, under which the WHO understands the process of development and maintenance of well-being in old age. Thus, the Commission has launched an initiative – European Innovation Partnership on Active and Healthy Aging (hereinafter – EIP) to promote innovation and digital transformation in the field of active and healthy aging. The EIP pursues a number of goals, including improving the health and quality of life of Europeans with a focus on the older people; support the long-term sustainability and effectiveness of health and social care systems and more. The EIP operates in two directions – action groups and reference sites. Action groups are a community of partners involved in working on specific issues concerning active and healthy aging. They do this by sharing knowledge and experience, identifying gaps that need to be filled at the European level. Six EIP groups include parties involved academics and governmental staff. They cover local, regional, national and European levels.

In addition, Blueprint, Innovation to Market (I2M), and MAFEIP are three initiatives that enable the implementation of EIP on active and healthy aging. Blueprint strives for health and care innovation in Europe; I2M aims to expand digital health and care solutions in a cross-border context; MAFEIP is an assessment tool to support evidence-based decision making for all institutions and users in the field of health-care.

It should also be mentioned that since 2004, when the First e-Health Action Plan was adopted, the European Commission has been developing certain policy initiatives in order to promote the spread of e-Health throughout the EU. The adoption in 2011 of the Directive on the application of patients' rights at cross-border health-care, which contains a rule on the creation of an e-Health network (Art. 14), marked another step in the formal cooperation in the field of e-Health to maximize social and economic benefits through the interaction and implementation of the e-Health system.

COM (2008) 689 final stipulates that the Europeans are aging and leave with chronical diseases. Their health often requires an improved health-care measures because medical aid is often unavailable. Tele-medicine can improve access to specialized care in areas with a lack of experi-

ence or in areas where access to health-care is difficult. Thus, tele-monitoring can improve the quality of life of chronically ill patients and shorten their hospital care. The services such as tele-radiology and tele-consultation can help reduce queues, optimize resource utilization, and increase the efficiency [7].

The scientific study by Ann L. Bossen, Kristine N. Williams, Heejung Kim, Molly Strieker and Andreanna E. Steinhoff on the use of ICT in the care of older people with dementia states that as the population with dementia increases the burden for carers increases too, tele-medicine and intellectual technology can support aging for people with disabilities at the same time, while reducing the burden on caregivers, improving the quality of life of families, and reducing health care costs. However, the realization of the technology's potential to meet dementia needs depends on a number of factors, including raising awareness of and availability of technology, promoting accessibility, and overcoming admission and use difficulties [8].

In addition, Winifred V. Quinn, Gregg Springan and Ellen O'Brien noted in their work that providing better and more cost-effective care for older persons with complex conditions requires care models that, among other things, better integrate health-care and social services and improve support for family caregivers. Tele-medicine is increasingly being used to achieve these goals. This includes a variety of technologies and services, including virtual video visits, remote patient monitoring, e-mail and other messaging tools, and activity monitoring – technologies that can be combined in different ways depending on individual needs. Remote patient monitoring includes technologies used to monitor and transmit health data (for instance, weight, blood pressure, heart rate), symptom reports, alerts and reminders, as well as feedback from a healthcare provider. The authors also pointed to a number of obstacles to the introduction of tele-medicine at home, including ambiguous evidence of its benefits, consumer interest and usability, logistical problems, cost recovery and other regulatory barriers [9].

It should be noted that some European countries have already taken small steps towards introducing innovative technologies for the provision of health-care services to older people, so the Flemish Region of Belgium has introduced "Flemish Care" programme to improve the provision of health-care to older persons through the development of innovative technology. The programme includes "demonstration projects" and a "pilot platform for health innovation". In addition, the Assistance Programme foresees the creation of a Flemish Assistant Technology Expertise Centre.

In the municipal district of Prague, Czech Republic, there is a dedicated multilingual website for older persons with useful information about their daily life in the area (social and medical services, cultural activities, leisure activities, etc.). The district also provides a help-line and legal advice for the elderly (Chapter VI. Care) [10].

At the same time, the use of modern e-Health achievements, including by the older persons, is complicated by a number of reasons that delay its effective use. These include: lack of awareness and confidence in e-Health solutions among patients, citizens and professionals in the area of health and care; lack of interaction between e-Health; lack of legal clarity on mobile health applications and transparency regarding the use of data collected by such applications; limited large-scale evidence of the cost-effectiveness of e-Health tools and services; fragmented legal and organizational framework, lack of cost recovery schemes for e-Health services; regional differences in access to ICT services, etc. [11].

Lack of legal clarity is one of the main obstacles to the use and dissemination of eHealth. The primary objective of providing legal clarity in this area is to ensure that tele-medicine is developed in such a way that it benefits the care of patients, while ensuring the confidentiality and highest standards of patient safety. Lack of legal clarity – in particular regarding licensing, accreditation and registration of tele-medicine services and professionals, liability, compensation, jurisdiction is a huge problem. Cross-border provision of tele-medicine services also requires legal clarification on confidentiality [7].

Effective data protection is crucial to building trust in e-Health and is a key to its successful implementation and cross-border exchange of health data.

The rules for the protection of personal information are contained in Art. 8 of the EU Charter of Fundamental Rights, according to which "every person is guaranteed the right to the protection of personal information concerning him or her. This information should be used in accordance with the established rules for specific purposes and on the permission of the person concerned or on other legitimate grounds provided by law...". In 2016, in order to adapt data protection rules to the digital age, a Regulation (EU) 2016/679 (GDPR) (effective May 2018). The adoption of the Regulation modernized the EU legislation on the protection of personal data, adapting it to existing realities in the context of the economic and social problems of the digital age. GDPR lays down the rules on the protection of individuals with regard to the processing of personal data, including health information (Art. 1, 9) [12]. It should be noted that the Directive on the application of patients' rights to cross-border health-care states that the objectives set out therein must be respected in accordance with the principles of data protection, as set out, in particular, in Directive 95/46/EC and 2002/58/EC (Art. 14 (2)) [13].

The mentioned issue is also covered in the researches of foreign scientists. Thus, Leszek Buliński, Aleksandra Błachnio in their article concluded that the need for the creation of appropriate protocols that would guarantee the basic rights of patients in the environment of tele-medicine applications [14]. Kristine Williams, Sally Mathis Hartwig, Ann Bossen, Alexander Gloeckner also noted that legal issues are one of the main obstacles to the introduction of tele-medicine. These include the lack of an international legal framework allowing health-care professionals to provide services in different countries; the issue of authentication of health-care professionals, in particular,

when dealing with e-mail and the risks of medical liability of professionals providing tele-medicine services; lack of policy in the area of patient privacy and confidentiality while transferring, storing and exchanging data between health-care providers in different jurisdictions [15]. In addition, they noted that older people may face the problem of using smart technologies because of some changes related to aging, lack of experience and different attitudes towards their use. Therefore, the ease of use of technology is an important factor in technology adoption [15].

Removing of legal barriers is vital to implementing an electronic healthcare system. It is crucial to establish safety measures that allow citizens to confidently use health and well-being applications, and to integrate user data with official medical data to make care more personalized and useful for patients.

CONCLUSIONS

1. Population aging is driven by technological changes that create opportunities never existed before. These important social and technological changes mean that policies should not be based on outdated social aging models, but should use existing opportunities that provide social and technological change for innovative approaches, including access to basic tools and information technology. Mobile technologies are becoming an important tool of delivering health-care services with ease of use, breadth of coverage and recognition. They are capable of revolutionizing the interaction of the public with health-care services. The use of innovations in the field of digital technology is aimed at ensuring the effective realization of the right to healthcare guaranteed by international human rights instruments and national laws. The introduction of digital health solutions can increase the quality of life for older persons who may need medical care for chronical deceases caused by aging.
2. Modern ICT, such as computers, the Internet and cellphones, have changed the way we communicate, search and share information, and have significantly improved our lives. These technologies have enormous potential in addressing today's global health problems, including for such vulnerable groups such as the older persons. The use of modern ICT in the field of health-care aims to help the elderly to remain healthy, independent and active at work or in society. ICT have great potential to overcome geographical barriers and increase access to health-care services. At the same time, in order to "put them into service" for the older persons, significant efforts should be made at the international and national levels to ensure their accessibility, fairness, quality, efficiency, etc.
3. Keeping sensitive information in line with their right to privacy is essential when using ICT, especially when it comes to serious illnesses (cancer, Alzheimer's disease, dementia), as well as diseases that have significant social resonance (sexually transmitted diseases, HIV/AIDS, etc.), disseminating information that is undesirable to the patient. Otherwise, it may cause additional psychological trauma to individuals.
4. Compliance with health-care ethical standards by the providers of health-care, the principle of non-discrimination, and the gender principle in the treatment of elderly patients is crucial nowadays.
5. Considering the fact that the problem of aging is a common problem for modern countries of the world, it is important to share the latest developments in the field of healthcare, including new diagnostic tools, transmission of health data, medical services and their forms, legal aspects of regulation. In addition, in order to facilitate exchanges in the field of elderly service provision, it is necessary to establish institutional structures in the territories of the states with a single universal center through which the cooperation of the states is essential, which is important when assisting displaced persons. It is also important to listen to the problems faced by elderly relatives, caregivers in the provision of health-care services, to take into account the practical aspects (disadvantages) of health-care and to enhance the services that can be provided to older people.
6. Measures to train medical staff in the field of geriatrics, to improve their skills to enhance their professional knowledge, to work with innovative technologies, to become familiar with the provisions of international acts in the field of health-care and human rights, are important for improving of healthcare services providing. The responsibility for training such staff should be relied on the state government. It is also urgent to establish geriatric centers in the states.
7. Undoubtedly, the use of smart technologies requires the provision of transparent legal support at all stages of implementation (licensing, accreditation and registration of telemedicine services, training of specialists, use of medicines, etc.), which is essential both for the protection of patients and individuals, providing medical services; regulation of liability issues, damages, jurisdiction.

REFERENCES

1. United Nations Population Fund (UNFPA) United Nations Population Fund (UNFPA). Aging in the Twenty-First Century: A Celebration and A Challenge. Available from: https://www.unfpa.org/sites/default/files/pub-pdf/Aging%20report.pdf [reviewed 2019.09.15]
2. Commission staff working document Progress of the European Innovation Partnership on Active and Healthy Aging SWD (2018) 437 final. Available from: https://ec.europa.eu/eip/aging/about-the-partnership_en [reviewed 2019.09.15]
3. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society SWD (2018) 126 final. Available from: https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering [reviewed 2019.09.15]
4. Karl A. Stroetmann, Lutz Kubitschke, Simon Robinson et al. How can telehealth help in the provision of integrated care? World Health Organization. 2010. Policy brief 13. Available from: http://www.euro.who.int/__data/assets/pdf_file/0011/120998/E94265.pdf [reviewed 2019.09.15]

5. World Health Organization. Draft 1: Global Strategy and Action Plan on Aging and Health. 2015. Available from: https://www.who.int/aging/aging-global-strategy-draft1-en.pdf [reviewed 2019.09.15]
6. United Nations Economic Commission for Europe. Policy Brief Active Aging. 2012. No. 13. Available from: https://www.unece.org/fileadmin/DAM/pau/age/Policy_briefs/ECE-WG.1.17.pdf [reviewed 2019.09.15]
7. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, health-care systems and society COM (2008)689 final. Available from: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0689:FIN:EN:PDF [reviewed 2019.09.15]
8. Bossen A, Kim H, Williams K et al. Emerging roles for telemedicine and smart technologies in dementia care. Smart Homecare Technology and TeleHealth. 2015;3: 49–57. doi:10.2147/SHTT.S59500.
9. Winifred V. Quinn, Ellen O'Brien, Gregg Springan. Using Telehealth to Improve Home-Based Care for Older Adults and Family Caregivers. AARP Public Policy Institute. May 2018: 1-12.
10. Recommendation CM/Rec(2014)2 of the Committee of Ministers to member Stateson the promotion of human rights of older persons. Available from: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016805c649f [reviewed 2019.09.15]
11. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions eHealth Action Plan 2012-2020 - Innovative health-care for the 21st century SWD (2012) 414 final. Available from: https://ec.europa.eu/transparency/regdoc/?fuseaction=list&coteId=10102&year=2012&number=414&language=en [reviewed 2019.09.15]
12. Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0001.01.ENG [reviewed 2019.09.15]
13. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border health-care. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011L0024 [reviewed 2019.09.15]
14. Leszek Buliński, Aleksandra Błachnio. Health in old age, and patients' approaches to telemedicine in Poland. Annals of Agricultural and Environmental Medicine. 2017; Vol 24, No 2: 322–328. doi: 10.26444/aaem/74200.
15. Williams K, Pennathur P, Bossen A et al. Adapting Telemonitoring Technology Use for Older Adults: A Pilot Study. Res Gerontol Nurs. 2016 Jan 1; 9(1): 17–23. doi: 10.3928/19404921-20150522-01.

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INTERNET OF THINGS TECHNOLOGIES IN MEDICAL SECTOR: CYBER SECURITY ISSUES

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ABSTRACT

Introduction: One of the areas of the Internet of Things (further IoT) popularisation is medicine. Along with significant progress in this area, cyber security threats are on the rise. Thus, the issue of IoT technology's scientific understanding in medicine is of particular relevance.

The aim: The purpose of the study is to analyze the global tendencies of IoT development in medicine, identify major threats and define priority areas for their localization and prevention.

Materials and methods: The materials were primarily international standards, norms of international and national law, analysis of international companies' activities. The theoretical basis was the IoT researches of A. Ross, O. Baranov, V. Vishnevsky. General theoretical (epistemological, functional-structural) and special (comparative, inductive) methods of research were used.

Conclusions: It has been proven that security and privacy issues are one of the main obstacles to IoT development. Specific recommendations for IoT developers in the medical field are proposed, which should include flexible standards, clear rules, and strict obligations with severe penalties for violations.

KEY WORDS: artificial intelligence, cyber threats, Internet of Things, IoT, robotics

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INTRODUCTION

The Internet expanding moves not only by increasing the users' quantity, but also by going beyond standard computers, tablets, smartphones and reaching new devices. Electronic communications and touch systems are no longer new. As a result, IoT is a top priority – a network of physical objects equipped with built-in technologies for transmitting and receiving data: from cars to watches, household goods and even clothing.

The benefits of artificial intelligence's using are obvious, so it's no wonder that medical IoT is gaining ground each year and will keep a positive trend. Markets' analysts believe that healthcare will become the fastest growing segment of IoT in the next five years [1]. Devices, gadgets and smart systems are designed not to replace doctors and nurses, but to facilitate and optimize their work. Thus, Tractica experts predict that deliveries of clinical and non-clinical connected sensors will reach 92.1 million units in 2022 (for comparison: 2.4 million units were in 2016) [2].

The aim:of the research is to analyze global trends in development of IoT in medicine, identify major threats, and develop priority areas for their localization and prevention.

MATERIALS AND METHODS

The paper primarily focused on international standards, in particular the cybersecurity standard of the Internet of Things TS 103 645. Requirements and conceptual principles and other standards are also taken into account: ISO / IEC 27001 "Information technology - Security methods - Information security management systems - Requirements", ISO/IEC 17799 "Information technology - Security technology - Practical information security management rules" ISO/IEC 27552 "Security methods. Extension of ISO/IEC 27001 and ISO/IEC 27002 to manage privacy information. Requirements and Guidelines, BS 7799-3 - IB Risk Management Guide.

The norms of international and national law became an integral part of the research materials. In particular, provisions of the Doctrine of the European Parliament and of the Council "On the protection of persons in processing of personal data and on free movement of such data", "Convention on Cybercrime", UNGA Resolution "Advances in Information and Telecommunications Context" Laws of Ukraine "On Access to Public Information", "On Information", "Doctrine of Information Security of Ukraine", "On Protection of Personal Data", "On Basic Principles of Cyber Security of Ukraine» were analyzed. Crucial element of the research materials was the analysis of international companies' activities (Fitbit, Apple, Intel, IBM, AdhereTech, iFlytek, Hewlett-Packard, D-Link, Johnson & Johnson, Exlab), which are actively engaged in development and implementation of IoT in the field of

medicine. Their experience has served to develop specific proposals for IoT developers in the field of medicine, as well as mechanisms for implementing the requirements of international standards into national law.

This article's theoretical basis was the leading researchers' works of the IoT, in particular A. Ross "Industry of the Future" (2017), who predicts and describes radical changes in all spheres of life, including medicine related to IoT implementation. O. Baranov's monograph "The Internet of Things: Theoretical and Methodological Foundations of Legal Regulation" (2018). The author examines the emergence and development of the IoT phenomenon through numerous examples, clarifies its unique role in the development of society, examines and summarizes the possible risks' content and barriers to IoT implementation and functioning. A valuable scientific work is a monograph of V.P. Vyshnevsky's "Smart Industry in the Digital Economy: Perspectives, Directions and Mechanisms for Development" (2018), which explores the features of the smart industry and its role in modernization of industrial potential; identified promising areas and potential efficiency of smart industry technologies; analysis of barriers and risks of its development; directions of development of smart industry in Ukraine.

Common methodical (epistemological, functional-structural) and special (comparatively legal, inductive) methods are used as a methodological basis in the article. They are used to: characterize the IoT concept, its features and information and legal nature of healthcare; specific threats connected with IoT expansion in health care system; international experience of IoT using in medical practice is explored; the conclusion was confirmed on the necessity of optimizing the legal mechanisms of cyber defense in the system of medical assistance to population, introduction into national information legislation of the basic principles and requirements of cyber security standard in IoT - TS 103 645.

REVIEW AND DISCUSSION

The term Internet of Things (IoT) was first introduced in 1999 by the founder Kevin Ashton at the Auto-ID Center at the Massachusetts Institute of Technology. The researcher defined it as follows: "if in the twentieth century, data were entered into computer only by a person who used to introduce additional devices for them, then in the twenty-first century we will already be dealing with gadgets that can collect and send data themselves" [3]. In the most common definition, IoT is a concept that allows physical objects ("thing-resources") to interact with one another or with external environment, partially or completely without human involvement. For this purpose, appropriate associations of such devices on the network are used. In fact, this means that things that surround us in everyday life, from the simplest, such as coffee makers, to a car, can transmit the necessary data, providing maximum comfort for a person without his/her intervention and control.

According to a well-known American innovation expert, Senior researcher at Johns Hopkins University, Alec Ross, in 2017 the number of devices connected to the Internet has exceeded 20 billion pieces, and by 2020 there will be about 50 billion of them [4, p. 52]. We are now on the verge of digitizing virtually all things, and this will become one of the determining factors of economic development in the next ten years. These processes will certainly affect healthcare system.

Today, IoT-connected devices are becoming an integral part of many healthcare facilities and help greatly in automate processes, save time and increase the efficiency (effectiveness) of physicians. The sensors' use and remotely operated medical devices will give patients access to advanced medical technology. The development of remote diagnostics, including telemedicine and extirpate surgery will bridge the geographical dividence in healthcare delivery, increase the effectiveness of emergency medical care and significantly reduce the cost of services provided. Internet-enabled medical devices will be able to collect and transmit patient's data over a long distance in seconds, significantly reducing medical errors level and, consequently, improving healthcare system.

So, services provided by Fitbit and based on Apple's ResearchKit platform give researchers access to vast repositories of biometric user data that can be used to collect and use nutrition information, fitness, disease progression, patient efficacy, etc.

Intel has made a "smart connection" that can measure the attacks' number in patients with Parkinson's disease, which is important for gathering information about the disease's dynamics. There are also devices that allow you to monitor elderly relatives who reside elsewhere [5].

Thus, with the help of IoT it is possible to collect the complete clinical chart, data on analyzes for treatment period, the body's state for a certain period of time. Data that is downloaded to database is quickly processed by a computer [6]. This will help to establish an accurate diagnosis and allow timely treatment.

This is how an IBM system called Watson Health works. It is able to identify potential problems with the vascular system, recognize cancer, determine whether a patient is prone to blood clots. IBM Watson can respond promptly when it comes to learning new information and drawing conclusions from it. Thus, artificial intelligence from IBM is in 10 minutes analyzing 20 millions of scientific articles on oncology and on their basis is giving a patient the correct diagnosis [7].

In December 2016, a prototype bracelet with an NFC chip, which provides emergency assistance to wounded soldiers, was introduced in Israel. The device stores information about a patient's health, treatment information, photos of patient's wounds, and GPS coordinates of locations where a soldier was injured. Scientists at the University of Tokyo have developed a system of artificial intelligence for phobias and post-traumatic stress treatment. This requires finding brain areas responsible for memory of fear. Artificial Intelligence quickly and accurately identified the required brain regions responsible for this memory. With this in mind, doctors have created an effective treatment

program. Microscopic sensor tablets are able to provide physicians with information about the patient's internal organs' state. For example, a Proteus Discover solution that uses tablets with rice grain size sensors built into them, and patch fitted with sensors that record and transmit information to a body, provides much more information about patient's health. AdhereTech has invented a medication box that sends patients a reminder if they don't use drugs on time. The sensors are fixating when the tablet or milliliter of fluid is removed from the box. If this does not happen at the right time, the box begins to flash and sound. At the same time, a message or a reminder call arrives on the patient's phone. The patient is then asked to indicate the reason why he/she missed the medication. Data are also available to the doctor [8]. In China, Xiaoy robot (Xiao I) with artificial intelligence has successfully passed medical examinations provided to become a licenced doctor. According to Interesting Engineering, the robot scored 456 points out of 600 possible, it was 96 points more than required for a satisfactory result. In the "consciousness" of work there were downloaded textbooks on medicine. In the exam, the robot could not search for information on the Internet and gave answers based on theory learned from the textbooks. Xiao I Robot was developed by iFlytek, China, as a helpful physician assistant who can receive and analyze patient information. The developers believe that such experience can improve the effectiveness of patient's treatment. In addition, iFlytek plans to use artificial intelligence technology to find ways to treat cancer [9].

There are many examples of successful IoT use in medicine and every day their scope and capabilities are expanding. Summarizing these opportunities, we can identify the main perspectives for their use and potential areas for their positive impact on health care system:

1) optimization of control and management system in medicine. Real-time monitoring of physicians and patients with emergency call (surgery or procedures), status monitoring and medical equipment, automated inventory and reporting based on intensity of equipment's use in a particular crisis situation. These functions could be successfully relied on IoT.

2) improving the quality and efficiency of health care. With the help of IoT the process of equipment maintenance and repair can be automated. The general visualized information on entire hospital's status (a complete map of medical facility indicating the location of required facility and its status) is displayed.

Therefore, on the IoT basis a full integration with all systems of equipment management is ensured and reports that allow to improve the process of conducting daily / periodic health care procedures are created.

3) ensuring patient safety. Controlling the location and status of hospitals, equipment, staff, and patients with IoT help is an important prerequisite for safety and improvement of patient care. Employees can use location and status information (equipment, patients) to ensure that procedures start on time, reducing the waiting period. Status information can be integrated into existing software systems, helping to optimize and stabilize hospital workflows, improve patient care and safety.

4) prevention of force majeure. Modern healthcare facilities are faced with a wide range of tasks, such as hospital and its staff's safety, need for constant recruitment to improve work efficiency, constant monitoring of regulatory climate, and monitoring of patients' physical performance. And all these problems have a common reason - the lack of a comprehensive solution that will perform continuous measurement and control of environmental parameters, technological processes, status and condition of patients, staff, medical and other equipment. A syringe pump that is not used regularly, an open refrigerator with thermosensitive drugs – all this adversely affects the quality of medical services provided. Through continuous monitoring of temperature, humidity, pressure and other weather data, IoT can capture events that occur, collect all necessary information according to set requirements, display it on a single information screen, warn of unacceptable deviations or their possible occurrence, automatically turn on alarm in the event of a non-standard situation, ensure that data is collected and archived and analytical reports are generated. The sensors are easily placed in refrigerators or freezers, in wards, corridors or other medical premises of a hospital.

Despite the obvious benefits of Iot practical use in medicine, the downside of these processes – cybersecurity – is also relevant. Right now, cybercrime costs about $ 600 billion a year, up from $ 445 billion in 2014. This compares with a 10-year average economic loss from natural disasters of $ 208 billion – three times more [10].

In the context of this, a serious threat is the loss / disclosure of patients' personal data. Modern hospitals use network monitoring to collect information from all their equipment and encrypt data. Creating different levels of access to information limits the range of people who can access it. You can also see and control in real time what actions are being taken from each device. Accordingly, when developing such devices, priority must be given to ensuring complete security of the data transmitted and stored by IoT devices.

According to Hewlett-Packard (2015), over 70% of IoT devices have vulnerabilities, and 60% have a dangerous web interface. However, most of them have access to such information of their owners as address, e-mail and even a bank account [11].

This is often due to the fact that manufacturers, in order to reduce their costs, radically save on security. Cheap video camera manufacturing companies ignore the inclusion of security products because, from their point of view, low cost is far more important characteristics for most camera users. On January 9, 2017, the US Federal Trade Commission even filed a lawsuit against D-Link for poor protection of webcams and routers [12].

In 2016, a major breakthrough came from the successful cracking of an insulin pump by a diabetes hacker on his own device. It was accessed via an unsecured Wi-Fi channel. This episode almost caused the Johnson & Johnson pumps to disappear from the market, but as a result, the

company limited itself to sending out alerts to all users and claiming the risk as "overrated" [13].

To illustrate the worst-case scenarios of what could happen due to hacking attacks in IoT, Exlab chief S. Minraz cites an example of pacemakers: "… Everyone talks about the benefits of joining a cloud. But at the same time, it is assumed that the cloud is completely protected ... Many talk about pacemakers attached to the cloud. In fact, here's the advantage – if something goes wrong with your heart rate, you'll get an automatic alarm. But what if a terrorist, or just a child, for fun, would decide to give alarm to all pacemakers in America?" [4, p. 86].

Bruce Schneier (an associate at the Berkman Klein Center for Internet and Society at Harvard, a board member at Electronic Frontier Foundation, chief technology officer at IBM Resilient, which helps other campaigns prepare for potential cyber threats), in his new book, "Click Here to Kill Everybody", argues that governments should force gadget companies that go online to put security at first place and not at last. [14]

A number of important IoT cyber security issues have served as the basis for the TS 103 645 cybersecurity standard to be issued by the Technical Committee of the European Telecommunications Institute (ETSI) on cybersecurity [15]. The document establishes a basic security level for consumer products connected to the Internet and sets the stage for future IoT certification schemes.

TS 103 645 requires developers to abandon universal passwords' use, which have become a source of many security issues. It also provides for a vulnerability disclosure policy to allow security researchers and others to report issues. In addition, the standard will ensure compliance with General Data Protection Regulation (GDPR) standards for IoT devices and services that store and process personal data of users.

In addition, on the basis of TS 103 645, developers plan to introduce certification schemes that will help to protect the users' personal data.

One important feature of the standard is to reduce the number of passwords used by default. Standard passwords are one of the main causes of cyber security threats in the IoT sphere. TS 103 645 also includes a vulnerability disclosure policy: this encourages users to report device issues.

The application of this standard will also allow full compliance with the rules of the General Data Protection Regulation (GDPR), a special EU regulation aimed at protecting and unifying the personal data of all EU citizens. In turn, using GDPR will help protect users' personal information and bring a single regulatory framework across the entire IoT and IT sector.

A responsible entity, such as a service provider or device manufacturer, is required to ensure that personal data are processed in accordance with applicable personal data protection legislation (such as European GDPR), and in accordance with applicable legislation and regulatory security requirements.

Thus, the above-mentioned standard, in terms of personal data protection, provides, inter alia:

Regulation 4.8-1. Device manufacturers and service providers are required to provide consumers with clear and transparent information about how, by whom and for what purpose their personal data is used. This also applies to third parties that may be involved, including advertisers.

Regulation 4.8-2. If personal data are processed based on consumer consent, this consent must be duly obtained.

Provisions 4.8-3. Consumers who have consented to the processing of their personal data should be given the opportunity to withdraw their consent at any time.

Getting a "valid" consent usually involves giving consumers, in this case - patients, a free, obvious and explicit choice (and by default, there is no such consent - opt-in) for the use of their personal data for a specific purpose by third parties.

Patients expect that they will be provided with the means to protect their privacy by properly tuning the functionality of the IoT devices and services used in the health care delivery process.

The issues outlined in this paper encourage the suggestions of the domestic researcher O. Baranov, who believes that introduction and use of IoT in medicine makes the following legal studies urgently relevant: legislative regulation of medical services IoT using, in particular, in remote mode; setting boundaries and content of legal liability for medical personnel, telecommunications operators, equipment manufacturers and software developers; legal regime of admission to the market of medical services of autonomous software for mobile devices, remote diagnostics, etc.; legal regime of admission to the market of medical services, devices and diagnostic equipment; defining legislative requirements for transparency in informing the public about all features of the provision of medical services using IoT technologies; legal regulation of information collection and remote access to patient's health information [16, p. 10].

CONCLUSIONS

The development of a cybersecurity standard is an important step in legal normalization of the whole IoT field, including the medical field. Nowadays, the users' personal data of IoT devices remain unprotected, while the scope of such devices is growing.

Another problem is the initial non-adaptability of products to use when devices have design features that prevent the use of security standards. Security and privacy issues are one of the main obstacles to IoT development. In this regard, and in accordance with the essential requirements of TS 103 645, the following are proposed to IoT developers in the medical field:

– to abandon universal passwords, which are often the cause of cyber security problems;
– to publish all data on identified vulnerabilities in order to inform all companies interested about necessity to improve their own systems;
– to verify vulnerability of data coming from a user-friendly interface transmitted through APIs or external networks to prevent hacking and theft of data by malicious users;

The main goal of IoT development in medicine is to obtain the most complete information about the human body, on the basis of which it is possible to make informed decisions that prevent the emergence and development of diseases. Top priority should be given to human security. That is why cyber security issues remain and should continue to be a priority in the development of IoT. Today no IoT manufacturer can guarantee that the medical data will not be stolen or modified.

The task of state control is to establish regulation to persuade manufacturers to take it seriously. This requires that clear legal mechanisms be put in place at the state level to apply measures to IoT companies. Such measures should include flexible standards, clear rules, and strict obligations with the system of penalties for breaches.

In addition, it is advisable to provide high standards of care, to issue specialized or to amend existing clinical guidelines for the management of patients with various diseases and conditions where IoT technologies may be used.

REFERENCES

1. IoT Healthcare Market by Component (Medical Device, Systems & Software, Service, Connectivity Technology), Application (Telemedicine, Work Flow Management, Connected Imaging, Medication Management), End User, and Region. Global Forecast to 2022. Available from: https://www.marketsandmarkets.com/Market-Reports/iot-healthcare-market-160082804.html [reviewed 2019.09.13]
2. How IoT enhances medicine. M-Health Conference Tallinn. Available from: https://tallinn.mhealth.events/article/iot-v-meditsine-kak-internet-veshchey-sovershenstvuet-sferu-zdravoohraneniya-97414 [reviewed 2019.09.13]
3. Kevin Ashton That 'Internet of Things' Thing. RFID Journal. Available from: https://www.rfidjournal.com/articles/view?4986 [reviewed 2019.09.13]
4. Ross A. Industrii Maibutnoho. [Industries of the future] Nash Format. 2017. 320 p. (Ua)
5. Apple Research Kit: Everything you need to know about the medical research platform. June 9, 2017. Available from: https://www.wareable.com/features/what-is-apple-researchkit-iphone-watch-everything-you-need-to-know-931 [reviewed 2019.09.13]
6. Savchuk T. «Internet Rechei» Koly Kukhonnyi Toster Mozhe «Zlyty» Vashi Osobysti Dani. ["Internet of Things": When a kitchen toaster can "drain" your personal information] 28.12.2017. Available from: https://www.radiosvoboda.org/a/28944177.html. [reviewed 2019.09.13]
7. IBM Research AI Advancing AI for industry and society. IBM. Available from: https://www.ibm.com/artificial-intelligence [reviewed 2019.09.13]
8. Shcho take internet-rechei i navishcho vin potriben? TECHNO. 18 chervnia 2017 Available from: https://techno.nv.ua/ukr/popscience/lektorij-shcho-take-internet-rechej-i-navishcho-vin-potriben-1326653.html [reviewed 2019.09.13]
9. Robot Makes History by Passing Medical Licensing Exam. Available from: https://interestingengineering.com/robot-makes-history-by-passing-medical-licensing-exam [reviewed 2019.09.13]
10. Allianz Risk Barometer 2019: Cyber joins business interruption as a leading global risk for companies for first time. Press Release |January 15, 2019 Available from: https://www.agcs.allianz.com/news-and-insights/news/allianz-risk-barometer-2019.html?fbclid=IwAR0W--I7FL2qBXCR03kxZRPLEZstTyXW7dwgyvYBA1TFh-LGG6OHN4NSMv4 [reviewed 2019.09.13]
11. HP Study Reveals 70 Percent of Internet of Things Devices Vulnerable to Attack. News Advisory. Available from: https://www8.hp.com/us/en/hp-news/press-release.html?id=1744676 [reviewed 2019.09.13]
12. Federal trade commission d-link corporation and D-link systems, INC. Case 3:17-cv-00039 Available from: https://www.ftc.gov/system/files/documents/cases/170105_d-link_complaint_and_exhibits.pdf [reviewed 2019.09.13]
13. Johnson & Johnson says insulin pump 'could be hacked' BBC NEWS. 4 October 2016. Available from: https://www.bbc.com/news/business-37551633 [reviewed 2019.09.13]
14. Bruce Schneier Click Here to Kill Everybody Security and Survival in a Hyper-connected World. September 2018 W. W. Norton & Company. 288 p. Available from: https://www.schneier.com/books/click_here/ [reviewed 2019.09.13]
15. CYBER; Cyber Security for Consumer Internet of Things. ETSI TS 103 645 V1.1.1 (2019-02) Available from: https://www.etsi.org/deliver/etsi_ts/103600_103699/103645/01.01.01_60/ts_103645v010101p.pdf [reviewed 2019.09.13]
16. Baranov O.I. Internet rechei (IoT): ohliad pravovykh problem. [Internet of Things: An Overview of Legal Issues] Internet of Things: Problems of Legal Regulation and Implementation: materials of the scientific-practical conference October 24, 217, Kyiv. National Technical University of Ukraine "Igor Sikorsky Polytechnic Institute" Vyd-vo «Politekhnika». 2017. 238 p.

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REVIEW ARTICLE
PRACA POGLĄDOWA

ASSESSMENT CRITERIA FOR THE LAWFULNESS OF ARTIFICIAL INTELLIGENCE TECHNOLOGIES APPLICATION IN HEALTH CARE

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ABSTRACT

Introduction: The topicality of this research is reasoned by the lack of the unified assessment criteria for the lawfulness of Artificial Intelligence technologies application in health care, on the one hand, and the significant extension of the scope of their utilization for medical purposes, on the other.

The aim: of this article is to develop the assessment criteria for the lawfulness of Artificial Intelligence technologies application in health care, as well as to clarify the specifics of their legal and practical implementation.

Materials and methods: During the study a number of methods have been used, namely: theoretical methods - dialectical, logical, historical, analysis and synthesis; specific legal methods - comparative and legal, formal and legal, historical and legal, etc.

Conclusions: The author suggests specific steps for further development of the assessment criteria system for the lawfulness of the health-care workers' conduct directly related to Artificial Intelligence technologies application.

KEY WORDS: artificial intelligence technologies, assessment criteria, health care, lawfulness, patients' rights

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INTRODUCTION

Due to the intensive development of the latest information and communication technologies (hereinafter referred to as ICT) health care industry has entered a new phase of health service delivery system based on the dynamic application of artificial intelligence technologies (hereinafter referred to as AIT). Nowadays, AIT functional and technological capacities allow us to convert any sphere of health care from hospital records to diagnosis. Thus, they ensure processes automation of and increase ща diagnosis' efficiency and accuracy [1].

The research conducted by Frost & Sullivan on AIT in health care shows that there is the explosive market growth for these technologies from $600 million in 2014 to $6,6 billion in 2021 (according to preliminary estimates) with the combined annual average growth rate of 40% [2]. Furthermore, sociological surveys conducted by the international audit company PwC demonstrate that most health care consumers consider innovative types of medical treatment and consent to replace medical staff with AIT [3].

However, the existing legal mechanism for AIT application is still one of the key problems in the world health practice. It is about identifying the criteria assessment for the lawfulness of AIT application in health care and determining the legal environment for their further practical implementation.

THE AIM

The aim:of this article is to develop the assessment criteria for the lawfulness of AIT application in health care, as well as to clarify the specifics of their legal and practical implementation.

The main hypothesis of this study is revealed in the following conceptual provisions: 1) measures of lawful application of AIT for health needs should be determined by regulatory, legal and factual criteria; 2) such criteria reflect legislative, judicial, administrative, and ethical approaches to the evaluation of medical information processing algorithms as well as the practical outcomes of AIT application in healthcare; 3) regulatory criteria should be enshrined in international legal acts of the Council of Europe; as for the factual and legal criteria, they may be determined by the agreement between the healthcare facility and the patient or his/her authorized representative.

MATERIALS AND METHODS

During the study a number of methods have been used, namely: theoretical methods - dialectical, logical, historical, analysis and synthesis; specific legal methods – comparative-legal, formal-legal, historical-legal, etc.

During the study scientific findings devoted to e-Health and AIT application, as well as the results of the research on AIT application conducted by international audit companies such as Deloiite, PwC, Frost & Sullivan have also been taken into account.

REVIEW AND DISCUSSION

Since the scientific discussion devoted to the concept of "artificial intelligence in medicine" goes beyond the scope of

this study, for this particular research a previously proposed definition is used. Thus, "artificial intelligence in medicine can be defined as the ability of a computer programme or of a system to reproduce, either fully or partially, the behavior of healthcare workers providing medical services, by using the established algorithm of transforming the data included in the system into the target result, thus serving the patients' needs and interests" [4].

The following definition indicates two important rules that directly address the issue of the lawful use of AIT in health care. It is about the capacity of information systems along with hardware and software complexes to reproduce, either fully or partially, healthcare workers' behavior, on the one hand, and on the other one, such capacity is always based on technological abilities to transform specific sets of medical data into a predictable result by predefined algorithms.

In its essence, the first rule derives from the latter one. This, in turn, allows us to agree on a widely spread thought that AIT application in the diseases prevention, diagnosis and treatment should be characterized by the same requirements to the processes and results as to the professional conduct of health care workers [5, p. 41]. At the same time, the use of robotics or AIT should not replace human activity in any form, nor limit their control over the use of appropriate technologies [6, p. 14-15]. Thus, the European Parliament Resolution of 16.02.2017 No 2015/2013 (INL) P8_TA-PROV (2017) 0051 "Civil law rules on robotics" (hereinafter referred to as European Parliament Resolution "Civil law rules on robotics") enshrines the relevant rule in paragraph 3 of General Principles and extend its force over the public and private relations in health care which arising in the EU [7].

The development of the above mentioned doctrinal and regulatory approaches provides us with the grounds for application of the assessment criteria for the lawfulness of the individual's conduct for resolving similar problems related to the use of AIT in health care.

Hanna V. Svyrydenko in her research on the theoretical and practical grounds for the lawful conduct suggests such assessment criteria for the lawfulness of conduct as formal (external) and substantive (internal) ones. The same approach is illustrated by Prof. Mykola I. Koziubra in his textbook "The Theory of the Law and the State" [9, p. 286] as well as by some other researchers of the lawfulness of conduct in health care [10, p. 90-91].

Thus, Hanna V. Svyrydiuk believes that the formal criterion is based on a simple contrast or on the comparison of specific actions or behavior and relevant legal provisions [8, p. 56]. Consequently, the lawful conduct is the link between the legal provision and the result or socially beneficial effect on which such legal provision is intended [8, p. 56].

On their functional purpose, formal and substantive criteria reflect legal, motivational and ethical requirements for the lawful conduct. The infringement of these requirements as well as non-compliance with them may constitute a wrongful act, unless otherwise provided by the essence of the motives themselves. However, scientific research on AIT application in health care [11, p. 141-142] shows the necessity to clarify the assessment criteria for the lawfulness of an individual's conduct specified in the theory of law.

From our perspective, the formal criterion can be equated with the regulatory one, but in the structure of a substantive criterion we distinguish legal and factual criteria for assessing the measures of the lawfulness of AIT application in health care. The analysis of the international legal acts reveals the absence of special unified requirements for the procedure of development, testing and delivery of AIT to healthcare institutions, as well as for the determination of regulatory measures for patients' personal data processing and for the separation of liability of AIT developers and medical organizations using these technologies in their activities.

Nowadays these regulatory gaps are largely filled by applying the general principles for the development, test, supply and use of AIT as enshrined in international legal acts and the codes of conduct approved by international software producers associations. In particular, the European Parliament resolution on Civil Law Rules on Robotics in Paragraph 13 of the General provisions concerning the development of robotics and artificial intelligence for civil use provides a fundamental rule according to which the system of guidelines for robotics must be based on the ethical principles of "do the good" and "do no harm", and on the principles of autonomy, justice, respect for human dignity, equality, non-discrimination, the right to informed consent, privacy, family life, right to data protection [7]. With regard to the validity of these provisions of the Regulation, the exceptions are health care relationships related to the automated provision of authorization, registration, information and other public health services.

Similar in content, but not related to specific groups of social relations, the system of principles of AIT application was approved by the Organization for Economic Cooperation and Development on 22 May, 2019. In this document the Organization emphasizes the need to conduct transparent developments in the field of artificial intelligence and indicate such systems with appropriate marking [12]. Moreover, in order to ensure the further practical implementation of AIT in various spheres of public life as well as to prevent the risks associated with their application and development on 08 July 2019 G-20 Member Ministers for Economic Development made a joint statement at the International G-20 Summit in Tsukobe (Japan). The main idea of the Statement is the following: in order to increase the confidence in artificial intelligence technologies and to fully realize their potential it is necessary for a human to be in the center of artificial intelligence application [13].

Dr Tedros Adhanm Ghebreyesus, Director-General of the World Health Organization (hereinafter referred to as WHO), at the World Summit "Artificial Intelligence for the Good", held on May 15, 2018 in Geneva, Switzerland, describes the impact of AIT on the world health care and mentions that the risk of abuse is quite common whenever a new technology appears, and in light of this human rights are of particular importance [14].

Summarizing the world-wide approach to the regulation of social relations related to AIT application, we suggest that the regulatory criterion for assessing their lawfulness is outlined precisely by the principles of their development, testing and implementation. At the same time, the principles of AIT application for private purposes are human-oriented. In this context, the essence of the regulatory criterion for assessing the lawfulness of AIT application in health care is revealed in the following provisions: 1) regulatory requirements and standards for the provision of medical services using AIT must be approved by the national governments of individual states and based on the relevant rules of international law; 2) the medical worker's conduct when using AIT should not cause more significant risks to the patient's health, including mental health, than such risks would occur in the case of medical services provision in the traditional way; 3) machine learning algorithms should only be based on reliable, non-prohibitive medical data, which ensures the transparency of the specific outcome offered to the patient by AIT; 4) AIT application should act as only one of the instruments of medical services and in no way exclude the doctor's constant control over the procedures for providing medical services; 5) the provision of medical services using AIT must not be the only possible way of obtaining such services; 6) the processing of patient's data with the help of AIT should not be excessive in comparison to the nature of the medical services provided to him/her; 7) AIT application in health care is allowed only when there is the prior, explicitly expressed consent of the health care consumer, as well as the mandatory prior insurance coverage of the healthcare providers', developers' or AIT providers' liability.

At the same time, the lack of legislative support for the given components of the regulatory criterion in terms of assessment of AIT application lawfulness in the field of health care leads to the limitation of unified use of special requirements to the behavior of health care professionals in the process of those technologies' utilization. The solution for the problem outlined could be facilitated by the adoption of the Universal Declaration on the Principles of Legal Use of Artificial Intelligence Technologies in Health Care by WHO, which could specify legal and ethical principles of AIT use in medical practice, as well as the requirements for the developers and providers of the given technologies for health care needs and the obligations of WHO Member States regarding further implementation of the relevant principles into national legislation.

Legal criterion is important for the assessment of the lawfulness of AIT use in specific cases of medical practice. In our opinion, its essence is manifested in the judicial or extrajudicial (administrative) criteria of acts, decisions or omission of acts, committed by health care professionals with the use of AI technologies due to their compliance with legal grounds, conditions and the procedures of those technologies' application in medical practice. By its very nature, the legal criterion reflects the substantive meaningful aspect of the health care professionals' behavior when dealing with AIT.

In other words, those are the decisions, acts or omission of acts of health care professionals, made or implied on the basis of the results, obtained in the process of AIT use, as well as the reasons for approval or refusal to perform recommendations, received as a result of individual actions automation along with the procedures for medical care provision. Thus, the legal criterion is manifested not only through mechanical comparison of a professional's behavior with the legal requirements for medical practice in a particular country, but also through legal assessment of his actions and the results obtained under specific circumstances of medical service provision.

In this context, it can also be considered that the legal criterion provides the assessment of the lawfulness of AI technologies' application from the perspective of health care professionals and medical institutions adherence to the rule of law and natural human rights. In this regard, the opinion of the Council of Europe Commissioner for Human Rights can be shared. Hence, the report "Protecting of Human Rights in the Age of Artificial Intelligence" made by Dunia Mijatovich at Strasburg, 03.07.2018, states that "today there has been a number of standards that must be proceeded from, for example, the precedents of the European Court of Human Rights that clearly state the adherence to the right of non-interference into private family life, and the right to personal freedom and safety."[15].

The analysis of ECHR decisions in terms of the issues raised in the article demonstrated that modern system of precedents has been mainly focused on the prohibition of excessive automated processing of patients' personal data, the prohibition of automated processing of that category of persons' data without their explicit consent as well as inadmissibility of public disclosure of medical information along with the use of ICT. The need for protection of patients' rights is reflected, in particular, in the ECHR decision in the case of L.H. v. Latvia of 29, April, 2014 (application no. 52019/07) [16].

Thus, while considering the cases for the protection of patients' rights in relation to ICT application, ECHR mainly proceeds from the observance by the responsible party of the following natural rights of the person: the right of the patient to obtaining information of the health status, the results of the progress of the patient's disease, the methods of treatment; the right to a guaranteed minimum automated processing of the patient's personal data; the right to prohibit further processing of medical data by any means, including ICT; rights to ensure the safety of automated medical intervention into the patient's body for the sake of his or her health, etc.

At the same time, the application of formal, logical, comparative and legal methods for the research of ECHR decisions has shown that no standards of precedent decisions have been formed to date regarding the impact of machine learning algorithms on the provision of patients with an adequate level of health care. Those, in particular, include several legal matters, namely, determining the patient's appropriate consent for AIT use, the clarity and unambiguity of the reasons for AIT use for the purpose

of medical service provision, the validity and reliability of medical data used for information systems machine learning on the basis of AIT, determination of non-discrimination of machine learning algorithms in relation to different groups of patients, arrangement of the system of appropriate guarantees for the consumers of medical services provided with the use of AIT, etc.

In view of the absence of ECHR precedents on the given issues, the main emphasis in ensuring their legal and technical regulation is placed on the technical conditions for AIT development in medical practice and the contracts for the corresponding use of AIT drafted by electronic health care providers. Specifically, the technical task for the development of medical service software with the use of AIT determines technical requirements for corresponding software, characterizes technical architecture of AIT, defines the requirements for information security in case of further use of those technologies and information exchange of medical data along with machine learning of health care professionals, whose activity will be associated with the use of AIT, etc.

In terms of contracts for the provision of medical services with AIT use, based on the regulatory requirements of international legal acts [7; 11], first of all, the rights and responsibilities of health care professionals and patients should be determined, as well as the conditions for obtaining the appropriate consent from the patient to use AIT with medical and consulting purposes along with the rules for acquaintance with the functioning algorithms of AIT, the conditions of insurance of the health care provider liability and the principles of monitoring the work of AIT by the authorized health care professional, etc.

Thus, the legal criterion for the assessment of the lawfulness of AIT use in health care is determined by three sets of requirements: case (judicial), contractual and technical ones.

In contrast to the previously analyzed regulatory and legal criteria revealing the legal aspects of health care management, the factual criterion reflects the professional, social and biological assessment of the results of the use of health care in the process of AIT provision. In fact, it is about the assessment of AIT application, including the nature of the proposed treatment, disease prevention, consulting from the point of view of the optimality of the services provided, assessment of the potential risks in the process of ICT use, and the process efficiency of the proposed medical solutions for patients' needs.

In another context, the factual criterion characterizes the ability of AIT algorithms to provide automation of a particular health care professional's behavior under specific medical circumstances, identify and correct individual program errors made by the developer, and offer the optimal solution to the patient's problem, based on the predefined technical coordinates.

Similar to the legal one, the factual criterion for the assessment of AIT lawfulness in the field of health care is individual. It is manifested on a case-by-case basis under the influence of the patient's disease progress, selected methods of treatment or disease prevention and cannot be applied to other similar cases of AIT use in the field of health care.

In general, the criteria for the assessment of lawfulness of AIT use in health care suggested in the given article cover both, the external (general) and internal (meaningful) sides of health care professionals' behavior, and provide the assessment of the consequences of specific decisions automation as well as actions and processes in medical practice.

At the same time, the application of general and specific scientific (legal) methods of cognition showed that further research of the criteria of legitimate application of AIT in the field of health care will require the advancement of interdisciplinary approach to the research of outlined problems. That will facilitate the avoidance of major methodological constraints when examining the criteria for the behavior of health care professionals' assessment in the process of AIT use and allow methodological linkage of the regulatory and contractual requirements for health care institutions activity in the field of medical services automation, based on appropriate ICT.

CONCLUSIONS

The analysis of the existing doctrinal views on the issues raised in the article and the applicable international law provisions in the field of AIT use for health care purposes allows specification and justification of normative, legal and factual criteria for the assessment of health care professionals' behavior with the use of appropriate ICT.

While the first of these criteria reflects general legal requirements for health care professionals' behavior in the process of AIT use, the legal and factual criteria reveal the substantive components of such behavior. In other words, those criteria characterize the behavior of health care professionals from the point of view of their compliance with the patient's natural rights to life, the adequate level of health care, patients' personal data confidentiality, the terms of AIT medical services contracts, and the ethical standards of health care professional's activity.

In our view, to ensure further practical implementation of the criteria for the assessment of the lawfulness of AIT use in the field of health care and the increase of their social importance, it is necessary to take the following measures: 1) adoption by WHO the guidelines for the AIT management in terms of health care provision, treatment, diagnosis or disease prevention; 2) the European Parliament approvement of the rules for the application of AIT in the field of health care and the protection of patients' rights provision as well as updating and ratifying the annexes to the given Regulation concerning the standard forms of contracts for the provision of consultative, diagnostic, medical and health services on the basis of AIT with exemplary drafts of the technical tasks for the development of those technologies; 3) advance the research aimed at the improvement of the criteria for the assessment of lawfulness of AIT use for health care purposes, including the practice of ECHR and national higher judicial institutions on relevant issues.

REFERENCES:

1. Späniga S, Emberger A, Jan K et al. The virtual doctor: An interactive clinical-decision-support system based on deep learning for non-invasive prediction of diabetes. Artificial Intelligence in Medicine. 2019; 100: 81 – 96.
2. From $600 M to $6 Billion, Artificial Intelligence Systems Poised for Dramatic Market Expansion in Healthcare. Frost & Sullivan Research. Available from https://ww2.frost.com/news/press-releases/600-m-6-billion-artificial-intelligence-systems-poised-dramatic-market-expansion-healthcare/?fbclid=IwAR23Qxr9eBN0SpQav-PQDR4LPHAr-dNWQsy3sGj3N9BTrgYBOEqrUkGoRIlE [reviewed 2019.08.15]
3. Sizing the prize. What's the real value of AI for your business and how can you capitalise? Available from https://www.pwc.com/gx/en/issues/analytics/assets/pwc-ai-analysis-sizing-the-prize-report.pdf [reviewed 2019.08.17]
4. Zaiarnyi O. Directions for improving the legal liability of medical organizations for artificial intelligence systems application. Medicine and Law. 2018; 37 (2): 363 – 382.
5. Topol E. Budushee mediciny: Vashe zdorove v vashih rukah [The future of medicine: your health is in your hands]. Moscow. Alpina Publisher. 2016. 491 (Ru)
6. Paladin OV, Kurhaiev OP, Shevhenko AI. Noosferna paradigma rozvitku nauki ta shtuchnij intelekt [Noospheric paradigm for science development and artificial intelligence]. Cybernetics and System Analysis. 2017; 53 (4): 12-21 (Ua)
7. European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)). Available from http://www.europarl.europa.eu/doceo/document/TA-8-2017-0051_EN.html?redirect [reviewed 2019.08.17]
8. Svyrydenko HV. Pravomirna povedinka: teoretiko-prikladni zasadi [Lawful conduct: theoretical and practical aspects]. Dissertation for obtaining the Phd of Law 2017 (Ua)
9. Koziubra MI (Ed.) Zagalna teoriya prava [General theory of law]. Kyiv. Vaite. 2015. 392 p. (Ua)
10. Swanson A., Khan F. The Legal Challenge of Incorporating Artificial Intelligence into Medical Practice. Journal of Health & Life Sciences Law. 2012; 6 (1): 90–146.
11. Yeo C.J.J. Ethical dilemmas of the practice of medicine in the information technology age. Singapore Medical Journal. 2003; 44 (3): 141–144.
12. OECD Legal Instruments. Recommendation of the Council on Artificial Intelligence. Available from: https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449 [reviewed 2019.09.05].
13. Koizumi M. G20 ministers agree on guiding principles for using artificial intelligence. The Japantimes. Available from: https://www.japantimes.co.jp/news/2019/06/08/business/g20-ministers-kick-talks-trade-digital-economy-ibaraki-prefecture/#.XXzuxPAzapo [reviewed 2019.09.05].
14. Ghebreyesus TA. Artificial Intelligence for Good Global Summit. World Health Organization. Available from: https://www.who.int/dg/speeches/2018/artificial-intelligence-summit/en/ [reviewed 2019.09.05].
15. Mijatović D. Safeguarding human rights in the era of artificial intelligence. Available from: https://www.coe.int/ru/web/commissioner/blog/-/asset_publisher/xZ32OPEoxOkq/content/safeguarding-human-rights-in-the-era-of-artificial-intelligence?_101_INSTANCE_xZ32OPEoxOkq_languageId=en_GB [reviewed 2019.09.05].
16. Case of L.H. v. Latvia, application no. 52019/07, judgment of 29 April 2014. Available from file:///C:/Users/%D0%9E%D0%BB%D0%B5%D0%B3/Downloads/case-of-lh-v-latvia.pdf [reviewed 2019.09.05].

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REVIEW ARTICLE
PRACA POGLĄDOWA

ON MEDICAL PROFESSIONALS AND CRIMINAL LIABILITY: A DARK SIDE OF GOOD INTENTIONS

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ABSTRACT

Introduction: The study is devoted to the complex legal analysis of the crucial issues of criminal liability of medical professionals, including the problem of the definition of the socalled 'medical crimes' and liability for such acts.

The aim: The objective of the study is to examine unlawful acts of medical professionals, their legal estimation and regulation, ways for improvement.

Materials and methods: The study is based on the analysis of scholarly researches, legislation, judicial practice and statistics. Philosophical, general scientific, theoretical and legal methods provided the methodological basis of this research.

Conclusions: An attempt is made to identify the essence of the so-called 'medical crimes' content, alongside with the liability for them. Making reference to overseas experience, the recommendations to improve the criminal legislation are developed.

KEY WORDS: medical professionals, medical crimes, medical offences, criminal liability, criminal liability of medical staff

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INTRODUCTION

Current practice proves the fact that there is obvious complex interconnection between medicine and law. Having long-lasting history of their establishment along with the contemporary high-profile sensitive cases, as well as the significant amount of various scientific researches clearly reflects that the issue of their correlation certainly remains a focus of public attention, especially when it comes to medical professionals, their actions and liability. The existence of a large number of such notions and concepts as 'medical errors', 'clinical errors', 'medical accidents', alongside with 'medical negligence' and 'medical malpractice' in the information space invariably leads to the issue of their legal assessment, especially when it comes to criminal law. But even then a lack of common vision on terminology and essence of medical professionals' offences, as well as the imperfections of criminal legislation leads directly to the issue of the necessity of the conceptualization of the unified notion of the so-called 'medical crimes' and their proper enshrinement in legislation, resulting in certain need for its improvement, while considering foreign experience. However, despite the fact that the major part of the abovementioned issues is being widely discussed, still the very most of the scholarly researches are fragmental and mostly focused on specific narrow and limited scope so further study is obviously relevant.

THE AIM

The aim of the study is to identify the place of criminal liability in the system of liability of medical professionals, considering the acts committed, as well as to establish the nature and types of such acts, to define an appropriate terminology concerning the so-called 'medical crimes' and the range of such category of offences, along with the making of an attempt to its conceptualization, exploring the ways of legal regulation of criminal liability, alongside with the outline of ways to refine and improve the legislation through the prism of foreign experience.

MATERIALS AND METHODS

The study is based on the researches of scholars and leading experts in the field of medicine and law, legal acts (including Criminal Code of Ukraine, Georgia and the Republic of Kazakhstan, as well as the criminal legislation of the Republic of Austria, the United States of America, Canada, the Kingdom of Spain, the Federal Republic of Germany and the Republic of Poland), judicial practice (in particular, the decisions of Ukrainian courts, namely, 84 (all) judgements that were available through the Unified State Register of Court Judgments at the time of this research) and statistics. It is based on the principles of concreteness, objectivity and methodological pluralism, including philosophical, general scientific, theoretical other general and special legal methods.

REVIEW AND DISCUSSION

The world literature classic A. P. Chekhov, being a doctor himself, once mentioned that medical profession is a

feat, it requires self-sacrifice, purity of soul and purity of thoughts, and we believe that it truly is. As for now, it is considered as one of the most noble calling, a very special and significant craft that demands a lot of dedication and passion, knowledge and skills and imposes the tremendous responsibilities [1, p. 93]. But what if the intentions are not pure or pretty much close to it? This moment might probably be a starting point of the imposition of a liability. But what kind of liability, what type, on what grounds, conditions and obstacles it is based on?

The analysis of the major variety of scientific sources on this matter indicates that liability in the most general understanding is socio-legal regulator or, figuratively speaking, a certain measure of freedom [2, p. 18]. In the light of this, different its types such as moral, ethical and legal liability (which is also typically differentiating between disciplinary, material, civil, administrative and criminal) are traditionally distinguished. Apart from that, the idea of such subtypes of legal liability as medical and/or medical professional liability are becoming increasingly popular in science.

In general without going into too much detail it is necessary to mention that moral and ethical liability are appear to be a certain reaction of a society, while the legal one seems to be a reaction of a state. With regard to the distinction of different types of liability within the legal one it is noteworthy that criminal liability is considered as the most extreme form connected with the most severe punishment. In this regard the prominent ophthalmologist and diligent student of a well-known academician V. P. Filatov, who was working with him for a very long time, V. N. Streltsova (ed. – at the same time, the mother of I. L. Streltsov, the co-author of this article), very often recalls the metaphoric expressions of the famous ophthalmologist and surgeon in her memories. These were the certain reflection concerning the liability of medical professionals, namely, a though that civil and administrative liability can be considered as 'pharmacological therapy', but the criminal liability definitely has to be perceived as 'surgical treatment' or 'surgical intervention'; … it has to be viewed as the 'last resort' [3, p. 153].

And if the disciplinary liability (as well as material) usually is triggered with a 'labour offence', which is a violation of the requirements of labour legislation, labour discipline and internal labour regulations, there has to be a 'civil wrongdoing' or a violation of civil legislation, aimed to protect personal property and non-property rights in case of civil liability (as well as material, by a way of situation); administrative liability generaly is caused by an 'administrative offence', or a violation of administrative legislation, for instance, in our particular case, largely in the field of the labour safety and public health.

Unlike that, criminal liability in fact is imposed for a violation of criminal law and traditionally 'starts' with the commitment of a 'crime', as it is stated, for instance, in Part 1 of Article 2 of the current Criminal Code of Ukraine (hereinafter – CC of Ukraine), the ground for criminal liability is the commission by a person of a socially dangerous act that has such elements of crime as stated by this Code [4]. But to be more precise, – with the commitment of a 'criminal offense', which might take the shape of 'criminal misdemeanour' or a 'crime', considering the most recent amendments to CC [5, p. 162]. However, there is still no single consensus opinion regarding the issue of what exactly constitutes a 'criminal offense' when it comes to the matter of the interface between medicine and law (criminal one, in particular). Indeed, in our view, this is not much a question about which act has to be considered criminal as it is mostly about the range of particular acts that have to be deemed criminal in the field of medicine as well as more or less of ensuring and developing an appropriate terminology.

In this regard, the scientific discourse is full of variety of different concepts and dimensions for identifying such 'criminal unlawful acts': starting with a more 'traditional' standpoint of 'crimes in the medical field' (in their diversity, like 'crimes in the medical sphere', 'crimes in the field of medicine', 'crimes in the sphere of medicine' and etc.) [6, p. 90], continuing with the 'professional crimes' [7, p. 283] (ed. – of medical professionals) and/or 'occupational crimes' [8, p. 1] (ed. – of medical professionals), ending with an idea of the socalled 'medical crimes' [9, p. 2] (less frequently, 'healthcare crimes' [10] or 'crimes, which take place during the provision of health care' [11, p. 464]) and so on. In contrast, such terms and notions like 'liability issues in clinical practice' [12, p. 32] or 'legal issues in medical practice' [13, p. 335], 'liability for medical malpractice' [14, p. 51], criminal liability for 'medical negligence' [15, p. 372], 'clinical errors' [16, p. 323] and/or 'medical errors' [17, p. 256], 'medical accidents' [18, p. 51] and others are also widely being in use nowadays. Therefore, it should be noted that such plurality of different terms certainly leads to the issues of the comprehensive reflection and understanding of their essence, along with the specificity of their correlation. Moreover, another equally pertinent and remarkable issue is that of the existence of such diversity. In order to address this concern, the most common explanation is usually the comprehensive nature of medicine and, therefore, the complexity of the legal constructions. However, without prejudice to this statement, it can be hardly considered exhaustive to the fullest extent, some points are worth noting in this regard.

The first one is basically lying in the fact that the essence of this specific group of criminal offenses, the so-called 'medical crimes' is largely determined by the presence of a 'special subject of a crime' (particular offenders, who are medical professionals, even without taking into consideration the lively discussion on who should be considered as medical professionals, and, particularly is there any difference between a medical and pharmaceutical personnel, for instance [19]). However, even in such case this is not a 'panacea' due to the fact that medical professionals can simply commit ordinary and/or common criminal offences, and be criminally prosecuted on a general basis, for instance, for the commitment of a simple theft (Article 185), an intended minor bodily injury (Article 125)

or a simple murder (according to Part 1 of Article 115), foreseen by the current CC of Ukraine [4] and etc. As to bodily injury, although, it is necessary to mention that, for instance, in the Republic of Austria, the classic list of crimes against bodily integrity, including involuntary manslaughter and negligent bodily injury, equally applies to the medical profession [20, p. 1031].

The second idea is trying to be justified with the existence of the category of acts of medical professionals, related directly to their professional activity. Basically, it is assumed that the so-called 'medical crimes' can be considered as such only in case of the commitment of criminally punishable acts, related precisely to the medical profession. Hence, they are often referred to as the 'professional medical crimes'. For instance, in Ukraine, the vast majority of such criminal offences are enshrined in Chapter II of the current CC of Ukraine, entitled 'Criminal Offenses against Life and Health of a Person' [4]. Basically they include professional misconduct causing infection of a person with human immunodeficiency virus or any other incurable contagious disease (Article 131); disclosure of information on medical examination for human immunodeficiency virus or any other incurable contagious disease (Article 132); illegal abortion or sterilization (Article 134); illegal medical practice (Article 138); failure of a member of medical profession to provide aid to a patient (Article 139); improper performance of professional duty by a member of medical or pharmaceutical profession (Article 140); violation of patient' rights (Article 141); illegal experimentation on a human being (Article 142); violation of procedures prescribed by law with regard to human organs or tissue (Article 143); forcible donation of blood (Article 144) and unlawful disclosure of confidential medical information (Article 145) [4].

In addition, it is also worth noting that there is one more ground for shaping the understanding of the notion of the so-called 'medical crimes'. This is the frequently expressed idea of the inclusion of criminally punishable acts that arise out of medical occupation to the abovementioned category. They are traditionally considered as the so-called 'criminal offenses in office', stipulated in Chapter XVII of the current CC of Ukraine, entitled 'Criminal Offenses in the Area of Official Activity and Professional Activity Relating to the Provision of Public Services' [4]. Commonly they include improper performance of duty with regard to children's life safety and health care (Article 137); violation of the right to free medical assistance (Article 184); abuse of authority or office (Article 364); forgery in office (Article 366); neglect of official duty (Article 367); acceptance of a proposal, promise or receipt of an unlawful benefit by an official (Article 368) [4] and etc.

Nevertheless, it is fair to say that there are much more ways of classifying the so-called 'medical crimes' depending on the approach used. Indeed, based on the understanding of these crimes' definition, it is possible to emphasize that there are much more criminal offences enshrined in the current CC of Ukraine in the broadest sense, except those, that are stipulated in Chapter II ('Criminal Offenses against Life and Health of a Person') and Chapter XVII ('Criminal Offenses in the Area of Official Activity and Professional Activity Relating to the Provision of Public Services') of the current CC of Ukraine [4]. Special attention in such a case also needs to be paid to Chapter III ('Criminal Offenses against Liberty, Honor and Dignity of a Person'), in particular, for instance, to such crimes as substitution of a child (Article 148); illegal placement of a person in a mental institution (Article 151), as well as to Chapter XIII ('Criminal Offenses Related to the Circulation of Narcotics, Psychotropic Substances, Their Analogues or Precursors, and Other Offenses against Public Health'), – illegal issue of a prescription authorizing the purchase of narcotics or psychotropic substances (Article 319); illegal production, making, purchasing, transportation, sending, storage for selling purposes, or sale of poisonous and drastic substances (Article 321); counterfeiting of drugs or trafficking of counterfeit drugs (Article 321^1); violation of established procedure for preclinical study, clinical trials and state registration of drugs (Article 321^2) [4] and so on. Although, even this list is far from being completely exhaustive.

It must be noted that other countries' experience shows using of pretty much similar approach, for instance, in Criminal Code of Georgia (hereinafter – CC of Georgia), in which the so-called 'medical crimes' mentioned in such different chapters, as Chapter XIX ('Crimes against Life'), Chapter XX ('Crimes against Health), Chapter XXI ('Endangering Human Life and Health'), Chapter XXIII ('Crime against Human Rights and Freedoms'), Chapter XXXII ('Crime against Public Health and Public Morals') and others, including killing at the victim's request (Article 110); negligent manslaughter (Article 116); different degrees of bodily injuries (Articles 117, 118, 120, 124); refusal to help (Article 129); abandoning a sick person in distress (Article 130); infecting with AIDS (Article 131); infecting with particularly dangerous infectious disease (Article 132); illegal abortion (Article 133); coercion into removing a human organ, part or tissue of an organ (Article 134); illegal trade of blood or blood components (Article 135); trade of human organs (Article 135^1); genetic manipulations (Article 136); illegal placement or detention in a psychiatric hospital (Article 149); illegal medical or pharmaceutical practice (Article 246); breach of sanitary-epidemiological standards (Article 248); breach of the regulations for poison circulation (Article 249); unlawful appropriation or extortion of poison (Article 250) [21] and etc.

Nevertheless, Criminal Code of the Republic of Kazakhstan (hereinafter – CC of the Republic of Kazakhstan), for instance, is constructed differently, as it contains a separate specific chapter, 'Chapter 12. Medical Criminal Infractions', which is dedicated directly to medical criminal offenses, including improper performance of professional obligations by medical or pharmaceutical employee (Article 317); violation of procedure of conducting of the clinical researches and use of the new methods and means of prevention, diagnosis, treatment and medical rehabilitation (Article 318); illegal performance of abortion (Article 319); failure to assist sick person (Article 320); disclosure of medical

secret (Article 321), illegal medical and pharmaceutical activity and illegal issuance or forgery of prescriptions or other documents, granting the right to obtain the narcotic drugs or psychotropic substances (Article 322); handling with counterfeit drugs, medical products or medical equipment (Article 323) [22] and so on.

But despite an impressive number of criminal offences, stipulated by the current CC of Ukraine, which is commonly associated with the so-called 'medical crimes', the vast majority of them remains unexploited. In fact, it is suggested that a very large part of criminal proceedings in Ukraine has been very often initiated related only to failure to perform or improper performance of professional duty by a member of medical or pharmaceutical profession due to neglect to discharge this duty, which caused grave consequences for a patient (Article 140 'Improper performance of professional duty by a member of medical or pharmaceutical profession'). However, sometimes two more articles such as illegal medical practice (Article 138) and failure of a member of medical profession to provide aid to a patient (Article 139) are also applied [23]. This concern was likewise reflected in the judicial practice. Therefore, at the time of this writing, the analysis of the decisions of the courts of Ukraine indicates that among 84 court sentences under Articles 131, 132, 134, 138-145 of the current CC of Ukraine (the so-called 'medical crimes' in one of the narrowest senses of their understanding), 76 convictions were rendered under Article 140, 1 – under Article 132, 1 – under Article 134, 4 – under Article 138 and 2 – under Article 139. At the same time, the overwhelming majority of them was either exemption from serving a sentence [24], either compensation for material and moral damages [25], or the acquittal [26]. Thus, the resulting data is a 'perfect illustration' of the previous statement as well as the allegations concerning the fact that cases of criminal prosecution of medical professionals, and even more so the conviction in Ukraine are relatively infrequent still may be considered as absolutely fair nowadays.

Moreover, according to the opinion of the national and foreign experts, a similar trend also applies to the judicial practices of the United States of America, where, among other things, such a situation is largely explained by the relatively high latency of the so-called 'medical crimes' [27, p. 36] and Canada, which had fairly limited number of cases and very small conviction rate that, in general, convey the idea that criminal law has quite restricted application in this area [28, p. 25]. In contrast, despite such a small number of cases, it is commonly believed that similar to other European countries, both Ukraine and, for instance, the French Republic have thus experienced a rise in the number of criminal proceedings relating to the liability of medical professionals [29, p. 46] and the Kingdom of Spain, where the number of claims has increased dramatically and so has the number of judicial decisions [30, p. 153].

However, it is worth noting that such a state of affairs substantially can be explained not only by the shortcomings of the criminal legislation, but due to the application of the law and procedural matter [6, p. 90]. There is no doubt that these issues are thorny and sensitive ones, which are provoking a public outcry. In this case, special attention should be given, for instance, to the electronic petition on the official web-site of the President of Ukraine concerning the liability of medical professionals [31]. Despite the fact that the collection of signatures was closed and the petition hasn't been supported, its content hasn't lost its significance. This involves, in particular, the artificial delay both of the investigation of the so-called 'medical cases' and their trial due to the inadequacy of the legislation, as well as the 'conspiracy of silence' between medical professionals [31]. Significantly that such situation is not exclusive exists not only in Ukraine, but also in a number of other countries. Thus, for instance, the issues of the shortcomings in the law and the 'complicity of medical professionals' are very familiar and widely debated in the Republic of India and are expressed in the problem concerning the assessment of the acts of the medical professionals by other medical professionals, who usually hesitate to testify against each other' (ed. – are biased and tainted), which ultimately makes it exceptionally difficult to found them criminally liable [32, p. 9]. A similar situation can be also observed in Federal Republic of Germany, where approximately ninety-five percent of cases have been stayed for the lack of evidence or public interest, while in cases that proceed to trial, the medical professionals will usually secure an acquittal or generally pay a fine [33, p. 1142]. In the Republic of Poland the situation is made difficult by the fact that malpractice cases are long-term and expensive while their result is usually uncertain and not easily predicted [34, p. 1261].

CONCLUSIONS

Realities of the twenty-first century sharply demonstrate how highly complex public relations that arise in the field of the activity of medical professionals are, especially with regard to the issues of liability for their 'unconscionable' acts. Their complicated nature gives grounds for asserting the formation of distinct type of liability – 'medical liability', along with the establishment of such separate group of criminal offences as 'medical offences'. 'Medical liability' is suggested to be as one of the peculiar types of legal liability, including disciplinary, material, civil, administrative and criminal liability, where the last one 'occupies a special place' and considered as the very 'last frontier', while 'medical offences' include 'labour offences', 'civil wrongdoings', 'administrative offences' and 'criminal offences', that, in turn, gives rise to the existence of such unique category in criminal law as 'medical criminal offences', which, in turn, can be roughly divided into criminal offences against life and health of a patient; criminal offences against rights of a patient; criminal offences in the field of economic activity in medical practice; criminal offences in the field of trafficking in narcotic drugs, psychotropic substances, analogues or precursors and other criminal offences, committed by medical professionals due to their professional activities. Such an attempt towards the conceptualization of 'medical criminal liability', as a part of 'medical liability' and 'medical criminal offences' leads to an appropriate legal enshrinement. In order to do so, however, the changes to legislation are highly necessary. To that end with due regard for the knowledge and foreign experience acquired the establishment of a separate chapter of the current CC of

Ukraine, which, in view of the structure of the existing code, might be possibly entitled as 'Criminal offences in the field of medical activity' or 'Criminal offenses related to the medical activity' considered as a feasible option.

REFERENCES

1. Săraru IC. Medical malpractice regulation. Civil, administrative, and criminal liability. Rom J Ophthalmol. 2018 Apr-Jun;62(2):93–5.
2. Tereshchuk M. M. Yurydychna vidpovidalnist: teoretyko-pravovyi analiz [Legal liability: theoretical-legal analysis]. Jurnalul juridic national: teorie şi practică. 2015;2:18–21. (Ua)
3. Streltsov E. Contemporary possibilities of state impact on crime: Some reflections. Journal of the South Regional Center of National Academy of Legal Sciences of Ukraine. 2014;1:151–60.
4. K ryminalnyi kodeks Ukrainy: Zakon Ukrainy [Criminal Code of Ukraine: Law of Ukraine] № 2341-III vid 5 kvitnya 2001 r. Available from: http://zakon2.rada.gov.ua/laws/show/2341-14. [reviewed 2019.08.20] (Ua).
5. Künnecke A., Kuzmin E.E. On the verge of change: Ukrainian understanding of the notion of crime & the model of the Federal Republic of Germany. / Streltsov Ye.L., Tuliakov V.O., Kedyk V.P. et al., editors. Criminal offense national and foreign dimension. Proceedings of International scientific-practical conference; 2019 May 24; National university "Odesa law academy", Odesa, Ukraine. Odesa: Yurydychna literatura; 2019: 161–165.
6. Aliieva OM. Zlochyny u sferi medychnoi diialnosti [Crimes in the field of medical activity]. In: Proceedings of the 69-i scientific conference faculty of the Faculty of Economics and Law Odessa. I. I. Mechnykov National University; 2014 November 26-28; Odesa, Ukraine. Odesa: Astroprynt; 2014: 90–92. (Ua)
7. Halkin IH. Kryminalna vidpovidalnist medychnykh pratsivnykiv za vchynennia profesiinykh zlochyniv [Criminal liability of medical professionals for the commission of professional crimes]. Current policy issues. 2015;55:283–92. (Ua).
8. Hogan S. Medical crime: occupational crime at its worst. Sociological Imagination: Western's Undergraduate Sociology Student Journal. 2016;5(1):1–6.
9. Fathi MJ. Examination of crime and similar concepts in the medical law. J Med Ethics Hist Med. 2016 May 1;9:4.
10. Office of the Maine Attorney General. Healthcare crimes. 2014. Available from: https://www.maine.gov/ag/crime/crimes_we_prosecute/healthcare_crimes.shtml. [reviewed 2019.08.20]
11. Vorobiova K. Vidpovidalnist medychnykh pratsivnykiv za nenalezhne nadannia medychnoi dopomohy [Responsibility of medical professionals for the inadequate provision of medical care]. State and law in the context of globalization: realities and prospects. Proceedings of the second International scientific-practical conference 2010 Apr 16-17; Simferopol, Ukraine. 2010: 464–465. (Ua)
12. Culbertson D., Scudder S.G. Liability issues in clinical practice. Perspectives on Administration and Supervision. 2008;18(1):32–40. doi: 10.1044/aas18.1.32
13. Thomas J. Ethical and legal issues in medical practice. Indian J Urol. 2009 Jul;25(3):335–6.
14. Danzon P.M. Liability for medical malpractice. Journal of Economic Perspectives. 1991;5(3):51–69.
15. Pandit M.S., Pandit S. Medical negligence: Coverage of the profession, duties, ethics, case law, and enlightened defense – A legal perspective. Indian J Urol. 2009 Jul;25(3):372–8. doi: 10.4103/0970-1591.56206
16. Oyebode F. Clinical errors and medical negligence. Med Princ Pract. 2013;22(4):323–33. doi: 10.1159/000346296.
17. Myers K. Medical errors: causes, cures, and capitalism. J Law Health. 20012002;16(2):255–88.
18. Meisel A. The expansion of liability for medical accidents: from negligence to strict liability by way of informed consent. Neb Law Rev. 1977;56(1):51–152.
19. Havrylenko L. Shchodo vidnesennia do katehorii medychnykh pratsivnykiv [Regarding the inclusion to the category of medical professionals]. 2011. Available from: http://parusconsultant.com/?doc=070EM14143. [reviewed 2019.08.20] (Ua)
20. Koch B.A. Medical malpractice in Austria. Chi.-Kent L. Rev. 2011;86(3):1027–52.
21. Parlament Gruzii. Ugolovnyj kodeks Gruzii [Criminal Code of Georgia]. 1999. Available from: https://matsne.gov.ge/ka/document/download/16426/143/ru/pdf. [reviewed 2019.08.20] (Ru).
22. Parlament Respubliki Kazahstan. Ugolovnyj kodeks Respubliki Kazahstan [Criminal Code of the Republic of Kazakhstan]. 2014. Available from: https://online.zakon.kz/document/?doc_id=31575252#pos=5;-157. [reviewed 2019.08.20] (Ru)
23. Zozulia N. Osoblyvosti prytiahnennia likariv do kryminalnoi vidpovidalnosti [Features of criminal prosecution of doctors]. 2019. Available from: https://protocol.ua/ua/osoblivosti_prityagnennya_likariv_do_kriminalnoi_vidpovidalnosti/. [reviewed 2019.08.20] (Ua)
24. Lychakivskyi raionnyi sud m. Lvova. Vyrok u spravi № 463/4211/17 vid 12 chervnia 2019 roku [Judgement in case no. 463/4211/17 of 12 June 2019] Available from: http://reyestr.court.gov.ua/Review/82352587. [reviewed 2019.08.20] (Ua)
25. Korostyshivskyi raionnyi sud Zhytomyrskoi oblasti. Vyrok u spravi № 280/490/17 vid 14 travnia 2019 roku [Judgement in case no. 280/490/17 of 14 May 2019] Available from: http://reyestr.court.gov.ua/Review/81701139. [reviewed 2019.08.20] (Ua)
26. Chornobaivskyi raionnyi sud. Vyrok u spravi № 709/3287/14-к vid 31 bereznia 2016 roku [Judgement in case no. 709/3287/14-к of 31 March 2016] Available from: http://reyestr.court.gov.ua/Review/56926280. [reviewed 2019.08.20] (Ua)
27. Boldizhar S. O., Khokhlova I. V., Pishta V. I. Osoblyvosti kryminalnoi vidpovidalnosti medychnykh pratsivnykiv u SShA [The main questions of criminal responsibility of medical personnel in the United States]. Uzhgorod National University Scientific Bulletin Law Series 2016;37(3):36–9. (Ua)
28. McDonald F. The criminalisation of medical mistakes in Canada: a review. Health Law J. 2008;16:1–25.
29. Faisant M, Papin-Lefebvre F, Rerolle C et al. Twenty-five years of French jurisprudence in criminal medical liability. Med Sci Law. 2018 Jan;58(1):39–46. doi: 10.1177/0025802417737402
30. Martín-Casals M, Ribot IJ, Solé FJ. Medical malpractice liability in Spain: cases, trends and developments. Eur J Health Law. 2003 Jun;10(2):153–81. doi:10.1163/092902703769681605
31. Shulzhenko YI. Elektronna petytsiia "Shchodo posylennia vidpovidalnosti medychnykh ta farmatsevtychnykh pratsivnykiv za svoie nedbale abo khalatne vykonannia profesiinykh obov'iazkiv ta pryiniattia spetsialnoho Zakonu pro vidpovidalnist medychnykh/ farmatsevtychnykh pratsivnykiv" [Electronic petition 'Concerning the strengthening of the liability of medical and pharmaceutical personnel for their malpractice and negligent performance of their professional duties and the adoption of special Law 'On the liability of medical and pharmaceutical personnel']. 2019. Available from: https://petition.president.gov.ua/petition/50536. [reviewed 2019.08.20] (Ua)

32. Singhal A. The veracity of laws relating to medical malpractice in India: Scope and nature. International Journal of Scientific and Research Publications. 2015. Available from: http://www.ijsrp.org/monograph/Veracity_of_laws_relating_to_medical_malpractice_in_India.pdf. [reviewed 2019.08.20]
33. Marc SS. Medical malpractice and compensation in Germany. Chi.-Kent. L. Rev. 2011;86(3):1139–68.
34. Kinga B-R. Medical malpractice and compensation in Poland. Chi.-Kent L. Rev. 2011;86(3):1217–61.

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REVIEW ARTICLE
PRACA POGLĄDOWA

INTERNATIONAL STANDARDS FOR APPLICATION OF COMPULSORY MEDICAL MEASURES

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ABSTRACT

Introduction: The study of the international standards of compulsory medical measures' (CMM) application to persons who have committed socially dangerous acts is relevant problematics of medical law.

The aim: of the research is to define international standards for the implementation of CMM, as well as assessing the state of their implementation in Ukrainian law and medical practice.

Materials and methods: The study is based on international acts, ECHR decisions, legislation of Ukraine and foreign countries, scientific articles in the fields of law and psychiatry as well as empirical materials that illustrate application of CMM in Ukraine. Dialectical, comparative-legal, statistical, induction and deduction, legal modeling, sociological research were used in this research.

Conclusions: As a result of the research the concept of the international standards of CMM application is defined, their scope in the law-enforcement and medical practice of Ukraine is determined, the system and meaning of these standards are formulated.

KEY WORDS: compulsory medical measures, psychiatric disorder, psychiatric care, mentally ill person, involuntary hospitalization

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INTRODUCTION

Legal regulation of compulsory medical measures (hereinafter - CMM) is of extraordinary importance in medical law as they are applied to persons who have committed socially dangerous acts and provide for forced restriction of their freedom. However, both in Ukraine and in foreign countries, there are numerous, but typical problems, which causes the international community a need to develop certain standards of their application.

THE AIM

The aim:of the scientific article is to define international standards for the CMM implementation, taking into account international legal documents, decisions of the European Court of Human Rights (hereinafter - ECHR) and some states' experience, as well as assessing the state of their implementation in Ukrainian law and medical practice.

MATERIALS AND METHODS

The legal basis for the study is the International Covenant on Civil and Political Rights (1966) (hereinafter - the Covenant), the European Convention for the Protection of Human Rights and Fundamental Freedoms (1950) (hereinafter - the Convention), "Principles for the Protection of Persons with Mental Illness and the Improvement of Psychiatric assistance", as approved by UN General Assembly Resolution No. 46/119 of 17.12.1991 (hereinafter - the Principles), ECHR decisions, legislation of Ukraine and foreign countries (Austria, Italy, Latvia, Poland, Germany, San Marino) in the field of CMM. The theoretical basis is the scientific researches on using of CMM and forensic psychiatry. The empirical basis is: 1) statistics of the Prosecutor General's Office of Ukraine on CMM implementation in 2014-2019; 2) results of public examination of the activity of the Ministry of Health of Ukraine; 3) results of the authors' survey of Ukrainian judges, prosecutors and lawyers on practical application of international standards for CMM; 4) results of the authors' summary of 50 t decisions of the Ukrainian courts on CMM application. The study is based on such methods as dialectical, comparative-legal, statistical, induction and deduction, legal modeling, sociological research.

REVIEW AND DISCUSSION

The increase in the number of people being subjected to compulsory psychiatric treatment is a pan-European tendency that has been observed for the last 20 years

[1]. At the same time, democratic countries' legislation attaches particular importance to the rights' protection of the mentally ill and assumes compulsory treatment as an absolutely exceptional measure [2]. This is due to the fact that the implementation of such measures involves the emergence of a number of ethical issues regarding the compulsory nature of treatment and the restriction of patients' personal freedom [3].

Such problems are most acute when using CMM, which is quite common in Ukraine. Thus, in 2014 940 petitions were submitted to the court for CMM implementation, 946 – in 2015, 866 – in 2016, 1110 – in 2017, 1070 – in 2018 [4]. In each such case not only the national law's rules but also the international standards must be strictly observed. At the same time, a survey of Ukrainian judges and prosecutors involved in deciding on CMM implementation showed that only 43% of judges and 27% of prosecutors recognize the importance of international standards in the CMM application; only 19% of judges and 13% of prosecutors are aware of ECHR practices in CMM using; and less than 5% refer to it proceeding decisions. The situation is somewhat better for lawyers, with more than 85% of respondents recognizing the importance of using such international standards; 70% are aware of practices in the field of CMM and more than 60% refer to it in practice. This can be explained by lawyers' interests in improving the legal status of their clients while CMM applying.

At the same time, the analysis of jurisprudence of Ukraine in the field of CMM makes it possible to conclude that in the relevant court decisions there is almost no reference to the international standards and practice of the ECHR in this area. This is a major drawback, since the principles of the rule of law and legality in Ukrainian criminal proceedings must be applied taking into account the ECHR practice.

International standards do not consolidate the concept of CMM, considering it in the context of forced confinement. Their basis is Art. 9 of the Covenant, according to which restriction of human freedom in any form is possible only by court's decision and Art. 5 of the Convention, which stipulates that no one shall be confined except in the established cases and by court's decision. Such cases include the lawful detention of mentally ill persons (item "e)" Part 1 of Art. 5 of the Convention). Some ECHR practices have been developed regarding the application of this provision, which clarifies and develops a system of international standards for CMM implementation. The international standards for CMM implementation are closely related to protection of mentally ill persons' rights, to whom such measures are envisaged. Therefore, such system should include the Principles that provide standards for the rights of persons with mental illness, definition of such diseases, their treatment, etc.

In Ukraine the CMM concept enshrined in Art. 92 of the Criminal Code (hereinafter – the Criminal Code), is in fact determined by the variants of relevant measure and an indication of the purpose of their application. CMM are measures of criminal nature that are an alternative to criminal punishment for mentally ill persons. They, according to V.I. Borisov and V.S. Batyrgareeva, are manifestation of the society's reaction to socially dangerous actions by borrowing measures and means inherent in medicine, psychiatry, psychology and other related spheres [5].

CMM's purpose is compulsory treatment of a person to prevent him/her from committing socially dangerous acts. This dual purpose is driven by the combination of medical and legal factors that determine CMM use. Thus, the medical (or more precisely, medical and social) factor determines the need for healthcare for mentally ill persons in accordance with the constitutional right of everyone to healthcare and medical care (Article 49 of the Constitution of Ukraine). The reference to CMM's medical purpose corresponds to scientists' position, according to which psychotropic drugs' use for socially dangerous mentally ill persons only to control their behavior and without therapeutic intent is unethical and contrary to the purpose of psychiatry [6]. However, in the Ukrainian legislation, CMM's medical purpose was formulated unsuccessfully, as it indicates a process (treatment) rather than a result (some positive changes in the health status of a patient being treated) [7]. Considering this, CMM's purpose should be to identify the cure or improvement of such persons' health status, the achievement of which is related at the same time to the complex of social rehabilitation measures and to pharmacological and other medical impact on patients' health whose care is required by court decisions [8]. The organization of treatment-rehabilitation and preventive process belongs to the field of psychiatry as a branch of medicine, which deals with diagnosis, therapy and prevention of mental illness [9]. Accordingly, medical aspect of CMM implementation in Ukraine is regulated by the Law on Psychiatric Care of 22.02.2000, which defines legal and organizational principles of providing individuals with psychiatric care, as well as by-laws of the Ministry of Health of Ukraine.

The legal factor takes into account the social dangers of persons who have expressed themselves in committing socially dangerous acts to those around them and to themselves, and determines the need to completely or partially isolating these persons from society and to correct their behavior to prevent them from committing other socially dangerous activities, as well as impossibility of bringing such persons to criminal liability in a general manner. The ECHR emphasizes that "legitimate" concept covers both procedural and substantive rules (p. 39 of the ECHR decision in Winterwerp's case, v. the Netherlands) [10], from which it can be concluded that this criterion has two components: criminal-legal and criminal procedural.

The criminal-legal component envisages committing a socially dangerous act by a relevant person, stipulated by the law on criminal liability, as a result of which CMM are applied instead of criminal liability, to which these persons cannot be prosecuted (in Ukraine, CMM types, grounds and conditions of their usage are regulated by Art. Art. 92-95 of the Criminal Code). According to this criterion, CMM differ from emergency compulsory outpatient or

inpatient psychiatric care in psychiatric institutions provided to patients who, by their mental health status, are dangerous to themselves or others but have not committed any socially dangerous acts, [8]. Therefore, it seems controversial that CMM using is based not on the fact of committing a socially dangerous act by a person, but on his/her mental illness [11], because without the fact of such action CMM are not used.

The criminal-procedural component stipulates that CMM have been applied to a person by a court order in accordance with the procedure established by law (in Ukraine such procedure is regulated by Chapter 39 of the CPC). In the ECHR's view, the formula "in the order prescribed by law" indicates the need to follow due process in accordance with national law [10]. This necessity is due to the fact that compulsory hospitalization of a person in a psychiatric institution often leads to interference with his/her private life and physical inviolability through medical interventions against his/her will (p. 53 of the ECHR decision in Zagidulina's case, v. Russia) [12].

Thus, CMM can be defined as an alternative to criminal punishment criminal-legal measures of a medical nature, which in the established criminal procedural law apply to mentally ill persons who have committed socially dangerous acts, provided by the law on criminal liability, with the purpose of their treatment and minimization of publicity.

Three minimum conditions that the ECHR has provided for assessing lawfulness of deprivation of freedom for mentally ill persons for CMM use: (1) competent authority has established the existence of a mental disorder on the basis of objective medical examination; (2) mental disorder must be of such a nature or degree as to justify forced deprivation of freedom; (3) The validity of long-term confinement depends on the persistence of such a disorder (p.39 of the ECHR decision in Winterwerp's case, v. the Netherlands) [10].

These criteria are further detailed in ECHR decisions. For example, the first criterion is complex and implies that procedure for deciding on CMM using requires three mandatory conditions: (1) presence of a person's mental disorder; (2) evidence of his/ her impartial medical examination; (3) establishment by the competent authority.

The presence of a mental disorder requires its establishment and proof in accordance with the law, based on the presumption of person's mental health. According to Art. 3 of the Law of Ukraine "On Psychiatric Care", each person is considered to be one who has no mental disorder, until its presence is established on the basis and in accordance with lawful procedure. With respect to criminal liability the effect of this presumption is quite clearly disclosed in the McNaughton rules, which operate in the Anglo-Saxon legal system, according to which a person is presumed to be mentally healthy and possessed of reasonable level of responsibility to be held accountable for his/her crimes unless otherwise is proven. A person is not criminally responsible for his/her behavior due to mental illness or inferiority, he/she has no ability to understand or evaluate its nature and consequences [13]. Therefore, presumption of mental health implies CMM use as a condition for exclusion of a patient with a mental disorder from the general rules and procedures for criminal prosecution.

Definition of the competent authority is carried out by national legislation. According to the Principle 17 "Supervisory Authority" is a judicial or other independent and third-party body, created and functioning in accordance with the procedures established by national legislation. During decision-making it uses the assistance of one or more qualified and independent practitioners in the field of psychiatry and takes their advice into account. In Ukraine such a competent authority is the court that has exclusive powers in CMM which in itself is an effective guarantee of the rights of the mentally ill persons.

Special medical knowledge not possessed by a court or other competent authority is needed for an objective medical examination. In Ukraine, deciding on CMM application, law provides for obligation of forensic psychiatric examination, which, according to Art. 509 of the CPC of Ukraine, should be conducted if: 1) according to medical document a person has a disorder of mental activity or mental illness; 2) behavior of a person during or after committing a socially dangerous act was or is inadequate (mental confusion, perception disorders, etc.).

In accordance with Principle 4, "Diagnosis of Mental Illness" diagnosis of a person suffering from a mental illness is made in accordance with internationally recognized medical standards. He/she cannot be treated for any other reason that is not directly related to mental health. In Ukraine, according to paragraphs 17-18 of the Procedures for conducting forensic psychiatric examination, in order to determine presence or absence of person's mental disorder, experts conduct a psychiatric examination, evaluate an objective history, including data on inheritance of mental disorders, features of mental development, family and social status, features of reacting to different life situations, mental traumas, peculiarities of mental state and behavior during the examination and in the course of actions concerning the proceedings in this case, etc. [14].

Therefore, psychiatric examination's conclusion plays an extremely important role in deciding whether to use CMM. The ECHR emphasizes that no one shall be deprived of his/her freedom as a "person with a psychiatric disorder" without a medical opinion stating that his or her mental state justifies compulsory hospitalization (p.39 of the ECHR decision in Winterwerp's case, v. the Netherlands) [10]. However, the ECHR admits that in urgent cases or when a person is detained as a result of aggressive behavior, it may be acceptable to obtain such a conclusion immediately after being detained. In all other cases, it must be preliminary. Where it is not possible, medical examination should at least be assigned and, if it is not done, the presence of person's mental illness has not been substantially proven (p. 97 of the ECHR decision in Zaichenko's case, v. Ukraine) [15].

In this case, the conclusion of psychiatric examination is a necessary but not sufficient condition for CMM using and should be carefully reviewed by the courts in conjunction

with other evidence in the case. In this regard, the ECHR notes that its task is to verify that national courts have examined the relevant findings with due diligence and whether they have duly substantiated their decision to compel the applicant to psychiatric institution (p. 71 of the ECHR decision in Raudevs' case, v. Latvia) [16]. The lack of evidence of such a critical review by courts is the basis for concluding that national authorities did not establish in a convincing manner and with necessary procedural guarantees the existence and persistence of a genuine psychiatric disorder, nature or extent of which justified the applicant's placement in psychiatric institution (p.112-119 of the ECHR decision in the case of Anatoliy Rudenko v. Ukraine) [17]. The Ukrainian courts practice stands on a similar position, stipulating that CMM can be applied only with assurance of a reasoned psychiatrists' opinion, which should be critically evaluated by court in terms of its scientific validity, persuasiveness and motivation. When such conclusions are unclear, incomplete or need to clarify additional issues, court should summon a psychiatrist expert or order additional or re-examination [8].

Regarding the second criterion, considering the issue of the proportionality of mental disorder and forced deprivation of freedom, it is necessary to evaluate a person's threat to others and himself/herself. According to the Principle 16 "Compulsory hospitalization", it can only be applied if a qualified psychiatric specialist determines that a person is suffering from mental illness and determines that: (a) there is a serious threat of direct or indirect harm or (b) in a person's case whose mental illness is severe and his or her mental capacity is impaired, refusal of hospitalization may result in serious impairment of his or her health or disability of proper treatment using.

For example, in the case of Vershynin (v. Russia) according to the forensic psychiatric examination, the patient was suffering from chronic mental illness - paranoid personality disorder - and required compulsory treatment in a specialized psychiatric institution. This was justified, inter alia, by the applicant's "intrusive ideas", numerous complaints to various authorities, attempts to find the truth, etc. However, the ECHR stated that although these aspects of mental health and behavior may justify the need for specific specialized treatment, they did not clearly demonstrate that the applicant was in any threat and that nature or extent of his/her mental illness required involuntary deprivation of liberty (p. 26 of the ECHR decision in Vershynin's case v. Russia) [18]. Scientists say that having a mental disorder is not in itself a reason for compulsory psychiatric treatment; it must be combined with need of treatment as well as patient's threat [19].

Given this, it is important to ensure in national law that CMM are only applicable to people who are socially dangerous. In most European countries, the legislator adheres to this rule. Thus, according to § 63 of the Criminal Code of Germany, a court passes a decision on referral to psychiatric hospital if the aggregate assessment of an offender and his/her actions proves that due to his/her state, he/she can be expected to commit serious unlawful acts, and therefore he/she is a threat to society. Compulsory treatment in psychiatric hospitals also applies to offenders with psychiatric disorders associated with drug use, and its effectiveness is evidenced by an absolute 19.9% reduction in the risk of new convictions [20]. According to Part 1 of Art. 94 of the Criminal Code of Poland, a court decides on the placement of non-convicted person to relevant psychiatric institution if he has committed a prohibited act that constitutes significant public harm and is highly likely to commit another such act. In Ukraine, according to Part 4 of Art. 503 of the Criminal Procedural Code, CMM apply only to persons who are socially dangerous. However, there are examples of its ignoring: according to Part 2 of Art. 69 of the Criminal Code of Latvia, compulsory treatment and type of medical institution are determined by a court depending on person's mental illness and act committed by him/her, that is, the degree of public danger of a person is not taken into account.

The degree of person's social danger influences not only CMM use to them but also the choice of a specific measures in case of their variability. Thus, in Ukraine, the law provides for CMM in the form of: outpatient compulsory psychiatric care, which does not provide for isolation of a person, as well as 3 types of hospitalization in psychiatric care hospital (hereinafter - PCH), which differ in personal restriction's degree and isolation [21]. However, it is worth noting that CMM, such as hospitalization for PCH with enhanced supervision, where it is prohibited to go beyond PCH without healthcare provider's assistance to patients, applies to a person who due to his/her mental state is not a threat to society (Part 4 Article 94 of the Criminal Code of Ukraine). This is seen by the Ukrainian legislature as not complying with the criterion of proportionality of mental disorder and forced deprivation of liberty.

With regard to the third criterion, the ECHR takes into account imprisonment's duration for a mentally ill person. However, legislation of Ukraine does not specify the application's terms of CMM. This is due to the fact that treatment's duration in each case is different and cannot be determined in advance. The same approach applies in some European countries' legislation, in particular, according to Part 1, § 25 of the Criminal Code of Austria, the measure of persons' with mental disorders detention to correction facility is prescribed indefinitely and must be performed for as long as required. However, there is also an approach in European countries that foresees determination of such term by court within the time limits set by law. For example, according to Art. 219 of the Criminal Code of Italy, detention to a special psychiatric hospital applies for a period of not less than two years. According to Art. 131 of San Marino Criminal Code, detention in a psychiatric hospital for a minimum of one year and a custodial clinic for a minimum of 6 months.

In the absence of the CMM's validity period it is important to consolidate the mechanism for reviewing the decision on their application. Thus, in Ukraine, based on Art. 95 of the Criminal Code and Art. 19 of the Law "On Mental Health Care", the grounds for continuation,

modification or termination of CMM using by the court are those changes in a state of person's mental health, in which there is no need to apply a previously prescribed measure. In order to establish this basis, patients are to be reviewed by psychiatrists' commission at least once every 6 months, after that CMM using is continued every time for this period. Therefore, there is a continuous monitoring of a person's mental health, which is the subject of court control. Such a mechanism is in line with Principle 17 of the Supervisory Authority, according to which such a body periodically reviews cases of involuntary hospitalization, determining whether the criteria for forced hospitalization are still met, and if not, a patient should be discharged.

There are two reasons for a court to consider extending, modifying or discontinuing the CMM using. First, it is the statement of a representative of psychiatric care hospital (psychiatrist) to which psychiatrist commission's conclusion is attached, which substantiates the need to continue, change or discontinue of CMM. Secondly, it is a person's to whom CMM are applied (or his/her advocate or representative) statement. Such a statement shall also be added by PCH's psychiatrist commission's conclusion in which a person is receiving psychiatric care, but a patient may add to an application his/her independent psychiatrist's conclusion. This protects patients' rights on the basis of an impartial examination of their health state outside psychiatric clinic by personally initiating a court review of CMM replacement or its termination.

This possibility is part of Principle 17, the Supervisory Authority, and is consistent with the ECHR's view that a person forcibly hospitalized for psychiatric treatment should be guaranteed the right to pursue the legality of such a measure on his/her own initiative, and his/her access to a judge should not depend on goodwill of detaining authority and on medical staff's discretion or administration of medical institution (p. 44-45 of the ECHR decision in Gorshkov's case v. Ukraine [22], p. 197 of the ECHR decision in Kucheruk;s case v. Ukraine). [23]). At the same time, subsidiary laws of Ukraine on CMM use do not contain mechanisms for referring a patient to a specialist in order to obtain an alternative point of view about the treatment process [24]. Therefore, in practice, this possibility is hardly used. This is confirmed by attorneys, prosecutors and judges interviewed by authors, as well as the case law generalization, where we did not find any court decision to change or cancel CMM on the basis of person's application.

CONCLUSIONS

International standards for CMM implementation are a set of generally accepted principles for treatment of mentally ill persons who have committed socially dangerous acts with the aim of treating them and minimizing their social danger as enshrined in the ECHR's legal instruments and practices. They include the following areas: (a) harmonizing of grounds procedure varieties for CMM legal implementation; (b) CMM designation for specific socially dangerous activities; (c) procedure and conditions for CMM use for a particular mentally ill person; (d) CMM continuation, modification or termination. There are three basic conditions for CMM to be applied: (1) competent authority must establish the existence of a mental disorder on the basis of an objective medical examination; (2) mental disorder must be of such a nature or degree as to justify forced deprivation of liberty; (3) validity of long-term imprisonment depends on the persistence of such disorder. Failure to meet these criteria of CMM application is a grave violation of mentally ill persons' rights.

REFERENCES

1. Keown P, McBride O, Twigg L et al. Rates of voluntary and compulsory psychiatric in-patient treatment in England: an ecological study investigating associations with deprivation and demographics. Br J Psychiatry. 2016;209:157–61. doi: 10.1192/bjp. bp.115.171009.
2. Zhang S, Mellsop G, Brink J et al. Involuntary admission and treatment of patients with mental disorder. Neurosci Bull. 2015;31(1):99–112. doi: 10.1007/s12264-014-1493-5.
3. Burn E, Conneely M, Leverton M et al. Giving Patients Choices During Involuntary Admission: A New Intervention. Front. Psychiatry. 2019;10:433. doi: 10.3389/fpsyt.2019.00433.
4. Iedyni zvity pro kryminalni pravoporushennia za 2014-2018 r.r. [Uniform criminal reports for 2014-2018]. Prosecutor General's Office of Ukraine. Available from: http://www.gp.gov.ua/ua/stat.html. [reviewed: 2019.08.15] (Ua).
5. Borisov V.I., Batyrgareeva V.S. Inye ugolovno-pravovye posledstviya sovershenіya obshestvenno opasnogo deyaniya [Other criminal law consequences of committing a socially dangerous act]. Criminology Journal of Baikal National University of Economics and Law. 2014;4:125–139. (Ru).
6. Steinert T. Ethics of Coercive Treatment and Misuse of Psychiatry. Psychiatric Services. 2017;68:291–294. doi: 10.1176/appi.ps.201600066.
7. Beklemishchev SO. Prymusovi zakhody medychnoho kharakteru: kryminalno-pravovyi aspekt [Compulsory medical measures: the criminal law aspect]. Dissertation for obtaining the Phd of Law. Zaporizhzhia. 2017, p. 107. (Ua).
8. Pro praktyku zastosuvannia sudamy prymusovykh zakhodiv medychnoho kharakteru ta prymusovoho likuvannia [On the Practice of Courts for the Use of Compulsory Medical Measures and Forced Treatment]. The Resolution of the Plenary Session of the Supreme Court of Ukraine dated 03.06.2005 No. 7. Available from: https://zakon.rada.gov.ua/laws/show/v0007700-05. [reviewed: 2019.08.15] (Ua).
9. Khamitov R.R. Klinicheskiye. sotsialnyye i lichnostnyye prediktory osobo opasnogo povedeniya psikhicheski bolnykh [Clinical, social and personality predictors of especially dangerous behavior of mentally ill persons]. Dissertation for obtaining the degree of Doctor of Medicine. Moskva; 2004, p. 2-4. (Ru).
10. Case of Winterwerp v. the Netherlands, application no 6301/73, judgement of 24 October1979. Available from: http://hudoc.echr.coe.int/eng?i=001-57597. [reviewed: 2019.08.15]
11. Loshchinkin V.V. K voprosu o yuridicheskoy prirode prinuditelnykh mer meditsinskogo kharaktera [To the issue of the legal nature of compulsory medical measures]. Tomsk State University Journal. Law. 2015;3(17):32-39. (Ru).
12. Case of Zagidulina v. Russia, application no 11737/06, judgement of 02 May 2013. Available from: http://hudoc.echr.coe.int/rus?i=001-119043 [reviewed: 2019.08.15]

13. Asokan T.V. Daniel McNaughton (1813-1865). Indian journal of psychiatry. 2019;49(3):223-224.
14. Poriadok provedennia sudovo-psykhiatrychnoi ekspertyzy [The procedure for conducting a court-psychiatric examination]. The Order of the Ministry of Health of Ukraine dated 08.05.2018 No 6. Available from: https://zakon.rada.gov.ua/laws/show/z0719-18. [reviewed: 2019.08.15] (Ua)
15. Case of Zaichenko v. Ukraine, application no 45797/09, judgement of 26 February 2015. Available from: http://hudoc.echr.coe.int/rus?i=001-152598. [reviewed: 2019.08.15]
16. Case of Raudevs v. Latvia, application no 24086/03, judgement of 17 December 2013. Available from: http://hudoc.echr.coe.int/rus?i=001-139268. [reviewed: 2019.08.15]
17. Case of Anatoliy Rudenko v. Ukraine, application no 50264/08, judgement of 17 April 2014. Available from: http://hudoc.echr.coe.int/rus?i=001-142421. [reviewed: 2019.08.15]
18. Case of Vershynin v. Russia, application no 42858/06, Judgement of 20 September 2016. Available from: http://hudoc.echr.coe.int/rus?i=001-166735. [reviewed: 2019.08.15]
19. Saya A, Brugnoli C, Piazzi G et al. Criteria, Procedures, and Future Prospects of Involuntary Treatment in Psychiatry Around the World: A Narrative Review. Front. Psychiatry. 2019;10:271. doi: 10.3389/fpsyt.2019.00271.
20. Schalast N, Frey M, Boateng S et al. What justifies an involuntary treatment measure for offenders with addiction problems? Recht & Psychiatrie. 2019; Vol. 37. 3:141-146.
21. Pravyla zastosuvannia prymusovykh zakhodiv medychnoho kharakteru v spetsialnomu zakladi z nadannia psykhiatrychnoi dopomohy [The Rules for the Application of Compulsory Medical Measures in a Special Institution for the Provision of Psychiatric Care]. The Order of the Ministry of Health of Ukraine dated 31.08.2017 No 992. Available from: https://zakon.rada.gov.ua/laws/show/z1408-17. [reviewed: 2019.08.15] (Ua).
22. Case of Gorshkov v. Ukraine, application no 67531/01, Judgement of 08 November 2005. Available from: http://hudoc.echr.coe.int/rus?i=001-70855. [reviewed: 2019.08.15]
23. Case of Kucheruk v. Ukraine, application no 2570/04, Judgement of 06 September 2007. Available from: http://hudoc.echr.coe.int/rus?i=001-82200. [reviewed: 2019.08.15]
24. Vysnovok za rezultatamy provedennia hromadskoi ekspertyzy diialnosti Ministerstva okhorony zdorovia Ukrainy vid 22.03.2016 [The Conclusion on the results of public examination of the Ministry of Health of Ukraine dated 22.03.2016]. Available from: https://helsinki.org.ua/8785-2. [reviewed: 2019.08.15] (Ua).

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REVIEW ARTICLE
PRACA POGLĄDOWA

CRITERIA FOR RECOGNITION OF APPROPRIATE MEDICAL ASSISTANCE TO DETAINEES IN THE EUROPEAN HUMAN RIGHTS COURT'S PRACTICE

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ABSTRACT

Introduction: Practical implementation of the provision of appropriate medical assistance to detainees raises a number of problems that needs scientific reflection in order to come up with proposals for improving regulation in this sphere. To date, the issues of particular concern are: proper documentation of a detained person's health status; promptness and accuracy of diagnosis of a person; providing a comprehensive therapeutic strategy for his/her treatment; delay in providing medical care and its quality; continuation of treatment of a sick person in custody.

The aim: of this paper is to highlight and analyze the key positions of the European Court of Human Rights (hereinafter - ECHR) on the criteria for recognizing appropriate medical care for detainees.

Materials and methods: Scientific articles, international regulations governing the provision of medical assistance to detaines, ECHR practice regarding the provision of medical assistance to detainees and criteria for recognition as appropriate (22 relevant decisions where ECHR addressed these issues were analyzed). To achieve this goal, we've used a set of general scientific and special methods of cognition, in particular, comparative-legal method, system-structural method, method of generalization, method of analysis and synthesis, etc.

Conclusions: Medical assistance to detainees is adequate, subject to the criteria set out in the ECHR's practice, which in turn will ensure respect for the human rights and freedoms guaranteed by the Convention for the Protection of Human Rights and Fundamental Freedoms (hereinafter – the Convention).

KEY WORDS: criminal proceedings, detention, human rights, medical assistance to detainees, proper medical care

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INTRODUCTION

Article 3 of the Convention provides that no one shall be subjected to torture or to inhuman or degrading treatment or punishment. These Convention provisions are of particular importance in the field of criminal justice, where fundamental human rights are, where appropriate, substantially restricted. Thus, the detainee's right to adequate medical care is one of the main ones, and its non-observance indicates a violation of Art. 3 of the Convention. In order to ensure it, the following issues are urgent: proper and timely documentation of the detainee's health status, maintenance of medical records, which provide for skilled care of a patient and their continuity; promptness and accuracy of diagnosis to such a person; providing a comprehensive therapeutic strategy for treatment; inadmissibility of delay in provision of medical care, as well as its appropriate quality; creating conditions for continued treatment of a sick person in pre-trial detention facilities; possibility and expediency of providing medical assistance outside the detention facility. A separate aspect of compliance with Art. 3 of the Convention problem raises the question of possible extradition or deportation of a person, taking into account the particularities of his/her illness and adequate medical care, which must be ensured while decisionmaking. The inability to provide such a person with appropriate medical care prevents him/her from being issued or deported and in the event of such a person would violate Art. 3 of the Convention [1].

THE AIM

The aim of this paper is to highlight and analyze the key positions of the ECHR on the criteria for recognizing appropriate medical care for detainees.

MATERIALS AND METHODS

The article is based on scientific researches, international regulations governing the provision of medical assistance to detainees, ECHR practices regarding the provision of medical assistance to persons in custody, and criteria for recognizing it as being appropriate (22 decisions where the ECHR addressed these issues were analyzed). General scientific and special methods of cognition to achieve this

aim in the research process, in particular, comparative-legal method, system-structural method, method of generalization, method of analysis and synthesis, etc. were used.

REVIEW AND DISCUSSION

Article 3 of the Convention imposes a duty on the State to ensure that every person in custody is held in conditions compatible with respect for human dignity, so that conditions of detention do not subject him/her to humiliation or endurance tests that exceed the inevitable level of suffering which is inherent in detention and that person's health is adequately ensured, in particular through the provision of appropriate medical care, with regard to the quality and conditions of care, qualification of medical staff etc.

Obviously, suffering caused by a physical or mental illness of a person in custody may be subject to review according to the Article 3 if they are exacerbated as a result of detention's conditions, expulsion or risk of being treated, for which relevant authorities can be responsible.

Considering the complaints of violation of Art. 3 of the Convention, the ECHR emphasized that if the authorities decide to detain a seriously ill person, they must show particular attention to the custody conditions that are framed by person's health [2].

On the basis of abovementioned, given the importance of providing a detainee with appropriate medical care in the context of compliance with Art. 3 of the Convention, the question arises as to definition, content and criteria for recognizing appropriate medical care for a detainee. Herewith, the ECHR recognizes that the concept of "appropriate medical care" remains the most important element to define. It seems that the quality of care provided to a detainee should be determined on a case-by-case basis, taking into account a detailed examination of medical history, diagnosis' features identified and individual approach to prescribing treatment.

In dealing with the complaints of violation of Art. 3 of the Convention,the ECHR formulated the criteria for recognizing appropriate medical care for a detainee. Thus, in order to achieve such a degree of medical care's quality, authorities should provide and prove: 1) fact of a doctor's examination and appointment of a certain type of treatment; 2) detailed documentation of detainee's health and their treatment during detention; 3) promptness and accuracy of diagnosis and treatment; 4) regarding the medical condition - regularity and systematic supervision and availability of a plan of therapeutic measures for treatment of prisoners' illnesses or prevention of their complications, not the elimination of symptoms; 5) creating the conditions necessary for actual provision of prescribed treatment, including outside the detention facility; 6) providing medical care at the level at which the public authorities have undertaken to provide it to population as a whole [3, 4]. Let us try to analyze the ECHR's decisions relevant to this problem and draw some conclusions on this basis.

Regarding the first criterion (the fact of doctor's examination and the appointment of a particular type of treatment), it is important to note that the mere fact that a detainee was examined by a doctor that prescribed a certain type of treatment cannot automatically lead to conclusion that medical care was appropriate. Authorities should also provide other measures aimed at providing medical assistance to a person [3]. That is why in the case of a detainee's complaint on the lack of proper medical assistance during his/her custody, other circumstances of the case are also a subject of investigation.

Regarding the second criterion, namely the detailed documentation of detaine's health status and his/her treatment at custody, the ECHR first of all draws attention to the completeness of applicant's health records documentation, which should be carried out not only in a patient's interests but also in the interests of custodial facility. In addition, a person in custody has the right to access his/her medical card, unless otherwise stated for therapeutic purposes.

Considering the complaint about the lack of adequate treatment for tuberculosis, the ECHR noted that, despite repeated medical examination by an applicant, there was no evidence of actual treatment being given to them. In addition, the applicant was not only provided with a special diet, special hygiene regimen or exercise necessary for treatment of tuberculosis, but he spent three years in a pre-trial detention center (hereinafter – PTDC) under conditions of extreme overcrowding and poor sanitation, which ultimately allowed ECHR to establish violation of Art. 3 of the Convention [5].

In another case, "Korneykova and Korneykov v. Ukraine" (24/03/2016) – regarding the inappropriate medical care of an applicant and her newborn baby, the ECHR has admitted plausible to the applicant that some of the entries in her son's medical record kept in the detention center were inaccurate (in particular, the date of the initial examination of the child after her discharge from the maternity hospital).

The ECHR also concluded that the son had not undergone medical examinations for a certain period; Neither the PTDC administration nor the head doctor at the local children's hospital were able to respond to child health inquiries; in addition, the pediatrician's examination was carried out in the absence of the applicant, while it was recorded in the child's medical record by the PTDC administration that the pediatrician provided her with child care advice. The ECHR found these circumstances sufficient to conclude that no proper health standards had been observed in the case and therefore did not consider it appropriate to analyze all other factual details (such as the applicant's health problems and lack of vaccinations), finding a violation of Article 3 of the Convention [4].

Regarding the third criterion on promptitude and accuracy of diagnosis and treatment, the actions of medical staff of the pre-trial detention facility should be carefully investigated in the study of a remand prisoner's medical history, timeliness of appropriate testing of a patient's resistance to certain medications, to ensure positive treatment result. This is the approach taken by the ECHR, paying considerable attention to the analysis of relevant circumstances in the context of assessing the quality of care. Yes, in the case of Sergey Smirnov v. Ukraine" (18/12/2018)

the ECHR stated that in this case the applicant's medical card had been lost for a certain period. The applicant was diagnosed with hepatitis, but no action was taken by the public authorities to establish the hepatitis' type, and the condition of the applicant's spine had deteriorated in custody, leading to disability. In this connection, the ECHR found that there had been a violation of Article 3 of the Convention and, in the absence of effective and available domestic remedies for such complaints, found a violation of Article 13 of the Convention [6].

The promptitude and accuracy of diagnosis and treatment as one of the most important grounds for recognizing proper medical care were highlighted by the ECHR and in the case of Savinov v. Ukraine" (22/10/2015), the ECHR found that since November 2011 the applicant's health had deteriorated and he had been transferred to medical service unit. At that time, the Odessa Correctional Colony administration, on its own initiative, submitted a request for the applicant's HIV status and received a positive response. Despite the information received, the applicant's blood test for HIV infection was first done within seven months, and antiretroviral therapy was only started at the end of December 2012, and only with the assistance of NGO. In view of the above, as well as the failure of the PTDC administration to provide the remand prisoner with prompt and appropriate treatment for HIV infection, the ECHR concluded that during the period from November 2011 to March 2013, the applicant had not been provided with an adequate medical assistance, which was inhuman and degrading treatment in violation of Article 3 of the Convention [7].

Another example of the drawbacks in diagnosing a person's illness is the decision in the case of Sergey Antonov v. Ukraine" (10/22/2015). In particular, the ECHR noted that the applicant's initial medical examination in September 2012 appeared to be very superficial and despite the fact that the PTDC administration was aware of his HIV infection, no HIV infection test and no attempt had been made to obtain more information regarding his HIV-related illnesses, and the first CD4 + cell analysis was performed only four months after the remand prisoner had arrived at the pre-trial detention center. In the light of the foregoing, the ECHR concluded that the applicant's failure to diagnose his illnesses quickly and not to provide him with emergency and comprehensive medical assistance was inhuman and degrading treatment and therefore a violation of Article 8 of the Convention.

The next criterion concerns the regularity and systematic supervision of medical state and existence of therapeutic measures' plan to treat remand prisoner's decease or to prevent their complication rather than to eliminate the symptoms. In view of this criterion, the adequacy of care should, in fact, be assessed in view of its regularity and systematic nature, providing a comprehensive therapeutic strategy for treating the disease or preventing its worsening.

This position is represented in the judgment on Medyanikov v. Ukraine case, (19 February 2019), in which the ECHR stated that the applicant's treatment for tuberculosis and C-hepatitis had lasted for eleven and six years, and the applicant had been treated for such a considerable period of time indicates that it was not accompanied by a comprehensive therapeutic strategy in accordance with the requirements of Article 3 of the Convention. The ECHR found that there had been the violation of Article 3 of the Convention due to inadequate medical care provided to the applicant had led to certain suffering or difficulties exceeding the inevitable level of remand prisoner's suffering [9].

At the same time, it should be noted that in order to prove that treatment was rendered inappropriate during his detention, the applicant must, in some cases, provide documents to confirm his illness and the fact that he had been treated before being taken into custody.

Another criterion for the recognition of appropriate medical care is to create conditions necessary for actual delivery of prescribed treatment. This criterion is extremely relevant in cases where a person was already given some treatment before being taken into custody, which he/she received prior the custody and it is appropriated to give further treatment of this quality.

However, examining the specificities of establishing this criterion in the ECHR's practice, the authors first consider it fruitful to pay attention to European law standards in this field, developed by the Committee of Ministers of the Council of Europe. According to p. 37 Recommendation No. Rec (2006) 13 of the Committee of Ministers to member states on the use of remand in custody, the conditions in which it takes place and the provision of safeguards against abuse, arrangements shall be made to enable remand prisoners to continue with necessary medical or dental treatment that they were receiving before they were detained, if so decided by the remand institution's doctor or dentist where possible in consultation with the remand prisoner's doctor or dentist. Remand prisoners shall be given the opportunity to consult and be treated by their own doctor or dentist if a medical or dental necessity so requires. Reasons shall be given if an application by a remand prisoner to consult his or her own doctor or dentist is refused. Such costs as are incurred shall not be the responsibility of the remand institution's administration [10].

Examining the case-law it should be noted that in applying this criterion, the ECHR draws attention to a number of factors including, in particular, unjustified delays and general absence of medical assistance (see decision in Case [11]); creation of necessary conditions for effective treatment (see decision in the case [12]), transferring to a medical facility outside the custody if his/her state of health required transfer to a hospital specialized in treatment of this person's disease [13].

The circumstances of the case of Sokil v. Ukraine (22.10.2015) are illustrative in this regard. In particular, the ECHR noted that in the present case the applicant had been suffering from a number of serious illnesses prior to his imprisonment during the period (February 2012 - January 2014). Despite the fact that most of the time during his detention he has been undergoing treatment at various medical facilities, there is no evidence that he has received

any treatment for HIV for a significant period of time. Thus, despite being informed by the authorities of the applicant's HIV infection, he had been prescribed antiretroviral therapy only in July 2013 - almost a year and a half since his imprisonment. In particular, the ECHR noted that PTDC administration had not provided the applicant with timely and appropriate treatment for HIV infection [14].

In other cases, the inadequate quality of medical care is due to the lack of documents confirming the doctor's adherence to prescribing medication. The inability to provide the applicant with adequate medical care and the necessary diet in detention in some cases has led to release of a person from custody [15].

One of the most urgent issues in ensuring the proper conditions required for the intended treatment is to provide medical assistance to a person outside the detention facility in absence of necessary equipment or staff of appropriate qualifications. If such facts are ascertained, unjustified delays in the transfer of the person to appropriate health care institution appears to be inadmissible and incompatible with the requirements of Art. 3 of the Convention.

In this context, the ECHR's decision in the case of Kushch v. Ukraine (03.12.2015). In particular, the ECHR stated that, after the PTDC administration had recognized the examination need and treatment of the applicant at the Ministry of Health's healthcare facility, it took the court about a month to allow him to be hospitalized. Two weeks later, the PTDC administration acknowledged the difficulty of arranging for the applicant to be transported, and a month later the PTDC doctors changed their mind about the need for his hospitalization. Subsequently, the examination required by the applicant took place one and a half months after being recommended by the doctor and twenty-one days after the Government had instructed the Court to apply a provisional measure under Rule 39 of the ECHR Regulation [16]. Therefore, as we see in this case, there are unjustified delays in transferring the applicant to the Ministry of Health facility, contradictions in the doctors' findings regarding the need for his hospitalization and inability to act accordingly, together with the subsequent deterioration of the applicant's health, testified about the violation of Art. 3 of the Convention.

A somewhat different aspect of this criterion is addressed in the ECHR's decision on the case of Osipenkov v. Ukraine" (29.01.2019). In particular, in this case it was a matter of a person expressing his will regarding the need to transport him to a specialized medical institution for medical consultation. On this occasion, the ECHR noted that, regardless of person's refusal of such transportation, public authorities had to ensure that these measures were implemented promptly and with appropriate conditions to their health (such as a special ambulance, etc.), stating violation of the Convention [17].

However, in examining this criterion for recognizing appropriate medical care for a detained person, one particular feature of this category should be addressed. This feature is that in order to prove that medical care was inappropriate, in some cases the applicant would have to prove the claim by providing the relevant documents. Where the applicant's allegations that he did not receive adequate medical assistance while in detention are general and are not supported by any factual information, then the Government are convincingly rebutted, and there are no shortcomings in the medical staff's work of the previous medical institutions. However, the ECHR concluded that there had been no violation of the Convention [18] [19] [20] [21].

Finally, the last criterion concerns the provision of health care at the level at which public authorities are obliged to provide it to population in general. Considering this criterion as an element of proper medical care, it should be noted that a person may not be completely left without it, but its level may not be sufficient. In this case, it may be referred to as insufficient equipment and provision by the medical unit's staff of the detention facility (in particular, in the case of Osipenkov v. Ukraine (29.01.2019), the applicant suffered from heart disease and received only symptomatic treatment at recommendation of coronary ventriculography of the heart required for correct diagnosis and subsequent treatment, which has not been performed [17]), as well as the lack of qualification of an available doctor for the urgent needs of the patient, as well as the specifics of the conducted checkup (for example, in the case of Serikov v. Ukraine (23/07/2015), the ECHR noted that the applicant was only examined by an ambulance paramedic, and the examination scope was limited and aimed at providing the most urgent medical care [23]).

Referring to scientific sources, it should be noted that the problem of providing inappropriate medical care to detainees in various contexts has already been raised by researchers. Concerning the consequences for commitments, it is worth noting the research of Giles Lindon and Stephen Roe, who conducted an analytical study based on statistics on the death rate of detainees [24]. Thoonen, E., Kubat, B. and Duijst W. raise similar questions [25]. In their article, Iain G, McKinnon, Stuart DM Thomas, Heather L Noga, and Jane Senior highlighted issues related to the incidence of morbidity among detainees [26]. Y. Nazarko, O. Iliashko, N. Kaminska conclude that the main problem of securing and exercising the right to health in the European Union countries is the financing of this sector, because in general it is impossible to speak about free medical care in the European Union [27]. Adhering to the same view, Jason Payne-James stresses the need to improve health standards to the levels set by national law and international conventions in order to prevent deterioration of health care services, to be sure that they are detained in safety, and the risks of death and harm in custody are minimized [28]. On the contrary, American researcher Joseph E. Paris comes to the conclusion that detainees in the United States have more social guarantees of medical care than other citizens, because detainees are provided with free health insurance [29].

CONCLUSIONS

An analysis of the issues of providing detained persons with adequate medical care, as well as the ECHR's practice on this issue, leads to the following conclusions.

First, the problem of not providing detenees with adequate medical care in some European countries, including Ukraine, is systemic, as evidenced by applications to the ECHR for violations of the right to adequate medical care and ECHR decisions that stated the violation of Art. 3 of the Convention. Such a situation must be qualified as a failure by the state to fulfill its positive obligation to uphold and respect human rights in the provision of detainees with proper legal assistance.

Secondly, according to ECHR practice, medical assistance to detainees should meet the following criteria: 1) timely examination by a doctor and prescription of a particular treatment; 2) detailed documentation of the person's being detained health status and his /her treatment during custody; 3) promptness and accuracy of diagnosis and treatment; 4) regarding the medical state - regularity and systematic supervision and availability of therapeutic measures's plan for the treatment of detainees' illnesses or prevention of their complications, not the elimination of symptoms; 5) creating the conditions necessary for actual provision of prescribed treatment, including outside the detention facility; 6) provision of health care at the level to which the public authorities have undertaken to provide it to the general population.

Thirdly, based on the principle of presumption of innocence, the guilt of a detainee has not yet been proven, and in some cases, as the case law shows, will not be proven in the course of future judicial proceedings, and therefore his/her treatment, in particular, and with regard to the provision of adequate medical care should be the same as that of the average citizen, taking into account the particularities of his procedural status. By the way, the assessment of medical services provided to persons in custody directly falls within the competence of the European Committee for the Prevention of Torture or Inhuman or Degrading Treatment, Punishment or Punishment [30, p. 5].

Fourth, the national law must contain effective regulatory mechanisms for implementing the provisions of Art. 13 of the Convention on the rights of everyone whose rights and freedoms recognized in this Convention have been violated, an effective remedy within a national authority, even if such violation was committed by persons exercising their official authority. In this sense, the Criminal Procedure Code of Ukraine does not contain the right to appeal to court on decisions, actions or omissions of employees of pre-trial detention facilities regarding the adequate medical care provision. The absence of such a procedure leads to refusal of granting judicial protection to the person's rights and legitimate interests, which is inadmissible in view of Art. 64 of the Constitution of Ukraine. The right to judicial protection belongs to those fundamental human rights, which in no way can be restricted under Constitution of Ukraine. In addition, according to Principle 33 of the Principles of the Protection of All Persons Detained or Imprisoned in Any Way, accepted by UN General Assembly Resolution 43/173 of 9 December 1988, a person arrested or sentenced should be able to appeal to court for misconduct by institution's administration.

The authors conclude that the consideration of complaints about the failure to secure detainees should be within the competence of investigating judge and, accordingly, be subject to judicial review. This will ensure prompt review of the complaint and measures to improve the complainant's status, and can therefore be considered as an effective and accessible national remedy in the context of Art. 13 of the Convention.

REFERENCES

1. Case of D. v. The United Kingdom, application no. 30240/96, judgment of 2 May 1997. Available from: http://hudoc.echr.coe.int/rus?i=001-100635 [reviewed 2019.07.20]
2. Case of Mechenkov v. Russia, application no. 35421/05, judgment of 7 February 2008. Available from: http://hudoc.echr.coe.int/rus?i=001-84896 [reviewed 2019.07.20]
3. Case of Pivovarnik v. Ukraine, application no. 29070/15, judgment of 6 October 2016. Available from: http://hudoc.echr.coe.int/rus?i=001-166965 [reviewed 2019.07.20]
4. Case of Korneykova and Korneykov v. Ukraine, application no. 56660/12, judgment of 24 March 2016. Available from: http://hudoc.echr.coe.int/rus?i=001-161543 [reviewed 2019.07.20]
5. Case of Kushnir v. Ukraine, application no. 42184/09, judgment of 11 December 2014. Available from: http://hudoc.echr.coe.int/rus?i=001-148627 [reviewed 2019.07.20]
6. Case of Sergey Smirnov v. Ukraine, application no. 36853/09, judgment of 18 December 2018. Available from: http://hudoc.echr.coe.int/rus?i=001-188382 [reviewed 2019.07.20]
7. Case of Savinov v. Ukraine, application no. 5212/13, judgment of 22 October 2015. Available from: http://hudoc.echr.coe.int/rus?i=001-157968 [reviewed 2019.07.20]
8. Case of Sergey Antonov v. Ukraine, application no. 40512/13, judgment of 22 October 2015. Available from: http://hudoc.echr.coe.int/rus?i=001-157970 [reviewed 2019.07.20]
9. Case of Medyanikov v. Ukraine, application no. 31694/06, judgment of 19 February 2019. Available from: http://hudoc.echr.coe.int/rus?i=001-190020 [reviewed 2019.07.20]
10. Recommendation No. Rec (2006) 13 of the Committee of Ministers to member states on the use of remand in custody, the conditions in which it takes place and the provision of safeguards against abuse (Adopted by the Committee of Ministers on 27 September 2006 at the 974th meeting of the Ministers' Deputies). Available from: https://search.coe.int/cm/Pages/result_details.aspx?ObjectId=09000016805d743f [reviewed 2019.07.20]
11. Case of Ivanov and Kashuba v. Ukraine, application no. 12258/09 and 54754/10, judgment of 29 January 2019. Available from: http://hudoc.echr.coe.int/rus?i=001-189619 [reviewed 2019.07.20]
12. Case of Kondratyev v. Ukraine, application no. 5203/09, judgment of 15 December 2011. Available from: http://hudoc.echr.coe.int/rus?i=001-108023 [reviewed 2019.07.20]
13. Case of Aleksanyan v. Russia, application no. 46468/06, judgment of 22 December 2008. Available from: http://hudoc.echr.coe.int/rus?i=001-90390 [reviewed 2019.07.20]
14. Case of Sokil v. Ukraine, application no. 9414/13, judgment of 22 October 2015 Available from: http://hudoc.echr.coe.int/rus?i=001-157969 [reviewed 2019.07.20]
15. Case of Barilo v. Ukraine, application no. 9607/06, judgment of 16 May 2013. Available from: http://hudoc.echr.coe.int/rus?i=001-119675 [reviewed 2019.07.20]

16. Case of Kushch v. Ukraine, application no. 53865/11, judgment of 3 December 2015. Available from: http://hudoc.echr.coe.int/rus?i=001-158963 [reviewed 2019.07.20]
17. Case of Osipenkov v. Ukraine, application no. 31283/17, judgment of 29 January 2019. Available from: http://hudoc.echr.coe.int/rus?i=001-189592 [reviewed 2019.07.20]
18. Case of A.N. v. Ukraine, application no. 13837/09, judgment of 29 January 2015. Available from: http://hudoc.echr.coe.int/rus?i=001-150651 [reviewed 2019.07.20]
19. Case of Baryshevskyy v. Ukraine, application no. 71660/11, judgment of 26 February 2015 Available from: http://hudoc.echr.coe.int/rus?i=001-152599 [reviewed 2019.07.20]
20. Case of Rudyak v. Ukraine, application no. 40514/06, judgment of 4 September 2014. Available from: http://hudoc.echr.coe.int/rus?i=001-146356 [reviewed 2019.07.20]
21. Case of Komarova v. Ukraine, application no. 13371/06, judgment of 16 May 2013. Available from: http://hudoc.echr.coe.int/rus?i=001-119676 [reviewed 2019.07.20]
22. Case of Blokhin v. Russia, application no. 47152/06, judgment of 23 March 2016. Available from: http://hudoc.echr.coe.int/rus?i=001-161822 [reviewed 2019.07.20]
23. Case of Serikov v. Ukraine, application no. 42164/09, judgment of 23 July 2015. Available from: http://hudoc.echr.coe.int/rus?i=001-156247 [reviewed 2019.07.20]
24. Giles Lindon and Stephen Roe Deaths in police custody: A review of the international evidence. Octouber 2017 Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/655710/Deaths_in_police_custody_A_review_of_the_international_evidence.pdf [reviewed 2019.07.10]
25. Thoonen, E., Kubat, B. and Duijst, W. 'Deaths under the responsibility of the Dutch Police', The Police Journal. 2015; 88: 123–136 doi: 10.1177/0032258X15585248
26. Iain G McKinnon, Stuart DM Thomas, Heather L Noga, and Jane Senior Police custody health care: a review of health morbidity, models of care and innovations within police custody in the UK, with international comparisons. 2016 ; 9: 213–226 doi: 10.2147/RMHP.S61536
27. Yuliya Nazarko, Oleksandr Iliashko, Natalia Kaminska Implementation of the right to health care in the countries of the European Union. Wiad Lek. 2019; 7. Available from: http://wl.medlist.org/2019_07_20/ [reviewed 2019.08. 28]
28. Jason Payne-James Healthcare and forensic medical services in police custody – to degrade or to improve? Clin Med (Lond). 2017 Feb; 17(1): 6–7 doi: 10.7861/clinmedicine.17-1-6
29. Joseph E. Paris Why Prisoners Deserve Health Care. American Medical Association Journal of Ethics February 2008; 10 (2): 113-115. Available from: https://journalofethics.ama-assn.org/article/why-prisoners-deserve-health-care/2008-02 [reviewed 2019.08. 28]
30. Lekhtmets A., Pont Y. Okhorona zdorovia ta medychna etyka v penitentsiarnykh ustanovakh [Healthcare and medical ethics in penitentiary institutions]: a manual for medical staff at penitentiary facilities and other staff responsible for the health of convicted and prisoners Council of Europe, 2016. Available from: https://rm.coe.int/manual-on-prison-healthcare-and-medical-ethics-ukr-2016/16806ab9b3 (Ua).

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REVIEW ARTICLE
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PENITENTIARY HEALTHCARE: LEGAL AND PRACTICAL ASPECTS

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ABSTRACT

Introduction: contains a brief overview of the state of scientific research in the field of medical care for inmates (prisoners, convicts) and indicates that research in this area is in constant dynamic development, identifying existing problems and scientific search for ways to solve them.

The aim of the article is to summarize and formulate the main features, principles, and regularities that serve as guidelines for determining the appropriate level of medical care in correctional facilities.

Materials and methods: used in the study are the basic general scientific ones, primarily related to the analysis, synthesis, and extrapolation of the results obtained on the entire set of the studied facts and documents.

Conclusions: set out the main features and principles that medical and legal practices have, or do not, have in place to ensure that health care is fully and appropriately provided.

KEY WORDS: morbidity of convicts; convicts living with HIV; availability of medical staff; typical diseases of convicts; supporting and substitutional therapy for convicts

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INTRODUCTION

Today, the provision of medical care to convicts is a major problem in almost all countries. Taking into account the results of the reports on the state of ensuring human rights and the quality of medical care, it is possible to conclude that the provision of proper medical care is one of the central problems existing in the world practice in general and in the practice of execution of punishments in particular.

Thus, statements and reports by national officials, in particular representatives of a relevant prosecutor's office bodies, indicate that penitentiary systems suffer from a catastrophic shortage of qualified medical personnel. The staffing of these positions is between 50 and 60 %. As for the government financing of prison health care, in some countries (for ex., Ukraine) it covers approximately 22-23 while medical equipment is obsolete or not working in almost 70% of the cases [1]. On the other hand, in the United States, for example, medical expenses increased by 20% between 2010 and 2014, from $905 million to $1.1 billion. However, despite the increase in health care costs, prisoners on average still have worse health than free persons. One of the reasons for the mismatch in health status was the standard of total care received, which David Redemské, Health Planning Principal at HDR, called "mostly ineffective". He said that the prison health care system largely lacks coordination with the health care providers needed to continue caring for prisoners after their release. "If we don't take care of these issues while they are incarcerated, they are going to bring these issues right back to the community," Redemské said [2].

The data indicate that the problems of providing medical care to convicts are related not only to deficiencies in legal regulation, legal technique or legal practice but also to purely medical activities. There are also challenges and difficulties here. In particular, one of them is the lack of qualified personnel. In addition, it is not uncommon for medical staff to be unable to provide adequate care because of the intervention of prison administration or because of the administrative functions assigned to the medical staff, which hinder or complicate the performance of their basic duties. It is difficult to ensure that the necessary conditions are in place to provide care. This includes a lack of equipment, medicines, and supplies, as well as a lack of facilities to provide full medical care.

Medical treatment for convicted persons is often the subject of study for both medical researchers and legal experts. However, existing research does not eliminate the need for their continuous conduct and the search for ways to improve medical care for inmates, since social relations and medical care practices are constantly and rapidly changing and require reconsideration.

All of the above indicates the need to study the problems and factors listed above and to develop ways and means of eliminating them and improving the provision of medical care to inmates, since the success of the correction and rehabilitation of these persons depends, *inter alia*, on its quality.

THE AIM

This study is to generalize and analyze the problems of medical practice regarding convicts, to consider the main problems of legal regulation of the provision of medical assistance to convicts and to develop recommendations for improving both the legal regulation of the provision of medical assistance to convicts and the medical practice itself on the basis of the material under study.

MATERIALS AND METHODS

In the course of the research, general scientific methods of generalization and analysis were used, as well as comparative methods, which made it possible to identify trends and patterns in the dynamics of the phenomenon under study, which are typical for many countries of the world, and which, thus, may be called typical for the provision of medical care to convicts.

Works and outcomes of other scientists, both medical professionals and legal experts, were taken for first-hand study, as well as the practice of the European Court of Human Rights with regard to decisions related to the provision of medical care to convicts. In addition, both official records and reports of the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT), as well as reports of the World Health Organization on prison medicine, have been examined.

REVIEW AND DISCUSSION

The main points of the present study were: 1. availability and accessibility of medical care for convicts, criteria of its appropriate standard; 2. quality of medical care for inmates and ways of improving medical services for inmates.

It is important to note that European penitentiary practices consider medicine for convicts in a broader sense. They include not only the treatment of those who have certain illnesses, but also issues such as hygiene, provision, lighting, ventilation, clothing, etc., which do not seem to be directly related to medicine but have an impact on the health of isolated people.

We are solely interested in the medical care of convicts. We consider these relations, because we understand that the conditions of physical isolation, as unnatural, give rise to a lot of violations and abuses, including in the medical sphere, and lead not only to the failure to provide, or incomplete provision of medical services, but also to harm to public health in general. After all, persons deprived of their freedom, after serving their sentence, are released and join the community of free citizens, which means that the diseases of convicts who were not treated or undertreated, including those dangerous to others, get fertile ground for spreading. Even today, such a problem exists in Ukraine with the spread of such diseases as tuberculosis, hepatitis, etc. As noted in IPRT Position Paper 4 Human Rights in Prison: According to the interpretation of human rights provisions, states are under an obligation to prevent the spread of infectious diseases in prisons. In recent years, states have been held responsible for breaches of human rights in cases where they did not take steps necessary to prevent the spread of tuberculosis [3].

It should be noted that the provision of medical rights for convicts includes two aspects, which we mentioned above: the legal aspect, which involves improving the legal regulation and implementation of the right to health care for convicts, and, more specifically, the availability, accessibility, and quality of medical care for convicts.

The Human Rights and Prison Standards formulated by the UN set out the following requirements for the provision of health care:

- Any necessary medical treatment should then be provided free of charge;
- Prisoners and all detained persons have the right to the highest attainable standard of physical and mental health;
- Prisoners should have free access to the health services available in the country;
- Decisions about a prisoner's health should be taken only on medical grounds by medically qualified people;
- Every prison should have proper health facilities and medical staff to provide for a range of health needs, including dental and psychiatric care [4];
- Prison Health Care should have a clinical Independence.

The standards appear to be very clear. However, the practice of their implementation shows that it is relatively easy to maintain a formal balance between the illusion that they are being implemented, on the one hand, and their non-implementation, on the other. And in this regard, it is the practice of the European Court of Human Rights (ECHR) that remains the main source of formulating criteria for proper and quality medical care for convicts, which sets the course of action for medical professionals, human rights defenders and lawyers.

In the practice of the ECHR, there are quite a few high-profile cases on the medical rights of convicted persons, the decisions in which have led to the formulation of generally applicable criteria for the provision of medical care to convicted persons deprived of their freedom. Among them, such cases are often mentioned: Mouisel v. France, Sakkopoulos v. Greece, Tekin Yıldız v. Turkey, Testa v. Croatia, Martzaklis and Others v. Greece, etc. As far as Ukraine is concerned, such judgments were also adopted by the ECHR and among the most prominent ones are Lunev v. Ukraine, Serhiy Antonov v. Ukraine.

In the majority of these cases, the Court found violations of Article 3 of the Convention for the Protection of Human Rights and Fundamental Freedoms and stressed the need to ensure the protection of the health of prisoners and their physical and moral well-being. Such an approach makes it possible to say that the conditions of detention meet the principle of respect for human dignity.

As it follows from the ECtHR judgments, the main problems of medical care of convicts in relation to legal regulation and implementation of the right to health care are inappropriate legal regulation, which does not formulate and establish mechanisms for the implementation of rights and abilities in the context of deprivation of freedom.

Thus, in many of these rulings, the Court noted that the formal side of the provision of medical assistance was fulfilled (Sakkopoulos v. Greece, Lunev v. Ukraine, Antonov v. Ukraine). Access to a medical officer was granted, and in each case, a medical officer examined the convict. However, during the consideration of all the circumstances of the case, it was found that such assistance was not provided, or was not provided in time or in full.

In this regard, the Court pointed out that determining the appropriate level of medical care provided is one of the most difficult points to clarify. After all, neither the very fact of examination of the convicted person nor the prescription of a certain treatment does not mean that the services rendered were appropriate (the Court came to such a conclusion in the case of Hummatov v. Azerbaijan, para. 116).

Penitentiary authorities must ensure that the health status of the convict is fully and accurately documented and that the treatment provided to him or her while serving his or her sentence of deprivation of freedom are as well (these rules are set out in the ruling in the case of Khudobin v. Russia) (Khudobin v. Russia), para. 83). In addition, the promptness and accuracy of the diagnosis is important (such provisions are stated in the decisions of Melnik v. Ukraine, paras. 104-106, Hummatov v. Azerbaijan, para. 115), as well as the regularity and consistency of medical observation in cases where it is essential, based on the state of health of the convict. In such cases, the main focus is on the availability of a treatment plan and therapeutic measures for the purpose of comprehensive rather than symptomatic treatment (Popov v. Russia (Popov v. Russia), para. 211). The penitentiary authorities are also obliged to create conditions that will make it possible to provide the prescribed treatment (this condition is stated in the decision in the case of Holomiov v. Moldova, para. 117). However, on the other hand, the Court held that the state's obligation to treat a patient in detention would be fulfilled, provided that the appropriate therapeutic measures were applied and not the result achieved (due diligence criterion) (established in Goginashvili v. Georgia, para. 71).

Thus, it is evident that the Court has in fact outlined in these rulings the main features of proper medical care provided to convicted persons. On the basis of the rulings which have been studied and which have become largely exemplary, we can highlight a number of indications of appropriate medical care:

- maintenance of a detailed documentary record of the state of health of the convict and the order and course of his or her treatment during the period of imprisonment. This feature is closely related to the right of the convict to information and, in particular, to information about his or her state of health. Indeed, the effective realization of the right to information for the convicted person provides an opportunity to effectively exercise other rights;

- efficiency and accuracy of diagnosis. In this regard, it is necessary to define in the legislation specific terms for examination and assistance to convicts. And in this part, the administration of penitentiary institutions should not face any difficulties, since persons deprived of their freedom are under the full control of the administration for a fairly long period of time, which makes the possibility of their examination and provision of medical care accessible.

- the regularity and consistency of medical examinations and supervision, as well as the availability of comprehensive treatment measures, which will also be effective after the term is served. Obviously, a medical professional is faced with the need to comply with the medical protocol, and this should be decisive in his case. Accordingly, the implementation of the requirements of the protocol cannot be difficult for the health care provider, as the convicted persons, as mentioned above, are under the control and supervision of the administration, which facilitates the organizational side of the treatment process.

- creation of conditions that will make it possible to provide the prescribed treatment. The current state of detention facilities in most countries, unfortunately, prevents this criterion from being met. Lack of funding and indifference to prisoners means that treatment conditions in many countries remain low.

- the criterion of due diligence in treatment, which, as we have mentioned above, aims to ensure that the necessary measures are in place rather than to achieve a result, indicates that the most important is the medical service provided to the prisoner, which is aimed at providing real assistance to him or her. The health care provider should, in relation to the prisoner, focus on the possible cure of the prisoner (in the short or long term), trying to provide comprehensive support to the sick prisoner [5].

These criteria are fundamental today and provide a basis for referring to the availability or absence of medical services for sentenced prisoners. These criteria can be considered as key. They, in turn, provide an opportunity to address the way in which a health care provider should act to assist a convicted person.

Therefore, it is important for us, in combination with the legal aspect, to consider the medical aspect, identifying its features and difficulties faced by health professionals.

It should be noted that health professionals around the world face very different problems and challenges, most of which, in the end, are not directly related to healthcare itself. These are mostly organizational problems, funding problems, problems with the autonomy of the health care professional and his or her independence from the prison administration, as well as problems related to the professional and personal qualities of the health care professional.

The reviewed bibliography allows us to conclude that the provision of quality and qualified medical care to convicts is one of the central problems of almost any penitentiary system. We have pointed out above the legal problems, which demonstrate how access to medical care can become a factor in the treatment of convicts, which is equivalent to torture. However, now we will focus on the reasons faced by the health care provider, which are often associated with legal problems.

Researchers have noted these general problems in the practice of medical care for convicts in prisons:

Prisoners in physical isolation are more likely to be affected by any disease in general, as their social status, financial resources and personal habits (e.g. alcohol and drug addiction) create fertile ground for disease.

Factors such as suicide risk, mental health problems and easily spread infectious diseases due to overcrowding also contribute to increased morbidity among prisoners.

Essentially, we advocate that the factors that increase the risk of morbidity, as well as the specific conditions of detention and behavior on the part of prisoners, should result in different therapeutic approaches to this category of patients in medical practice.

Practitioners have also noted that prison conditions contribute to the spread of diseases and the difficulties in treating them. For example, poor ventilation and restrictions on access to fresh air increase the risk of airborne disease transmission. Substandard and outdated equipment also does not help cure and prevent disease. Mental health problems, general depression, and mood disorders also increase the risk of illness, including somatic diseases. As noted in the studies conducted with the help of statistical data, incarceration itself has a significant impact on the life expectancy of a prisoner. As noted by Evelyn J. Paterson in "The dose-response of time served in prison on mortality: New York State" the likelihood of death on early release increases by 15.6% each year, which in turn reduces life expectancy by 2 years for each year spent in prison. This risk is highest immediately after release and is gradually reduced, with a proportion of conditional recovery occurring after two-thirds of the time spent in custody [6]. Similar conclusions have been drawn by researchers in other studies, noting that there is an increased risk to life for those who have recently been released from prison [7; 8].

The following are some of the most common diseases and disorders that are diagnosed in prisoners and that are specific to places of detention:

- dependencies of all kinds (drug and alcohol use, smoking). In addition to mental health problems, these addictions also give rise to somatic illnesses;
- infectious diseases; their prevalence is due to the fact that, as mentioned above, prison conditions do not contribute to the maintenance of health and immunity;
- one of the most common groups of diseases were oral disease. The prevalence was also related to poor hygiene, malnutrition, and poor or untimely medical care; in this regard, it was repeatedly observed that the reason for this situation was not only the conditions and circumstances of the prison system but also the unprofessional and negligent attitude of health professionals. Some national studies conducted in Ukraine point to this problem. In particular, the attitude on the part of medical staff is characterized as indifferent or poor by more than 70% of those who were able to communicate with the group of researchers [9].
- chronic complex diseases (diabetes mellitus, diseases of the genitourinary system, cancer and diseases of the heart, lungs, liver, and kidneys). These disorders, being rather complex, also occupy one of the leading places in the pattern of morbidity of convicts.
- mental health problems are quite common among inmates. They are also exacerbated by the conditions of physical isolation, which is unnatural for a person. Such disorders, in particular, result in general negative mood, anxiety, and depression of inmates, lack of self-confidence, hurt self-esteem, etc.

Pointing to all these clinical features, Andrew Fraser makes the following arguments, which, in his opinion, can contribute to the improvement of medical care, the health of prisoners and, as a consequence, optimize the process of execution of a sentence: all medical services should be qualified, provided in an unbiased manner. Prisoners should have access to specialists in mental health and drug-dependent pathologies. Initial medical examinations and specialized services should be carried out in close cooperation. [10].

CONCLUSIONS

It is necessary to recognize that the practice of the ECHR and studies, as well as the reports of prison physicians in their totality, have formed certain rules that, on the one hand, take into account the specifics of the status of a convicted person, and on the other hand, do not create additional discriminatory conditions for their treatment. Such rules, conditioned by the practice of the ECHR, should include these points:

- medical care for convicts should not differ from that for free persons. First of all, it is about the ability of the convict to receive qualified medical consultations, about the possibility to choose a doctor, about the availability of emergency medical care, about the possibility of involving specialists who are not available on the premises of a penitentiary institution. In this regard, it is essential to ensure a simple and accessible mechanism for contacting a health worker;
- the right of the sentenced person to access information about his or her health and the confidentiality of such information is important. In the absence of such a right, the ECtHR has found a large number of violations, which ultimately led to acts of torture;
- mandatory special procedures for convicts whose health condition requires such procedures (HIV-positive people, diabetics, convicts in substitution therapy, etc.).
- mandatory preventive measures should be taken to maintain the health of inmates and to prevent morbidity among the healthy. Here, a very important therapeutic component is the information campaigns aimed at explaining the etiology of various diseases, ways of their transmission and prevention; as Andres Lehtmets and Jörg Pont note in their work on medical ethics in penitentiary institutions, the frequency of training activities on health care and morbidity among convicts should depend on the frequency of changes in the group of convicts and prison staff, and should be tied to the preservation of relevance and awareness [11].

Thus, it can be concluded that the current formula for

proper medical practice in places of detention is a system in which a prisoner has unconditional access to health care, information on diseases and health, with effective and continuous preventive work and a guarantee of professional competence, impartiality, and independence of prison health personnel.

REFERENCES

1. Penitentsiarna medytsyna mozhe pereity u sferu upravlinnia ministerstva okhorony zdorovia [Penitentiary medicine can be transferred to the Ministry of Health] Available from: http://umdpl.info/news/penitentsiarna-medytsyna-mozhe-perejty-u-sferu-upravlinnya-ministerstva-ohorony-zdorov-ya/ [reviewed 2019.08.15] (Ua)
2. Steven R. Johnson. Prison health systems need better integration into the community. 2018. Available from: https://www.modernhealthcare.com/article/20181011/NEWS/181019963/prison-health-systems-need-better-integration-into-the-community [reviewed 2019.08.15]
3. IPRT Position Paper 4 Human Rights in Prison, August, Irish Penal Reform Trust. 2009 Available from: http://www.iprt.ie/files/IPRT_Position_Paper_4_-_Human_Rights_in_Prison.pdf [reviewed 2019.08.15]
4. Human rights and prisons: a Pocketbook of International Human Rights Standards for Prison Officials. United Nations: New York and Geneva. 2005: 17 Available from: https://www.ohchr.org/Documents/Publications/training11Add3en.pdf [reviewed 2019.08.15]
5. Romanov M., Kozarenko N. Analitychnyi zvit UHSPL «Osoblyvosti pravovoho rehuliuvannia zabezpechennia prava na medychnu dopomohu liudiam shcho zhyvut z VIL/SNID ta khvorym na tuberkuloz, yaki trymaiutsia v mistsiakh nesvobody» [Analytical Report "Features of Legal Regulation of the Right to Medical Assistance to People Living with HIV / AIDS and Tuberculosis Patients in Detention Units"] Available from: https://helsinki.org.ua/wp-content/uploads/2018/12/Analitychnyj_zvit_finalnyj-2.pdf) [reviewed 2019.08.15](Ua)
6. Patterson E.J. The dose-response of time served in prison on mortality: New York State, 1989-2003. Am J Public Health. 2013;103(3): 523-528. doi: 10.2105/AJPH.2012.301148
7. Karaminia A et al. Extreme cause-specific mortality in a cohort of adult prisoners – 1988–2002: a datalinkage study. International Journal of Epidemiology, 2007, 36:310–316. doi: 10.1093/ije/dyl225
8. Graham L et al. Estimating mortality of people who have been in prison in Scotland. Edinburgh, Chief Scientist Office. 2011 Available from: http://www.cso.scot.nhs.uk/Publications/ExecSumms/OctNov2010/GrahamPH.pdf [reviewed 2019.08.15]
9. Bukalov O. Monitorynh stanu realizatsii sotsialnykh prav zasudzhenykh v ustanovakh vykonannia pokaran Kyivskoi oblasti [Monitoring of social rights of prisoners in penal institutions of Kyiv region] Available from:http://ukrprison.org.ua/expert/1228050295 [reviewed 2019.08.15] (Ua)
10. Fraser A. Prisons and Health, 20 primary health and care in prisons. Prisons and health 2002:173-179 Available from: http://www.euro.who.int/__data/assets/pdf_file/0008/249209/Prisons-and-Health,-20-Primary-health-care-in-prisons.pdf?ua=1 [reviewed 2019.08.15]
11. Lehtmets A, Pont J. Prison health care and medical ethics. A manual for health-care workers and other prison staf with responsibility for prisoners' well-being. 2016. Available from: https://rm.coe.int/prisons-healthcare-and-medical-ethics-eng-2014/16806ab9b5 [reviewed 2019.08.15]

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REVIEW ARTICLE
PRACA POGLĄDOWA

INDEPENDENT FORENSIC MEDICAL EXAMINATION AS A MEAN OF PROVING THE FACTS OF A TORTURE USAGE

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ABSTRACT

Introduction: In most countries detainees are often subjected to physical and mental abuse by law enforcement officials, but very rarely victims of torture can prove the guilt of these offenders due to the poor quality of findings of state forensic medical and forensic psychiatric experts and due to inconsistency of their findings with international guidelines (Istanbul Protocol).

The aim: To determine the role of forensic medical examination in the investigation of torture crimes, to provide arguments for necessity to security of the victim's right to collect evidence independently, including through using of special knowledge of independent forensic medical and forensic psychiatric experts in criminal proceedings.

Materials and methods: The authors used the European Court of Human Rights (ECHR) Decisions on the complaints of the victims' torture, international and Ukrainian human rights legal acts, the results of numerous torture investigations conducted by medical and criminalistics scientists. The research is carried out on the basis of a harmonious combination of philosophical approaches, general and special scientific methods.

Conclusions: In order to exercise the rights of victims of torture in accordance with the Convention on Human Rights and Fundamental Freedoms, the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, and according to other international and Ukrainian legal acts on human rights the arguments given for the need to enable the victim to engage independent forensic medical and forensic psychiatric experts to provide their conclusions in torture-related criminal proceedings.

KEY WORDS: medical documentation of torture, bodily harm, independent forensic medical examination, medical standard

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INTRODUCTION

Torture as the most dangerous form of physical and mental violence is prohibited by a number of international legal acts, including: Universal Declaration of Human Rights [1], The Geneva Conventions of 1949 and their Additional Protocols [2], the Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) [3], the United Nations Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (UNCAT) [4] and etc. According to Article 3 of the Convention for the Protection of Human Rights and Fundamental Freedoms: «No one shall be subjected to torture or to inhuman or degrading treatment or punishment» [3]. The United Nations Convention (UNCAT) states that «each State Party shall take effective legislative, administrative, judicial or other measures to prevent acts of torture in any territory under its jurisdiction» (Article 2) and «each State Party shall ensure that all acts of torture are offences under its criminal law» (Article 4) [4]. However, provisions of Ukrainian legislation does not always comply with international one, which leads to the «impunity» for the use of torture, and also encourages victims to apply to the European Court of Human Rights (ECHR) for the restoration of their rights.

In view of the above, it is important for Ukraine and other countries to grant the rights to victims of torture to obtain the conclusions of an independent forensic medical and forensic psychiatric expert for proper legal protection in the ECHR, whose decisions are not only legally binding, but also serve as a grounds for a positive impact on the development of the human rights protection in legislation of different countries [5].

THE AIM

To identify factors that interfere or prevent the collection of evidence by a torture victim to exercise his/her right to fair justice and to restore their rights. To evaluate the impact of the results of an independent forensic examination on the objectivity of the court's decision and the investigation of torture crimes. To justify the need of granting the right of torture victims in criminal proceedings to involve independent forensic medical and forensic psychiatric experts.

MATERIALS AND METHODS

For achieving the objectives of the study 29 decisions of the European Court of Human Rights were analyzed on claims

of torture victims, accessed through the official websites of the European Court of Human Rights. In addition, international and national legal acts (Universal Declaration of Human Rights, The Geneva Conventions of 1949 and their Additional Protocols, Convention for the Protection of Human Rights and Fundamental Freedoms, United Nations Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, etc.) were studied.

The methods of theoretical analysis and synthesis were used while studying of the content of legal norms and concepts contained in international legal acts, the Criminal Procedure Code of Ukraine, the Law of Ukraine «On forensic examination», in scientific publications of foreign and domestic researchers. Certain issues required the use of a system analysis method, first of all, in determining the content of the human right to fair justice and human right not to be tortured and while determining ways of their implementation in Ukraine.

Formal-legal analysis of the international and Ukrainian legislation on ensuring human right to fair justice and human right on being free from torture allowed us to identify deficiencies and contradictions of legal acts and to formulate proposals for improving legal regulation, in particular, regarding the use of independent forensic-medical research's results in criminal torture-related proceedings. The comparative legal method was used for studying of the experience of certain countries in preventing tortures. Formal-logical method was used for classification of torture methods and their traces, functional method was used while establishing the impact of low quality of expert's conclusions on the effectiveness of investigating of this category of crimes, sociological method was used while analyzing the results of monitoring groups' activities on the torture detection etc.

REVIEW AND DISCUSSION

In many countries (Great Britain [6], Greece [7], France [8], Turkey [9], Bulgaria [10], Russia [11], Ukraine [12], etc.) detainees are exposed to the physical and mental violence in law enforcement agencies during interrogation as well as in prisons [13]. Analysis of 29 ECHR decisions on the appeals of torture victims has shown that torture is most often done through: beatings with hands, feet and other objects; limbs twisting; use of electricity and high temperatures; handcuffing; asphyxia; injury by sharp tools and firearms; rape; genital injury; etc. As a result of these actions, traces appear on the body of the victim, with the help of which the facts of torture during the forensic examination are clarified.

Notwithstanding the numerous torture victims' complaints on tortures by law enforcement officers worldwide, only a small number of them have been substantiated by specific evidences [14, 15]. This evidences is usually established on the basis of forensic-medical and forensic-psychiatric examinations.

In 1998, the UN Subcommittee on the Prevention of Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment was established, which the Ukrainian State is effectively cooperating with. This authority checks countries' places of detention for torture detection and for the disclosure of this information in order to encourage the governments of certain countries to execute measures that will prevent such unlawful acts [16].

To improve the torture detection process quality a guidelines for effective investigation and documentation of torture (Istanbul Protocol) has been developed, which contains internationally recognized standards and procedures for identifying and recording evidence of tortures. Section 5 of the «Physical evidence of torture» of the Istanbul Protocol emphasizes that «a medical evaluation for legal purposes should be conducted with objectivity and impartiality» and «it is the physician's responsibility to discover and report upon any material findings that he or she considers relevant, even if they may be considered irrelevant or adverse to the case of the party requesting the medical examination». The protocol contains illustrations and descriptions of the most common types of torture and their characteristics, which serve as a methodological basis for describing the results of forensic medical examination of alive persons and corpses that have torture traces [17].

Despite the availability of such legal methodological materials, often the descriptions of bodily injuries and their diagnosis in the conclusions of forensic medical examination on torture cases are incomplete or untrue, which in most cases makes qualitative investigation of these facts impossible. This is evidenced by a numerous decision of the European Court of Human Rights, which concludes that the applicants were tortured during the interrogation in order to obtain a confession. The descriptions of the victim's injuries in the conclusions of states' forensic-medical experts were incomplete and biased, and thus the facts of torture were not properly investigated [18, 19].

Based on the analysis of ECHR decisions, Aisling Reidy emphasizes that the court found the following as the most important problems in the prevention of torture: inadequate medical examination of detainees; lack of proper qualification of medical staff while issuing forensic medical reports; non-detailed medical reports, which do not contain any description of the person's complaints and detailed descriptions of the injuries; lack of analysis of traumas detected and descriptions of their appearance mechanism in forensic medical reports; non-using of photo-fixation of torture traces on victim's body, etc. [20, p. 39-40].

Nowadays, international and national human rights experts have pointed to the considerable number of abuses of human right to be free from torture in criminal proceedings and in the criminal justice system as a whole, as well as the difficulty in proving of torture facts in Ukraine. Thus, according to the data of the Kharkiv Institute for Social Research and the Kharkiv Human Rights Protection Group (Ukraine), during 2017 every 49 seconds there are illegal police violence was occurred [21, 22]. The number of victims of torture by Ukrainian police in 2018 was 64,300 people [23]. The researchers mention that the low quality of the forensic medical and forensic psychiatric examinations reports results in negative influence on the level of disclosure of the investigated category of crimes [23, 24].

Due to the fact that findings of forensic medical and forensic psychiatric experts are documents on which the quality of the evidence of torture depends, the Ministry of Health of Ukraine has started developing the medical standard «Medical evidence of torture or inhuman or degrading treatment or punishment». In this regard, members of the international NGO «Physicians for Human Rights» emphasize the importance of involving of non-state forensic-medical experts to participate in the development of this standard and in the detection and investigation of torture traces [25, 26].

The European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT) has repeatedly emphasized in its Reports on medical records' low quality on fixation of injuries of detained persons in Ukraine. The Committee's (CPT) members' analysis of the medical reports and conclusions of state experts on bodily injuries showed their incompleteness and inconsistency with the explanations of detainees regarding the number and nature of injuries, the absence of photographs and schemes of torture traces in this report [25]. Other researchers also have noted on low quality of medical documentation while examining persons with traces of torture [27]. In paragraph 142 of the 2018 Report, the Committee (CPT) emphasizes on the need for victims to have access to independent medical and psychiatric examination during the execution of the right to fair justice while the investigation of torture [26].

Unlike the practice of dealing with «medical» cases in European countries, where the punishment for a doctor is deprivation of one's license and needing to compensate victim's material and moral damage, in Ukraine the proceedings on offenses in the sphere of medical services in most cases are carried out in the framework of criminal proceedings. At the same time, Ukrainian researchers found that in 80% of criminal proceedings under Art. 140 of the Criminal Code of Ukraine (Failure or improper performance by a medical or pharmaceutical professional of one's professional duties as a result of negligent or dishonest attitude to if it caused grave consequences for the patient) the guilt of doctors was not proved due to incompleteness of expert's reports and poor quality of the description of injuries in medical documents [23]. In this situation, victims are forced to apply to the ECHR for the renewal of their rights and compensation. Thus, from 2014 till 2018 there are 73 cases under Art. 3 («Prohibition of torture») for a total amount of more than € 800 thousand where ECHR is stated on Ukraine's violation of human rights [28]. But even if the court decides in favor of the applicants, the damage is usually recovered from the budget of Ukraine and not from the own funds of the doctor who violated the law.

Deficiencies in the activities of law enforcement agencies and courts in investigating crimes and in fair trial of cases, related to human rights violations are also the main reason of a huge number of torture victims' appeals to the European Court of Human Rights and its decisions against Ukraine [28, p. 186- 187]. In particular, the ECHR Decree of 21.04.2011 (appeal no. 42310/04, in which the torture victim complained on using of electricity during the interrogation) stated the incompleteness and inaccuracy of the detained persons' forensic-medical examination of bodily injuries results, as well as the neglection of important source of evidence (the conclusion of an alternative forensic medical examination of a licensed private forensic medical center) by law enforcement agencies and the court's employees. The court recognized the victim's right to engage an independent forensic medical expert and decided this case in favor of the applicant. The ECHR noted that there had been a violation of Art. 3 of the Convention and that an effective investigation of the applicant's allegations on one's torture by police officers was not carried out [18].

It should be noted that in the Member States of the European Union, in general, the form of ownership of the institution where the forensic expert works is not decisive in its selection as a forensic expert for expert research or assistance in evaluating the expert's conclusion. However, in accordance with Art. 7 of the Law of Ukraine «On forensic examination» forensic expert activities related to criminalistic; forensic medical, forensic psychiatric examinations are carried out exclusively by state specialized institutions. At the same time, some state expert institutions do not conduct some kind of expertise at all due to lack of equipment or specialists. There are also cases where certain courts do not recognize forensic medical reports as an evidence in criminal cases, referring to the fact that it contradicts to the current legislation of Ukraine and forensic examinations were conducted not in state expert institutions, but in institutions that of communal property [29, 30]. At the same time, there is a legal ban on attracting non-state forensic experts to conduct criminalistic examinations in Ukraine.

In addition, in Ukraine state expert institutions monopolized not only the conduct of forensic examination in criminal proceedings (part 1 of Article 7 of the Law of Ukraine «About forensic examination»), but also are insisting on the inadmissibility of a critical analysis of a state forensic experts' conclusion by made by a person, who is not a state expert institution's employee. A number of publications and public discussions have addressed this issue [31]. However, scholars, human rights experts and lawyers, on the contrary, emphasize that the review of the expert's conclusion and expert's research received by the defense party, the victim, the representative of the legal entity, etc., by directly addressing the relevant person with a scientific or other special knowledge in the relevant field, although not an employee of state specialized institutions, can be recognized as written evidence in criminal, commercial, administrative and civil proceedings [32]. In particular, Yosyp Buchynsky rightly states that «the first and the most effective «first aid» for business, the real economy for enterprises and their officials are the critical reviews of experts conclusions by independent highly qualified specialists who have knowledge in the same spheres [33]. In our opinion, the abovementioned is fair and is in line with the national laws of the EU Member States. For example, in Poland, while assessing the expert's opinion, authorized persons usually turn to specialists or experts (including private ones) to determine the objectivity, validity, completeness of the study, etc. [34, p. 115]. It helps to identify the cause and connection between the identified signs of the examination object and the established fact, and also gives a reason for determining the appropriateness, admissibility, reliability and sufficiency of the expert's conclusion as a source of evidence.

Moreover, it appears that the prohibition of independent review of an expert's conclusion may interfere the prosecutor, the head of the pre-trial investigation body, investigator to study fully and impartially the circumstances of the criminal proceedings, to identify both the convicting and justifying circumstances, as well as that mitigating or aggravating one's punishment, to provide their legal assessment, and to ensure that legal and impartial procedural decisions are made (Part 9 of Article 9 of the CPC of Ukraine). It is also evident that the expert's conclusion, which is not a proper and reliable source of evidence, cannot have an evidentiary weight but is only misleading and impedes the objective investigation of the crime.

Some state forensic experts in their publications considered a critical analysis of expert's opinion only as a method of in-house control of the experts' provision of justice in Ukraine, and stated that «it is only by reviewing the conclusions are checked on being in line with requirements of regulations and the correctness of the application of research methods», which is «one of the engines of realization of the parties' rights to discover the real situation, its legality and scientific validity». They assert that «reviewing is necessary for confirming or denying the conclusions already drawn to prevent errors or inaccuracies, inconsistencies» [31, p. 175-176]. That is, state experts understand that an expert's erroneous conclusion cannot serve as a source of evidence. However, the authorized person who appointed to the examination is deprived of the opportunity during the investigation of the crime to find out the shortcomings and errors in the expert's conclusion because of the fact that the inter-departmental planned reviewing of the conclusions is made no earlier than one year after their issuing, when the materials will already be submitted to court. Moreover, the state expert institutions are not obliged to report to the persons who set the reviewing of the conclusions on the results of such review.

The results of our analysis of ECHR decisions are in line with Natalia Handel's research, which states that when studying torture victims' claims, the ECHR usually trusts the facts proved by national authorities, unless the materials of the proceedings contain materials that prove them to be inaccurate or unlawful ways of obtaining them [35]. Therefore, it is extremely important to exercise the right of the victim of torture to fair justice by ensuring the right to independently submit evidence, including obtained through the use of the results of an independent (non-state) forensic examination.

We also consider it to be necessary to pay attention to the possible involvement of certain doctors and forensic experts in torture. It is about the actions of doctors who violate the rules of medical ethics and human rights and use their specialized medical knowledge for falsifying expert conclusions and thereby assisting the investigator in using of improper means of obtaining the necessary information during the interrogation [14, p. 467-468]. An illustrative example is when non-state forensic experts from the United States Vincent Iacopino and Stephen N. Xenakis examined medical documents, written testimony by victims of torture, materials provided by attorneys, the conclusions of forensic-medical and forensic-psychiatric examinations of 9 detainees who were tortured by law enforcement officials, mainly during interrogations. The authors conclude that in all of the studied cases the facts of torture are confirmed, although the employees of state medical institutions neglected or concealed the evidence of intentional harming of the victim of torture, and in some cases - even illegally edited medical documentation [36, p. 3]. The results of this study helped to prove in court the guilt of law enforcement officials during the review of the commission of torture acts.

The above-mentioned shows once again that the conclusion of non-state forensic experts plays a decisive role in protecting the rights of the victim of torture in which a complex analysis of medical documentation, traces of torture and the psychological state of the victim makes it possible to prove the fact of torture. It is possible despite the presence in the case materials of poor-quality conclusion of state forensic-medical expert on the victim's injuries the cause of which has not been determined.

In scientific publications, researchers often use the term «defect in the provision of medical services» trying to create a classification of such defects. Thus, Korobtsova N.V. correctly classifies defects in the provision of medical services as a medical error (objective and subjective) and a professional violation or crime [37, p. 77]. The author proposes to consider a violation of the standards of the Code of Ethics of a doctor of Ukraine [38] as a crime. It seems appropriate to support this proposal, since in Ukraine about there are annually over 600 criminal proceedings against medical professionals are instituted and less than one percent of their perpetrator are brought to court [15].

Consequently, a strict adherence to the standards of clinical forensic medical examination in torture cases set out in the Istanbul Protocol [17] would significantly reduce the number of expert errors in forensic medical expert's conclusion.

CONCLUSIONS

Although torture is prohibited by numerous international and national legal acts, they remain being widespread worldwide. Often such negative actions are carried out in places of imprisonment and during interrogations in law enforcement bodies.

The main source of evidence of torture is the conclusions of forensic medical and forensic psychiatric examinations. Often, state forensic medical and forensic-psychiatric experts make mistakes and shortcomings that negatively affect the forensics conclusions and final court decisions. Such errors include the superficial study of torture traces, their inaccurate description, the lack of photographs of torture traces, etc. In some cases, health care officials and forensic experts of state agencies intentionally provide false conclusions or falsify medical documentation.

Exercising of the rights of torture victims to fair justice and proving guilt of the perpetrators of torture is possible through the introduction of independent forensic medical and forensic psychiatric examinations.

The monopoly of state expert institutions in Ukraine to conduct forensic examinations in criminal proceedings and to evaluate expert's conclusions does not meet the require-

ments of numerous international legal acts on regulating of human rights to fair justice and freedom from torture in criminal proceedings and is not in line with the principle of equality and competitiveness of proceedings.

In order to optimize the private form of evidence in criminal proceedings, the victim should have the right to independently involve the expert or reviewer of expert's conclusion (including the private one), to declare disqualification of the expert and reviewer, to initiate the appointment of an expert or reviewer among the persons mentioned by him/her. Reviews on expert's conclusions should be recognized as written evidence (sources of evidence). It is a right approach to the evidence base formation in the investigation of torture crimes that can significantly reduce these shameful social phenomena, and to ensure objective and fair court hearing.

REFERENCES

1. Universal Declaration of Human Rights. United Nations Department of Public Information, NY, 1948. Available from: https://www.un.org/en/universal-declaration-human-rights/. [reviewed 2019. 07.20]
2. The Geneva Conventions of 1949 and their Additional Protocols. Available from: https://www.icrc.org/en/doc/war-and-law/treaties-customary-law/geneva-conventions/overview-geneva-conventions.htm. [reviewed 2019. 07.20]
3. Convention for the Protection of Human Rights and Fundamental Freedoms as amended by Protocols No. 11 and No. 14 *, Rome, 4.XI.1950. Available from: https://rm.coe.int/1680063765. [reviewed 2019. 07.20]
4. Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment. New York, 10 December 1984. Available from: https://treaties.un.org/doc/Treaties/1987/06/19870626%2002-38%20AM/Ch_IV_9p.pdf . [reviewed 2019. 07.20]
5. Viktor V. Horodovenko, Vitalii M. Pashkov, Larysa G. Udovyka. 2018. Protection of patients' rights in the european court of human rights. Wiadomości lekarskie. Czasopismo polskiego towarzystwa lekarskiego. 2018;71 (6):1200-1206. Available from: http://wl.medlist.org/06-2018-13/. [reviewed 2019. 07.20]
6. Case of Ireland v. The United Kingdom, application no. 5310/71, judgment of 18 January 1978. Available from: https://hudoc.echr.coe.int/eng#{%22itemid%22:[%22001-57506%22]} [reviewed 2019. 07.20]
7. Case of Affaire Karagiannopoulos v. Grèce, application no 27850/03, judgment of 21 June 2007. Available from: https://hudoc.echr.coe.int/eng#{%22itemid%22:[%22001-81234%22]} [reviewed 2019. 07.20]
8. Case of Selmouni v. France, application no. 25803/94, judgment of 28 July 1999 Available from: https://hudoc.echr.coe.int/eng#{%22fulltext%22:[%22Selmouni%20v.%20France%22],%22itemid%22:[%22001-58287%22]} [reviewed 2019. 07.20]
9. Case of Aksoy v. Turkey, pplication no. 21987/93, judgment of 18 December 1996. Available from: https://hudoc.echr.coe.int/eng#{%22itemid%22:[%22001-58003%22]} [reviewed 2019. 09.7]
10. Case of Nikolay Dimitrov v. Bulgaria (№ 2), application no. 30544/06, judgment of 8 January 2013. Available from: https://hudoc.echr.coe.int/eng#{%22fulltext%22:[%22Nikolay%20Dimitrov%20v.%20Bulgaria%22],%22itemid%22:[%22001-115851%22]} [reviewed 2019. 09.7]
11. Case of Kalashnikov v. Russia, application no. 47095/99, judgment of 15 July 2002. Available from: https://hudoc.echr.coe.int/eng#{%22fulltext%22:[%22Kalashnikov%22],%22itemid%22:[%22001-60606%22]} [reviewed 2019. 09.7]
12. Case of Shabelnik v. Ukraine, application no. 16404/03, judgment of 19 February 2009. Available from: https://hudoc.echr.coe.int/eng#{%22fulltext%22:[%22Shabelnik%20v.%20Ukraine%22],%22itemid%22:[%22001-91401%22]} [reviewed 2019. 09.7]
13. Case of Druzenko and Others against Ukraine, applications nos. 17674/02 and 39081/02 judgment of 15 January 2007. Available from: https://hudoc.echr.coe.int/eng#{%22fulltext%22:[%22Applications%20nos.%2017674/02%20and%2039081/02%20by%20Gennadiy%20Yuryevich%20Druzenko%20and%20Others%20against%20Ukraine-%22],%22itemid%22:[%22001-79372%22]} [reviewed 2019. 09.7]
14. McColl, Helen; Bhui, Kamaldeep; Jones, Edgar. 2012. The role of doctors in investigation, prevention and treatment of torture. Journal of the Royal Society of Medicine. doi: 10.1258/jrsm.2012.120100
15. Valentyn V. Franchuk, Svitlana V. Trach Rosolovska, Petro R. Selskyy, Anna Z. Mykolenko, Petro Ya. Bodnar. 2018. Analysis of final judgements In cases of medical negligence occurred in Ukraine. Wiadomości lekarskie. Czasopismo polskiego towarzystwa lekarskiego. 2018;Vol. LXXI:3. Available from: http://wl.medlist.org/03b-2018-28/ . [reviewed 2019. 09.7]
16. Optional Protocol to the Convention against Torture and other Cruel, Inhuman or Degrading Treatment or Punishment. Adopted on 18 December 2002 at the fifty-seventh session of the General Assembly of the United Nations by resolution A/RES/57/199. Protocol is available for signature, ratification and accession as from 4 February 2003 (i.e. the date upon which the original of the Protocol was established) at United Nations Headquarters in New York. Available from: https://www.ohchr.org/Documents/ProfessionalInterest/cat-one.pdf. [reviewed 2019. 09.7]
17. Manual on the Effective Investigation and Documentation of Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (Istanbul Protocol). Professional training series. United nations. New York and Geneva. 2004. Available from: https://www.ohchr.org/Documents/Publications/training8Rev1en.pdf. [reviewed 2019. 09.7]
18. Case of Nechiporuk and Yonkalo v. Ukraine, application no. 42310/04, judgment of 21 April 2011. Available from: https://www.legal-tools.org/doc/030430/ [reviewed 2019. 09.7]
19. Case of Bocharov v. Ukraine, application no. 21037/05, judgment of 17 March 2011. Available from: https://hudoc.echr.coe.int/eng/#{%22fulltext%22:[%22Bocharov%20against%20Ukraine%22],%22documentcollectionid2%22:[%22GRANDCHAMBER%22,%22CHAMBER%22],%22itemid%22:[%22001-103998%22]}/ [reviewed 2019. 09.7]
20. Reidy A. The Prohibition of Torture: a Guide to Implementation of Article 3 of the European Convention on Human Rights. Human Rights Handbooks. 2003;6:52 Available from: https://rm.coe.int/168007ff4c [reviewed 2019. 09.7]
21. Vojtovy`ch O. Tortury novoyi policiyi: chomu j nadali katuyut` ukrayinciv? [Torture of the new police: why they continue to torture Ukrainians?] Deutsche Welle (international broadcasting company in Germany). Available from: https://p.dw.com/p/2qygV . [reviewed 2019. 09.7] (Ua)
22. Kobzin D., Chornousov A., Shcherban S., Bashgaev V. Otsinka masshtabiv nezakonnoho zastosuvannia syly v politsii Ukrainy u 2018 rotsi [Evaluation of the scale of use of force in the police of Ukraine in 2018]. Human Rights in Ukraine: Kharkiv Human Rights Defenders Group Information Portal. EU project "Fight against torture, ill-treatment and impunity in Ukraine". Available from: https://khpg.org/index.php?id=1561465967. [reviewed 2019. 09.7] (Ua)

23. Pashkov V., Kotvitska A., Noha P. 2017. Protecting the rights of producers of original medicines. Wiadomości Lekarskie. 2017;Vol. LXX (4):834 – 837. Available from: https://docplayer.pl/amp/67974839-Tom-lxx-2017-nr-4-rok-zalozenia-senat-rp-ustanowil-rok-2017-rokiem-wladyslawa-bieganskiego-aluna-publishing.html . [reviewed 2019. 09.7]
24. Ustinov O.V. V Ukraini rozrobliaiut medychnyi standart z dokumentuvannia katuvan ta tortur [Medical standard for documentation of torture is being developed in Ukraine]. Ukrainian Medical Journal. Available from: https://www.umj.com.ua/article/110672/v-ukrayini-rozroblyayut-medichnij-standart-z-dokumentuvannya-katuvan-ta-tortur [reviewed 2019. 09.7] (Ua)
25. Report to the Ukrainian Government on the visit to Ukraine carried out by the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT) from 9 to 21 October 2013. Strasbourg, 29 April 2014. Available from: https://www.ecoi.net/en/file/local/1352151/1226_1398759834_2014-15-inf-eng.pdf [reviewed 2019. 09.7]
26. Report to the Ukrainian Government on the visit to Ukraine carried out by the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT) from 8 to 21 December 2017. Strasbourg, 6 September 2018. Available from: https://rm.coe.int/16808d2c2a . [reviewed 2019. 09.7]
27. Ukrainske zakonodavstvo robyt tortury «nevydymymy» – eksperty. [Ukrainian law makes torture "invisible" - experts.] International Foundation "Renaissance". Available from: www.irf.ua/allevents/news/ukrainske_zakonodavstvo_robit_torturi_nevidimimi_eksperti/ . [reviewed 2019. 09.7] (Ua)
28. Gnatovsky M., Belousov Yu., Shvets C., Wenger B., Bondarenko O. Implementatsia mizhnarodnykh standartiv u sferi zapobihannia nenalezhnomu povodzhenniu v dialnist orhaniv kryminalnoi yustytsi Ukrainy [Implementation of international standards in the field of preventing misconduct in criminal justice bodies of Ukraine]: Framework program for cooperation for Armenia, Azerbaijan, Georgia, Republic of Moldova, Ukraine and Belarus . Edited by Yu. L. Belousov. Council of Europe, 2016. 194 p. Available from: http://ecpl.com.ua/wp-content/uploads/2019/03/Implementatsiya-mizhnarodnyh-standartiv-u-sferi-zapobihannya-nenalezhnomu-povodzhennyu-v-diyalnist-orhaniv-kryminalnoji-yustytsiji-Ukrajiny.pdf . [reviewed 2019. 09.7] (Ua)
29. Uzahalnennia sudovoi praktyky pro zastosuvannia sudamy kryminalno-protsesualnoho zakonodavstva pry pryznachenni sudovykh ekspertyz i vykorystannia yikh vysnovkiv u kryminalnomu sudochynstvi [Generalization of court practice on the application by the courts of criminal procedure legislation in the appointment of forensic examination and the use of their conclusions in criminal proceedings]: The decision of the plenum of the Supreme Court. Available from: https://zakon.osmark.com.ua/узагальнення-вссу-судові-експертизи/ . [reviewed 2019. 09.7] (Ua)
30. Pro rozmezhuvannia derzhavnoho maina Ukrainy mizh zahalnoderzhavnoiu (respublikanskoiu) vlasnistiu i vlasnistiu administratyvno-terytorialnykh odynyts (komunalnoiu) vlasnistiu [On the demarcation of state property of Ukraine between national (republican) property and property of administrative-territorial units (communal) property]: Resolution No. 311 of the Cabinet of Ministers of Ukraine of 05.11.1991. Available from: http://zakon5.rada.gov.ua/laws/show/311-91-%D0%BF [reviewed 2019. 09.7] (Ua)
31. Fedchyshina V.V. Retsenzuvannia vysnovkiv sudovykh ekspertiv — metod vnutrividomchoho kontroliu upravlinnia ekspertnoho zabezpechennia pravosuddia Ukrainy [Reviewing the conclusions of forensic experts - a method of intra-departmental control of the administration of expert support of justice of Ukraine]. Investment: practice and experience. .2014;17: 173-176. Available from: http://nbuv.gov.ua/UJRN/ipd_2014_17_39 . [reviewed 2019. 09.7] (Ua)
32. Sidorenko D. Retsenzuvannia vysnovkiv sudovykh ekspertiv: buty chy ne buty? [Reviewing the conclusions of forensic experts: to be or not to be?] Ukrainian weekly legal edition. Available from: http://yur-gazeta.com/golovna/recenzuvannya-visnovkiv-sudovih-ekspertiv-buti-chi-ne-buti.html . [reviewed 2019. 09.7] (Ua)
33. Buchinskyi Joseph. Retsenziia na vysnovok eksperta - balast chy riativnyi kruh dlia biznesu? [Expert Conclusion Review - Ballast or Business Lifebuoy?] Ukrainian weekly legal edition. 2019;7(661). Available from: http://yur-gazeta.com/publications/practice/inshe/recenziya-na-visnovok-eksperta--balast-chi-ryatuvalniy-krug-dlya-biznesu.html . [reviewed 2019. 09.7] (Ua)
34. Bronowska K. Teoretyczne zagadnienia kontroli ekspertyzy i oceny opinii biegtego. [w:] H. Koleski (red.). Kryminalistyka i nauki penalne wobec przestepczosci. Ksiega Pamiatkowa dedykowana Profesorowi Miroslawowi Owocowi, Wydawnictwo Poznanskie. Poznan. 2008. Pp. 103-117.
35. Khendel N. Protection of the right to health in the European Court of Human Rights. Ukrainian law. 2016 Available from: http://ukrainepravo.com/international_law/european_court_of_human_rights/zakhyst-prava-na-zdorov-ya-u-evropeys%60komu-sudi-z-prav-lyudyny/ . [reviewed 2019. 09.7]
36. Iacopino V, Xenakis SN. Neglect of Medical Evidence of Torture in Guantanamo Bay: A Case Series. PLoS Medicine. 2011;Vol. 8:1-6. doi: 10.1371/journal.pmed.1001027
37. Korobtsova N. V. Defekty v nadanni medychnykh posluh [Defects in the provision of medical services]. Scientific Bulletin of Kherson State University. 2016;5,Vol 1:75-78. Available from: http://www.lj.kherson.ua/2016/pravo05/part_1/20.pdf . [reviewed 2019. 09.7] (Ua)
38. Etychnyi kodeks likaria Ukrainy [Code of Ethics of the doctor of Ukraine] Medicine of transport of Ukraine 2009;4:6-11 Available from: http://www.vitapol.com.ua/user_files/pdfs/mtu/615651495680396_1401 2010190217.pdf [reviewed 2019. 09.7] (Ua)

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REVIEW ARTICLE
PRACA POGLĄDOWA

OBLIGATION OF THE DISCLOSURE OF MEDICAL CONFIDENTIAL INFORMATION IN CRIMINAL PROCEEDINGS

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ABSTRACT

Introduction: the right to medical confidentiality is one of the fundamental human rights, which is provided by several international legal acts. Analyzing of Ukrainian legislation gives grounds to assert that the issue of medical secret disclosure is not regulated sufficiently. It determines the necessity of conducting research on legal regulation of medical confidential information disclosure in criminal proceedings.

The aim: of the research is determining the system of obligations of medical staff to disclose the medical confidentiality in the criminal proceedings.

Materials and methods: The empirical base of the research is Ukrainian, Polish, USA, Canada legislation, decisions of the European Court of Human Rights, data of the Unified State Register of Court Decisions. The methodological basis is a set of general and special scientific methods, in particular, logical methods of research, comparative legal method, statistical method, system-structural method.

Conclusions: On the basis of the research, the authors created a system of obligations regarding disclosure of medical secrets in criminal procedure. The authors have offered to amend the current criminal procedural legislation of Ukraine in order to improve legal regulation of the studied problem.

KEY WORDS: medical confidentiality, obligation of the disclosure of medical confidential information, disclosure of medical confidentiality in criminal proceedings, involvement of medical staff in criminal proceedings

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INTRODUCTION

The issue of non-disclosure of information obtained by medical worker due to discharge of his professional duties was raised in the 4th century BC. The scientific literature notes that the concept of medical secret is almost as old as medicine itself which is confirmed by one of the chapters of the Hippocratic oath. Subsequently, the obligation to keep the medical secrecy acquired a clearer regulatory consolidation, and in 1810 the criminal liability for the disclosure of medical secret was provided by the Criminal code of France (except when public health of state security was at stake).[1] Therefore, it should be noted that the obligation to keep information about the patient or his family members at the beginning of the 19th century was not absolute. Modern national legislation of almost any country has provisions that acquit medical professionals from keeping medical secrets in some cases, moreover, they are obliged to disclose them in cases determined by law. The obligation to disclose medical secrets becomes particularly important in such public field of law as criminal proceedings where in many cases the disclosure of medical confidential information is connected with the possibility to start criminal procedure and an effective pre-trial investigation of a criminal offense.

THE AIM

The aim:of this work is to distinguish the bases of occurrence of the obligation to disclose the medical confidential information in criminal procedure on the basis of Ukrainian legislation and conducting a comparative analysis of other countries' legislation in this regard.

MATERIALS AND METHODS

The national legislation of Ukraine, international acts, decisions of the European Court of Human Rights, data of the Unified State Register of Court Decisions were the materials for studying the bases of occurrence of the obligation to disclose the medical confidential information in criminal procedure. The methodological basis was the totality of general and special scientific methods of scientific cognition. The use of the comparative legal method has become useful during the analysis of national and international acts that provided the obligation to disclose medical secrets. The statistical method helped to generalize judicial practice regarding the granting permission to access the documents which contain a medical secret. While building up the system of the obligation to disclose the medical confidential information in criminal procedure,

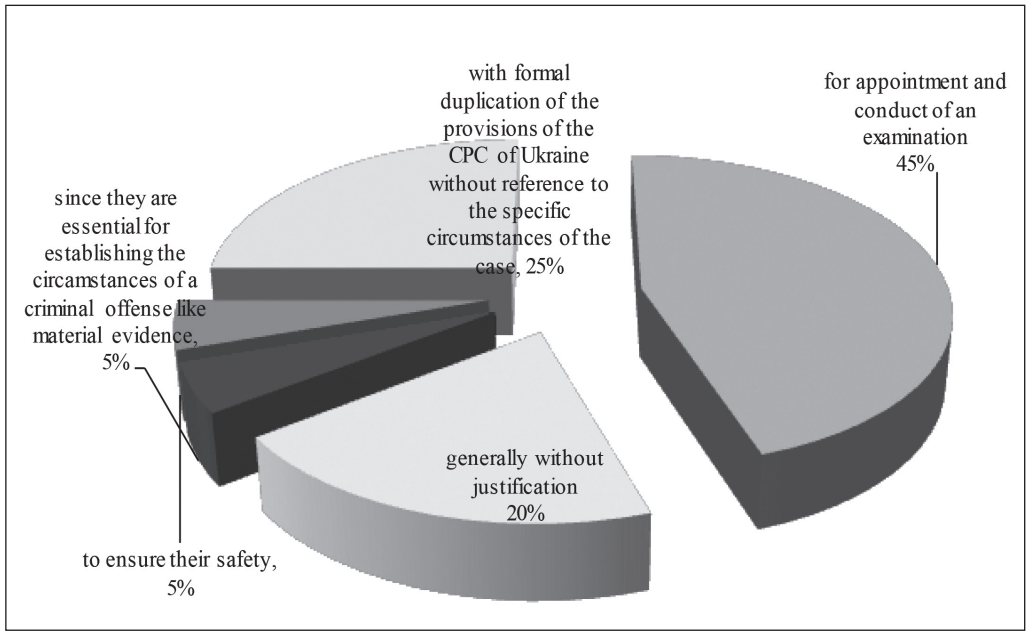

Fig. 1. Reasoning of the need for access to documents which contain a medical secret

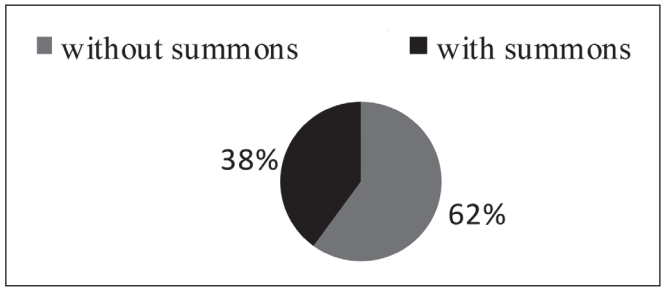

Fig. 2. Consideration of applications for temporal access to documents, which contain a medical secret (in the aspect of involving representatives of medical institution in the trial)

we used the system-structural method, as well as logical method of research.

REVIEW AND DISCUSSION

The decisions of the European Court of Human Rights in the cases of "Avilkina and others v. Russia", "Konovalova v. Russia ", "L. H. v. Latvia" and about 300 decisions of the national courts of Ukraine were analyzed. The study of the national judicial practice gave the following results: Fig.1, 2.

The right to medical confidentiality is provided by a number of international legal acts: The International Code of Medical Ethics, the Declaration of the Development of Patients' Rights in Europe, the European Patients' Charter. In addition, it is provided by 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 consolidates that everyone has the right for respect of his or her personal life with regard to information about his or her health [2]. Therefore, information about the health status of a person is one of the components of the right to respect for private life, which was protected by Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms [3].

The fact that the current national legislation of Ukraine does not clearly define the concept of medical secret is of a scientific interest. Thus, in accordance with Part 1 of Art. 40 of the Law of Ukraine "Fundamentals of Ukrainian Legislation on the Health Care", medical personnel and other persons who have become aware of illness, medical examination, review and their results, intimate and family life of a person, do not have the right to disclose this information, except cases which are provided by legislative acts. Having analyzed the specified norm, we've made a conclusion that medical secret includes information about illness, medical examination or review and their results, intimate and family life.

We consider that such provision of national legislation does not completely correlate with the practice of the European Court of Human Rights (hereinafter - ECHR) on the following grounds. As we've already noted, the right to medical confidentiality is enshrined in article 8 of the Convention, in connection with it the ECHR recalls that according to Art. 8 the concep of "private life" in law enforcement practice is a general concept that cannot be fully defined. It covers, among other things, information relating to such distinctive features of a person as his name, photos and his physical and psychological inviolability [4].

As for the scientific literature, G. Maydanik, for example, notes that the medical secret is a complex of medical and non-medical information about the health status of an individual-patient, which cannot be disclosed. The right to medical confidentiality is not to disclose information about the fact of the treatment at the hospital, health status, the diagnosis of his/her illness and other information which was obtained during the medical examination, in particular, information about a person's family, intimate life, and also about the health state of the patient's relatives etc. So, the following issues cannot be disclosed: data about the disease, functional features of the body, physical defects, harmful habits, peculiarities of the psyche, property status, acquaintances and interests circle, the circumstances that preceded the disease or provoked it, etc. [5].

Also, medical secret is considered as information about the patient and his environment, which was received by a doctor in connection with the execution of professional activities. Both the results of the tests and the diagnosis made on their basis will be medical secret. The same situation is with the treatment methods and the results which are achieved in the treatment process [6].

Without the purpose of providing a definition of medical confidentiality, and agreeing that both medical and non-medical information are its subject matter, we consider it necessary to explore it as any information obtained by a medical professional during the execution of his professional activity about the person's health, his/her relatives or close persons, personal, family, intimate life of such person or his / her environment, diagnosis, treatment and its results.

As it has been already mentioned, the obligation to keep medical secrets is not absolute. For example, the Ethics Code of the Ukrainian Doctor enshrines that medical information about the patient may be disclosed due in case of: a written consent of the patient; a motivated request of the bodies of inquiry, investigation, prosecutor's office and court, sanitary and epidemiological service; if the keeping of the secret threatens the health and life of the patient and/or others (dangerous infectious diseases) significantly; involving other specialists for whom this information is necessary for the professional treatment [7]. In comparison, according to part 2 art. 40 of the Law on the Profession of Doctors and Dentists of the Republic of Poland, the duty to keep medical secrets is not applied in cases if: 1) it is enshrined in law; 2) the medical examination was carried out at the request of an authorized person and institutions on the basis of separate normative acts; then the doctor is obliged to inform only these authorities and institutions about the patient's health; 3) the keeping of secrecy can endanger life or health of the patient or other people; 4) the patient or his legal representative agrees to disclose the secret after being informed about the negative consequences of such disclosure for the patient; 5) the doctor needs to provide the court with the necessary information about the patient; 6) it is important to provide the necessary information about the patient related to the provision of medical services to another doctor or authorized person [8]. In addition, for example, according to the Principle IV of the American Medical Association's Code of Medical Ethics it is stated that the law may demand a physician to disclose information that indicates that a crime has occurred or may occur [9].

Despite the fact that cases of disclosure of medical secrets without the consent of the patient are regulated by normative acts in most countries, there are numerous appeals to the international human rights institutions regarding the violation of the right to confidentiality of medical care information. It causes the necessity of distinguishing the minimum international standards for the disclosure of medical secret without the patient's consent. From our view such standards are: 1) disclosure of medical confidential information is carried out in accordance with the law; 2) disclosure is necessary in a democratic society; 3) the primacy of public interests over private ones; 4) the subject of the disclosure is the minimum amount of information required to achieve the appropriate purpose.

(1) In accordance with Art. 8 Part 2 of the Convention, intrusion on the right of the respect for private and family life is carried out only in accordance with the law. In this regard, the ECHR points out that the interference should not only be provided by national legislation, but also notes on the quality of the legislation, which is being considered, requiring that it should be available to people and the result of it should be predictable. In order to be predictable, the law must be sufficiently precise to determine the conditions under which the application of a specific measure may be such that the persons concerned may, if necessary, use the appropriate consultation to regulate their conduct [4].

(2) State interference in the realization of human rights is considered "necessary in a democratic society" to achieve a legitimate aim if it meets the "pressing social necessity " and, among others things, is proportional to the legitimate aim and if the grounds which were referred to by the national authorities are "appropriate and sufficient" [10].

(3) The analyzing of normative acts demonstrates that if the non-disclosure of medical secrecy is a threat to life and health of other persons or society as a whole, the medical personnel is exempted from keeping the confidentiality of such information (for example, the spread of a certain disease or the investigation of a criminal offense). The ECHR emphasizes that the interests of the patient and the siciety in protecting confidentiality of medical information abnegate their significance for the sake of investigating crimes and punishing criminals, as well as ensuring the transparency of the trial if it is proved that such interests are more significant. Competent public authorities should retain some discretion regarding the establishment of a fair balance between the relevant public and private interest that contradict each other. However, such freedom of discretion is accompanied by European oversight and its scope depends on factors such as the nature and significance of the affected interests as well as the significance of the interference [11].

(4) The Code of Medical Ethics advises that when, by law, patient confidentiality must be breached, the physician should notify the patient and disclose to law-enforcement authorities the minimum amount of information required [9]. In addition, Recommendations № R (87)15 of the Committee of Ministers to member states regulating the use of personal data in the police sector provide that the collection of personal data for police purposes should be limited to the extent that is necessary to prevent a real danger of a special criminal offense. Any exception to this provision should be the subject of regulating by the special national law [12].

Let's turn to the issue of disclosure of medical confidential information in criminal procedure. On the basis of national legislation's provisions systematic analysis taking as a criterion for the division the grounds of obligation to disclose the medical confidential information in criminal procedure we propose to distinguish the following two groups of obligations: (1) those directly arising from the provisions of law; (2) those that occur by existence of a legal basis – the decision of the subject.

The first group of obligations, in our opinion, includes requirement for health facilities explicitly provided by law to notify the law enforcement bodies about specific cases

of bodily injury, as well as establishing the fact of death. In this case, the direction of the medical institution initiates the disclosure of the medical secret.

The normative basis of the above obligation is the following legal acts such as the conjoint Order of the Ministry of Internal Affairs of Ukraine and the Ministry of Health of Ukraine dated 06.07.2016 №612/679 "On the procedure for recording the facts of treatment and delivery to health facilities of persons in connection with causing them bodily harm of a criminal nature and informing about such cases to police bodies and units" and the Order of the Ministry of Internal Affairs of Ukraine, Ministry of Health of Ukraine, General Prosecutor's office of Ukraine dated 29.09.2017 № 807/1193/279 which approved the "Procedure for the interaction between the bodies and units of the National Police, Health Care Institutions and the Prosecutor's Office of Ukraine in establishing the fact of the person's death".

Analyzing the nature of legal regulation of this issue, it is necessary to pay attention to the legal requirement stipulated by Article 32 of the Constitution of Ukraine. It prohibits the collection, storage, use and dissemination of confidential information about a person without his or her consent, except cases determined by law and only in the interests of national security, economic well-being, and human rights. That is, the normative content of the above provision indicates that exceptions to the general rule on prohibition, in particular, the disclosure of medical secret, in the without person's consent, should be established by law. Instead, as noted above, the obligation of the healthcare institutions heads to inform law enforcement authorities about certain cases of injuries, as well as to establish the fact of a person's death regulated at the level of subordinate normative legal acts, however, is not directly provided for, for example, in the relevant codified law - the Criminal Procedure Code of Ukraine (CPC).

The aforementioned thesis determines the question of whether it is possible to consider the specified procedures approved by the relevant orders, the power of attorney in the context of settling the grounds and procedures for the disclosure of confidential information. In connection with the specified, immediately mentioned similar legal uncertainty and some contradictions related to the absence of a law on the procedure for granting permission and possibility of bringing a person to criminal liability for the acquisition, possession and storage of firearms without such permission. It should be noted that even the existence of several decisions of the Supreme Court on this issue could not completely stop the debates among lawyers. Therefore, in order to ensure legal certainty in the settlement of the grounds and procedure for notification by the heads of medical institutions of law-enforcement bodies regarding certain types of bodily injuries, as well as the facts of death, it is expedient to apply a corresponding legal modification of the provisions of Ukrainian CPC's Art. 214 for example, using the blanket method of setting the legal prescription – with reference to the provisions of the already mentioned orders.

A comparative study of the obligation that is the subject of our research is also of a certain interest. In this regard, it should be noted that, for example, legislation in many US states and provinces of Canada contains provisions requiring medical managers to report certain types of injury (firearms, violent wounds, second and third degree burns if it is assumed that they are caused by violence and criminal activity) [13; 14; 15]. At the same time, Ukrainian legislation establishes a more limited list of physical injuries, according to the availability of which doctors are obliged to report them to police authorities. In particular, it refers to "bodily injuries of a criminal nature (gunshot, stab, cut, chopped, clogged wounds)" [16]. In our opinion, such clarification of specific types of injuries provided in brackets, without indicating their open list, significantly limits the cases in which the heads of healthcare institutions are obliged to inform the police units about the facts of treatment and admission to healthcare institutions immediately. At the same time, it should be noted that positive changes in Ukrainian legislation associated with the prevention and counteraction to domestic violence occur: from now healthcare institutions during the implementation of measures in the field of prevention and combating to domestic violence should report to the competent departments of the National Police of Ukraine on the detection of injuries, which could have resulted from the acts of domestic violence (Clause 1, Part 2, Article 12 of the Law of Ukraine "On Prevention and Counteraction Domestic Violence") [17].

Returning to the analysis of the system of obligations to disclose medical secret in the criminal procedure we've noted that the first group that is those duties which directly derive from the provisions of the law, it is also appropriate to include cases of doctors' participation as specialists during the conduct of some investigatory (search) actions. In such cases, health personnel can get information about the disease, medical examination, review and its results, etc. First of all, what it means is to involve the doctor in conducting a view of corpse (Article 238 of the CPC of Ukraine), including that relating to exhumation (Article 239 of the CPC of Ukraine), inspection (Article 241 of the CPC of Ukraine), involvement of an expert and conducting an examination (Articles 242-244 of the CPC of Ukraine), obtaining samples for examination (Article 245 of the CPC of Ukraine).

A selective comparative analysis of the regulation of such obligation demonstrates that, for example, in Polish law, this issue is regulated in more detail. Thus, as we've already mentioned, Art. 40 of the Law on the Profession of Doctors and Dentists of the Republic of Poland provides that a doctor is not obliged to keep confidentiality of information related to the patient and received in connection with the performance of professional activities, when the medical examination was conducted precisely at the request of certain authorities and institutions, in particular, police, prosecutor's office, and court. In this case, the doctor should inform only them about the patient's condition. That is, the person is not deprived of the status of a patient, and therefore of such privilege as medical confidentiality, but in such cases the medical secret is limited, which is connected with the essence of the informational nature of such research [18, pp.241-242]. At the same time, before the examination begins, the doctor is obliged (in accordance with Article 26 of the Medical Ethics Code) to inform the patient that it is carried out at the request of the body/institution, and its results, as well as related information, will be transferred for that purpose

[19, p. 448]. It seems that such prescriptions are to be found in Ukrainian legislation.

Turning to the analysis of the second group of obligations, that is, those that occur with existence of a legal basis – the decision of the subject, first of all, we note that in this case the duty to disclose the medical secret does not follow directly from the law, but only on the initiative of the corresponding officials persons (investigator, prosecutor, court), which is embodied in a certain procedural document (summon, decision of the investigating judge or court). A systematic analysis of the provisions of the Ukrainian Criminal Procedure Code makes it possible to distinguish the following grounds for the obligation to disclose of medical confidential information, such as: (1) the decision of the investigating judge/court on temporary access to things and documents; (2) the decision of the investigating judge/court for permission to search homes or other property; (3) a summons to participate in the interrogation (only under certain conditions). Let's analyze in more detail each of these grounds.

Firstly, we will contextually note that according to Part 1 Article 159 of the CPC of Ukraine, temporary access to the things and documents is to provide a person with the opportunity to look at them, make copies of them and seize them to the representative of criminal proceedings. Such documents may include, in particular, medical records which, obviously, contain medical confidential information, and the requirement to provide it for examination, copying or extradition causes the obligation to disclose it. We notice that the CPC of Ukraine does not prohibit access to things and documents which contain information that may constitute a medical secret. This law only provides the increased requirements for proving the necessity of obtaining such access – particularly, in addition to the circumstances envisaged in Part 5 of Art. 163 in the Criminal Procedure Code of Ukraine, the possibility to be used as evidence as for information contained in these documents and things, and the impossibility of other ways to prove the circumstances that are intended to demonstrate through these things and documents (Articles 161-162, Part 6, Article 163, the Criminal Procedure Code of Ukraine) must be proven. In this regard, we pay attention to the results of the generalization of judicial practice which unfortunately testifies the fact that such requirement is almost always carried out only through the formal duplication of the above provisions of the CPC of Ukraine without specifying particular circumstances or being ignored at all. In our opinion, in this case, if the decision of the investigating judge/court does not meet the requirements of the CPC of Ukraine or corresponds only to the "letter" and not to the "spirit" of the law, there are no grounds for the obligation to disclose the medical secret. We emphasize also on some of the results obtained in connection with the rights of the healthcare institution's representative to participate in the consideration of the petition for temporary access to things and documents. Thus, in a law enforcement practice, investigating judges or courts occasionally refer to the existence of a real threat of change or destruction of things or documents. In this case, if a doctor is suspected of committing a criminal offense related to his professional activities, it seems quite logical. But when it comes to access to the information, such as the victim's injuries or condition of the suspect – a reference seems rather far-fetched.

In the framework of the analysis, the decision on a permission to search homes or other property as the basis of the obligation to disclose the medical secret, we suggest drawing the attention to some aspects. First, according to the Ukrainian Criminal Procedural Law, this procedural decision is already sufficient to restrict the right to privacy, since the CPC of Ukraine, even in cases where certain things or documents are not explicitly stated in the resolution, does not provide for additional permission to intervene in private life, nor does it establish a special procedure for extracting documents that may contain a secret protected by law, in particular, a medical one. In this regard, a certain comparative legal interest is caused by the provisions of the Criminal Procedure Code of Poland, namely Articles 225-226, according to which, if the person, whose objects were seized or whose premises were searched, declares that a written or any other document discovered during the search contains information related to the state, official, professional or other secret protected by law, the persons who conduct the search should immediately transmit such letter or other document without preliminary reading to the state prosecutor or court in a sealed container. At the same time, this requirement does not apply to such documents if they are in the possession of a person suspected of committing a crime, as well as documents, the owner, the author or the addressee of which is such person. Decisions on the possibility of using the documents containing medical confidentiality as an evidence during preparatory proceedings are taken by the prosecutor [20]. Secondly, we note that access to information about other patients may also be obtained during the search. Obviously, it is desirable that the medical staff collaborate with the law enforcement agencies and execute the requested documentation with avoiding of knowing outsider persons with information that does not matter to this criminal proceeding and relates exclusively to third parties. However, even in this case, law enforcement agencies may not restrict themselves to this and carry out a search in full. Therefore, it seems that in such situation it may be appropriate to regulate the procedure for conducting a search similar to that provided for the search of a lawyer (Part 3 of Article 23 of the Law of Ukraine "On Advocacy and Advocacy practice"[21]).

Finally, when considering whether a summons to participate in the interrogation could be the basis for the obligation to disclose medical confidentiality in the criminal procedure, we should immediately note that Ukrainian legislation establishes a witness immunity for certain categories of subjects, in particular, for medical personnel and other persons who have become aware of a disease, medical examination, review and results, intimate and family life of a person in connection with the performance of professional or official duties. That is, sending summons to such persons and their arrival to participate in the interrogation does not entail the appearance of the such obligation. However, such a testimonial immunity is not absolute, but relative – by a written permission signed by the person who entrusted the specified information, medical personell may be exempted from the duty to maintain professional secrecy in full and in a certain part (Part 3 of Article 65 of the CPC of Ukraine). Thus, the base for the obligation to disclose

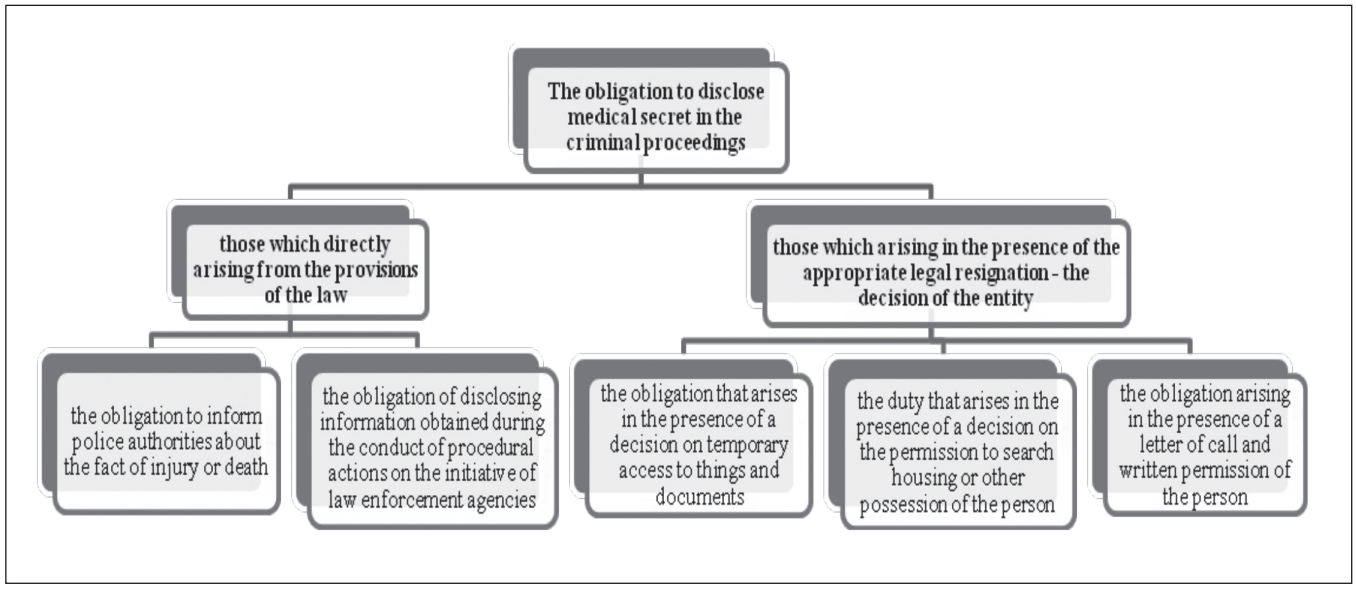

Fig. 3. The system of obligations to disclose medical confidentiality in criminal procedure

medical confidentiality is the presence of two documents - a summons for the participation in the interrogation and a written permission of the person who entrusted the secret. However, we've noted that such regulation of this issue does not take place in all states. For example, according to the US law [13], Canadian law [22], Polish law[20] etc., equal grounds for disclosure of medical confidentiality in a criminal procedure is the written permission of the person who entrusted this information and also the court authorization, in the presence of which, it is logical not to receive the consent of the person who obviously may not be interested in informing the law enforcement authorities of certain information about him/her. It seems that such approach can be implemented in Ukrainian legislation as it will not contradict the normative content of the principles of non-interference with private life enshrined in Article 32 of the Constitution of Ukraine and Article 15 of the CPC of Ukraine. In addition, the introduction of the so-called "three-element test", which is taking place in the United States, is also a promising direction for improving Ukrainian criminal procedural legislation in terms of regulating the issue of the obligation to disclose medical confidentiality. In particular, before transmitting certain medical documentation or providing other information, the medical officer must evaluate the relevant procedural decision that he is given taking into account three aspects: (1) relevance (affiliation) – the requested information must be actual and relevant for the lawful investigation of the circumstances of a particular case; (2) concreteness - the request must be specific and as limited as possible, taking into account the purposes of the law enforcement authorities for which information is requested; (3) identification - impersonal information cannot be used reasonably [13].

CONCLUSIONS

The right of individuals to privacy of medical information is a part of the fundamental right to respect for private and family life, protected by several international instruments. Therefore, interference with such a right must comply with the minimum international standards that are observed: (1) disclosure of medical secrets is carried out in accordance with the law; (2) disclosure is necessary in a democratic society; (3) the primacy of public interests over private ones; (4) the subject of the disclosure is the minimum amount of information required to achieve the appropriate purpose.

Based on the research, the system of obligations to disclose medical confidentiality in criminal procedure can be represented as follows: Fig. 3.

A systematic analysis of the Ukrainian criminal procedural legislation and the relevant judicial practice in terms of the emergence of medical professionals' obligation to disclose confidential information entrusted to them unfortunately indicates a rather formal approach to the regulation of this issue. If fact the abovementioned persons are required to transfer the documentation which contains a medical secret protected by law if there is a judicial authorization for this regardless of whether such court decision corresponds not only to the "letter" but also to the "spirit" of the law. It seems that Ukrainian lawmakers and law enforcement officers should in the long term borrow a positive, in our opinion, example of individual states which would enable medical professionals to evaluate independently the information which disclosure is required by law or court decision on its relevance, certainty, specificity and significance, and only then, and not automatically, report or not to report it to the competent persons.

REFERENCES

1. Philip Rieder, Micheline Louis-Courvoisier,Philippe Huber The end of medical confidentiality? Patients, physicians and the state in history. Med Humanities: first published as 10.1136/medhum-2015-010773 on 22 June 2016. doi: 10.1136/medhum-2015-010773
2. 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. Oviedo, 4.IV.1997. Available from: https://rm.coe.int/168007cf98 [reviewed 2019.08.15]

3. Convention for the Protection of Human Rights and Fundamental Freedoms. Rome, 4.XI.1950. Available from: https://www.echr.coe.int/Documents/Convention_ENG.pdf [reviewed 2019.08.10]
4. Case of Konovalova v. Russia, application no. 37873/04, Judgment of 16 February 2015. Available from: https://hudoc.echr.coe.int/eng#{%22itemid%22:[%22001-146773%22]} [reviewed 2019.08.20]
5. Maidanyk R. Pravo na medychnu taiemnytsiu: zakonodavstvo i praktyka yoho zastosuvannia. [The right to medical secrecy: legislation and practice of its application]. Legal Bulletin of Ukraine, 2018; 28 (941). Available from: https://yurincom.com/legal_practice/analitychna_yurysprudentsiia/pravo-na-medychnu-taiemnytsiu-zakonodavstvo-i-praktyka-joho-zastosuvannia/ [reviewed 2019.08.18] (Ua).
6. Dominika Sikora. Tajemnica lekarska. Gazeta Prawna. Pl Available from: https://www.gazetaprawna.pl/encyklopedia/medycyna,hasla,339553,tajemnica-lekarska.html [reviewed 2019.08.08]
7. Etychnyi kodeks likaria Ukrainy [Code of Ethics of the doctor of Ukraine] dated 27.09.2009. Available from: https://zakon.rada.gov.ua/rada/show/n0001748-09 [reviewed 2019.08.11] (Ua).
8. Ustawa z dnia 5 grudnia 1996 r. o zawodach lekarza i lekarza dentysty. Available from: http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU19970280152/U/D19970152Lj.pdf [reviewed 2019.08.11]
9. Kristin E. Schleiter, JD. When Patient-Physician Confidentiality Conflicts with the Law. American Medical Association Journal of Ethics, February 2009; 11 (2) doi: 10.1001/virtualmentor.2009.11.2.hlaw1-0902.
10. Case of S. and Marper v. The United Kingdom, application nos. 30562/04 and 30566/04, judgment of 04 December 2008. Available from: https://hudoc.echr.coe.int/eng-press#{%22itemid%22:[%22003-2571936-2784147%22]} [reviewed 2019.08.05]
11. Case of Avilkina and others v. Russia, application no. 1585/09, Judgment of 06 June 2013. Available from: https://hudoc.echr.coe.int/eng#{%22itemid%22:[%22001-120071%22]} [reviewed 2019.08.05]
12. Recommendation No. R (87) 15 of the Committee of Ministers to member states regulating the use of personal data in the police sector (Adopted by the Committee of Ministers on 17 September 1987 at the 410th meeting of the Ministers' Deputies). Available from: https://rm.coe.int/168062dfd4 [reviewed 2019.08.09]
13. HIPAA requirements and Florida law: disclosures of protected health information for law enforcement purposes (February, 2016). Available from: www.fha.org/showDocument.aspx?f=HIPAA...and_Law [reviewed 2019.08.09]
14. Guidelines for Releasing Patient Information to Law Enforcement. Available from: https://www.aha.org/standardsguidelines/2018-03-08-guidelines-releasing-patient-information-law-enforcement [reviewed 2019.08.10]
15. Physician interactions with police (Originally published March 2011 / Revised December 2018). Available from: https://www.cmpa-acpm.ca/en/advice-publications/browse-articles/2011/physician-interactions-with-police [reviewed 2019.08.12]
16. Pro poriadok obliku faktiv zvernennia ta dostavlennia do zakladiv okhorony zdorovia osib u zviazku iz zapodiianniam yim tilesnykh ushkodzhen kryminalnoho kharakteru ta informuvannia pro taki vypadky orhaniv i pidrozdiliv politsii.[On the Procedure for Accounting for the Facts of Appeal and Delivery to the Health Care Institutions Persons in Relation with inflicting to them bodily injury of a criminal nature and Informing about Such Cases Police Bodies and Police Units] the Order of the Ministry of Health of Ukraine, dated 06.07.2016, No 612/679. Available from: https://zakon.rada.gov.ua/laws/show/z1051-16 [reviewed 2019.08.12] (Ua).
17. Pro zapobihannia ta protydiiu domashnomu nasylstvu[On the prevention and counteraction to domestic violence] Law of Ukraine, dated 07.12.2017, No 2229-VIII. Available from: https://zakon.rada.gov.ua/laws/show/2229-19/print [reviewed 2019.08.12] (Ua).
18. Michalak K. The essence medical secrecy according Polish law. Prog Health Sci, 2014;4(1): 239-244.
19. Jaroszyński Janusz, Husarz Renata, Jurek Anna, Mela Aneta. Doctor-patient confidentiality - right and duty of a doctor in law regulations. Journal of Education, Health and Sport. 2018; 8(3): 444-452.
20. Kodeks postępowania karnego: ustawa z dnia 6 czerwca 1997 r. Available from: http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU19970890555/U/D19970555Lj.pdf [reviewed 2019.08.13]
21. Pro advokaturu ta advokatsku diialnist [On The Bar and Legal Practice] Law of Ukraine, dated 05.07.2012, No 5076-VI. Available from: https://zakon.rada.gov.ua/laws/show/5076-17#n179 [reviewed 2019.08.12] (Ua).
22. Subpoenas — What are a physician's responsibilities? (Originally published in March 1995, revised April 2008, December 2009P0904-2-E). Available from: https://www.cmpa-acpm.ca/en/advice-publications/browse-articles/1995/subpoenas-what-are-a-physician-s-responsibilities
23. Moskalenko K. Rozgholoshennia likarskoi taiemnytsi: deiaki pytannia teorii ta praktyky [Disclosure of medical secrets: some issues of theory and practice]. Entrepreneurship, Economy and Law. 2016;8: 27-31. Available from: http://pgp-journal.kiev.ua/archive/2016/08/6.pdf [reviewed 2019.08.15] (Ua).

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REVIEW ARTICLE
PRACA POGLĄDOWA

THE MEDICAL CRITERION OF RECOGNITION OF PERSON'S INSANITY DEFENCE: UKRAINIAN AND FOREIGN EXPERIENCE

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ABSTRACT

Introduction: Problems of recognition of person's insanity defence occupy borderline between jurisprudence and medicine as they are based on a combination of medical and legal criteria. This makes them relevant in the context of medical law.

The aim: of the article is to determine the medical criterion of recognition of person's insanity defence on the basis of international standards, Ukrainian and foreign experience.

Materials and methods: International documents, national legislation of Ukraine and foreign countries, theoretical works in the field of jurisprudence and psychiatry, empirical materials on the recognition of persons's insanity defence in Ukraine.

Conclusions: As a result of the research the universal medical criterion of insanity was formulated as "mental disorder defined by the International Statistical Trauma Classification, death resulting in a person being unable to understand and direct his or her actions", that may be implemented into the criminal legislation of any state.

KEY WORDS: insanity defence, mental disorder, psychiatric help, a mentally ill person, medical criterion

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INTRODUCTION

One of the most debatable issues in legal science is the question of state's response to perpetration of socially dangerous acts by mentally ill persons. In certain cases, mental disorders exclude the possibility of criminal prosecution of such persons. In this context, "insanity" concept, that is, inability of a mentally ill person to stand trial and be sentenced to criminal penalties, arises. At the same time, problems of recognition of person's insanity defence occupy borderline between jurisprudence and medicine. This makes them relevant in the context of medical law.

THE AIM

The purpose of the scientific article is to determine the medical criterion for recognizing a person as non-convicted on the basis of international standards, Ukrainian and foreign experience.

MATERIALS AND METHODS

The research is based on scientific developments in the field of judicial psychiatry and criminal law, international legal instruments, in particular the European Convention for the Protection of Human Rights and Fundamental Freedoms of 1950 (hereinafter – the Convention), "Principles for the Protection of People with Mental Illness and Improvement in Mental Care, Psychiatric Care" approved by United Nations General Assembly Resolution No. 46/119 of 17 December 1991 (hereinafter –the Principles), the decisions of the European Court of Human Rights (hereinafter –ECHR), national legislation of Ukraine and some foreign countries: Latvia, Poland, France and the Anglo-American legal system. The empirical basis for the study was the data of the State Statistics Service of Ukraine on persons with mental disorders, the Supreme Court on application of compulsory medical measures, results of survey of Ukrainian investigators, prosecutors and judges on application of medical criterion of insanity in practice, as well as summarizing materials of forensic psychiatrists. The research is based on the use of dialectical, comparative, synthesis and analysis and other methods of scientific research.

REVIEW AND DISCUSSION

Recognizing a person as non-convicted is based on the need to consider the special state of mentally ill persons in criminal-lawful sphere, due to patients' mental disorder. It can be seen as a separate manifestation of a broader and more complex concept - legal protection of mentally ill persons, which is given considerable attention both in national legislation and international law. This is evidenced by the fact that item "e)" Part 1 of Art. 5 of the ECHR Convention and practice of its implementation provide for a number of safeguards of freedom restriction of such persons. It is also specifically for the protection of people with mental illness at an international level the Principles have been developed. Their goal is to set minimum standards for treatment of the mentally ill.

At the same time, it is important to note that in the Convention and Principles the "mentally ill" concept is not defined. The ECHR points out that this term cannot be strictly defined as its meaning is constantly changing with development of psychiatric research; treatments are becoming more flexible and societal attitudes toward mental illness are changing, with societal understanding of mental health issues increasing (paragraph 37 of the ECHR decisions in Winterverp' case; v. the Netherlands) [1]. Therefore, in terms of the concept of a "mentally ill person", most states do not use a specific definition but formulate certain criteria based on which it is established whether someone is a mentally ill person.

This approach is also applied to determination of non-jurisdiction, which is carried out by the laws on criminal liability (criminal codes - hereinafter – CC) of a state. The concept of "mentally ill" and "insane person" are related as a whole, that is, each insane person is mentally ill, but not every mentally ill person is an "insane" one. It should also be emphasized that insanity's issue of a mentally ill person arises only in the case of committing a socially dangerous act. It is worth agreeing that the distinction is to be made between legal insanity and medical insanity. Anyone who is suffering from any kind of mental illness is called "medical insanity," however "legal insanity" means, a person suffering from mental illness should also has a loss of reasoning ability. The term legal insanity also refers to the "mental state" of a person at the time of committing crime and nothing else [2].

Considering the correlation between examined concepts, it is worth noting that according to statistics as of 2017 there were a total of 74 143 mentally ill patients, of which 23 709 were under psychiatric care, and 50 434 were under psychiatric counseling [3]. During the same period, compulsory measures of a medical nature were applied to 657 persons by court decisions, including 339 persons for committing grave and especially grave crimes [4]. Thus, the issue of insanity for the specified period was decided by courts in relation to 0.88% of persons recognized as mentally ill in Ukraine.

Thus, the concept of "mentally ill person" is predominantly medical in nature, while "insanity" is a purely legal term, which means that a mentally ill person cannot be held criminally responsible for a socially dangerous act. Recognizing a person as not guilty also has a number of other important legal consequences, in particular: application to a non-convicted subject of a socially dangerous act of compulsory medical measures instead of criminal penalty; conducting proceedings against such a person under a special procedure that is different from general criminal proceedings; need for sufficient qualification and competence of judges, prosecutors and lawyers conducting criminal proceedings against insane persons [5], etc.

But these results' use of insanity is debatable both among scientists and society. In particular, American researchers J. L. Bloom and J. D. Bloom draw attention to the question «Widespread concern that the insanity protection does not defend the public». Approaches to this issue are varying, they are: total elimination of protection; utilization of evidence of state of mind only to the seriousness of a crime for which a defendant can be convicted; acceptance of a plea of guilty by mentally ill keeping disposition within a correctional system; maintaining the defense as it has been traditionally conducted while clarifying and bolstering the disposition phase procedures, so that human and civil rights, society needs are protected [6]. These views reflect the ethical dilemma between the inability to condemn and punish mentally ill persons and the need to protect the public interest from a real threat to them. Jurisprudence and psychiatry are trying to solve this problem each on its own. As D. W. Jones points out, for many centuries there has been strong state-driven concern with the control of deviance forms that might threaten public order. Thus, the capacity to speak authoritatively on forms of mental disorder that might be associated with crime has been an important spur to the development of the psychiatry [7].

In these circumstances, the perfect legal formulation of insanity notion, which would consider the benefits of psychiatry, becomes essential. It should be noted that the approaches to this model differ somewhat depending on each individual state and type of legal system of that state.

Thus, in the jurisprudence of the countries of the Anglo-Saxon system of law, in determining of non-jurisdiction not the statutory prescriptions are predominant but those formulated in McNaughton's rules and case law. Five questions were answered on June 19, 1843, and they were interpreted as McNaughton's rules. The following are the main points of the McNaughton rules: 1) everyone should be considered to be sane and has a sufficient degree of reason to be responsible for their crimes, until proven otherwise; 2) an insane is punished "if he/she knows" during a committing a crime; 3) to protect against insanity, an accused, due to lack of reason or mental disorder, cannot understand the nature and consequences; 4) an insane person should be considered in the same situation as with respect to liability, as if the facts in respect of which there is a delusion were real; 5) jury had to decide whether the defendant was insane [8].

Researchers point to a numerous problem of protecting non-convicts in criminal proceedings based on McNaughton's rules. In particular, it is noted that the vast majority of persons protected as non-convicts had serious mental illness, but only a quarter were justified. The popular notion that protection against insanity is an "easy way out" for defendants who pretend to be mentally ill or claim temporary insanity is clearly not true [9]. At the same time, McNaughton's rules do not imply the obligation of a medical report on person with a mental disorder for deprivation of his/her freedom, which contradicts item "e)" Part 1 of Art. 5 of the Convention [10] and the ECHR's practice, which provides for the need to establish the existence of a mental disorder by a competent authority on the basis of an objective medical examination (paragraph 39 of the ECHR decision in Winterverp's case; v. the Netherlands) [1]. This raises questions about McNaughton's clause legal imperfection and the need of its adjusting.

Also, there are problems with McNaughton's rules for the current development of forensic psychiatry. According to M. Bennett, the rules should be revised in light of the discoveries of cognitive neuroscience made 160 years after Ray's treatise. For example, it is shown how cognitive neurobiology does not agrees with the interconnection of the "power of self-control" with the "insurmountable impulse" of Cockburn, because these are separate abilities that require normal activity in various brain's structures to express them. Thus, cognitive neurobiology helps to distinguish different abilities. In addition, it has been shown that inability of appropriate restraint in expressing ability can be associated with the failure of synapses in certain brain areas. This raises the question of what level of synaptic loss the legislature and the courts consider sufficient to ensure that the subject is no longer considered responsible for the lack of restraint [11]. This is how the development of medicine is leading to changes in approaches to the formulation of legal rules for insanity.

The laws of the various European countries that belong to the continental legal system generally follow a single approach to defining the concept of non-jurisdiction, which is enforced by national criminal liability laws. According to Art. 122-1 of the Criminal Code of France, a person is not subjected to criminal liability who at the time of committing the act was struck by any mental or neuro-psychiatric disorder, which deprived him/her of the opportunity to realize or control his/her actions. According to Part 1 of Art. 13 of the Criminal Code of Latvia, a person is not subjected to criminal liability if during the crime committing was in a state of insanity, that is, could not be aware of their actions or manage them due to mental disorders or mental retardation. According to § 16 of the Criminal Code of Denmark, persons who were not aware of their actions at the time of committing an act due to a mental illness or a condition that equates to a mental illness are not punished. According to § 1 Art. 31 of the Criminal Code of Poland, if a person committed a crime and because of a mental illness, dementia or other morbid state of mind, was not able to understand or control their behavior is not subject to criminal punishment. A similar approach was applied in the Criminal Code of Ukraine, based on Part 2 of Art. 19 of which "insanity" can be defined as a condition in which a person could not be aware of their actions (inactivity) or to manage them due to chronic mental illness, temporary disorder of mental activity, dementia or other morbid state of mind.

An analysis of the notion's definitions of insanity makes it possible to conclude that it is based on two criteria: psychological (legal) and medical, which are used in unity and interconnection. The first one involves the inability of a person to commit his/her actions when he/she is aware of their actions and to direct them, and serves to differentiate between convicted, non-judgmental and limited convicted persons. The medical criterion of insanity is determined by person's mental and nervous disorders, mental retardation, etc.

Among the analyzed European countries, the most detailed is the definition of the medical criterion of insanity is in Ukraine, which is carried out through the following forms: (1) chronic mental illnesses, which include long-term mental disorders, leading to profound and lasting personality changes, which tend to increase and are almost incurable, such as schizophrenia, epilepsy, paranoia, maniac-depressive psychosis, etc. [12], (2) temporary disorders of mental activity, which include temporary, psyche acute disorders, in particular reactive psychoses, alcoholic psychoses in the form of delirium, hallucinosis, paranoid, symptomatic psychoses, exceptional states: pathological intoxication, pathological affect, paroxysmal disorders of a diencephalic nature, with instantaneous disturbances of consciousness and motor activity [13]; (3) dementia, which is considered to be the most severe mental disorder, which is a permanent and incurable degradation of intelligence: congenital (oligophrenia in the forms of debility, imbecility and idiocy) or acquired (dementia of total, lacunar, concentric and transient); (4) another morbid condition of the psyche, to which such disorders of mental activity and morbidity which do not fall under the signs of the named three categories, but depending on the disease's course, may be equated to them: severe forms of psychopathy, mental infantilism, individual cases of deafness, psychiatric disorders arising from severe infectious diseases or during the period of drug starvation, etc. [15].

However, researchers of forensic psychiatry indicate that in practice it is very difficult to attribute the mental state of an offender to one or another group of medical criteria [16]. Therefore, the medical criterion's forms given by the Ukrainian legislator have no practical significance, but also complicate the law enforcement, since they require investigators, prosecutors and judges to properly determine a person's mental disorder, which is enshrined in the law, although this is a task of psychiatrists, not lawyers. In particular, the majority of interviewed by us Ukrainian judges (56%), prosecutors (62%) and investigators (71%) indicated that it was inappropriate to differentiate the medical criterion of insanity in the Criminal Code; 33% of judges, 40% of prosecutors and 52% of investigators said that they did not see a significant difference between them; more than 90% of judges, 95% of prosecutors and 100% of investigators believe that establishing the medical criterion of insanity depends on conclusion of forensic psychiatric examination, that is the task of doctors. In view of these results, it is worth agreeing that criminal law cannot and should not contain the list of all psychiatric disorders that characterize the medical criterion of insanity, as well as their classification, since these terms are special and only used by psychiatrists [17].

It is worth paying attention to discrepancy enshrined in the Criminal Code of Ukraine formulation of the medical criterion of irresponsibility of the Law of Ukraine "On Psychiatric Care" [18], which is not used in the mentioned terms, which is fixed in the Criminal Code of Ukraine. However, Art. 1 of this Law enshrines the concept of "mental disorders" as disorders of mental activity, recognized as such in accordance with the International Statistical Classification of Diseases, Injuries and Causes of Death in Ukraine, as well as "severe mental disorder" as a disorder

of mental activity (blurred consciousness, impaired perception, thinking, will, emotion, intelligence, or memory) that deprives one of the ability to adequately understand the reality, their mental state, and behavior. The Law of Ukraine "On Psychiatric Aid" is a special normative act that defines the legal and organizational principles of providing citizens with psychiatric care, that's why it is considered necessary to modify the Criminal Code of Ukraine in compliance with its provisions, providing the general concept of "mental disorder" of the International Statistical Classification of Diseases, Injuries and Causes of Death in Ukraine as a medical criterion of insanity.

Thus, the current International Statistical Classification of Diseases, Injuries and Causes of Death for Mental and Behavioral Disorders addresses Class V, which includes the following groups of disorders: (1) organic, including symptomatic, mental disorders (F00-F09); (2) psychoactive substance use disorders and behaviors (F10-F19); (3) schizophrenia, schizotypal conditions and delusional disorders (F20-F29); (4) mood disorders (F30-F39); (5) neurotic, stress-related and somatoform disorders (F40-F48); (6) behavioral syndromes associated with physiological disorders and physical factors (F50-F59); (7) mature and behavioral disorders (F60-F69); (8) mental retardation (F70-F79); (9) disorders related to psychological development (F80-F89); (10) conduct and emotion disorders that begin mostly in childhood and adolescence (F90-F98); (11) unspecified psychiatric disorder (F99-F99) [19]. Therefore, it is ultimately the Psychiatric and Behavioral Disorders listed in the International Statistical Classification of Diseases, Injuries and Causes of Death that should be the basis for determining the medical criterion of insanity.

Summarizing the materials of forensic psychiatric examinations in Ukraine shows that the most common psychiatric disorders leading to acquiescence of a person being mentally defective were: schizophrenia, schizotypal conditions and delusional disorders (F20-F29); organic, including symptomatic, psychiatric disorders (F00-F09); mental retardation (F70-F79); mental and behavioral disorders due to substance use (F10-F19). The primacy is traditionally held by schizophrenia, which can be explained by the prevalence of this disease (which, according to some psychiatrists, constitutes one percent of the population of humanity) [20], and the typical manifestations of this disease, which often take the character of socially dangerous activities. In general, it can be concluded that from a large number of psychiatric disorders known to modern psychiatry, a relatively limited group of psychopathologies leads to committing socially dangerous acts, which are usually combined with other non-medical factors.

Thus, in the scientific psychiatric literature it is emphasized that formation of psychopathological mechanism of socially dangerous action can lead to interaction of clinical and psychopathological and socio-psychological conditions [21]. In particular, among the most common clinical and psychopathological factors are the following forms of mental pathology: 1) psychopathic syndromes with increased behavioral activity and pathology of addictions (including heboid); 2) delusional ideas of certain content, especially directed against specific persons or organizations (personified) and accompanied by affective tension (first of all, ideas of jealousy, harassment, sexual influence, etc.); 3) periodic and paroxysmal psychotic states, which are accompanied by aggression and tend to occur frequently; 4) depressive states with nonsense of self-blame (risk of committing socially dangerous actions by the mechanism of "extended suicide"); 5) maniacal and hypomaniacal states with general disfigurement and pseudosensitivity [22]. Therefore, psychiatric disorders, which imply such clinical manifestations, are at increased risk of committing of socially dangerous acts by patients.

Socio-psychological factors imply the influence of the mentally ill persons' living conditions on their behavior, such as the attitude of their families, colleagues, environment, the presence or absence of employment, financial support, etc. Their impact on the course and manifestations of psychiatric disorders is a matter of debate and varies significantly depending on the individual's mental disorder. For example, in the scientific psychiatric literature attention is drawn to the fact that psychosocial cause-and-effect beliefs had different effects: belief in current stress as a reason was associated with a higher level of recognition of schizophrenia, while belief in adversity in childhood led to a lower perception of a person with depression [23].

However, these socio-psychological factors in committing socially dangerous acts of mentally ill persons are indirectly conditioned by psychopathological ones. So, scientific research proves that there was a corresponding tendency of the public to attribute notions "dangerous" and "unpredictable" to psychiatric patients, which is exacerbated by the facts of committing socially dangerous acts by mentally ill persons, for example violent attacks by schizophrenic persons [24].

Thus, a person with a mental disorder contributes to the formation of public stigma about them, which impedes employment, family creation, social networking and more. According to the researchers, people with mental disorders can be biased and discriminated by others (that is, be stigmatized), and they can absorb feelings of devaluation (that is, self-stigmatization) [25]. It, in turn, can lead to the asocial behavior of the mentally ill. Thus, a "closed circle" is created when stigma is formed on the basis of public beliefs about the social danger of mentally ill persons, but at the same time promotes the committing of socially dangerous acts.

Aware of the interlink between medical and social factors in perpetration of socially dangerous activities by mentally ill persons, it is necessary to use comprehensive measures to eliminate or minimize their negative effects. Thus, the main goals of counteracting psychopathologies is to find and apply the most effective methods of their diagnosis and treatment, including enhanced outpatient supervision (and, if necessary, involuntary hospitalization) for patients with psychiatric disorders, which represent the greatest potential social danger. Socio-psychological factors should be counteracted by overcoming the stigma of the

mentally ill and maximally integrating them into society. Concerning this problem, one should agree that stigma reduction strategies may require to shift to an emphasis on competence and inclusion [26]. Taking the necessary measures in a timely manner not only prevents the mentally ill from committing socially dangerous activities, but also improves their health and social status.

CONCLUSION

Definition of insanity defense reflects the protection of the rights of mentally ill persons in the criminal sphere and implies the inadmissibility of bringing them to justice for actions that they could not be aware of and manage. Despite the legal nature of the term, it has a medical basis, which presupposes the non-convicted person's mental disorder. Given that the establishment of type and nature of such a mental disorder is a task of psychiatry, specification of the medical criterion in national criminal law is not appropriate, therefore, when determining insanity in the Criminal Code, it is advisable to limit the reference to "mental disorder defined by the International Statistical Trauma Classification, death resulting in a person being unable to understand and direct his or her actions". Understanding socially dangerous acts committed while state of insanity as a critical combination of medical and social factors makes it possible to develop and apply a set of measures adequate to them, which will prevent such actions, as well as improve the health and social status of the mentally ill persons.

REFERENCES

1. Case of Winterwerp v the Netherlands, application no 6301/73, judgment of 24 October 1979 Available from: http://hudoc.echr.coe.int/eng?i=001-57597 [reviewed 2019.09.01]
2. Math SB, Kumar CN, Moirangthem S. Insanity Defense: Past, Present, and Future. Indian Journal of Psychological Medicine. 2015; 37(4):381–387. doi: 10.4103/0253-7176.168559.
3. Zakhvoriuvanist naselennia na rozlady psykhiky ta povedinky za rehionamy u 2017 rotsi [Morbidity of the population for mental disorders and behavior in regions in 2017]. Health facilities and morbidity of the Ukrainian population in 2017: statistical collection. Kyiv, 2018. Available from: http://www.ukrstat.gov.ua/druk/publicat/kat_u/2018/zb/06/zb_zoz_17.pdf. [reviewed 2019.09.01] (Ua).
4. Analiz stanu zdiisnennia sudochynstva sudamy kryminalnoi yurysdyktsii u 2017 rotsi [Analysis of the state of judicial proceedings by the courts of criminal jurisdiction in 2017]. The Supreme Court. Kyiv, 2018. Available from: https://supreme.court.gov.ua/userfiles/Analiz_krum_sud_2017.pdf. [reviewed 2019.09.01] (Ua)
5. Perlin ML. "Too stubborn to ever be governed by enforced insanity": Some therapeutic jurisprudence dilemmas in the representation of criminal defendants in incompetency and insanity cases. International journal of law and psychiatry. 2010; 33(5-6): 475-481.
6. Bloom JL, Bloom JD. Disposition of insanity defense cases in Oregon. Journal of the American Academy of Psychiatry and the Law Online. 1981; 9(2): 93-99.
7. Jones DW. Moral insanity and psychological disorder: the hybrid roots of psychiatry. History of Psychiatry. 2017; 28(3):263–279 doi: 10.1177/0957154X17702316
8. Andoh B. The M'Naghten Rules-the story so far. Medico-Legal Journal. 1993;61(2):93-103 doi:10.1177/002581729306100205
9. Callahan LA, Steadman HJ, McGreevy MA et al. The volume and characteristics of insanity defense pleas: An eight-state study. Journal of the American Academy of Psychiatry and the Law Online. 1991;19(4):331-338.
10. Hopper S, McSherry B. The Insanity Defence and international human rights obligations. Psychiatry, Psychology and Law. 2001;8(2):161-173 doi: 10.1080/13218710109525016
11. Bennett M. Criminal law as it pertains to 'mentally incompetent defendants': a McNaughton rule in the light of cognitive neuroscience. Australian and New Zealand Journal of Psychiatry. 2009;43(4):289-299 doi: 10.1080/00048670902721137.
12. Zhabokrytskyi SV, Chuprykov AP. Sudova psykhiatriia [Forensic Psychiatry]. A training manual. Kyiv: Interregional Academy of Personnel Management; 2004, p. 50. (Ua)
13. Pervomayskiy VB. Nevmenyayemost [Insanity]. Kyiv; 2000, p. 82. (Ru)
14. Sonnyk HT, Naprieienko OK, Skrypnikov AM. Psykhiatriia [Psychiatry]: a textbook. Kyiv: Zdorovia; 2003, p. 57. (Ua).
15. Beklemishchev S. O. Prymusovi zakhody medychnoho kharakteru: kryminalno-pravovyi aspekt [Compulsory medical measures: the criminal law aspect]. Dissertation for obtaining the Phd of Law. Zaporizhzhia; 2017, p. 127. (Ua)
16. Levenets IV. Sudova psykhiatriia [Forensic Psychiatry]. A training manual. Ternopil: Economic thought; 2005, p. 26. (Ua)
17. Zaitsev OV. Deiaki problemy vyznachennia formuly neosudnosti u kryminalnomu pravi Ukrainy [Some Problems in Defining the Formula of Insanity in the Criminal Law of Ukraine]. Herald of the Association of Criminal Law of Ukraine. 2015;1(4).118. (Ua).
18. Pro psykhiatrychnu dopomohu [On psychiatric care]: The Law of Ukraine no 1489-III dated 22.02. 2000. Available from: https://zakon.rada.gov.ua/laws/show/1489-14 [reviewed 2019.09.03] (Ua).
19. International Statistical Classification of Diseases and Related Health Problems 10th Revision -edition 2010 Available from: https://icd.who.int/browse10/2015/en. [reviewed 2019.09.03]
20. Bitenskyi VS, Horiachev PI, Melnyk EV. et al. Psykhiatriia [Psychiatry]. Lecture Course: a training manual; edited by Bitenskyi VS. Odesa: Odesa State Medical University; 2004, p. 336. (Ua)
21. Kerbikov OV, Korina MV, Nadzharov RA et al. Psikhiatriya [Psychiatry]: a textbook. 2nd edition. Moskva: Meditsina; 1968, p. 33. (Ru)
22. Bersh A. Ya. Prymusovi zakhody medychnoho kharakteru: pravova pryroda ta vydy [Compulsory medical measures: legal nature and types]. Dissertation for obtaining the Phd of Law. Odesa; 2017, p. 123. (Ua).
23. Schomerus G, Matschinger H, Angermeyer MC. Causal beliefs of the public and social acceptance of persons with mental illness: a comparative analysis of schizophrenia, depression and alcohol dependence. Psychological medicine. 2014;44(2):303-314 doi: 10.1017/S003329171300072X
24. Angermeyer MC, Matschinger H. The effect of violent attacks by schizophrenic persons on the attitude of the public towards the mentally ill. Social Science & Medicine. 1996;43(12):1721-1728 doi:10.1016/s0277-9536(96)00065-2
25. Yang L, Phelan JC, Collins P. Measuring mental illness stigma. Schizophr Bull. 2004;30:511–541 doi:10.1093/oxfordjournals.schbul.a007098
26. Pescosolido BA, Martin JK, Long JS et al. "A disease like any other"? A decade of change in public reactions to schizophrenia, depression, and alcohol dependence. American Journal of Psychiatry. 2010;167(11):1321-1330 doi: 10.1176/appi.ajp.2010.09121743

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REVIEW ARTICLE
PRACA POGLĄDOWA

LEGAL REGULATION OF COOPERATION IN THE FIELD OF FORENSIC MEDICAL EXAMINATION IN CRIMINAL PROCEEDINGS BETWEEN UKRAINE AND THE REPUBLIC OF POLAND

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ABSTRACT

Introduction: The first task of forensic medical examination is to identify the actual data that can be used by health authorities when developing preventive measures of various types of injuries, poisoning, sudden death, as well as hurdles to provision of medical care to patients. The second challenge is to assist law enforcement bodies in cases related to crimes against life, health, person dignity and public health in general. In this case, there is often an urgent need to conduct forensic medical examinations with the participation of foreign experts, including the composition of joint groups.

The aim: is an investigation of the procedure and grounds for the cooperation in forensic medical examinations in case of objects' examination that relate to the crimes committed in Ukraine and the Republic of Poland.

Materials and methods: nearly 300 law enforcement acts for the period of last 6 years in Ukraine were analyzed concerning the subject of the study, as well as legislation of Ukraine and Poland. The framework of research methods is including dialectical, formal-logical, systematic-structural, hermeneutical, comparative-legal and generalization ones.

Conclusions: The cooperation in the field of forensic medical expertise in criminal proceedings between Ukraine and the Republic of Poland is quite formal, which does not promote the effective use of the results of experts' professional activity in Criminal proceedings.

KEY WORDS: Forensic examination; forensic expert; medical report

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INTRODUCTION

Discussing the relevance and peculiarities of forensic medical examinations, it is necessary to emphasize their importance as an action, which may be the basis for initiating the investigation of a criminal offence, prosecuting criminals, planning of investigation. Forensic examination is aimed primarily at solving the issues that arise before the judicial and investigative bodies, which include: establishing the cause and time of death; determination of severity and nature of bodily harm, consistency and time of their causing; abilities of victims to perform purposeful actions after the trauma; blood type in the case of external bleeding; presence and degree of alcohol intoxication; death category (violent or nonviolent).

Forensic medical examination is conducted on the basis of special knowledge to research material objects containing information about the circumstances of the crime. The need for it usually arises during the investigation of crimes against the life and health of a person or some war crimes that is also not a rare phenomenon.

Importance of the examinations' results is emphasized by the fact that the conclusions of forensic medical expert in criminal proceedings have the power of evidence. Thus, according to the criminal procedural legislation of Ukraine [9] the expert's conclusion is one of only four possible sources of evidence in criminal proceedings. In the criminal procedural legislation of Poland [10] the activity of the expert in criminal proceedings is regulated by section 22 of chapter V – "evidences". Of course, in criminal proceedings on transnational crimes there are special procedures for International cooperation of countries involved in such an investigation. Forensic examination is not an exception, because it is difficult to overestimate the possibility of using an additional intellectual and technical resources in this area, and in some cases due to objective reasons it could be impossible to conduct medical examination repeatedly or there are risks of information loss due to procrastination while the objects for examination are located abroad.

THE AIM

Analysis of the legal regulation of cooperation in the field of forensic medical examination in criminal proceedings between Ukraine and the Republic of Poland, developing of proposals for its improvement.

MATERIALS AND METHODS

To achieve the purpose of this research and to propose a reasonable conclusion we've used a complex of general

and special methods of scientific research: dialectical, formal-logical, systematic-structural, legal, comparative law and generalization.

In order to achieve the abovementioned goal nearly 300 court's decisions since 2013 were analyzed, where the use of medical examinations' forensic reports of both Ukrainian and foreign experts was settled. Also, legal acts of Ukraine and Poland were analyzed in this study.

REVIEW AND DISCUSSION

The Institute of expertise in Ukraine is regulated by the Law of Ukraine "On judicial expertise", procedural law, international treaties and agreements on mutual legal assistance and cooperation, instruction on the conduct of forensic Examination and legal documents approved by the Order of the Ministry of Health of Ukraine (hereinafter – MOH).

International cooperation in this area is regulated primarily by the law of Ukraine "On forensic examination", [1] which provides for the possibility of forensic examination on behalf of the relevant body or person of another state, with which Ukraine has an agreement on mutual legal assistance and cooperation (article 22). It is also possible to involve specialists from other States to jointly conduct forensic examinations (article 23). However, the law does not provide detailed mechanism and conditions for involvement of foreign experts and their conclusions' legal validity.

An international base for regulation of cooperation in criminal proceedings between Ukraine and Poland is a Treaty between Ukraine and the Republic of Poland on legal aid and legal relations in civil and criminal matters from 24.05.1993 [2] (hereinafter – the Treaty). Of course, the expertise issue is not central to this agreement, but some other issues concerning the regulation of cooperation in this field are contained in the document and indicate a possibility of legal assistance in criminal proceedings also by means of conducting relevant forensic examinations.

Art. 4 of the Treaty ("Scope of Legal Aid") provides within the framework of mutual legal assistance the possibility of **examination**. Article 8 of the Treaty ("The summons of the witness, the **expert** or the victim and their protection") establishes, "If in the case, which is carried out by the institutions of Justice of one Contracting party, **there is a need for an expert**, who is located on the territory of the other Contracting Party, **to be in person,** you must contact the competent body of this contracting Party with petition on transmit a summons "(Part 1). "... The expert, in addition, has **the right to reward for conducting expertise**" (Part 8).

The provisions of art. 77 The Treaty is quite abstract and at first glance does not cover experts, however, is quite relevant. Thus, according to the article, representatives of the requesting institution may be present in **carrying out actions related to the provision of legal assistance** on the territory of the requested party.

We could admit that international treaty by its legal nature reflects the possibility of expertise within the framework of providing mutual legal assistance, as well as the participation of an expert (representative of the requesting Parties) in the performance of actions related to the provision of legal aid only in general.

Special Ukrainian legislation on forensic medical expertise also does not address the issue of the foreign expert involvement mechanism, its functions and competencies, as well as the legal validity of his conclusions. [3] Moreover, there is no provisions with regard to the international cooperation as such, there's only mention that "without additional coordination with the person, who appointed the examination, for participation in the conduct of forensic expertise **as an experts** the professors and lecturers of the departments of forensic medicine, health care institutions' and other departments' specialists could be involved". It is important to note that such statuses of the person does not have a clear binding to citizenship or institutions residence, which allows to conclude on the possibility of foreign experts to be involved in conducting forensic medical expertise if they correspond to the abovementioned demands (but further analysis will show that these demands are not exhaustive and there's also an additional requirements for certification and registration of all forensic experts in Ukraine).

Using of foreign forensic medical experts' conclusions that have the necessary knowledge and qualifications to provide a conclusion on the issues studied does not contradict to legal requirements. [4; 5] The participation of international experts could be useful in the investigation of criminal proceedings on murders and disasters (for example, air accidents), which have a wide resonance in the society, when the examination of Identification of the body by DNA and establishing the time and causes of death could be performed by commissions of experts from different states.

However, as evidenced by law enforcement practices, the issues of foreign expert involvement and his conclusions' use by the court is treated quite differently. For example, using of certain facts of foreign experts' conclusions as an evidence in civil proceedings is allowed. Thus, in the decision of the Court of Appeal of Cherkasy region (Ukraine), case No 22-c/793/978/16, The court stated that the examination is performed by the Genetic Laboratory "JenaGen" (Federal Republic of Germany), and the specified conclusion is certified by State notary of Jena city, (Federal Republic of Germany) and then legalized for implementation as an official document on the territory of foreign countries by an apostillation in accordance with the provisions of The Hague Convention 1961. Given that Ukraine joined the Convention, such conclusion can be used as evidence.

But the analysis of law enforcement practices *in criminal proceedings* does not allow to make a conclusion about the real possibility of forensic experts' conclusions or examinations conducted in other States use in the Ukrainian investigation and proceedings. For instance, in the verdict of Zolochivsky District Court of Kharkiv Region (Ukraine), case № 622/781/14-K the court refers only to the conclusions of the experts from Ukraine [7]. In the judgment of the Shevchenkivsky District Court of Chernivtsi (Ukraine), case № 727/5570/18 the court also used the conclusions

of experts from Ukraine while not taking into account the conclusion of "center of Forensic Services" Mibi-Lex" given by the defendant, since considered it as not an experts' conclusion under Ukrainian legislation, thus as not a source of evidence, stating that such a conclusion may not have any advantage over the existing expert conclusions, which are drawn up by the forensic experts of the state Institutions of Ukraine [8]. Such position of the courts is generally accepted, widespread in national courts' of Ukraine decisions and motivated by the following.

According to Part 1 art. 101 of the CPC of Ukraine [9] expert's finding is a detailed description of the examination carried out by the expert, as well as the findings of such an examination and grounded responses to the questions posed by the person who invited the expert or the investigating judge, or court requesting his opinion. According to article 69 of CPC of Ukraine An expert in criminal proceedings shall be an individual who has scientific, technical or any other special expertise, has the right under the Law of Ukraine "On Forensic Examination", to conduct expert examination and who is assigned to examine objects, events and processes that contain information on circumstances under which a criminal offence was committed, and to provide an opinion on issues arising in the course of criminal proceedings and relating to the sphere of his knowledge.

The legislation of Ukraine also establishes that, in particular, forensic and medical expertise could be carried out exclusively by the **specialized state institutions.** Forensic expert of the State specialized institutions could be a specialist with an appropriate higher education, educational qualification level not lower than specialist, have undergone appropriate training and qualifications of forensic expert for a particular specialty. The forensic medical examination is carried out by the experts of State forensic Institutions of the Ministry of Health of Ukraine or on entrepreneurial basis based on the license issued by the Ministry of Health of Ukraine. Specialists of State forensic institutions should have higher medical (pharmaceutical) education, undergo special training for forensic examinations and obtain a certificate for forensic medical expert.

Moreover, certified forensic experts (including forensic medical) are included in the State Register of Certified forensic experts, whose maintenance is entrusted to the Ministry of Justice of Ukraine. It is clear that foreign experts (and moreover the abovementioned foreign "professors and lecturers of forensic medicine departments, specialists of health care institutions and other agencies") could not be an experts of the state specialized institutions in Ukraine and not do not have an appropriate licenses of the Ministry of Health of Ukraine for conducting of forensic medical expertise in Ukraine on entrepreneurial basis. Therefore, the conclusions of forensic examinations carried out by the experts (foreigners), which are not included in this register, cannot be recognized by the national legislation of Ukraine. It is also worth noting that such situation is in fact eliminates the possibility to ask the requesting party to conduct an examination within mutual legal assistance, as provided in art. 4 of the Treaty.

Ukrainian legislation admits that the heads of State specialized institutions conducting forensic examinations if necessary, have the right (with consent of the institution or the person, who appointed forensic examination) to include leading specialists of other states to the expert commissions. However, the legal effect of the conclusions of such joint commissions is disputable. In fact, foreign experts are participating in the commission without a procedural status of experts, but only as an "expert advisors" or representatives of the requesting institution in the performance of actions related to the provision of legal aid (Article 77 of the Treaty mentioned above), and only on the basis of corresponding request. In such case they only have the right to observe the procedural actions without the right to participate. Therefore, they are only nominally involved in such an expertise (consultative function or observation) otherwise such conclusion will be signed by an improper subject (by means of CPC of Ukraine) which would lead to inadmissible of such evidence. To avoid such negative consequences, it is necessary to allow the foreign experts to be involved in the examination without inclusion into the register or with their temporary inclusion for the period of the research in a simplified manner.

In contrast to Ukrainian legislation, the Polish legislation does not contain a separate provision that would define the procedural status of an expert [10]. Moreover, the definition of "expert" or "forensic examination" is absent at all and his status is customary equated to the "external means of specialized knowledge", which is accessed by the Court or the prosecutor in case of necessity to use of these knowledge [11].

In Polish criminal proceeding at its various stages (preparatory and judicial proceedings) the involvement of the following categories of experts is allowed: 1) Forensic expert from the list of forensic experts, coordinated by the head of the district Court; 2) ad hoc expert (any person who can provide a conclusion on a particular matter); 3) expert or experts of a scientific or specialized institution [12]. Unlike Ukraine, there is no single register of forensic experts in Poland, as well as no unified standard for inclusion of forensic experts in such regional lists and verification of their skills by the chairman of the District Court [13].

Thus, this feature significantly extends the possibility of various experts' involvement, as well as the possibility for cooperation in criminal proceedings framework with the request for the expertise conduction.

This approach is quite useful given its aim and has practical implementation in other countries. Thus, the forensic experts from the Member States of the European Union can freely provide such services in Lithuania, if such persons are recognized as forensic experts in accordance with the rules of this Member State [14].

Considering a specificity of subject of research, we can state that it is obviously understudied and underregulated. Forensic expertise in criminal proceedings in general repeatedly were a subject of Ukrainian scientists' discussion, but most of the researches are devoted to the theoretical aspects of forensic expertise or to practical issues of special

knowledge use in Ukraine. Polish experience is obviously understudied. Some fragmental aspects of the Polish experience of forensic experts' involving are examined by N. Klimenko in the context of the general study of forensic experts' legal status in European countries [15]. It is also worth to be mentioned that the issue of forensic expert's participation in Criminal proceeding, certain issues of conducting DNA examinations in criminal proceedings or other criminal issues of forensic medicine, as well as the issues of experts' conclusions admissibility are studied by such foreign scholars as Paul W. Grimm [16], G. Samuel, B. Prainsack [17], H. Machado, R. Granja [18], M. Hubiga, H. Muggenthalera, I. Sinicina, G. Malla [19], p. Kruse [20], J. G. Cino [21]. However, cooperation of the countries in the field of forensic examination and the problems of their legal regulation has been ignored by numerous researches and therefore has an obvious relevance and scientific perspective.

CONCLUSIONS

Forensic examination (including forensic medical examination) cannot functionate in isolation only within the individual state. It will not actively perform its law enforcement functions outside of integration with the international community. Therefore, international cooperation between expert institutions and individual experts is needed in order to experience exchange, taking into account the evolution of science and technology. In addition to expanding the use of relevant databases, promising areas for co-operation improving in the field of forensic expertise are also harmonization of the states' law and law enforcement in accordance with international standards and experience of European countries in this field, as well as mutual recognition of foreign experts' conclusions as admissible sources and evidence by national courts and international judicial institutions.

Thus, on the basis of about 300 courts' decisions, specialized legal acts of Ukraine and Poland, as well as foreign researchers' articles, we can state that cooperation in the field of forensic expertise in criminal proceedings between Ukraine and the Republic of Poland is quite formal and unsatisfactory. The existing procedural mechanisms for involving of foreign experts, as well as the use of their conclusions, are declarative, limited and imperfect. Differences in approaches to legal regulation of experts' procedural status also does not contribute to the effectiveness of cooperation between both countries. In order to improve this, it is necessary to review and modify the provisions on the certification and the registration of foreign experts in order to create practical conditions not only for carrying out such expertise in the framework of mutual legal assistance by the Parties, but also for the adoption of such expert findings by the courts as an admissible evidence in the proceedings.

REFERENCES

1. Pro sudovu ekspertyzu: Zakon Ukrajiny vid 25 ljutogho 1994 r. № 4038-XII [On Forensic Examination: Law of Ukraine of February 25, 1994 No. 4038-XII] Available from: https://zakon3.rada.gov.ua/laws/show/4038-12. [reviewed 2019.09.10] (Ua)
2. Doghovir mizh Ukrajinoju i Respublikoju Poljshha pro pravovu dopomoghu ta pravovi vidnosyny u cyviljnykh i kryminaljnykh spravakh: vid 24 travnja 1993 r. [Agreement between Ukraine and the Republic of Poland on Legal Assistance and Legal Relations in Civil and Criminal Matters: of May 24, 1993] Available from: https://zakon.rada.gov.ua/laws/show/616_174 [reviewed 2019.09.10] (Ua)
3. Instrukcija pro provedennja sudovo-medychnoji ekspertyzy : vid 17 sichnja 1995 r. № 6 [Instruction on forensic examination: of January 17, 1995 No. 6] Available from: https://zakon.rada.gov.ua/laws/show/z0254-95. [reviewed 2019.09.10] (Ua)
4. Gholovchenko L, Lozovyj A, Simakova-Jefremjan E et al. Osnovy sudovoji ekspertyzy: navchaljnyj posibnyk dlja fakhivciv, jaki majutj namir otrymaty abo pidtverdyty kvalifikaciju sudovogho eksperta [Basics of Forensic Science: a study guide for professionals who are intending to obtain or certify forensic expertise]. Kharkiv: Pravo; 2016 (Ua)
5. Akhtyrsjka N. Pytannja ekspertnogho zabezpechennja mizhnarodnogho spivrobitnyctva u kryminaljnomu provadzhenni [Question expert support international cooperation in criminal proceedings]. In: Theory and Practice of Forensic Science and Forensic Science: Collection of Proceedings of the All-Ukrainian Scientific and Practical Conference, February 27, 2018. Kyjiv: Mariupolj; 2018: 29–30. Available from: https://dsum.edu.ua/upload/doc/konf_27.02.2018_3.pdf. [reviewed 2019.09.10] (Ua)
6. Ukhvala Apeljacijnogho sudu Cherkasjkoji oblasti vid 19 travnja 2016 r. u spravi № 22-c/793/978/16 [The judgment of the Court of Appeal of Cherkasy region of May 19, 2016 in Case No. 22-c/793/978/16] Available from: http://reyestr.court.gov.ua/Review/57822046 [reviewed 2019.09.10] (Ua)
7. Vyrok Zolochivsjkogho rajonnogho sudu Kharkivsjkoji oblasti vid 11 veresnja 2014 r. u spravi № 622/781/14-k [The verdict of the Zolochiv district court of Kharkiv region of September 11, 2014 in Case No. 622/781/14-k] Available from: http://reyestr.court.gov.ua/Review/40637706 [reviewed 2019.09.10] (Ua)
8. Vyrok Shevchenkivsjkogho rajonnogho sudu m. Chernivci vid 07 serpnja 2019 r. u spravi № 727/5570/18 [The verdict of the Shevchenkivsky district court of Chernivtsi of August 07, 2019 in Case No. 727/5570/18] Available from: http://reyestr.court.gov.ua/Review/83527249 [reviewed 2019.09.10] (Ua)
9. Kryminaljnyj procesualjnyj kodeks Ukrajiny: vid 13 kvitnja 2012 r. № 4651-VI [Criminal Procedure Code of Ukraine: of April 13, 2012 No. 4651-VI] Available from: https://zakon.rada.gov.ua/laws/show/4651-17#n5735 [reviewed 2019.09.10] (Ua)
10. Law of 6 June 1997, Code of Criminal proceedings. Available from: http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU19970890555/U/D19970555Lj.pdf. [reviewed 2019.09.10] (Ua)
11. Dufeniuk O. M. Dosvid Poljshhi stosovno uchasti sudovogho eksperta u kryminaljnomu provadzhenni [Poland experience regarding participation of a forensic expert in criminal proceedings]. Scientific Bulletin of Lviv State University of Internal Affairs. Legal series. 2018;1:240–249. (Ua).
12. Hrehorowicz M. Opinion of the expert in economic criminal matters and its judicial review. Poznan: Poznan Publishing house; 2013.
13. Kupczyński J, Winczakiewicz A. Scientific evidence in the Contraditorial criminal process-comparison of Polish and Norwegian legal solutions. Quarterly National School of Judiciary and Public prosecutors ' office. 2016; 2 (22): 66 – 85

14. Juodkajte-Ghranskiene Gh. Korotka prezentacija sudovo-ekspertnoji naukovoji systemy Lytvy [Brief presentation of forensic scientific system of Lithuania]. In: Arotskerivski reading: Proceedings of the international scientific conference, Poltava, May 25, 2017. Kharkiv: Pravo; 2017: 31–34. (Ua).
15. Klymenko N. Pravovyj status eksperta u dejakykh krajinakh Jevropy [Legal status of experts in some countries of Europe]. Kryminalistychnyj visnyk. 2017;1(27):6–12. (Ua).
16. Grimm PW. Challenges Facing Judges Regarding Expert Evidence in Criminal Cases. Fordham Law Review. 2018;86(4):1601–1615.
17. Samuel G, Prainsack B. Forensic DNA phenotyping in Europe: views "on the ground" from those who have a professional stake in the technology. New Genetics and Society. 2019;38(2):119–141. doi: 10.1080/14636778.2018.1549984.
18. Machado H, Granja R. Ethics in Transnational Forensic DNA Data Exchange in the EU: Constructing Boundaries and Managing Controversies. Science as Culture. 2018;27:242–264. doi: 10.1080/09505431.2018.1425385.
19. Hubiga M, Muggenthalera H, Sinicina I, Malla G. Temperature based forensic death time estimation: the standard model in experimental test. Leg Med. 2016;17(5):381–387. doi: 10.1016/j.legalmed.2015.05.005.
20. Kruse C. The Social Life of Forensic Evidence. Oakland, CA: University of California; 2015. p. 208
21. Cino JG. Tackling Technical Debt: Managing Advances in DNA Technology That Outpace the Evolution of law. American Criminal Law Review. 2017;54:373–421. doi: 10.4172/2169-0170.1000183.

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REVIEW ARTICLE
PRACA POGLĄDOWA

USE OF MEDICAL KNOWLEDGE BY A SPECIALIST IN THE INVESTIGATION OF PREMEDITATED MURDER COMMITTED IN A STATE OF STRONG COMMOTION

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ABSTRACT

Introduction: The results of court practice generalization convincingly indicate that a group of special medical knowledge in the frame of involving a specialist in the procedural actions is an important component of the system of specialized knowledge using during the investigation of murder committed in a state of strong commotion. Moreover, this knowledge is accumulated in psychology and psychiatry areas.

The aim: of the article is to determine the procedural status of a specialist in the criminal procedural legislation of certain countries of the European Union, and, on the basis of comparison with the Ukrainian legislation, to establish his role in procedural actions; coverage of procedural and forensic aspects of using specialized medical knowledge in the form of involving a specialist in the procedural actions during the investigation of murder committed in the state of strong commotion.

Materials and methods: The materials of the study are 67 court decisions on premeditated murder commission, including those in the state of strong commotion, passed by the courts of Ukraine and Poland during 2007-2019, and the results of survey of 23 employees of the pre-trial investigation bodies of the National Police, operative units, public prosecutor's office and certain psychiatrists and psychologists involved in the investigation of relevant crimes in Ukraine; statistical reports of the Prosecutor General's Office of Ukraine for the period of 2013-2019 concerning registered criminal proceedings on this relevant crimes.

Methods, used in the study are dialectical, systemic-structural, formal-logical, sociological and statistical.

Conclusions: The analysis of forms and directions of special knowledge using allows us to establish the fact that involving a specialist in the field of psychology or psychiatry in procedural actions by means of special medical knowledge during the investigation is of particular importance. More likely it will help to establish the state of strong commotion of a person who committed premeditated murder as a reason for qualifying his/her actions under the privileged crime (corpus delicti) provided for by Article 116 of the Criminal Code of Ukraine.

KEY WORDS: specialist, premeditated murder, the state of strong commotion, a psychiatrist, a psychologist

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INTRODUCTION

During the pre-trial investigation it is important to identify all the circumstances to be investigated, in the first place the ones that may affect the qualification of the criminal offense. In particular, while criminal proceedings against a person suspected of premeditated murder, it is necessary to establish the fact of the state of the suspect's strong commotion during the crime act, since, for example, in the Article 148 § 4 of the Criminal Code of the Republic of Poland, the Article 130 of the Criminal Code of the Republic of Lithuania, the Article 120 of the Criminal Code of the Republic of Latvia as well as in the Article 116 of the Criminal Code of Ukraine, it is provided a special privileged qualification of premeditated murder and related mitigation of criminal liability. It is important to note that the investigator by himself does not have sufficient knowledge to solve situational, diagnostic, identification issues related to determining the likelihood of a specific psychological condition (physiological affect) of suspect at the time of causing death to another person, establishing the fact of sudden occurrence of such a situation as a result of the victim's unlawful acts.

Due to the recent researches, in order to understand how instant mental states activate other mental states, there is the idea that network structure of mental states is closely linked to the structure of vulnerability underlying psychopathology. For example, the scientists Re M. L. and Wigman J. T. found that the connection between instant emotions is stronger for individuals with depression than for healthy people [1; 2]. Subsequently, Wichers M. M. and Groot, P. C. determined that the increase in connection in the network structure of mental states had preceded the significant increase in the level of a person's depressive symptoms in the course of time [3]. It is impossible to establish mental states that cause the state of strong commotion without the use of specialized knowledge during the pre-trial investigation. Therefore, there is a need to involve persons with relevant medical knowledge that are able to carry out necessary examination and issue qualified conclusions.

According to the Prosecutor General's Office of Ukraine, the number of registered criminal proceedings under the Article 116 of the Criminal Code of Ukraine in 2013

was 13; in 2014 - 4; in 2015 - 7; in 2016 - 11; in 2017 - 5; in 2018 - 6; in January-August of 2019 - 1 [4]. However, this number of homicides cannot be considered as a final one, since the fact that the emotional state of the offender during the pre-trial investigation and the trial was properly assessed cannot be totally excluded.

Besides, during the analysis of the decisions passed by the courts of Ukraine under the Article 116 of the Criminal Code of Ukraine, it was found that in 57% of the cases the court carried out a re-qualification of the act which was qualified in the pre-trial investigation from the Article 115 of the Criminal Code of Ukraine (premeditated murder) to the Article 116 of the Criminal Code of Ukraine.

Thus, **the aim** of the article is to determine the procedural status of a specialist in the criminal procedural legislation of certain countries of the European Union, and, on the basis of comparison with the Ukrainian legislation, to establish his role in procedural actions; coverage of procedural and forensic aspects of using specialized medical knowledge in the form of involving a specialist in the procedural actions during the investigation of murder committed in the state of strong commotion.

MATERIALS AND METHODS

Methods, used during the study, are dialectical, systemic-structural, formal-logical, sociological and statistical.

Scientists researches in the field of forensic medicine, psychology, psychiatry, expert science, as well as criminalistics, criminology, criminal law, criminal procedure law and other areas of scientific knowledge related to the problem of combating crime became the theoretical basis of the article.

The materials of the study are 67 court decisions on premeditated murder commission, including those in the state of strong commotion, passed by the courts of Ukraine and Poland during 2007-2019, and the results of survey of 23 employees of the pre-trial investigation bodies of the National Police, operative units, public prosecutor's office and certain psychiatrists and psychologists involved in the investigation of relevant crimes in Ukraine; statistical reports of the Prosecutor General's Office of Ukraine for the period of 2013-2019 concerning registered criminal proceedings on this relevant crimes.

Methods, used in the study are dialectical, systemic-structural, formal-logical, sociological and statistical.

REVIEW AND DISCUSSION

The Ukrainian legislation in the Article 116 of the Criminal Code of Ukraine provides criminal responsibility for the commission of premeditated murder committed in a state of strong commotion caused by the violent treatment or the one that demeans person's honor and dignity, as well as the presence of a systematic nature of such treatment by the victim [5].

The Criminal Code of Poland provides for the privileged qualification of premeditated murder, committed in a state of strong commotion, provoked by justified circumstances (Article 148 § 4 of the Criminal Code of the Republic of Poland) [6]. The Latvian legislator in the Article 120 of the Criminal Code of the Republic of Latvia provides the responsibility for the homicide, committed in a sudden emergence of a state of strong commotion, caused by the violence or grievous abuse by the victim [7]. Article 130 of the Criminal Code of the Republic of Lithuania defines homicide committed in a state of sudden strong mental commotion caused by the victim's unlawful act or a particularly grievous abuse to him or his beloved people [8].

As to the positions, expressed in the acts of the judiciary on the notion of "state of strong commotion" in Poland, it should be noted that the courts have repeatedly drawn attention to this concept. Thus, the Krakow Court of Appeal stated that "strong commotion is a state of physiological influence, in which emotions, which a guilty person gets due to a particular motivational situation, limits the controlling function of intellect" [9]. In the judgment of the Lublin Court of Appeal, it is said that "the nature of commotion (physiological affect) is characterized by the fact that the emotional process, experienced by the offender due to a particular motivational situation limits the controlling function of the mind" [10]. In the judgment of the Gdansk Court of Appeal it is stated that "in the situation, determined by the Article 148 § 4 of the Criminal Code, it goes about the excitement of the highest intensity which, obviously, goes beyond the ordinary and the average arousal in such a way that emotional experiences dominate the intellectual becoming the reactions to external facts that are extraordinal" [11].

The Ukrainian courts use similar approach. In the judgment of The Supreme Court of Ukraine/Criminal Court of Cassation of Ukraine in the case № 234/8200/16-k dated by August 29, 2018, it is said that "strong mental commotion (physiological affect) is a sudden emotional process caused by the victim's behavior which proceeds quickly and violently and, to some extent, reduces a person's ability to be aware of his actions and to manage them". A state of strong mental commotion is recognized as the one that occurred suddenly, the process of occurrence and course of which is characterized by unexpectedness, evanescence, turbulence, and transience. The separation of premeditated murder from an intentional homicide committed in a state of strong commotion is carried out both on the objective and subjective side of these crimes. Particularly, when qualifying a crime under the Article 116 of the Criminal Code of Ukraine, a socially dangerous act of a person is provoked by violence, systematic abuse or grave abuse by the victim [12].

In the judgment of the Hrebinka District Court of the Poltava region it is stated that "the physiological affect does not indicate insanity, as it is not a kind of morbid state of mind" [13].

Also, a state of strong commotion has repeatedly become a platform for scientists' discussion. For example, according to Reid Griffith Fontaine in the US criminal law the trial requires the suspect to demonstrate that he has been strongly provoked and, as a direct result of the provoca-

tion, extremely emotionally disturbed, so has committed a homicide being in this uncontrolled state. Thus, partial considering of emotional dysfunction is taken; the unlawfulness of murder is mitigated when emotionally charged reactivity limits the killer's ability to rational thought and reasoned behavior [14].

In the Encyclopedia of Behavioral Medicine, a state of strong commotion refers to affective states that may differ in various ways, including their duration, intensity, specificity, pleasantness and arousal level. They play an important role in regulating cognition, behavior, and social interactions [15].

Thus, we see that the notion of a specific emotional state is reflected in the procedural acts and scientific literature of many European countries, the approaches to which are, in most cases, similar.

It should be noted that in the investigation of premeditated murder in a state of strong commotion along with obtaining evidential information during investigative (search) actions, one of the ways of obtaining actual data is the use of special knowledge in the form of involvement of a specialist and an expert. This position is confirmed by the results of practitioners' questioning, in particular, the staff of the pre-trial investigation bodies of the National Police of Ukraine, the employees of the operational units and the public prosecutor's office, who identified the importance of special knowledge using in the form of expert involvement - 59% and a specialist involvement - 41% respectively in the pre-trial investigation of criminal proceedings.

The involvement of a specialist and an expert in criminal proceedings has a lot of similarities. In particular, they are involved when it is needed to use their specialized knowledge. However, the knowledge and skills of a specialist are used only to assist in the detection, consolidation and extraction of evidence, in conducting of procedural actions and examining of evidence in the court, in the use of technical measures during investigative (search) and judicial actions. He may provide explanations regarding special issues arising during the conduct of investigative (search) actions or during the judicial investigation, as specified in the Article 71, paragraph 2 of the Criminal Procedural Code of Ukraine. The results of his activities are reflected in the report of the investigative (search) action and in the court log, as well as in the annexes to them in the form of plans, diagrams, charts, schedules, etc. [16].

The involvement of a specialist in certain procedural actions is also regulated in a number of criminal procedural laws in Europe. According to § 1 of the Article 205 of the Criminal Procedural Code of Poland, a specialist is empowered with most of the powers delegated to an expert with the exception of the Articles 193, 197, 200, 202 and, if needed, an expert may be interviewed as a witness (§ 2 of the Article 206 of the Criminal Procedural Code of Poland) [17].

Therefore, it should be assumed that in accordance with the Article 205 of the Criminal Procedural Code of Poland, both expert and a specialist have specialized knowledge with the difference that the expert is included in the special list (registry) of experts, but the specialist is not. In addition, the expert carries out the activity on the basis of the collected evidence, and the specialist actually gather them [18].

According to the Article 113 of the Criminal Procedural Code of Latvia, a specialist is a person who provides assistance with the use of his specialized knowledge or skills in a particular field. Thus, the specialist is obliged: 1) to join at the time and place specified by the official and participate in the investigative action if the procedure for his involvement is followed; 2) to assist in conducting an investigative action using his knowledge and skills, but without conducting practical research looking for the traces of a criminal act, finding out facts and circumstances, as well as fixating the course and results of the investigative action; 3) to pay attention of the officials in the course of their investigative action to the circumstances relevant for the identification and understanding of the circumstances; 4) not to disclose the content and the results of the investigative action if he is specially warned about its non-disclosure [19].

In our opinion, the most complete and accessible procedural status of a specialist is described in the Article 89 of the Criminal Procedural Code of the Republic of Lithuania, where it is established that the specialist is a person with necessary special knowledge and skills, who is assigned to examine the object and draw his own conclusion or explanation of issues that fall within his competence. A specialist, as well as in the Criminal Procedural Code of Poland, may be an official of the pre-trial investigation or investigation bodies, as well as the persons who do not work there. Also, the Lithuanian legislature made a designation. In accordance with Part 3-4 of the Article 89 of the Criminal Procedural Code of Lithuania court medical examiners are specialists who carry out examinations of a human body or corpse; forensic psychiatrists and forensic psychologists are specialists who conduct examinations of a person's mental state. Regarding the duties of a specialist, the specialist is obliged to come upon request of the investigative authorities, the pre-trial investigation, the prosecutor or the court; to issue independent conclusions, give the explanations on special issues that arise during the conduct of investigative action. According to the Article 235 of the Criminal Code of Lithuania, the specialist is criminally liable for making deliberately false conclusions and providing false explanations [20].

Conducting of the examination is an independent activity of an expert. He deals with the collected evidence. By examining them he establishes a new evidence and makes the conclusion which is a detailed description of the research conducted by the expert and the conclusions drawn from its results, substantiated answers to the questions asked by the person, who had invited the expert (Article 69, 101 of the Criminal Procedural Code of Ukraine; Article 200 of the CPC of Poland; Article 88 of the Criminal Procedural Code of Lithuania; Article 33 of the Criminal Procedural Code of Latvia).

Thus, in our opinion, the main purpose to engage a specialist is to expand the practical capabilities of an

investigator, prosecutor in the detection, extracting and recording of evidence during investigative (search) actions to establish the truth in criminal proceedings.

In general, it should be noted that the activity of two procedurally independent persons (specialist and expert) in the investigation of criminal proceedings on premeditated murder committed in a state of strong mental commotion is essential and is a key to prompt, complete and impartial pre-trail investigation.

During the study we conducted a survey of employees of the National Police bodies' investigative units, operational units, public prosecutor's office and individual psychologists and psychiatrists. As a result, it was found that due to special medical knowledge during the investigation more than 61.3% of the respondents preferred to involve psychologist or psychiatrist specialists to conduct procedural actions involving a suspect in the types of criminal offenses we are investigating. The results convincingly indicate that a group of special medical knowledge in the frame of involving a specialist in the procedural actions is an important component of the system of specialized knowledge, used during the investigation of premeditated murder committed in a state of strong commotion. Moreover, this knowledge is accumulated in such areas as psychology and psychiatry.

Also, cognition in psychology is more often needed to solve various issues that arise when conducting certain investigative (search) actions. Thus, when examining the scene of a crime, the knowledge of psychological patterns allows to put forward thorough investigative versions, to predict the most probable motives for the crime, personal, psychological qualities and the status of the offender; to identify during the search the most likely places and methods of concealment, which is related to the study of the psychological characteristics of a suspect, such as his interests, hobbies, knowledge, character, emotional qualities, his psychophysical reactions during the procedural action. The tactics of interviewing the victim, witnesses, suspects and accused are largely determined by the ability to understand and evaluate the psychological qualities and condition of the persons being questioned [21, 158].

The use of specialized medical knowledge at the stage of the pre-trial investigation of premeditated murder committed in a state of strong commotion in most cases involves specialists and experts in the field of psychology or psychiatry by the investigator in conducting various types of investigative (search) actions. Therefore, in our research we focused on the study of the use of specialized knowledge in the form of involving of a specialist, such as a psychologist or a psychiatrist, to the conduction of procedural actions.

As already have been mentioned, the first and foremost investigative (search) action of the specified type of criminal proceedings is the inspection of the scene. Involvement in this investigative action of specialists in the field of psychology optimizes the process of investigation. The knowledge of psychology or psychiatry when inspecting the scene makes it possible to emphasize the existence of certain circumstances that indicate the course of the crime actions; allow you to analyze the factors that indicate cause of death – suicide or murder; help to evaluate the mental state of the victim as being likely to lead to suicide; identify the factors that could have influenced such decision that led to such act; find out personality traits, level of balance, vitality, worldview, attitude to life and others etc. Also, in the further investigation, the knowledge of this specialist will help to establish the connection between the victim and the offender.

Besides, when investigating the premeditated murder, the psychologist or psychiatrist may be involved in communicative investigative (search) activities, such as interrogation or investigative experiment. After all, according to our analysis of criminal proceedings, in 60% of cases during the interrogation of the suspects they did not remember the events related to the crime. For example, by the verdict of the Hrebinkov RS of the Poltava region on July 27, 2019, a woman was convicted of 13 stabbing of her son with an ax blade and two stabbing in the torso, the last of which caused an immediate death. Her interrogation shows: "30.04.2018 night, when her son once again demanded alcohol from her, pushed her on the sofa, swearing at her, grabbed her by the throat, she pushed him onto the sofa, then ran to the kitchen for the water for him and saw the kitchen ax in the kitchen; she took it and returned to the room, hit her son with the ax hat once in the head, after which he started to rise; she was frightened and hit him again like she had hit him already. After that she did not remember anything and waked up have found herself on the floor of a bathroom with severed veins, there were many people near; she saw the knife only when it was lying in the sink" [13].

In our opinion, a psychologist should be invited to conduct the interrogation of the suspect. These specialists create a psychological portrait and give investigators their recommendations on interrogation tactics. Proper organization of this activities will help the investigator to solve a number of practical tasks: to analyze the materials of the proceedings, examine the person of the interviewee, predict and plan the process of communication and possible behavior of the person, overcome the negative emotional state and barriers of communication for establishing psychological contact, provide recommendations to the investigator regarding interrogation tactics, etc. [22, 20].

During the interrogation of the suspect or simultaneous interrogation with the participation of the suspect, a psychologist or a psychiatrist can help the investigator to formulate the questions taking into account the psychological characteristics of the interrogation participants, work out with the investigator the most effective tactics of interrogation and simultaneous interrogation of two or more interviewed, help to create informal atmosphere, eliminate alertness, distrust to law enforcement agencies. The interaction of the investigator with a psychologist or psychiatrist during the interrogation is essential to establish a psychological contact between the interviewee and the investigator, without which it is impossible to find the truth in criminal proceedings. During the interrogation the spe-

cialist may, with the permission of the investigator, ask the other participants of the investigative (search) action. The activity of a specialist psychologist or a psychiatrist helps the investigator to establish that the suspect or accused was in a state of strong commotion at the time of committing the crime, in the presence of such obligatory signs as suddenness and occurrence as a result of unlawful violent acts of systematic abuse or severe abuse. The investigator with the help of a specialist should find out interviewee's personal assessment and subjective perception of the situation, in which he has a corresponding emotional reaction to the violent treatment or the one that degrades the person's honor and dignity by the victim.

During the investigative experiment with a suspected person in premeditated murder committed in a state of strong commotion, in our opinion, one should also involve a psychologist or a psychiatrist, since demonstrating and describing of the crime circumstances could be a stressful condition for a person, and he or she will not be able to fully explain the circumstances of the act. The involvement of a psychologist or a psychiatrist during the investigative experiment is also useful because their joint actions with the investigator in obtaining additional information can enhance tactical technique by the doctrine of psychology about the dependence of memories on human activity. Its essence is that the person at the suggestion of the investigator reproduces on the spot only what he remembers. During such reconstructions it is often possible to revive person's memory to such extent, that the investigator receives very detailed information about seemingly completely forgotten facts. The person not only remembers certain facts but also corrects them, rejecting everything that does not corresponds with the real situation, specifies certain information and gives justification for that was reported during the interrogation. Therefore, the involvement of a psychologist or a psychiatrist in this case is mandatory.

CONCLUSIONS

We've conducted a study of the concept of a state of strong commotion reflected in a number of criminal laws of Europe. We have also established the presence of a procedural figure – a specialist in the Criminal Procedural Codes of Ukraine, Poland, Lithuania and Latvia, whose activity in most cases is similar and is called upon to play an auxiliary role during pre-trial or judicial proceedings. Also, the results of the scientific investigation clearly show that at the stage of the pre-trial investigation of criminal proceedings on premeditated murder committed in a state of strong commotion, the use of specialized knowledge, in particular of psychological and psychiatric profile, is important. In general, the use of specialist's medical knowledge in the investigation of crimes is a prerequisite for the proper qualification of the crime, the nomination and verification of reasonable investigative versions, improving the effectiveness of the tactics of investigative actions, establishing the specific causes and conditions that contributed to such a crime, as well as individualization of the punishment. The use of specialized medical knowledge in the form of involvement of a psychology or psychiatry specialist to investigative actions with the participation of the suspect helps to establish and ensure the state of strong emotional commotion at the time of committing a criminal offense, promotes the proper legal qualification of criminal actions.

REFERENCES

1. Re M.L. et al. Emotion-network density in major depressive disorder. Clinical Psychological Science. 2015; 3: 292–300. doi: 10.1177/2167702614540645
2. Wigman J.T. W. et al. Exploring the underlying structure of mental disorders: Cross-diagnostic differences and similarities from a network perspective using both a top-down and a bottom-up approach. Psychol. Med. (2015); 45: 2375–2387. doi: 10.1017/S0033291715000331
3. Wichers M. M., Groot, P. C., Psychosystems, ESM Group & EWS Group. Critical Slowing Down as a Personalized Early Warning Signal for Depression. Psychother. Psychosom. 2016; 85: 114–116. doi: 10.1159/000441458
4. Yedynyi zvit pro kryminalni pravoporushennia za 2013-serpen 2019 roku [Criminal Offenses Report 2013-July 2019]. Available from: http://www.gp.gov.ua. [reviewed 2019.09.06]
5. Kryminalnyi kodeks Ukrayiny [The Criminal Code of Ukraine]. № 2341-III vid 5.04. 2001 Available from: https://zakon.rada.gov.ua/laws/show/2341-14 [reviewed 2019.09.06] (Ua)
6. Kodeks karny Rzeczypospolitej Polskiej Available from: http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU19970880553/U/D19970553Lj.pdf [reviewed 2019.09.06]
7. Krimināllikums [The Criminal Code of Latvia]. Available from: http://www.pravo.lv [reviewed 2019.09.06]
8. Lietuvos Respublikos baudžiamasis kodeksas [The Criminal Code of Lithuania]. Available from: ttp://law.edu.ru/norm/norm.asp?normID=1243877&subID=100107735,100107738,100107755,100107816#text [reviewed 2019.09.06]
9. Wyrok Sądu Apelacyjnego w Krakowie, KZS 2009/12/60. Available from: http://orzeczenia.ms.gov.pl [reviewed 2019.09.06]
10. Wyrok Sądu Apelacyjnego w Lublinie, KZS 2010/1/47. Available from: http://orzeczenia.ms.gov.pl [reviewed 2019.09.06]
11. Wyrok Sądu Apelacyjnego w Gdańsku, POSAG 2010/1/181. Available from: http://orzeczenia.ms.gov.pl [reviewed 2019.09.06]
12. Postanova VS/KKS sprava №234/8200/16-к vid 29.08.2018 [SC / CCC Resolution Case No. 234/8200/16-k of 29 August 2018]. Available from: http://reyestr.court.gov.ua/Review/76350783 [reviewed 2019.09.06]
13. Vyrok Hrebinkivskogo RS Poltavskoi obl. № 539/2008/18 від 27.07.2018 [Verdict of Hrebinka district court № 539/2008/18 from 27.07.2018]. Available from: http://reyestr.court.gov.ua/Review/75572354 [reviewed 2019.09.06]
14. Reid Griffith Fontaine. The Wrongfulness of Wrongly Interpreting Wrongfulness: Provocation, Interpretational Bias, and Heat of Passion Homicide. New Criminal Law Review: An International and Interdisciplinary Journal. 2009; Vol. 12 No. 1 : 69-92. doi: 10.1525/nclr.2009.12.1.69
15. Gellman M.D., Turner J.R. et al. Encyclopedia of Behavioral Medicine. Springer, New York, NY. doi: 10.1007/978-1-4419-1005-9
16. Kryminalnyi procesualnyi kodeks Ukrayiny [The Criminal Procedural Code of Ukraine] № 4651-VI vid 13.04.2012 Available from: https://zakon.rada.gov.ua/laws/show/4651-17[reviewed 2019.09.06] (Ua)

17. Kodeks postępowania karnego. [The Criminal Procedural Code of Poland]. Available from: http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU19970890555/U/D19970555Lj.pdf [reviewed 2019.09.06]
18. Marek Stachowski. Specjalista w procesie karnym Available from: http://prawnakancelaria.eu/teksty/kpk/specjalistawprocesiekranym.html [reviewed 2019.09.06]
19. Ugholovno-procesualnyi zakon Latvii [Tha criminal-procedural Code of Latvia]. [Internet]. Available from: http://www.pravo.lv/likumi/29_upz.html [reviewed 2019.09.06] (Ru)
20. Kryminalnyi-procesualyi Kodeks Lytovskoi Respubliky [Tha criminal-procedural Code of Lithuania]. Available from: http://pravo.org.ua/files/_(2).pdf [reviewed 2019.09.06] (Ua)
21. Kuntiy A. I. Metodyka rozsliduvannya umysnogo nvbyvstva, vchynenogo v stani sylnogo dushevnogo chvyliyvannya [Metods of investigation of premeditated murder committed in a state of strong commotion]. Lviv. 2016: 219 (Ua)
22. Yusupov Y.M. Psypolohiya vzaymoponymanya [Psychology of Understanding]. Kazan. 1991: 20 (Ru)
23. Sirenko O.V., Linnik E.V. et al. Current legal issues of conducting a forensic medical examination of newborn's corpses. Wiadomości Lekarskie 2019, tom LXXII, nr 5 cz II: 1140-1144. Available from: http://medlist.org/pdf/wl/2019_05_78.pdf [reviewed 2019.09.06]
24. Dufeniuk O.M., Kuntii A.I. Kompleksna sudova psuhologo-psyhiatrychna expertyza yak forma vykorystyannya specialnych znan pid chas rozsliduvannya umysnoho vbyvstva, vchynenogo v stani sylnogo dushevnoga hvyliyvannya. [Complex psychological-psychiatric examination as a form of use of special knowledge during investigation of premeditated murder committed in a state of strong commotion]. Bulletin of the Lviv State University of Internal Affairs, 2015; 1: 387-397 (Ua)

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THE LEGAL FOUNDATIONS OF FOOD SAFETY AS A MEANS OF PROVIDING PUBLIC HEALTHIN GLOBALIZATION

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ABSTRACT

Introduction: Human health and the ability to exercise human's natural right to life are directly dependent on the level of food safety. Art. 25 of the Universal Declaration of Human Rights, adopted by the United Nations General Assembly in 1948, prescribes the right of every person to such a standard of living, including food, that is necessary to maintain the health and well-being of himself and his family. The problem of food safety in globalizing world is gaining global significance.Its solution is a public health remedy and is largely dependent on the perfection of legal regulation.

The aim: The aim of this article is to find solutions of the public health' problems by establishing an effective legal mechanism for ensuring food safety in the context of globalization both nationally and internationally.

Materials and methods: The methodological basis of this research is the general and special scientific methods. Empirical materials used were scientific works, international legal acts, legislation of Ukraine, EU, USA and other countries, statistics from UN, FAO, ISAAA and IFOAM.

Conclusions: Differentiation of the food safety level among different countries is reflected in its legal security at the national level. But the globalization of this problem and the need to find the solutions to ensury public health require global approach, namely, to join forces with the international community and to develop an effective international legal food safety framework.

KEY WORDS: food safety, globalization, legal foundations, agrosphere, organic products

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INTRODUCTION

Human health and the ability to exercise human's natural right to life are directly dependent on the level of food safety. Art. 25 of the Universal Declaration of Human Rights, adopted by the United Nations General Assembly in 1948, prescribes the right of every person to such a standard of living, including food, that is necessary to maintain the health and well-being of himself and his family [1].

The problem of food safety in globalizing world is gaining global significance. Increasing of food production, improving its quality and safety is one of the most important tasks of the world economy. This is due to a number of factors including: 1) predicted food crisis caused by further growth of the planet's population. As of beginningof 2019, the world population was over 7.7 billion [2], and by 2050, according to the UN's prediction, it may reach 10 billion. According to FAO, as of 2019, the number of starving people is around 113 million in 53 countries. Almost two-thirds of them are residents of Afghanistan, the Democratic Republic of the Congo, Ethiopia, Nigeria, South Sudan, Syria and Yemen [3].Over 821 million people in different regions of the world are one step ahead of the state of acute hunger (every 9th people) [4]; 2) natural anomalies resulting from climate change, emerging of global warming (change in frequency and nature of rainfall, desertification of territories suitable for agricultural production); 3) depletion of soils and other natural resources due to their environmentally unbalanced agricultural use; 4) military conflicts; 5) economic crises, etc.

THE AIM

The aim:of this article is to find solutions of the public health' problems by establishing an effective legal mechanism for ensuring food safety in the context of globalization both nationally and internationally.

MATERIALS AND METHODS

Methodological basis of this research are the general and special scientific methods: dialectical, analysis and synthesis, synergism, historical-legal, formal-logical, system-structural, comparative-legal, formal-legal and statistical.

The empirical materials of this research were theoretical articles of legal and economic science experts, international legal acts (The Universal Declaration of Human Rights,Codex Alimentarius), legislation of Ukraine(Law of Ukraine "On State Support for Agriculture of Ukraine" (2004), Law of Ukraine "On the state biosecurity system for the creation, testing, transportation and use of genetically modified organisms" (2007)), EU (Commission Regulation

(EC) № 889/2008 with provisions on the implementation of Council Regulation (EU) № 834/2007 on organic production, labeling of organic products and control, Council Regulation (EC) № 834/2007 of 28 June 2007 on organic production and labelling of organic products), USA (The Food Security Act (1985)) and other states, which is regulating public relations in food safety, statistics from UN, FAO, ISAAA and IFOAM.

RESULTS AND DISCUSSION

The problem of food safety occupies a leading position in the national security of each country because it is a prerequisite and a necessary factor for the one's social and economic stability. Thanks to it a stable socio-economic development of society, its demographic reproduction is achieved. In many countries worldwide special laws on food safety have been adopted. For example, the US Food Safety Act was passed in 1985.In the European Union the need for food safety has become the main reason for the emergence of the Common Agricultural Policy. Food shortages helped to develop policy aimed at increasing production. Subsequently, other goals (competitiveness, environmental protection, rural development) emerged. Food safety has national characteristics, its inherent complexity and permanence. Some countries are achieving food safety through self-sufficiency (China), while others are forced to import a significant portion of food and raw materials (Japan), which requires not only an adequate resources but can also increase their economic and political dependence on the supplying countries.

The term "food safety**" was formally introduced into international practice after the grain crisis of 1972-1973. In this regard, the 1974 World Summit on Food, which adopted the Universal Declaration on the Eradication of Hunger and Malnutrition, first identified the concept of "food** safety**" as an uninterrupted availability of sufficient global food supplies to support sustainable growth. Consumption of food and repayment of fluctuations in production volumes and prices.**

The transformation of the food safety category was due to the deepening of the globalization and internationalization food production and consumption processes under the influence of new knowledge and concepts of rational nutrition, as well as the awareness of the need to unite efforts and interaction of different countries to fight hunger [5]. From a global understanding of food safety only as a quantitative indicator (availability of grain stocks at the global and national levels) we gradually made the transition to taking into account the economic and social accessibility of food, solving problems of "hidden hunger", rational and balanced nutrition, introducing the criterion of foodrange, improving the quality and safety of food.

In this regard, the definition of the term "food safety" in paragraph 2.13, art. 2 of the Law of Ukraine "On State Support for Agriculture of Ukraine" of June 24, 2004 is unreasonably narrow: it is the protection of the vital interests of man, which is expressed in guaranteeing the state of unimpeded economic access to food for the purpose of maintaining his or her ordinary activities [6]. However, food safety is not only about providing the population of the state with the necessary amount of food, achieving food independence and ensuring economic and physical access to food for all segments of the population. It is also a filling of state reserves for this purpose, the creation of stabilization funds, as well as guaranteeing the quality of such products, their safety for consumers - the population of the state.

Food safety should be understood as a significant component of the national security of the state, which presupposes the protection of the vital interests of the person It is expressed by guaranteeing the state on the principles of self-sufficient physical and economic access to food in the quantity, assortment, quality and safety necessary for maintaining health and routine life activities.

Today the global community is trying to develop a system of measures to counter the threat of the food crisis, including relevant international legal instruments and programs in this area. Eradicating hunger, food safety, improving nutrition, promoting sustainable agriculture, promoting healthy lifestyles and well-being for all at any age have all taken root in the UN Global Sustainable Development Goals (SDGs) «Transformingourworld: the 2030 Agenda for Sustainable Development» [7]).

International organizations - FAO, World Food Program (WFP), International Fund for Agricultural Development (IFAD), World Health Organization (WHO) monitor and analyze the world food safety and provide recommendations on how to improve it. Due to the implementation of FAO's actions by 2030, it is planned to completely eradicate hunger in the world and reach a "zero famine limit" [8]. In particular, a set of indicators characterizing the state of food safety has been developed. The most comprehensive rating of food safety in various countries is in the Global Index [9]. It determines the state of food safety, taking into account factors such as availability, sufficiency, quality and product safety. The FAO's Department of Economic and Social Development has elaborated the national food safety profiles (features) containing 97 indicators. The profiles are unique for all countries, except for the indicators of commodity structure of production, import and export of agricultural products and food, which are selected according to the specific features of each country.

Approaches to addressing food safety problemat the national level are also changing. Among these are: 1) the shift from an import-oriented approach to self-sufficiency by increasing agricultural production. For example, in 2019, the Qatar National Research Foundation and the Ministry of Municipalities and Environment of Qatar announced a competition for applied research projects in the field of food safety aimed at promoting and developing productive and stable local food production systems that improve their safety, quality and contribute to sustainability [10].The increase in agricultural production, i.e. the level of self-sufficiency, has a significant impact on improving the food supply of the population. For this purpose, the

agricultural sector needs investments, access of small producers (including family farms) to production resources, improvement of agrarian legislation on state support, taxation, introduction of innovative forms of agricultural production, etc; 2) the widespread use of biotechnological activities, including GMOs, to address the food problem. Among the largest producers of GM crop products are the USA, Canada, Argentina, Brazil, India and China, which account for 80% of all world GMO plantings. According to the International Agency for the Monitoring of the Application of Agrobiotechnology (ISAAA) and Greenpeace, the area of crops of GM crops reached 185 million hectares in 29 countries of the world [11].

The reasons for growing transgenic crops in crop production are obvious–they are characterized by growth rate, long-term storage, resistance to pests, high yields, unpretentious growing conditions, the ability to plan products quality and more. In animal husbandry – it is disease resistance, accelerated growth, the possibility of obtaining livestock products with adjustable quality indicators etc. Proponents of genetic engineering believe that biotechnology and GMOs will help to solve the food problem, dispose of agricultural waste, combat pests and diseases in plant and animal husbandry etc. Thus, the use of fertilizers, biopesticides and biofertilizers in agricultural production is considered by scientists as a means of preserving agroecosystems and a healthy environment. They emphasize that in countries such as India, Canada, USA there is a separate legal regulation on the use of these biological products [12, p. 3-17].

At the same time, the active development of modern biotechnology and genetic engineering has not only positive aspects. First, it is a matter of concern that the effects of the transgenic agricultural products'use are still unknown as only the first generation of humanity consumes them. Issues related to GMOs and other biotechnology products are caused by the actual or potential harm that can be caused to humans when consumed in food or other direct application to the human body and to the environment (reduction of biodiversity, gene transfer, the destruction of non-target organisms along with pests, climate change). Regarding the impact on the human body there is a potential threat that prolonged use of such products can adversely affect human health, lead to cancer, antibiotic resistance, severe allergic reactions, impaired nervous, reproductive systems, vision and other issues.

It is necessary to avoid the simplified understanding of biotechnology in only one aspect – either as a positive or as a negative phenomenon that we usually see in the literature or in the Internet. Biotechnologies used in agricultural production can be divided into the following types [13, p. 295-297] depending on their impact on human health and the state of the environment:

- biotechnologies that are useful to humans and so-called "environmentally friendly". For example, the use of biopesticides, in particular, of appropriate microorganisms that are toxic to certain agricultural pests but safe for humans, animals, birds, beneficial insects and the like. The uniqueness of the biopesticides'mechanisms action provides protection against pests resistant to traditional agents. Thus, in early 1930s US farmers began to use the microorganism Bacillus thuringiensis (Bt)as a biopesticidewhose natural environment is soil. Some of the proteins synthesized by this microorganism are deadly to insect pests including the corn butterfly (Ostrinianubilalis), which annually damages $ 1.2 billion in US agriculture. The use of aerosols containing proteins of Bacillus thuringiensis (Bt) allows to destroy insect pests without the use of synthetic chemicals and does not cause harm to the environment, humans, animals or plants [14];

- biotechnology, which may have a potential risk to human health or to the environment butsuch risk can be prevented by using of appropriate measures. It requires an effective legal monitoring and prevention mechanism for any possible risks and adverse effects from the use of biotechnology in agricultural production;

- biotechnology, which may have a potential or even real risk to human health or to the environment, which cannot be predicted, tracked or prevented by existing technologies and technical means. These threats and risks, of course, do not correlate with the concept of sustainable development, which underpins human well-being and environmental protection, not only for the present but also for future generations, organically combining environmental, economic and social components. Given the above, the issues of proper legal regulation of relations arising from the use of biotechnologies, in particular GMOs, in the process of agricultural production and in ensuring the safety of transgenic food products are of particular relevance. Thus, humanity by accumulating knowledge and achievements of the natural, social and other sciences and incorporating them into the legal form should use all those possible positive aspectsregarding agricultural products. At the same time, the law should prevent all, even potentiall risks to human life and health, environment, biodiversity and more. That is why it is unacceptable to underestimate the role of legal instruments in regulating biotechnology (in particular GMOs) using in the agro-sphere.

International standards for the management of GMOs have been enshrined in the Cartagena Protocol on Biosafety to the 1992 Convention on Biological Diversity. There are two conceptual approaches to the legal regulation of these relations at national level. According to the former, food safety derived from biotechnology (mainly GMOs) should be considered within the framework of the integrated concept of "food safety". This approach is characterized by the doctrinal established special principle of substantive equivalence [15, p. 571]. It is used in the USA where they believe that transgenic products aren't different from their normal counterparts. The second approach is the European one which proceeds from the precautionary principle. It requires the establishment of a special legal regime for products obtained using GMOs until their absolute safety is proved. The second approach is reflected in the Law of Ukraine of May 31, 2007 "On the state biosecurity system for the creation, testing, transportation and use of geneti-

cally modified organisms"; 3) development of the alternative forms of agricultural production. Organic agricultural production is one of the modern measures for implementing the sustainable food policy and ensuring food security. It is the key to ensuring a high level of safety and quality of agricultural products, environmental protection and rural development. Growing organic products of plant and animal origin also has a number of environmental, social and economic benefits since it provides energy savings with minimal environmental impact of agriculture, and healthy, organic food is a guarantee of preserving the health of the population, increasing life expectancy, raising the standard of living. Consumption of organic products at a higher level provides for the physiological needs of humans for vitamins, trace elements and nutrients.

Proper legal regulation of the quality and safety of organic agricultural products is a way of guaranteeing food safety. The formation of the organic products quality is influenced by technological measures, conditions and requirements pertaining to the processes of its cultivation. Agricultural products of plant and animal origin acquire organic properties only as a result of compliance with the rules for the production of such products. Its quality indicators should be different from those of traditional products. These include safety, reliability, economy, environmental friendliness, compliance with sanitary, technological, hygienic and physiological standards, etc.

The safety of organic agricultural products is its most important characteristicin terms of its potential impact on human health and life. Its essence is the absence of the threat of harmful effects of these products to the human body. At the same time, the production of organic products is a means of ensuring environmental safety, because it contributes to the conservation of the environment, biodiversity in agrolandscapes and therefore should be characterized by the absence of harmful effects bothto consumer and environment.

Today organic farming is widespread in more than 170 countries most of which have their own regulatory system. The United Nations Organization for Agriculture and Food (FAO) and the International Federation of Organic Agricultural Movements (IFOAM), World Health Organization play an important role in shaping the international regulatory framework for organic production. In 1963, the Organization for Agriculture and Food of the United Nations created an intergovernmental organization - the Codex Alimentarius Commission, which introduced International Food Standards (Codex Alimentarius) [16]and, with a view to introducing uniform international requirements developed "Recommendations for the Production, Processing, Labeling and Sales of Organic Foods". IFOAM has established the first Basic Standards for Organic Farming. Products cannot be declared organic unless certified by an IFOAM accredited body.

The legal basis for European legislation in this sphere is Commission Directive (EU) No 889/2008 of 5 September 2008 «Detailed rules for organic production, labeling and control for the implementation of Council Regulation (EC) No 834/2007 on organic production and labeling of organic products, Council Regulation (EU) No 834/2007 of 5 September 2008 "On Organic Production and Labeling of Organic Products" [17]. In non-EU countries the standard of the International Accredited Certification Bodies for Organic Production and Processing is applied equivalent to the European Union Standard according to Council Regulation (EC) No 834/2007, No 889/2008 [18].

The essential properties of organic agricultural products are environmental friendliness, naturalness, the absence of preservatives, antibiotics, other chemicals, GMOs and others. Compliance with these properties must be confirmed by a certificate. This feature is legal in nature because it has a regulatory framework. In addition, it is essential to consider the specific needs of the consumer. An important consumer value of such products is its naturalness, the absence of inorganic components. When buying organic products, consumers expect higher quality level. Therefore, when formulating the content of the legal category "quality of organic products" should be considered as an objective component –fixating of quality requirements in special regulations, standards and other technical documentation, confirmation of compliance with the certificate of conformity, and subjective – the ability to satisfy consumer needs in natural, environmentally friendly products.

Among the responsibilities of any state to guarantee the right to adequate nutrition at the national level there are: respect for the population's right to access to food; protection against encroachment by third parties (for example individuals, groups, private enterprises, other states, etc.); strengthening the economic and social capacity of people to access food. If for objective reasons the population is unable to use the right to food the state should provide access to it, for example, in the framework of food aid or coverage by means of social assistance to the most vulnerable categories of persons [19]. In order to fulfill this obligation, the list of internal and external threats to national food safety (political, economic, environmental, social, industrial, technological, legislative, etc.) with identification of possible instruments of state support for domestic producers and protection of the domestic food market, as well as the functions and competence of public authorities,the order of their monitoring and forecasting, forms and mechanisms of counteraction to these should be established at the legislative level.

CONCLUSIONS

Thus, human health and the ability to exercise human's natural right to life are directly dependent on the level of food safety.Differentiation of the food safety level among different countries is reflected in its legal security at the national level. But the globalization of this problem and the need to find the solutions toensury public health require global approach, namely, to join forces with the international community and to develop an effective international legal food safety framework.

REFERENCES

1. The Universal Declaration of Human Rights. 1948.Available from:https://www.un.org/en/universal-declaration-human-rights/index.html [reviewed 2019.08.08]
2. World Population Review. 2019. Available from: http://worldpopulationreview.com/index.html[reviewed 2019.08.08]
3. FAO: more than 100 million people on the planet go hungry. UN news. 2019, April 4.Available from:https://news.un.org/ru/story/2019/04/1352241[reviewed 2019.08.08]
4. World hunger on the rise with more than 820 million at risk, UN report says. France24.Available from:https://www.france24.com/en/tag/fao/ [reviewed 2019.08.10]
5. Revenko L. S. Parametryiriskiprodovol'stvennoybezopasnosti[Food Safety Options and Risks].Mezhdunarodnyyeprotsessy. 2015. Ch. 13. 41: 6-20. Available from: http://elibrary.ru/download/60836160.pdf [reviewed 2019.08.10] (Ru).
6. Pro derzhavnupídtrimkusíl's'kogogospodarstvaUkraíni [On state support for agriculture of Ukraine]: ZakonUkrayiny vid 24.06.2004. VidomostiVerkhov. RadyUkrayiny. 2004; 49: 527.(Ua).
7. Consensus Reached on New Sustainable Development Agenda to be adopted by World Leaders. United Nations. Available from:https://www.un.org/sustainabledevelopment/blog/2015/08/transforming-our-world-document-adoption/[reviewed 2019.08.08]
8. Botkin O.I., Sutygina A.I., SutyginP.F. Interpretatsiyaponimaniyaprodovol' stvennoybezopasnostinamezhdunarodnomurovne [Interpreting an understanding of food safetyon the international level]. VestnikUdmurtskogo un-ta. 2016; 26 (2),7-14. (Ru).
9. SustainableDevelopmentGoals (SDGs) «Transformingourworld: the 2030 AgendaforSustainableDevelopment. Available from:https://foodsecurityindex.eiu.com/[reviewed 2019.08.11]
10. QNRF-MME Joint Funding. Available from:https://www.qnrf.org[reviewed 2019.08.11]
11. Ploshchad' posevov GMO kul'tur v mire dostigla 185 mIngektarov [The cultivated area of GMO crops in the world has reached 185 million hectares]. Agrarnik: vseukr. gazetadlyarabotn.APK. Available from:https://agrarnik.com/index.php?option=com_k2&view=item&id=4077:gmo&Itemid=416[reviewed 2019.08.16](Ru)
12. ArjjumendHasrat. Ukrainianlegislationforsafeguardingagroecosystem sandenvironmentalhealth: thechallengesahead. Pravovizasadyekolohichnoyi ta prodovol'choyibezpeky: problemyimplementatsiyimizhnarodnykhstandartiv: mater. dyskus. paneliPershoho Kharkiv. Mizhnar. yuryd. forumu «Pravo ta problemystalohorozvytku v hlobalizovanomusviti» (m. Kharkiv, 3-6 zhovt. 2017 r.). Kharkiv: Pravo, 2017; 3–17(Ua)
13. Kurman T. V. Stalyyrozvytoksil's'kohospodars'kohovyrobnytstva: problemypravovohozabezpechennya [Sustainable development of agricultural production: problems of legal support]. Kharkiv: Yurayt, 2018; 376.(Ua)
14. Ryabtseva E.Biotekhnologiya v sel'skomkhozyaystve: rasteniya [Biotechnology in Agriculture: Plants]. 2006.Cbio.ru: Internet-zhurnal o kommercheskikhbiotekhnologiyakh. Available from:http://cbio.ru/page/51/id/2834/[reviewed 2019.08.16] (Ru).
15. Piddubnyy O. Yu. Pravovizasadydosyahnennyaekolohichnoyibezpeky u sferibiotekhnolohiy [Legal bases of achievement of ecological safety in the field of biotechnologies]. Aktual'niproblemypravovohorehulyuvannyaahrarnykh, zemel'nykh, ekolohichnykh ta pryrodoresursnykhvidnosyn v Ukrayini/ vidp. red. T. Ye.Kharytonova, I. I. Karakash. Odesa: Hel'vetyka, 2018; 568–582. (Ua).
16. Codex Alimentarius. International food standards. FAO of the UN, World Health Organization. Available from:http://www.fao.org/fao-who-codexalimentarius/codex-texts/maximum-residue-limits/en/[reviewed 2019.08.11]
17. Commission Regulation (EC) 889/2008 with provisions on the implementation of Council Regulation (EU) № 834/2007 on organic production, labeling of organic products and control. Official Journal of the European Union (OJ L), 2008; 189: 1-78.Available from: http://media.wix.com/ugd/9aa478_ea7e358e110f477f8b921c13ada5373c.pdf[reviewed 2019.08.16]
18. Council Regulation (EC) № 834/2007 of 28 June 2007 on organic production and labelling of organic products. Official Journal of the European Union (OJ L) 2007; 189: 1.Available from:https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:L:2007:189:FULL&from=EN. [reviewed 2019.08.11]
19. Office of the United Nations High Commissioner for Human Rights. Human rights. The right to adequate food. Statement of facts. 2011; 34: 58. Available from: http://www.ohchr.org/Documents/Publications/FactSheet34ru.pdf [reviewed 2019.08.11]

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