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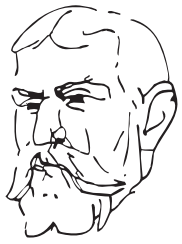
Official journal of the Polish Medical Association



Memory of
dr Władysław
Biegański

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ORIGINAL ARTICLES

REVIEW ARTICLE

ORIGINAL ARTICLE

LEGAL MEANS OF ENSURING COMPETITION IN PHARMACY

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Nataliya Gutorova[1], Vitalii Pashkov[1], Oleksii Soloviov[2]
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ABSTRACT

The aim: To research the consequences of pharmacy chains monopolization and establishment of legal means of neutralization of such consequences.

Materials and methods: The study is based on acts of the European Union, the United States, and Ukraine and international regulations and documents on health care. The study's materials were the results of a questionnaire survey of managers and specialists in a pharmacy on marketing contracts. The views of scientists on the above issue were also studied. The study analyzes generalized information from scientific journals using scientific, legal methods. Among the main research methods are systematic approach, analytical, statistical, comparative, dialectical, graphical, and a questionnaire survey of respondents.

Results: Consolidation of massive pharmacy chains leads to an artificial increase in drug prices by almost 50 percent, which significantly reduces their availability to patients, and in many cases, makes treatment impossible due to lack of funds.

Conclusions: As a result of further monopolization of the pharmacy market, the pharmaceutical industry, small pharmacy enterprises, and the complete distribution of medicines will be destroyed.

KEY WORDS: pharmacy chains, monopolization of pharmacies, marketing services in pharmacy

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INTRODUCTION

The process of horizontal integration in the retail segment, which is manifested in the formation of large pharmacy chains, is typical for pharmaceutical companies, especially in recent years.

The pharmacy network can be both individual pharmacies (centralized networks) and their totality (holding type networks), united by a joint owner or on several contractual parameters (goals, means, brand, etc.). However, holding pharmacy networks may include dozens of licensees. This type of integration has both several advantages (the possibility of promotional projects, a system of discounts and bonuses, etc.) and disadvantages. One of the most significant disadvantages of the existence of pharmacy chains, particularly if they occupy a large market share, is the monopoly on the retail sale of medicines and, consequently, the process of uncontrolled pricing of medicines [1]. Besides, the researchers emphasize, pharmacy chains cannot provide adequate quality of services [2].

This state of affairs among European countries is most common in Ukraine and, until recently, these problems existed in Poland and Hungary. However, these countries have timely amended their legislation to improve pharmaceutical care quality and combat monopolies among pharmacies. Given that the pharmacist is in direct contact with the patient, these countries have embarked on the path of establishing pharmaceutical activity as a professional and have established special requirements for the founders of pharmacies. However, most EU countries, in particular Germany, have never abandoned the principle of professionalism, i.e., the principle of "one pharmacist - one pharmacy".

THE AIM

To research the consequences of pharmacy chains monopolization and establishment of legal means of neutralization of such consequences.

MATERIALS AND METHODS

The study is based on acts of the European Union, the United States, and Ukraine and international regulations and documents on health care. The study's materials were the results of a questionnaire survey of managers and specialists in a pharmacy on marketing contracts. The views of scientists on the above issue were also studied. The study analyzes generalized information from scientific journals using scientific methods from a medical and legal perspective. Among the main research methods are systematic approach, analytical, statistical, comparative, dialectical, graphical, and a questionnaire survey of respondents.

RESULTS AND DISCUSSION

It should be noted that many European countries have an active policy of combating pharmacy chains, provide the opportunity to open a pharmacy only to professionals

Table 1. Results of the analysis of the requirements for the implementation of pharmacy activities in different European countries

Name of country	Qualification requirements for founders	Requirements for the qualification of the management of pharmacies	Requirements for the geographical location of pharmacies	Demographic requirements	Limiting the number of pharmacies per pharmacy operator
Austria	yes	yes	500 m.	5500 persons	4 pharmacies
Hungary	Yes	Yes	250 m.	4000 – 4500 persons	4 pharmacies
Italy	Yes	Yes	200 m.	3000 – 5000 persons	absent
France	Yes	Yes	No	2500 – 3000 persons	4 pharmacies
Spain	Yes	Yes	250 m.	2800 persons	4 pharmacies
Estonia	No	Yes	500 m.	3000 persons	4 pharmacies
Germany	Yes	Yes	No	No	4 pharmacies
Finland	Yes	Yes	certain territory	No	4 pharmacies
Cyprus	Yes	Yes	certain territory	No	1 pharmacy
Denmark	Yes	Yes	certain territory	No	1 pharmacy
Latvia	Yes	Yes	500 m.	3000 persons	No

with specialized education, and impose restrictions on the number of pharmacy enterprises by various criteria. Also, scientists believe that chain pharmacies are expanding in many low and middle-income countries [3].

The fact is that unlike other activities: we do not choose drugs, but we are prescribed them. Furthermore, the pharmacy is, first of all, a health care institution, not a trading enterprise, and the primary purpose of the pharmacy, like any health care institution, is to perform the functions of medical care as one of the chains of ensuring the right to health. Therefore, most EU countries set professionalism requirements for pharmacy activities, not only for pharmacy workers but also for pharmacy founders, limiting their number depending on population and pedestrian accessibility.

Thus, the report of the WHO European Bureau on the legal and regulatory status of pharmacy (The legal and regulatory framework for community pharmacies in the WHO European Region) [4] refers to the existing restrictions on the specifics of doing business in the pharmacy segment.

The first thing to pay attention to is the qualification restrictions on the right to own pharmacies. For example, in Germany, Estonia, Finland, France, Luxembourg, Austria, Poland, Slovenia, Spain, Hungary, in Cyprus, pharmacies are owned only by specialists (pharmacists). Moreover, the European Court in 2009 (on the example of Germany and Italy) concluded that the guarantee of freedom of enterprise and free movement of capital are not obstacles to the prohibition at the national legislation level of pharmacy ownership for non-pharmacists (Case C-531/06) [5]. A Member State has the right to consider a pharmacy headed by a non-pharmacist as posing a risk to public health.

The WHO European Office then draws attention to the existing restrictions on the number of pharmacies.

Thus, in Bulgaria, Estonia, France, Hungary, Poland, Portugal, there are restrictions – no more than four pharmacies per owner. Multiple ownership is prohibited in Denmark, Finland, Germany, Spain, Turkey, Monaco. In virtually all EU countries, there are population restrictions per pharmacy. Also, there are other restrictions, including the availability of pedestrian accessibility, a ban on communication with medical representatives, and so on.

The results of the analysis of the requirements for the implementation of pharmacy activities in different European countries are analyzed and presented in table 1.

It should also be noted that in most European countries, there are restrictions on demographic and / or geographical criteria. Attention is also paid to the management of pharmacies; in most cases, it is pharmacists who are also the founders of these pharmacies [6]. In such conditions, it is necessary to mention the experience of some European countries and, even not those where the principle "one pharmacist - one pharmacy" continues to operate today. These are the countries that first followed the deregulation path and then came to their senses, particularly Poland and Hungary.

In fact, all pharmaceutical specialists know about the experience of Poland. The key elimination of deregulation's consequences began in Poland with the adoption of the Law of the Republic of Poland "On Amendments to the Law" On Pharmaceutical Law "of 06.09.2001" of 07.04.2017. It amended the Law of the Republic of Poland "On Pharmaceutical Law" of 06.09.2001 [7].

The main message is the following requirements: 1) a pharmacy license can be issued if the number of residents

per public pharmacy in the area is at least 3000 people as of the date of application (for a license), and the distance between the planned location pharmacy and the nearest pharmacy is at least 500 meters in a straight line; 2) pharmacy management can be carried out only professionally based on a pharmacy license.

However, not many people remember that in Poland, until 2008, only a pharmacist by education could manage one pharmacy. However, in 2008-2017 there was a redistribution in favor of massive pharmacy chains. And it was then that the citizens of Poland felt the deterioration of the quality of pharmaceutical services.

That is, Poland and Ukraine's pharmacy market, where for some period of time was formed according to a single scenario.

At the same time, the example of Hungary was the impetus for Poland to make changes. From 2007 to 2010, Hungary followed a course of market deregulation. According to analysts, such a policy has helped create a healthy competitive environment and lower pharmaceuticals prices. However, the Hungarian government drew other conclusions: it was decided at a high level that deregulation had led to a reduction in the quality of service in pharmacies, as well as to their availability in rural areas and, as a result, in Hungary, the rules of operation in the Hungarian pharmacy market changed in 2011.

Thus, according to the new version of the law "Gyftv" [8] in Hungary to own a pharmacy was allowed only to a pharmacist (during the period of market deregulation, anyone could open a pharmacy). And those owners who managed to open a pharmacy business during the legislative "thaw", but do not have the appropriate diploma, are ordered to sell or close it by early 2017. The distance between pharmacies must now be at least 300 m; one pharmacy serves 4.5 thousand inhabitants. In large cities, the requirements are a little softer: the distance between pharmacies - at least 250 m, and one pharmacy has 4 thousand inhabitants.

Compared to other sectors of the economy, it is no secret that the pharmaceutical industry is the least vulnerable to the crises that have occurred in recent years.

However, in Ukraine, there are different views on the prospects for further development of the retail pharmacy market. Moreover, the most exciting thing is that the pharmaceutical market subjects and the subjects of retail pharmacy networks have contradictory plans for further coexistence.

Thus, the hidden monopolization of pharmacy chains, the creation of unfavorable conditions for small pharmacies that do not withstand unfair competition, the further destruction of municipal and state pharmacy networks, with their gradual depletion in rural areas, lead to the final consolidation in the retail pharmacy market of several final beneficiaries which actually own retail pharmacy chains in the Ukrainian market. Furthermore, it is they who are currently deciding the fate of pharmaceutical manufacturers and distributors. As a result, the price of medicines in Ukraine is inflated by almost 50 percent due to the cost of so-called marketing services, according to the Antimonopoly Committee of Ukraine in a letter №126-29 / 01-14481 dated November 8, 2019, addressed to the "Patients of Ukraine" Charitable Foundation. Besides, the official of the Antimonopoly Committee of Ukraine drew attention to the well-known concept of the so-called power of the buyer (the drug manufacturer), i.e., a situation where there seem to be no signs of monopoly (dominant) position, but in negotiations, such a buyer is stronger than the seller. She added: "Unfortunately, no one has yet developed a truly effective way to combat such manifestations through the tools of competition law" [9].

That raises a few questions: what are the services causing such a significant increase in the cost of medicines? Who sets the price of medicines, and do marketing services really affect the structure of the pharmacy market? With whom contracts for marketing services are concluded, and who initiates their conclusion?

The task of marketing contracts is to provide services to promote drugs, primarily the manufacturer who has entered into a "marketing agreement" with the pharmacy. Furthermore, here the question arises: how should a pharmacy, which, according to current legislation, is a health care institution, increase sales of certain drugs? Doesn't this mean that the pharmacist by communicating directly with the patient during the release of medicines, undertakes to promote specific products? The situation regarding the prescription drugs is more than strange: any promotion of them by advertising, placement in the service hall in shop windows, in glass and open cabinets, as well as selling without a prescription in Ukraine is officially prohibited.

Researchers of Poltava Law Institute, together with representatives of the pharmaceutical and medical community in 2019 - 2020, conducted a survey of pharmaceutical workers in the Poltava region in order to determine criteria for purchasing pharmaceutical products from manufacturers. As a result, there are trends in the purchase of pharmaceutical products depending on the amount of interest on the purchased pharmaceutical products, which is related to the volume of purchased goods. Purposeful selection of respondent experts was carried out, taking into account the following main factors: high level of education and qualification, availability of the necessary professional experience, and the ability to influence the purchase of pharmaceutical products. In accordance with the purpose of the study, respondents were interviewed on the fact of concluding marketing agreements, involving intermediaries in concluding marketing agreements, and establishing criteria for suppliers of pharmaceutical products depending on the terms of marketing agreements.

The majority of respondents indicated that they actively offer marketing contracts for concluding, for example, the following companies with foreign capital: Mega Livesciences, MOVI HELLS, Organistin LTD, Abbott Ukraine, GLED-PHARM LTD, Asino Ukraine, Alpen Pharma AG, Astrapharm, Unipharm Ukraine, Medo Bayer, Unipharm Ukraine, Dolphi Ukraine, Konark Intermed, Nobel Ilach Sanai Ve Ticaret Anonymous Shirketi, Polpharma, Stada Ukraine, Reckitt Benkiser Ukraine, etc. Interestingly, Asino Ukraine includes

such prescription drugs as Diocor Solo in tablets, Lamotrin, Levocord Retard Asino among GLADPHARM LTD, and such prescription drugs are included in GLEDPHARM LTD. as "Fanigan" in tablets. That is, there is a promotion of goods that a priori are not subject to the promotion.

Among domestic manufacturers and importers of pharmaceutical products, such companies as Phyto Lek LLC, PJSC Khimpharmzavod Chervona Zirka PJSC, Kyiv Vitamin Plant PJSC, Astrapharm LLC, Novalik Pharm LLC, LLC "Production and trading company Sarepta", LLC "Micropharm", LLC "Ternopharm", LLC "Medico", LLC "Pharma House", LLC "Medical Center MTK", PJSC Research and Production Center Borshchahiv Chemical-Pharmaceutical Plant, 1A Diagnostic Company LLC, PJSC Lubnipharm, Agropharm LLC, etc. are actively offering marketing contracts to pharmacy chains for concluding marketing agreements.

PJSC "Kyiv Vitamin Plant" offers an impressive form of payment for marketing agreements: 75 multiplied by the number of units of goods and the number of pharmacies (in the presence of 100 pharmacies 750 000 UAH paid to the owner of the pharmacy network for 100 items, which is approximately 45 thousand euros). And for example, PJSC "Lubnipharm" offers from 15 to 25 percent surcharge for the goods received under marketing contracts to pharmacy chains.

A separate part of importers, domestic manufacturers, marketing organizations enters into marketing agreements with pharmacy chains through intermediaries under the "gray schemes." For example, Olive Pharm Service LLC, B2B Pharm LLC, B2B Pharm Service LLC, B2B Pharm Company LLC, B2B Pharm Group LLC. All of these companies have the same final beneficiaries and/or related parties.

The second part of marketing organizations, namely LLC "Pharm-Rost Plus," LLC "Spectrum Pharm". The final beneficiaries are the second group of related parties.

Under the same schemes LLC "OMP Marketing", LLC "Galapharm", LLC "TMSKO", LLC "Armantis", LLC "Medlist Marketing", LLC "Smart Pharma" are working.

It should be noted that the initiators of marketing agreements, along with the owners of pharmacy chains, are pharmaceutical manufacturers and / or their representatives.

Thus, according to the Antimonopoly Committee of Ukraine set out in the recommendations of the Ministry of Health dated 16.09.2018, which by the way have not been implemented, it is recorded that the initiators of such marketing are importers, domestic manufacturers, marketing organizations, and some pharmacy chains "[10].

At the same time, importers, domestic manufacturers, marketing organizations enter into marketing agreements with pharmacy chains both independently and through intermediaries.

Returning to the real state of affairs in Ukraine, we note that, as a survey of middle managers showed, the greater the volume of goods of a particular manufacturer, then, of course, the greater the amount of payments under marketing contracts. Pricing in the presence of marketing payments, conditionally, occurs according to the following scheme, for example 100 + 50 = 100.

That means that the pharmacy chain or association of pharmacy chains buys one name of a medicinal product from a pharmaceutical manufacturer for UAH 100 and, at the same time, still receives, in addition to the goods, an additional 50 UAH under the marketing contract for recommending this item to the patient. While receiving such funds, it does not make sense to the pharmacy owner to additionally overprice the goods; he already has 50 percent of the value of the goods, which, moreover, is not correctly taxed and accounted for under the "gray scheme". According to one of the participants in the pharmaceutical market, the director of a small company "Aesculapius": "«… manufacturers, in order not to remain at a loss, under the pressure of mega-networks and monopolized markets are forced to inflate the price by 40%, and give this interest to mega-networks. At the same time, mega-networks have the opportunity to dump and thus destroy small pharmacy chains, which are faced with the need to purchase drugs from distributors at manufacturer's prices, inflated in connection with marketing agreements by 20-40% "[11].

However, this scheme is valid only for large volumes of goods, so small pharmacy chain owners cannot afford to use such a scheme. And they, buying goods from the manufacturer at the same price, are additionally overpricing them to cover their own costs and pay the appropriate taxes. As a result, they do not withstand competition and are gradually eliminated. If they continue their activities, then mainly in rural areas, where large pharmacy chains are not very profitable.

According to Proxima Research, the average revenue of one pharmacy of a legal entity is UAH 455.6 thousand per month, and a pharmacy owned by a private entrepreneur – only 140.4 thousand UAH per month [12]. And the reason for the big difference in revenue is not only in the placement of pharmacies, but a more important reason is the conclusion of so-called marketing agreements. Simply no one concludes them with small pharmacy chains because of the small volume of drug sales, however, the main burden on the location of pharmacies in sparsely populated areas is borne by them.

In fact, the description of this scheme provides an answer to the question: who exactly forms the prices? Our hypothesis is confirmed by other participants in pharmacy activity.

For example, the director of the Public Union "Pharmacy Professional Association of Ukraine" has repeatedly drawn attention to the fact that the final cost of drugs is never formed in the pharmacy. Most of all, the formation of their value, he rightly believes, is influenced by the manufacturer [13]. He believes that prices depend only on the manufacturer [14].

And indeed, the price is truly formed by the manufacturer of pharmaceutical products, while the retail markup of the pharmacy remained fixed - up to 15 percent. However, the question remains: why should a manufacturer invest up to 50 percent of their cost in the pricing of medicines in order to pay individual pharmacies under "gray" schemes for so-called marketing services? And why don't all pharmacies get paid for marketing services?

To answer this question, let us analyze the structure of the pharmacy market of Ukraine:

1) Under the brand "Apteka nyzkykh tsin", which unites 18 legal entities in different regions of Ukraine operates 900 pharmacies [15], under the logo "ANTs", "Apteka nyzkykh tsin", "Blagodiya", "Kopiyka".

The founders and ultimate beneficiaries of these entities are related parties.

2) The private company "Gamma-55" has a brand "Pharmacy Network 9-1-1" [16] and according to the application PharmXplorer of company "Proxima Research", it can be noted that these persons have 700 pharmacies under their control [15] , operating under the logo Pharmacy 9-1-1 ", "Apteka optovykh tsin". At the same time, all these logos are on the facades of such subjects of pharmacy activity as PE «Firma Mahiia Farm», LLC "Apteka 97", LLC Elroi Menedzhment, LLC "Tsentralna raionna apteka №16", LLC "Danunts", LLC "TVA-HRUPP", PE "Apteka 211", LLC «Ie APTEKA». The ultimate beneficiaries are related parties
3) Sirius-95 LLC, a network of pharmacies "Bazhaiemo zdorovia", according to the license register, in the amount of 709 units [17], and according to the PharmXplorer application of the company "Proxima Research" - 800 pharmacies [15] and covers all regions countries other than the occupied.
4) PE "SOLOMIA-SERVICE" operates under the logo "Plantain", unites 24 legal entities in different regions of Ukraine and has 638 pharmacies under its control [17].
5) LLC "Pharmastor" together with LLC "Apteka dobroho dnya" work under the brand "Apteka dobroho dnya" and control according to the application PharmXplorer company "Proxima Research" 500 pharmacies [15].
6) Med-Service Group LLC unites fourteen legal entities and controls 400 pharmacies [17].
7) LLC "Market Universal LTD". The company is engaged in pharmaceutical activities virtually throughout Ukraine. The company has two pharmacy chains - "D.S." and "Apteka nashoho mista", which unites five legal entities and controls 768 pharmacies [17].
8) The network of pharmacies "Zdorova rodyna" consists of the Private Enterprise "Pharmaceutical Company" Zdorova rodyna"" and LLC "Pharmaceutical Company "Zdorova rodyna"", LLC "Salve", LLC "Romashka" and controls 254 pharmacies [17].
9) PJSC "Aptechna merezha "Farmatsiya"" controls 213 pharmacies [17] in Odessa, Kyiv, Mykolaiv and Kherson regions.
10) LLC "3i" according to the Lviv Chamber of Commerce and Industry has about 100 pharmacies in Lviv, Ternopil, Ivano-Frankivsk, Zakarpattia, Rivne, Khmelnytsky and Chernivtsi regions. Further, if you analyze the information sites of Lviv, in particular "LVIV ONLINE" [18], you can find some addresses of the network of pharmacies LLC "3i", but it is interesting that at those addresses, pharmacies which, according to the license register, belong LLC "Apteka Doviry" [17], but the logos on the facades of these pharmacies are called "Apteka 3i" [19]. Further interesting is the fact of the existence of LLC "Apteka 3i", the legal address in Mykolaiv, the beneficiary of the company "Sunrise Holding International Limited" Belize, the final beneficiary Jozelin Quiros, Costa Rica. Furthermore, this company's official partner is already known to us LLC "Apteka Doviry", in which according to the License Register, 50 pharmacies are registered [21]. In addition, among the partners of groups of companies "3i" there are [17] pharmacy chain "LLC "Lider-Zakhid", operating under the logo Pharmacy "SIDUS" [17], according to the license register has 57 pharmacies and 8 pharmacies. Also among the partners there are the network of pharmacies "Etalon zdorovya" [17], the addresses of pharmacies allow to establish according to the license register that they belong to LLC "Firma "Medfarm", in the amount of 71 pharmacies [17].

Thus, the company "3i", including through offshore, controls 186 pharmacies.

11) LLC "Tas-Pharma" operates under the brand pharmacy chain "Apteka TAS" ta "Apteka pryyemnykh tsin" and control 141 pharmacies [17].
12) Volynpharm in the form of a limited liability company - a network of pharmacies in the Western region of Ukraine, covers Volyn, Lviv, Rivne, Ternopil, Ivano-Frankivsk, Zhytomyr and Khmelnytsky regions. According to the License Register, it consists of 119 pharmacies and drugstores [17].
13) LLC "Ukrayins'kyy aptechnyy kholdynh" was established on the basis of pharmacy chains "Dobri liky", "Zdravitsa" and a subsidiary "Tsentral'na rayonna apteka №147" LLC "Sigma Rent". The network of pharmacies "Dobri liky" includes, according to the license register [17] - 53 pharmacies, "Zdravytsa" - 21 pharmacies. However, according to PharmXplorer's Proxima Research application [15], the LLC "Ukrayins'kyy aptechnyy kholdynh" controls 100 pharmacies.
14) LLC "Rehional'na aptechna merezha Ruan", consists, according to the license register of 99 pharmacies [17].
15) Vitalux LLC, according to the license register, has 40 pharmacies [17]. Together with this company works in the market of LLC "APTEKAR-GROUP", according to the license register has 58 pharmacies [17], the final beneficiaries are related parties [18]. Both legal entities position themselves as a single network of pharmaceutical markets and operate under the brand "Vitalux + APTEKAR". A total of 98 pharmacies are under control.
16) Private enterprise "Konex" [22], place of activity - Vinnytsia, Chernivtsi and Khmelnytsky regions. According to the license register there are 63 pharmacies and drugstores [17].

In total, the pharmacy entities unite at least 5,595 pharmacies, and it is only the minimum that could be established by analyzing the activities of these entities and their affiliates.

Meanwhile, according to the state quality control of medicines [23], the number of pharmacies in the dynamics over the past three years can be seen in Table 2.

Table 2. The number of pharmacies in the dynamics (2018 - 2020)

	01.01.2018	01.01.2019	01.01.2020
Total pharmacies, of which:	17920	17670	17425
Legal entities	12278	12611	12868
Individuals	5642	5059	4557
Total pharmacies, including:	4690	4445	4215
Legal entities	3675	3547	3385
Individuals	1015	898	830

The analysis of the activities of those subjects that we have identified is impressive. Based on the fact that one pharmacy's average revenue per month is 455.6 thousand UAH, the total amount for all pharmacies that we analyzed is 2,549,082,000 UAH. In total, this figure will amount to UAH 30,588,984,000 per month for the year, which is equal to 926 million 938 thousand 910 euros at the exchange rate of the National Bank of Ukraine.

Thus, if we conditionally deduct the 50 percent that these companies receive under marketing agreements, this figure will be UAH 15,294,492,000 or approximately EUR 464 million.

However, these calculations are confirmed by the information of Proxima Research in 2019, which states that the consolidation of pharmacy retail is actively underway and, over the past two years, the share of top 100 pharmacy chains in terms of pharmacy sales in the monetary form increased to 74.5 percent [24]. It makes no sense to recall that most of these pharmacy companies use their advantages to protect their monopoly position in order to increase revenue from the provision of alleged marketing services. Moreover, it is they who dictate the rules of conduct in the pharmaceutical market, and, for the most part, pharmaceutical manufacturers are forced to comply with the requirements of these mega-networks in terms of concluding marketing agreements. That is why manufacturers include in the cost of medicines, the cost of marketing services, which reach 50 percent of the product's actual price. As a result, small pharmacies fail to compete and cease operations. In this context, the question arises: what will happen in the pharmacy market when these mega-networks finally become one hundred percent monopolists? It is clear that the question is rhetorical and does not even need an answer.

Manufacturers can be understood, says one of the subjects of pharmacy. For example, two large manufacturers - conditionally, there are manufacturers "A" and "B". They have a lot of similar products. Now imagine that several large mega-networks unite in the matter of "wringing the hands" of one of the manufacturers. To achieve this goal, they readily agree with each other and simultaneously stop buying products from one manufacturer in favor of another. Of course, the consumer will not notice that because drugs with a particular active ingredient will not disappear from pharmacies. And what will happen to the manufacturer against which the anti-competitive actions have started? He will be forced to negotiate on the terms dictated by mega-networks. And all this is already happening in the Ukrainian pharmaceutical market [11].

What conclusions should be drawn from the information provided?

1) The price of medicines in Ukraine is artificially inflated by almost 50 percent, significantly reducing their availability for patients. In many cases, it makes treatment virtually impossible due to lack of funds. This situation directly affects the life expectancy and quality of life of Ukrainians, which are much lower than in neighboring European countries.
2) The pharmacy market is monopolized by national mega-networks, which methodically and consistently displace from the market the remnants of professionals who, for many years, and sometimes even several generations, carried out pharmaceutical activities. They are being replaced by non-specialists who, under the brands of national mega-networks, are engaged in distributing drugs and their unprofessional, and in many cases extremely harmful to the patient's health promotion. It is not uncommon for a pharmacist to strongly recommend medication to a patient that is not only unnecessary but is dangerous to his or her health, given the diagnosis and other medications he or she is using.
3) National mega-networks, demanding from pharmaceutical manufacturers up to 50 percent of the cost of goods for so-called marketing services, on the one hand, ruthlessly destroy professional pharmaceutical activities, on the other - artificially inflate drug prices and lure them with dishonest marketing.
4) These monopolists, having large funds and enjoying virtually complete impunity, are actively lobbying to protect their interests through influential public organizations, representatives of the legislature, and the executive. That may explain the categorical reluctance to legally implement the successful experience of neighboring countries in limiting the monopolization of the pharmacy market and lowering the prices of medicines.

CONCLUSIONS

Further consequences of the consolidation of pharmacy chains can be observed:

1) The pharmaceutical industry will be virtually destroyed, leaving only those who agree to merge with large pharmacy chains or to transfer controlling stakes in their companies to such final beneficiaries of retail pharmacy chains. Even today, in the conditions of monopolization

of the retail pharmacy market, Ukrainian pharmaceutical manufacturers are losing their economic attractiveness to foreign investors;

2) The existence of pharmaceutical distributors will be questioned, their functions, in the absence of competition, will be significantly limited, and it would be logical to covertly merge with large pharmacy chains (including by assigning controlling stakes);
3) Small retail pharmacies cannot compete and will be destroyed. Analysis of the pharmacy market shows that the process of active destruction of such entities has been observed for the last three years.
4) Due to the monopolization and the above perspective of the pharmaceutical market, there will be a further increase in prices for pharmaceutical products for end-users (patients and medical institutions), including due to the further spread of marketing agreements that force pharmaceutical manufacturers to shift this burden on the shoulders of end consumers.

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ORIGINAL ARTICLE

LABOUR SAFETY OF MEDICAL WORKERS DURING THE COVID-19 PANDEMIC: LEGAL ASPECT

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ABSTRACT

The aim: To develop an algorithm of legal support of the system that guarantees safe working conditions of medical workers at medical institutions during the COVID-19 outbreak.
Materials and methods: The following materials were used in the paper: Interim Recommendations of the World Health Organization, documents of The World Medical Association, international human rights instruments, international labour protection acts, European health legislation, the decision of the European Court of Human Rights, judicial practice and survey of 60 specialists. The following methods were used in the paper: system method, comparative method, the method of questionnaires and formal logical method.
Results: The survey of physicians allowed to state the need to create local protocols or technological maps of the use of personal protective equipment and the development and approval of the relevant results of their use - standards to ensure safe working conditions.
Conclusions: Proposals for legal support of the system of guaranteeing safe working conditions for medical workers at the local level have been formulated. Every medical enterprise should have a system of guaranteeing safe working conditions for medical workers by: distribution of responsibilities between the heads of medical enterprises, issuing departmental and local acts on ensuring their work and acquainting medical workers with them, ensuring proper quality and quantity of personal protective equipment and, accordingly, monitoring their use and the functioning of the system of guaranteeing safe conditions.

KEY WORDS: Employee Health, means of protection, pandemics

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INTRODUCTION

The issue of labour safety is a priority in any area of social life, particularly in the field of medical services. During the COVID-19 pandemic, about a third of the total number of infected people are health workers who come into direct contact with patients. Thus, the International Council of Nurses stated that currently about 230,000 health workers in the world are infected with coronavirus and this number, in their opinion, is underestimated [1]. At the same time, 9,684 (as of August 16) [2] health workers were infected in Ukraine, 30,000 in Italy [3], and 51,849 in Spain [4] (as of July 29).

COVID-19 has become a serious challenge for countries' health care systems. It is the medical workers who have to face the risk of infection every day due to lack of personal protective equipment (hereinafter – PPE) for staff, lack of manpower, lack of effective mechanism for medical staff protection from the risk of infection, etc. [5, p. 740].

This paper is devoted to identifying problematic issues (gaps) in the legal regulation of labour safety system in health care facilities. The survey revealed legal problems that arise in the field of labour safety of health workers during the COVID-19 pandemic.

THE AIM

To develop an algorithm of legal support of the system that guarantees safe working conditions of medical workers at medical institutions during the COVID-19 outbreak.

MATERIALS AND METHODS

The following materials were used in the paper: Interim Recommendations of the World Health Organization (hereinafter - WHO), (Interim Recommendation "Infection prevention and control during health care when coronavirus disease (COVID-19) is suspected or confirmed" as of January 25, 2020 [6] and an interim recommendation "Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages" as of April 6, 2020 [7]), documents of The World Medical Association (Declaration of Geneva [8], International Code of Medical Ethics [9]), international human rights instruments (Universal Declaration of Human Rights [10], International Covenant on Economic, Social and Cultural Rights [11], Convention on Human Rights and Fundamental Freedoms [12]), international labour protection acts (International Labour Organization Convention №155 on Occupational Safety and Health and the Working Environment [13], Council Directive № 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work [14]), European health legislation (UK, Poland, Ukraine, Germany), the decision of the European Court of Human Rights (Brincat and others v. Malta, Vilnes and Others v. Norway), judicial practice (decisions of courts of France, Russia), survey of 60 specialists.

The following methods were used in the paper: system method (study of the right of a health worker to refuse to perform professional duties as a component of the human

right to safe working conditions), comparative method (comparison of legal regulation of labour safety and responsibility for failure to meet labour safety requirements), the method of questionnaires (establishing both the level of their legal protection and safety of their activities, and the level of provision of PPE in the provision of medical care to patients, as well as whether there are local acts on these issues in the institutions where they work) and formal logical method (using analysis, synthesis, induction and deduction, the main conclusions of the paper were made).

RESULTS AND DISCUSSION

Most European countries have faced the problem of mass infection of health workers. Analysis of international organizations and individual countries statistics on the incidence of COVID-19 allows us to conclude that it is necessary to improve the labour safety of health workers in the medical institutions and provide PPE of appropriate quality and in the required quantity.

The basis of the legal regulation of the medical workers' labour safety is the right of a person to appropriate working conditions, an integral part of which is the right to require the employer to create safe working conditions and minimize the risk to life and health of the employee. This right is provided by international acts, such as the International Labour Organization Convention 155 on Occupational Safety and Health and the Working Environment [13] (hereinafter - ILO), the main purpose of which is to prevent accidents and injuries resulting from work (Part 2 of Article 4 of the Convention), and by national law.

In the practice of the ECtHR, the court considers violations of labour safety requirements through the prism of Art. 2 (right to life) and Art. 8 (right to respect for private and family life) of the Convention for the Protection of Human Rights and Fundamental Freedoms. Thus, the Court found a violation of these articles by the employer's failure to notify the employee of the negative impact of work activities on their health, which led to the death of a person *(see judgment Brincat and others v. Malta)* [16]. The Court later ruled that the fact that employees do not have access to labour safety documentation violated Art. 8 of the Convention, according to which they could assess the potential negative risks to their health *(see judgment Vilnes and Others v. Norway)* [17].

At the same time, the employer is obliged to provide the employee with safe working conditions. According to Art. 16 of the ILO Convention 155 and Art. 5 and 6 of Council Directive № 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work, the employer must take measures to protect workers, provide appropriate training and provide the necessary means of protection [14].

Relevant provisions are reflected in the regulations of individual states. Thus, according to Art. 8 of the Law of Ukraine "On labour protection", the employer is obliged to provide employees with special clothing, footwear, detergents and other PPE free of charge [18]. A similar rule related to the provision of medical care is provided in Art. 11 of the Polish Law on Prevention and Control of Infections and Infectious Diseases of People. It obliges employers to take preventive measures aimed at minimizing the risk of infection of health workers by monitoring their health, ensuring the use of individual and collective remedies [19].

One of the tools to protect workers' rights to safe working conditions is the employer's liability for failure to comply with these requirements. Thus, in accordance with Art. 160, 165 and 220 of the Polish Penal Code in cases of violation of labour safety, which led or may lead to a threat to life and health of the employee, the employer may be sentenced to imprisonment [20]. In Ukraine, an employer can also be prosecuted for violating labour safety rules according to Article 271 of the Criminal Code, if such an act caused harm to the health of the employee or their death [21]. In this case, the guilty person may be sentenced to a fine or imprisonment.

The Court of Cassation of France/ the French Republic in decision №17-18712 of 11.10.2018 found the employer guilty that he, knowing about the dangerous conditions and potential risks to life and health of the employee, did not take all necessary measures to prevent the occurrence of negative consequences, as a result of which the worker died of an industrial injury. The employer was sentenced to negligent homicide committed during the employee's work [22].

Ensuring safe working conditions is a necessary condition for a medical worker to perform their professional duties. It is known that the general professional duty of a healthcare worker is to provide qualified and qualitative medical care to the patient. This duty is fundamental to conduct medical practice as a whole (see Declaration of Geneva, paragraph 3 of the International Code of Medical Ethics) [23, p. 1840].

At the same time, in carrying out a professional activity, a health worker is said to have the right to appropriate working conditions that meet safety requirements (Article 23, paragraph 1, of the Universal Declaration of Human Rights [10] and Article 7, b, of the International Covenant on Economic, Social and Cultural Rights [11]). In cases where such conditions were not provided in accordance with Art. 13 of the ILO Convention 155, the employee has the right to refuse to perform their professional duties [13]. This provision is reflected in Article 153 of the Labour Code of Ukraine, according to which in cases where there is a danger to life and health of the employee, they have the right to refuse to perform professional duties [24]. Such cases also occurred during the COVID-19 pandemic.

Thus, on April 7, 2020, in Greece, doctors and medical workers went on strike, during which they came out with demands to increase the number of doctors, places in intensive care units and provide PPE of better quality [25].

A similar case took place in Kharkiv, when on May 18, 2020, doctors of the Centre for Emergency Care and Disaster Medicine refused to perform their professional duties in providing medical care and used their right to strike due to the fact that they did not have the opportunity to use PPE due to its lack, as a result of which they are forced to reuse the same tool [26].

It should be noted that if the employer did not provide safe working conditions (for example, did not provide PPE), the liability of the health worker for failure to provide medical care to a person or improper performance of professional duties is excluded because there is a circumstance that excludes liability for inaction of the health worker. Such circumstance is the lack of a real opportunity to provide medical care without endangering one's own life and health.

The verdict of the Industrial District Court of Kursk of the Russian Federation recognized the actions of the employer who did not provide the PPE to the employee as a violation of the person's right to safe work, so the latter refused to perform their professional duties. By court decision, the employer was obliged to pay the employee wages for the time during which they did not work, and to pay moral compensation [27].

In return, if a healthcare worker was provided with safe working conditions and PPE, the necessary measures (instruction) were taken to familiarize them with the rules of their application, etc., but they did not fulfil their professional duties, which caused harm to the patient's life and health, the healthcare worker is subject to disciplinary action, even criminal liability for failure to provide medical care (Article 139 of the Criminal Code of Ukraine) or failure to perform or improper performance of professional duties (Article 140 of the Criminal Code of Ukraine).

Thus, in order to increase the effectiveness of the life and health protection of health workers working during the COVID-19 epidemic and to ensure the conditions for them to perform their professional duties, a system to ensure their safe working conditions must function. Such system has the following components:

- scientifically substantiated requirements for PPE and the existence of appropriate rules for its application;
- doctors and medical staff must be familiar with these rules;
- the presence of PPE of appropriate quality and in the required quantity;
- system of control over the use of PPE and other safety equipment both at the medical institution as a whole and at the individual workplace of the medical worker.

Elements of this system should be reflected in every health care institution in the relevant local legal acts on labour safety of health workers, rules for the application of PPE and other safety measures.

Based on studies of the way of infection and symptoms of COVID-19 and the dynamics of its spreading, the WHO has developed a temporary recommendation "Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages" as of April 6, 2020. It regulates the use of each type of PPE in a specific situation (when examining patients, during resuscitation, in an ambulance, etc.) [14].

Taking into account these recommendations of the WHO, the order of the Ministry of Health of Ukraine № 552 of 25.02.2020 approved the Standard of medical care "Coronavirus disease 2019", which provides not only the prevention, diagnosis and treatment of the disease, but also the responsibilities of the parties in area of labour safety, including the use of PPE [28]. Based on the WHO recommendations and the specified standard, local rules for the use of PPE should be developed in medical institutions. Not only the type of PPE should be estimated, but also the number of PPE required for a medical worker in the performance of their professional duties.

After approval of such rules at the local level, the employer must familiarize medical workers with them and ensure the availability of PPE of appropriate quality and in the appropriate quantity. Section 4 of the WHO Interim Recommendation "Infection prevention and control during health care when coronavirus disease (COVID-19)is suspected or confirmed" as of January 25, 2020, provides the employer's responsibility to train health workers in the care and treatment of patients and the use of PPE during the provision of medical care to patients with COVID-19, to ensure the supply of PPE in sufficient quantities and control its use by health workers [6].

In turn, if PPE is available and provided in sufficient quantities, Section 3 of the WHO Interim Recommendation requires the health worker to use PPE during the provision of medical care and other professional responsibilities.

In particular, paragraph 15 of the Law of Germany on the implementation of labour safety measures to improve the safety and health of workers at work provides for the obligation of the employee to take care of their own safety and health and follow the relevant local instructions of the employer, including use of PPE and other protective devices [29]. Similarly, Article 7 of the UK Occupational Safety and Health Act obliges the employee to take care of their own health and the safety of others and to comply with the labour safety and health requirements set by the employer and provided by the relevant legislation [30].

The WHO acts pay close attention to the administrative control to be exercised by the employer in the form of ensuring the operation of the patient sorting system to reduce the burden on healthcare workers, the organization of the process of surveillance for acute respiratory infections that can be caused by nCoV among healthcare workers and monitoring their observance of standard precautionary measures and their improvement if necessary.

Therefore, the requirements for PPE, its quantity, quality, rules of application and control over their use by health workers, which are regulated at the international and national levels, should be detailed at the level of the health care institution, which will minimize the risk of infection of healthcare workers with COVID-19 and the cause of harm to their life and health.

In order to establish the state of awareness of health workers in matters of legal protection of their safety, particularly related to the current legal regulations governing the safety of health workers during the COVID-19 outbreak, a survey among the doctors was conducted.

The questionnaire was anonymous, and the sample among medical doctors was random. The survey was remote; respondents were selected on the basis of databases of relevant clinical departments of the Kharkiv Medical Academy of Postgraduate Education. The requirement to participate in the survey was to have at least 7 years of work experience in the specialty. The number of respondents in the group ranged from 6 to 12, which met the requirements for achieving the conditions of permissible error of expert analysis of 5% ($p = 0.05$), when the expert group must include at least 6 experts [31, p. 766].

The respondents were represented by doctors of communal medical enterprises that provide medical care during the COVID-19 outbreak. In particular, these were primary care physicians – general practitioners of family medicine (6 questionnaires), specialists of polyclinics (12), physicians of therapeutic hospitals (12) and surgeons of surgical hospitals (12), maternity hospital doctors (6), doctors of infectious diseases hospitals (6) and doctors of emergency and disaster medicine centres (6) – a total of 60 respondents.

The questions are grouped into three groups: the first is the respondents' awareness of regulatory and administrative information on labour safety, in particular during the COVID-19 outbreak; the second – their assessment of the state of labour safety at a particular medical institution during the COVID-19 outbreak; third – proposals from respondents to improve the provision of PPE and other safety equipment for health workers in the institutions where they work.

The analysis of the first group of questions showed that knowledge of the legal norm, which provides the right of an employee to refuse to perform professional duties in cases of dangerous working conditions (Article 153 of the Labour Code of Ukraine), showed 50% of family doctors and specialists, most have more than 10 years of experience. Respondents of other groups did not show awareness of the existence of Art. 153 of the Labour Code of Ukraine. Thus, out of the total number of respondents (60), only 9 specialists provided a positive answer to the question, which is 15% of the total number of respondents. However, almost all respondents in all groups showed knowledge of the CORONAVIRUS DISEASE Standard (COVID-19) and its appendix №6 "Rational use of PPE in COVID-19". Only one person in the group of polyclinic doctors was unfamiliar with it.

The presence of an order or other local act of the medical institution was also indicated by all respondents, except for the above-mentioned doctor who works in the polyclinic. At the same time, all doctors from inpatient care groups (infectious hospitals, therapeutic and surgical departments, maternity hospitals), 50% of family doctors and doctors of emergency care and disaster medicine, 25% of doctors working in polyclinics gave a positive assessment of such acts.

A study of the conditions for implementing the requirements of these regulations and administrative documents shows that all respondents from the groups of hospitals and doctors of emergency and disaster medicine centres and polyclinics indicated the availability of instruction on the use of PPE in the provision of medical care during the COVID-19 epidemic. Only two family physicians stated that they were unaware of the existence of the briefing and accordingly did not participate in the event.

Respondents were asked to rate the effectiveness of the briefing on a scale from 1 to 3, where: 1 - dissatisfied, 2 – neutral, 3 - completely satisfied. Groups of doctors from infectious hospitals and maternity hospitals were completely satisfied with the briefings. Among family physicians and surgeons from among those who were instructed, all gave a score of 2 points: "neutral." Among other respondents, 50% of therapists, as well as two doctors - a third of the respondents - from the centres of emergency care and disaster medicine, and two - 17% - from the group of doctors of polyclinics were completely satisfied. Thus, the assessment (neutral) of the briefing was provided by: 50% of doctors from therapeutic hospitals, two thirds from the number of doctors of emergency care and disaster medicine and 83% from the number of doctors of polyclinics.

The next series of questions was devoted to the study of the state of real provision of PPE for health workers. The state of provision of personal protective equipment and other means of safety of medical workers in the relevant medical institutions was asked to be rated on a scale from 1 to 3, where: 1 - dissatisfied, 2 – neutral, 3 - completely satisfied. All respondents from the group of doctors of infectious diseases hospitals and one respondent from the group of doctors of polyclinics were completely satisfied. The vast majority of respondents from other groups gave a score of 2 points - "neutral." The following questions reveal the grounds for this dissatisfaction with the state of PPE provision. Thus, respondents indicated that the personal protective equipment provided did not always correspond to the level of danger. This was noted by: half of the respondents from the groups of doctors of therapeutic and surgical hospitals, family doctors, as well as 75% of doctors of polyclinics.

An important factor of dissatisfaction is the insufficient number of PPE provided at the expense of the institution itself, as indicated by doctors of all groups, except for employees of infectious diseases hospitals. As a result, 75% of respondents were forced to provide themselves with PPE at their own expense, and only 25% of respondents from the therapeutic and surgical groups and maternity hospitals did not do so.

An integrative indicator that allows to draw a conclusion about the conditions and effectiveness of the use of PPE may indicate the presence of an appropriate control system. Its presence was positively indicated by respondents from all groups, except for 3 respondents (25%) from the group of family doctors and 6 respondents (50%) from the group of polyclinic doctors. Further research on this issue shows that in family medicine institutions and polyclinics, the heads of structural departments are (in the vast majority) responsible for monitoring the use of PPE and other means of safety, while in other medical enterprises the chief physician or director of the medical enterprise are responsible for that. This fully correlates with the doctors' answers about the existence of an appropriate local order on the organization of control over the use of PPE and other safety equipment and familiarization with it. Those were the groups of family doctors and doctors of polyclinics who pointed out the absence of such an order.

Analysis of doctors' proposals to improve the provision of PPE and other means of safety of health workers showed that those are doctors of family medicine and outpatient care who insist on implementing a full range of proposals included in the questionnaire, namely: a) ensure the use of PPE in accordance with the level of danger; b) increase the number of PPE and other safety equipment; c) acquire more convenient PPE and other safety equipment, d) provide effective training and regular briefings on the use of PPE and other safety equipment, e) improve the control system for the use of PPE.

At the same time, respondents from other groups chose only a few options, namely: c) acquire more convenient PPE and other safety equipment (100% of respondents); b) increase the number of PPE and other safety equipment (80%); d) provide effective training and regular briefings on the use of PPE and other safety equipment (60%); a) ensure the use of PPE in accordance with the level of danger (60%).

The results of the survey indicate the existing problems in the labour safety of health workers, resulting in their mass infection with COVID-19. This is also pointed out by Chinese scientists J. Wang, M. Zhou, F. Liu, who conducted a survey in Guangdong province and concluded that the causes of infection

of health workers are: 1) inconsistency of PPE with the threat posed by coronavirus (doctors were not aware of the ways of its penetration, symptoms and negative impact on the body); 2) prolonged contact with a large number of infected, high labour intensity, lack of rest; 3) lack of PPE for doctors; 4) low level of training of doctors to counteract a specific virus [2, p. 101].

At the same time, the effectiveness of the use of PPE in the treatment of patients with COVID-19 has been confirmed by numerous scientific studies. To illustrate the importance of the use of PPE in Singapore, a study of case in which 41 healthcare workers had contact with a patient was conducted. After 14 days of self-isolation and several tests, these individuals were confirmed to not have the disease, as they used the necessary PPE. Researchers have concluded that the basis for the protection of healthcare workers from infection is strict observance of hygiene rules and proper use of PPE [32, p. 766].

As rightly remarks M. Paszkowska, it is the state that is responsible for protecting healthcare workers during the pandemic by taking a number of measures, including the issuance of regulations governing the rights and obligations of the subjects of legal relations in the field of medical services. [33, pp. 802]. All international acts and acts of national legislation, acts concerning the provision of the right to safe working conditions for medical workers must contain scientifically substantiated requirements for the protection of medical workers, which, in turn, must be specified in the health care institution.

CONCLUSIONS

The study proves that doctors' knowledge of their right to safe working conditions is very limited. The healthcare workers are much more aware of the requirements contained in departmental regulations and administrative acts. In this case, it is the Standard of medical care "CORONAVIRUS DISEASE" (COVID-19) and its appendix №6 "Rational use of personal protective equipment (PPE) in case of COVID-19". Despite the fact that in infectious departments and hospitals of surgical and therapeutic profiles, maternity hospitals such work is generally carried out at the appropriate level, the implementation of departmental acts can not be considered sufficient, as in other institutions that provide mass outpatient, specialized outpatient and emergency assistance, the implementation of departmental acts requires persistent and urgent work.

Based on the study, it was found that the shortage of PPE is a mass phenomenon and, as a result, healthcare workers are forced to buy it at their own expense.

The questionnaire also shows some connection with the state of provision of PPE to doctors and the level of organization of such provision. In institutions where the responsibility for this is placed personally on the heads (directors and chief physicians of medical institutions), the level of satisfaction of doctors with the state of provision and use of PPE is much higher than where the heads of departments are responsible for that.

Suggestions from doctors to improve the situation with the provision of PPE during their activities provide grounds for assessing the current state of the organization of this work in a particular medical institution. Particular attention in this area should be paid to medical institutions of family medicine, polyclinics and emergency centres.

The things mentioned above allow us to formulate proposals for the legal support of the system of guaranteeing safe working conditions for medical workers at a particular medical institution. Legal regulation of safe working conditions for medical workers includes: 1) the existence of legislative provisions and departmental, administrative acts on the right of medical workers to safe conditions, in particular during the COVID-19 pandemic; 2) acquaintance of all medical workers of the enterprise with these acts; 3) creation of a system that guarantees safe working conditions for medical workers in a particular enterprise by: a) distribution of responsibilities between the heads of medical enterprises, b) issuing orders and other administrative acts on local labour safety, c) acquaintance with such acts of medical workers by systematic training, d) ensuring the proper quality and quantity, as well as adequate convenience of PPE in accordance with existing needs, e) monitoring the use of PPE and the functioning of the entire system. This requires the creation, in particular, of local protocols or technological maps of the use of PPE in each medical institution and the development and approval of relevant results of their use that are safe working conditions standards. In this paper, it is expedient to combine the efforts of medical workers and specialists in the legal provision of safe working conditions, in particular, for medical workers during the COVID-19 pandemic.

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ORIGINAL ARTICLE

PREVENTION OF THE STIGMATIZATION OF INDIVIDUALS IN RESPONSE TO DIGITAL TRACKING (CONCIDERING COVID-19 ISSUE)

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ABSTRACT

The aim of the research is to identify possible manifestations of the stigmatization of individuals stemming from the use of digital applications while conducting anti-epidemic measures in Ukraine and developing measures to prevent stigmatization caused by the introduction of such applications.

Materials and methods: The study is grounded on dialectical, analytic, synthetic, comparative, statistic, sociological and criminological research methods. More than 120 citizens were interviewed to find out their attitude to *Act at Home* mobile application. The calculations were performed with the use of Excel spreadsheets of Microsoft Office 2016. The theoretical basis of the article is the specialized literature on medicine, law and computer science.

Results: The paper substantiates the connection of the mechanism for the prevention of stigmatization of people who use mobile applications to track their contacts in the conditions of COVID-19 with the positive and negative obligations of member states of the Council of Europe on insuring of non-interference in private and family life. A system of general and special means of prevention of this antisocial phenomenon has been developed. The authors also identify the requirements for mobile applications that could reduce the risk of stigma.

Conclusion: The conclusions suggest the ways of further prevention of stigmatization of people who use mobile applications to track their contacts. The paper outlines the content of the positive and negative obligations of the member states of the Council of Europe to ensure non-interference in the private and family life of citizens who are under observation or self-isolation due to COVID-19 pandemic.

KEY WORDS: stigmatization, COVID-19 pandemic, digital tracking technologies, *Act at Home* mobile application

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INTRODUCTION

The problem of social stigmatization of people suffering from certain types of mental and physical illnesses has become a widely discussed topic in the past 50-60 years in the format of acute social discourse and among health care and other human sciences representatives. The beginning of the systematic research of the phenomenon of stigmatization per se and the stigmatization of people with any existing health disorders, in particular, was initiated by I. Hoffman, the American sociologist and the father of the stigma theory, who defined stigma as the number of physical or social indications that discredit the identity of an individual to the point that they make that individual incapable of social perception on the one hand, and, as a dynamic process of devaluation of an individual that causes intense discreditation of those individuals on the other hand [1]. However, I. Hoffman's scientific research was mainly focused on the issues of stigmatization of patients with mental disorders and their lives within total institutions [2].

In the last quarter of the XXth century, instead of a psychiatric bias, the process of stigmatization significantly changes its vector, allegedly acquiring the feautres of territorial expansion in which stigmatization began to expose to entire social groups and even countries on a scale of any dangerous infectious disease (for example, given the percentage of HIV-infected inhabitants of a number of countries on the African continent[1]), or the area (region) from which a certain disease has spread around the world. Therefore, "Mexican flu", "Asian fever", "Spanish flu", "Hong Kong flu" and others became the common names. According to foreign experts K. Usher, J. Durkin and N. Bhullar, anxiety and fear associated with the infection can lead to acts of discrimination [3, p. 315]. So, S.-Y. Ren et al. report that Wuhan residents are accused of COVID-19 outbreak and attacked by other Chinese people; in addition, the Chinese have since been exposed to international stigmatization [4]. Once, according to S. Monson, the outbreak of Ebola in 2014, which was considered to be a problem of African origin, led to the discrimination of African people [5].

[1] Note. Today, for example, in Lesotho, the proportion of people affected by HIV is 17.4%, in Botswana – 16.0%, in South Africa – 11.88%, in Namibia – 10.86%, in Zimbabwe – 9.92%, in Mozambique – 6.2%. See: The spread of HIV in the world. 2020. [Online]. Available: https://www.radiosvoboda.org/a/26723139.html.

In addition, the objects of stigmatization and discrimination can become particular people who have become infected or being informed about as asymptomatic carriers of the infection. In Ukraine, the incidents are known when the houses of infected people or the people with suspected coronavirus infection were marked with so-called "information leaflets" [6]. Thus, one can't but agree that stigma can: 1) drive people to hide the illness to avoid discrimination; 2) prevent people from seeking health care immediately; 3) discourage them from adopting healthy behaviors [7].

At the same time, while becoming increasingly publisized (especially in the context of global COVID-19 pandemic), stigmatization because of a desease goes with another determinant manifestation of globalization, namely, digitalization of the world. After all, almost no one disputes the fact that the use of high technologies, and mobile applications (hereinafter - MAs) in particular, appears to be a reasonable alternative to human resources "spending" for controlling the spread of the disease and overcoming its consequences. Thereby, it becomes possible to save the capacity and resources of many social institutions in terms of necessary organizational anti-epidemic measures conducting, thus allowing them to focus on purely curative actions.

A number of researches can be mentioned devoted to the problem of stigmatization stemming among people with deseases or those having relatives with deseases, as well as the use of high technologies for the prevention of further spread of infectious diseases.

In particular, prominent results in that regard are accumulated in the scientific papers of R. Barrett *et al.* (2008) [8], M. Schoch-Spana (2010) [9], Michael P. McCauley *et al.* (2013) [10], Arjan E. R. Bos *et al.* (2013) [11], B. Link *et al.* (2016) [12], Daniel S. Goldberg (2017) [13], Luke D. Mitzel (2018) [14], G. Cohen *et al.* (2020) [15; 16], S. Park *et al.* (2020) [17], L. Ferretti *et al.* (2020) [18], Emma E. McGinty *et al.* (2020) [19] and others.

Nevertheless, there are no scientific research in Ukraine and abroad that would be focused on the evaluation of the risks of negative consequences, specifically, manifestation of stigmatization caused by the use of mobile applications as the means of monitoring the spread of any disease. There are objective reasons for that.

One of them is that those applications have been widely introduced fairly recently. However, the large scale of the disease and a rather skeptical attitude to those applications suggests that we need to initiate the research of their effectiveness and the effectiveness of similar applications as well as their role in prevention the stigmatization of patients in response to digital transformations of the world. The urgency of the issues chosen for the research is also indicated by the real possibility of risks of violation of the right to non-interference in private and family life stipulated by Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms in response to the use of mobile applications by the individuals in self-isolation or those infected with COVID-19.

THE AIM

The aim of the research article is to identify and analyse the features of possible (socio-economic, legal, psychological morale, technological etc.) manifestation of the stigmatization of individuals stemming from the use of digital (mobile) applications for those individuals' contacts tracking at the time of anti-epidemic measures in the country (self-isolation and observation), along with the developing of both, the ways of neutralization of identified manifestation of stigmatization among the patients using those applications and the requirements for those mobile applications.

MATERIALS AND METHODS

The given research was conducted from May to August 2020. It is based on the results of summarizing: 1) the anonymous survey answers of citizens of Ukraine by means of Google Form to find out their attitude to the national mobile application "Act at Home"; 2) analytical papers of the Ministry of Health of Ukraine and the World Health Organization; 3) data of state and branch statistics of Ukraine. The collected empirical and statistical data were processed with the capabilities of descriptive statistics. The article is based on dialectical, analytical, synthetic, comparative, statistical and specific sociological research methods. The calculations were performed by means of Excel spreadsheets of Microsoft Office 2016. The theoretical basis of the article is the specialized literature on medicine, law and computer science.

RESULTS

Despite their versatility and accessibility to the general public along with optionality and confidentiality, the use of mobile applications (hereinafter - MAs) to counteract COVID-19 is often accompanied by public stigmatization of users. This process is manifested through the implementation of social pressure on an individual or a group of people, with a certain stigma imposed as a result, which further determines the behavior of the stigmatized individual and becomes the part of that individual's "Self [20, p. 264]".

Manifestation of stigmatization can be both internal (among the staff or within educational groups, among the residents of an apartment building etc.) and external (within the society, among the residents of territorial communities, national minorities etc). This implies the existence of certain differences in the ways of stigmatization and discrimination of people endowed with negative (stereotypical) characteristics. In view of this, it would be useful to provide information obtained during the survey of Ukrainian citizens about their attitude to the mobile application "Act at home". Thus, almost three fourths of surveyed citizens said that they tried to analyze the possible consequences before using this mobile application.

The article analyzes the cases implying dissemination of specific information about the individuals who use the above-mentioned MAs, as well as information about those

being temporarily relieved of duties, among members of social groups. It also concerns the imposing of fear on the other staff members, dissemination of private and family life information of an individual, advisory opinions regarding to the avoidance of those individuals along with intentional creation of psychological barriers for communication with such individuals (internal stigmatization).

At the external level, stigmatization is usually manifested through the access to publicly available sources of information, social networks, often supported by the media, certain public associations and even some states [21].

Regardless of the form of existence, manifestation of the given phenomenon in society is the result of a set of factors that, depending on their direction, can be general or special. Thus, according to the recommendations for preventing and overcoming stigmatization, developed by the Center for Strategic Communications of Hopkins University, there are three main groups of factors that cause stigmatization in concern with COVID-19.

They are defined as follows:

1) as a new disease with unknown characteristics;
2) people tend to be afraid of unknown things;
3) the existing fear is easily explained by the hostility of "strangers" [22].

The provided factors have common socio-psychological nature, they reveal the main causes of stigmatization of people with COVID-19, those under observation or in self-isolation.

In this respect, according to the systematic analysis of the practice of the effects of COVID-19 overcoming in different countries [23], the use of MAs to track contacts also leads to a separate group of factors, namely, specific nature prerequisites for stigmatization. In our opinion, those factors can be:

1) non-compliance with the principles of confidentiality, voluntariness, inadmissibility of interference in the private and family life of individuals with contacts processed by means of MAs;
2) formation the stereotypes of danger from people obliged to use corresponding information and communication technologies (hereinafter – ICT) in the media, labor, educational and other social groups;
3) use of IT-architecture model in the developing of MAs, which provides for centralized processing of personal data of individuals who have installed corresponding applications during the implementation of measures to overcome COVID-19, maintaining the default geolocation of a subscriber and low security of relevant ICT;
4) the lack of a consistent systematic information campaign in some countries aimed at overcoming stereotypes in society of the potential danger of those used MAs for the purpose of contacts digital tracking in the process of implementation the measures to overcome COVID-19;
5) the existence of a wide range of officials vested with access to personal data obtained as a result of contacts digital tracking by the national legislation of individual states;
6) inadequate public awareness of the methods, grounds and consequences of the MAs use for digital tracking of contacts in the process of measures to overcome COVID-19 implementation, as well as the rights and guarantees of the users of those applications;
7) media dissemination of information about the occurance of specific cases of stigmatization among MAs users, etc.

Therefore, it is not for nothing that 54% of respondents after using this application said that they are afraid that the information collected may harm them in the future.

The scientific assessment of the manifestations and preconditions for the spread of stigmatization of those using MAs to track contacts, indicates the indispensable link between the essence of this phenomenon with the processing of sensitive personal data of the population. This relationship is crucial for the formation of national mechanisms to prevent stigmatization of individuals who use MAs to track their contacts in the context of the implementation of measures to overcome COVID-19. After all, this involves building a mechanism to prevent stigmatization of this specific category of population on the basis of positive and negative obligations of member states of the Council of Europe arising from the provisions of Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms [24].

Although the purpose of Article 8 of the above-mentioned international legal act is mainly to protect individuals from arbitrary interference by public authorities, it does not require the state to refrain from such interference only; in addition to this initially negative task, there must be positive obligations and ties inseparable from real respect for private life. Those obligations may include measures to ensure respect for privacy, even in the field of relations between individuals [25, p. 7].

Thus, the prevention of stigmatization of individuals with their contacts tracked by means of MAs from the standpoint of Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms should be carried out both by introducing regulatory requirements for the development and use of relevant ICTs and application and implementation of measures aimed at neutralizing the manifestation of factors that cause stigmatization by the subjects of public or private law. Therefore, states should ensure the protection of health information collected in the process of COVID-19 pandemic counteraction, promote awareness of the rights and consequences of ICTs use by MAs users, and create conditions for their non-discrimination in society.

In its turn, from the standpoint of negative commitments, it is a question of preventing interference in an idividual's private life during the implementation of anti-epidemic measures to a greater extent than allowed by national legislation. In particular, Council of Europe documents have repeatedly stressed the need for member states to avoid processing of information related to MAs users geoplocation, limit the processing of personal data to information sufficient for counteracting the effects of the pandemic, promote the use of ICTs to enable intercommunication among the devices, rather than the uses of MAs and authorized officials.

In its judgment in Leander v. Sweden, the European Court of Human Rights stated for the first time that the storage by public authorities of information about an individual is an interference with his or her right to privacy and that such interference must comply with Article 2 (2) 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms [26, p. 13].

As far as the given provision restricts the right of an individual for non-interference into private and family life for health reasons, it imposes an obligation on the member states of the Council of Europe to ensure a balance between the interests of individuals whose personal data are processed with MAs and the interests of the society in terms of overcoming the consequences of COVID-19.

Therefore, it is essential to ensure that the above-mentioned measures and the associated data processing are necessary and relevant to the legitimate aim, so that they reflect a fair balance of all relevant interests as well as rights and freedoms at risk at all stages, as stipulated in the Convention. For the Protection of Human Rights and Fundamental Freedoms (Article 8) and the Convention 108+ (Articles 5 and 11) [27].

The necessity to fulfill those commitments by the member states of the Council of Europe and the European Union in the context of implementing measures to overcome COVID-19 pandemic is emphasized in a number of "soft law" acts, including, Joint Statement on Digital Tracking of Contacts by Alessandra Pierucci, the Committee of the Council of Europe Convention Commissioner on the protection of individuals with regard to automated processing of their personal data ("Convention 108") and Jean-Philippe Walter, the Council of Europe Commissioner for Data Protection on 28.04.2020 [27], and "Guidelines on geolocation and other tracking tools" in the context of the COVID-19 outbreak approved by the European Data Protection Council of the European Union on 21.04.2020 [28].

Thus, in the member states of the Council of Europe and the European Union, the prevention of stigmatization is based on the human rights standards proclaimed by the Council of Europe and the related legal policy instruments of specific states.

In this context, the analysis of the practice of preventing the situation with stigmatization that has developed in the member states of the Council of Europe as a result of COVID-19 counteraction allows us to distinguish two main levels of counteraction to this anti-social phenomenon - general and special ones. Each of these levels of stigmatization preventing not only reflects the manifestations of social stigmatization and the factors that contribute to the proliferation of the given phenomenon against those people whose contacts are processed with MAs, but also takes into account the division of responsibilities of Council of Europe among the member states regarding to non-interference into private and family life of individuals.

Legal literature proves the development of the above-mentioned approach to illegal behavior prevention with the use of ICTs. Within the framework of implementation of the basic provisions, such prevention of manifestations of illegal behavior can be carried out through the formation of a system of normative measures aimed at eliminating the causes and conditions that contribute to the illegal use of ICTs in society and conducting nationwide information and education campaigns on the prevention of discrimination on the grounds of use or refusal to use ICTs for specific purposes (general prevention) [29].

Special prevention involves practical implementation of a set of legal, organizational and information technology measures aimed at overcoming the consequences of illegal behavior of certain individuals or collective entities and preventing the actions of people prone to the use of ICTs for illegal purposes.

Concerning stigmatization, the separation of general and special types in the structure of its prevention implies the need to concentrate efforts on regulatory and informational measures aimed to prevent the emergence in the society of factors endowing it with negative traits of people who use MAs for tracking contacts.

The implementation of normative measures can be determined through the application by law-making bodies of specific states of legislative techniques and normative constructions that will eliminate or minimize the "legalization" of factors potentially leading to stigmatization. This may include, in particular, the definition of regulatory requirements for security and confidentiality of data processing with specifically designed MAs, the imposition of sanctions and other measures to influence those allowing the facts of stigmatization.

In order to prevent violations of fundamental human rights, the Joint Statement on Digital Contact Tracking emphasizes the need for Council of Europe member states to take, inter alia, the following general preventive measures:

1) large-scale processing of personal data must be carried out only if, according to scientific evidence, the potential health benefits of such digital epidemic monitoring, in particular contact tracking, and its accuracy outweigh the benefits of alternative and less intrusive solutions;
2) the establishment of the MAs for digital contact tracking should be voluntary and open;
3) considering any possibile impact of digital contact tracking systems on the rights and fundamental freedoms of individuals, the development of such systems should be based on a preliminary analysis of this impact prior to their implementation;
4) the purpose of the digital system for tracking COVID-19 contacts is to identify individuals having a potential risk of the virus infection. This strictly excludes further data processing for any unrelated purposes, such as commercial or law enforcement ones;
5) the information processed for the purpose of digital contact tracking should be minimized without collecting any unnecessary or unrelated data;
6) there should be no direct identification of users of the data tracking system, as such systems must use only unique and impersonal identifiers generated by the system and inherent to it;
7) data used for digital contact tracking should be stored

only during the COVID-19 pandemic overcoming period [27].

According to their purpose, the above-mentioned measures are aimed at the implementation of international standards for the development and use of MAs designated to monitor contacts while implementing the measures of COVID-19 overcoming. Our study found that the main inconveniences of using *Act at home* application include: limited travel, leisure, technical imperfections of the programme and the inability to obtain comprehensive information on its use at the time of installation.

Along with the introduction of sanctions and other measures of legal coercion for manifestations of stigmatization into national legislations, the requirements for MAs actually form legal guarantees to prevent manifestations of stigmatization in response to COVID-19 at the level of individual states or the society as a whole.

At the same time, the positive commitments of the member states of the Council of Europe and the European Union on the general prevention of possible stigmatization may be reflected in national strategies, programs to overcome negative public attitudes towards people or individual social groups taking into account digital tracking of their contacts while overcoming COVID-19 pandemic. In our opinion, the given context implies the focuse of such measures on facilitating the process of elimination the distrust for MAs as well as common prerequisits for violating the rights of people with ICTs use to non-interference into their private and family life, overcoming media stereotypes as for danger and other risks from the relevant category of population.

At the stage of stigmatization preventing, systemic and adequate media campaign for the ensurance of public awareness of the features of infection, the course and ways of overcoming the effects of COVID-19, the behavior of individuals with the disease and preventing discrimination against that specific category of individuals becomes vitally important.

As stipulated in the Guidelines for Preventing and Overcoming Stigmatization introduced by the Center for Strategic Communications of Hopkins University, some words and expressions used to discuss COVID infection (e.g., "suspicious case", "isolation", etc.) may be perceived by people in negative context and provoke stigmatizing behavior. Therefore, all means of communication, including the media, are recommended to use wording that promotes respect for human dignity, recognition of human rights and opportunities [22].

Collectively, the general means of stigmatization prevention among those using MAs to track their contacts while overcoming COVID-19 are intended to overcome the prerequisits for the phenomenon at the stage of potential emergence of those prerequisits within the society and the change of public attitude towards certain ICT users.

Without reducing the functional potential of general prevention of stigmatization, special prevention of this phenomenon is largely based on measures of individual legal coercion, educational and socio-psychological work within specific social groups. The implementation of this level of stigmatization preventing involves the development of special measures designed to ensure elimination and prevention of discrimination against people with contacts processed by means of MAs in future. In this context, the main emphasis is shifted to preventing individual cases of disclosure of confidential information about people with contacts tracked by means of mobile applications, eliminating the manifestations of their labor and socio-economic rights restriction as well as manifestations of hostile behaviour and fearful attitudes of other individuals towards them [30].

Thus, at this stage the model of behavior is built either by certain groups or individuals, in which discrimination against stigmatized individuals is subject to public condemnation, and the cases specified by national law are subject to administrative or criminal penalties.

Therefore, the prevention of stigmatization of people obliged to use MAs in response to COVID-19 overcoming is a complex multi-level social and legal mechanism, the successful implementation of which should take into account the forms of manifestation and the factors that cause the existence of the given phenomenon within the society. Based on world human rights standards, the above mentioned social and legal mechanism acquires a meaningful national content (both, instrumental and functional), which determines its effectiveness and appropriateness for the extinction of the facts of stigmatization of individuals at the level of certain states.

DISCUSSION

Multifunctionality and complexity of implementation as well as heterogeneity of the approaches of the member states of the Council of Europe and the European Union to the formation of the mechanism to prevent stigmatization of individuals concerning the feature of MAs use for the purpose of COVID-19 effects overcoming have provoked a fierce debate in the scientific literature.

The main result of the debate lies in the need for each state to formulate a national information policy in a way that minimizes the imposition on the society of stereotypes associated with distrust towards mobile applications designed to track the contacts of people infected with COVID-19 and the risks of individuals installed those applications [31].

According to the International Report "On Human Rights and COVID-19", all the states must urgently act while counteracting fearful rhetoric and ensure that measures concerning COVID-19 do not increase the vulnerability of certain social groups in the face of violent abuse and discrimination. Dissemination of accurate, clear and evidence-based information and public awareness campaigns are the most effective means of overcoming discrimination fueled by misinformation and fear. Additional efforts are needed to monitor cases of discrimination, as well as timely and public response measures [13].

Thus, the authors of the above-mentioned international document emphasize the importance of preventing stigmatization at the level of general prevention. At the same

time, placing the main emphasis on the informational, explanatory campaign against stigmatization in concern with COVID-19 without mentioning the risks of this phenomenon in response to the use of MAs for tracking contacts causes the inexhaustibility of these measures to overcome the manifestation of stigmatization.

In his statement on 25.06.2020, dr. Hans Henri P. Kluge, the Director of the European Regional Office of the World Health Organization, expressed the idea that digital tools could not work without public trust. Any interference must take into account the need to protect individuals' privacy and personal data. In the digital environment, all the necessary measures must be taken to protect fundamental human and gender rights, and the epidemic is not a basis for deviating from this principle. The responsibility for solving the tasks related to data ownership, data protection and obtaining the consent of citizens lies with the state [31].

The analysis of the existing debates on the problem of preventing stigmatization of individuals with the use of MAs to track their contacts in response to COVID-19 in the scientific literature and international documents revealed that they generally have a common denominator in solving the given problem. Its essence is the need for the increase of general preventive measures with the purpose of overcoming corresponding anti-social phenomenon, specifically educational measures to avoid social stigmatization, ensuring a balance between public awareness of COVID-19 and privacy of personal and family life. At the same time, overcoming discrimination against individuals using specific mobile applications should be emphasized as well as preventing misinformation about their public danger and individual sanctions for manifestation of stigmatizing behavior.

CONCLUSIONS

The conducted research on the prevention of the stigmatization of individuals whose contacts are tracked in the conditions of Covid-19 by using MAs allows us to reach the following main conclusions:

1. The prevention of stigmatization of individuals who use MAs is carried out with the use of general and special means of prevention of this phenomenon. But, in any case, the content of these tools is determined by the national legislation of specific states.
2. At the heart of the national policy to prevent stigmatization of people who use MAs for digital contact tracking are the positive and negative commitments of the member states of the Council of Europe to ensure the right of everyone to privacy and family life.
3. In order to avoid stigmatization of individuals whose contacts are tracked during COVID-19 using the MAs, it is important that the use of these applications eliminates or minimizes the recording of geolocation information of people whose contacts are subject to digital tracking.
4. An important condition for stigma combating is the development of national programs and their approval by the governments of the member states of the Council of Europe. Such programs should include forms and tools for monitoring the manifestations of infodemia and misinformation, responsible actors, the principles of media behavior during the coverage of Covid-19, as well as a mechanism to stop this phenomenon. In addition, it is important to ensure that the principles of confidentiality, adequate protection and the minimum necessary processing of personal data of employees with Covid-19 are observed.

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ORIGINAL ARTICLE

ARTIFICIAL INTELLIGENCE IN MEDICAL PRACTICE: REGULATIVE ISSUES AND PERSPECTIVES

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ABSTRACT

The aim of the research is to identify specific of AI in healthcare, its nature, and specifics and to establish complexities of AI implementation in healthcare and to propose ways to eliminate them.

Materials and methods: This study was conducted during June-October of 2020**.** Through a broad literature review, analysis of EU, USA regulation acts, scientific researches and opinions of progressive-minded people in this sphere this paper provide a guide to understanding the essence of AI in healthcare and specifics of its regulation. It is based on dialectical, comparative, analytic, synthetic and comprehensive methods.

Results: One of the first broad definitions of AI sounded like "Artificial Intelligence is the study of ideas which enable computers to do the things that make people seem intelligent ... The central goals of Artificial Intelligence are to make computers more useful and to understand the principles which make intelligence possible." There are two approaches to name this technology - "Artificial intelligence" and "Augmented Intelligence." We prefer to use a more common category of "Artificial intelligence" rather than "Augmented Intelligence" because the last one, from our point of view, leaves much space for "human supervision" meaning, and that will limit the sense of AI while it will undoubtedly develop in future.

AI in current practice is interpreted in three forms, they are: AI as a simple electronic tool without any level of autonomy (like electronic assistant, "calculator"), AI as an entity with some level of autonomy, but under human control, and AI as an entity with broad autonomy, substituting human's activity wholly or partly, and we have to admit that the first one cannot be considered as AI at all in current conditions of science development. Description of AI often tends to operate with big technological products like DeepMind (by Google), Watson Health (by IBM), Healthcare's Edison (by General Electric), but in fact, a lot of smaller technologies also use AI in the healthcare field – smartphone applications, wearable health devices and other examples of the Internet of Things.

At the current stage of development AI in medical practice is existing in three technical forms: software, hardware, and mixed forms using three main scientific-statistical approaches – flowchart method, database method, and decision-making method. All of them are useable, but they are differently suiting for AI implementation. The main issues of AI implementation in healthcare are connected with the nature of technology in itself, complexities of legal support in terms of safety and efficiency, privacy, ethical and liability concerns.

Conclusion: The conducted analysis makes it possible to admit a number of pros and cons in the field of AI using in healthcare. Undoubtedly this is a promising area with a lot of gaps and grey zones to fill in. Furthermore, the main challenge is not on technology itself, which is rapidly growing, evolving, and uncovering new areas of its use, but rather on the legal framework that is clearly lacking appropriate regulations and some political, ethical, and financial transformations. Thus, the core questions regarding is this technology by its nature is suitable for healthcare at all? Is the current legislative framework looking appropriate to regulate AI in terms of safety, efficiency, premarket, and postmarked monitoring? How the model of liability with connection to AI technology using in healthcare should be constructed? How to ensure privacy without the restriction of AI technology use? Should intellectual privacy rights prevail over public health concerns? Many questions to address in order to move in line with technology development and to get the benefits of its practical implementation.

KEY WORDS: AI, Artificial Intelligence, Healthcare, Medical devices, Software

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INTRODUCTION

Healthcare is one of the most rapidly growing spheres of sciences, so it is wide open for new technologies. One such being on the cutting edge is Artificial Intelligence (hereinafter - AI), which is started from entertainment and now spreading to other social life segments.

The trend of AI emerging is supported by several factors of modern life. Among them are the shortage of qualified doctors in the USA and Europe on the background of population aging and the necessity of cost-effective treatment. According to prognoses [1], by 2050, in Europe and North America, one in four people will be the age of 65+, and consequently, it will overload the healthcare system with aged patients with complex needs, long-term care management plan, and costly treatment. All that will demand switching of healthcare paradigm to meet new demands. So, there will be not only a need to attract and train more healthcare professionals increasing their number, but we

also redistribute their workload focusing on patients' care avoiding time-spending on things that could and, in fact should be automated. And this scope is one of where AI has a massive potential to grow, modify healthcare, and address some ongoing and perspective challenges.

THE AIM

The research aims to identify specific of AI in healthcare, its nature, and peculiarities, to establish complexities of AI implementation in healthcare and to propose ways to eliminate them.

MATERIALS AND METHODS

This study was conducted during June-October of 2020. Through a broad literature review, analysis of EU, USA regulation acts, scientific researches and opinions of progressive-minded people in this sphere this paper provide a guide to understanding the essence of AI in healthcare and specifics of its regulation. It is based on dialectical, comparative, analytic, synthetic and comprehensive methods.

RESULTS AND DISCUSSION

In the earlier 1970s' "the possibility that the computer as an intellectual tool can reshape the present system of health care, fundamentally alter the role of the physician, and profoundly change the nature of medical manpower recruitment and medical education--in short, the possibility that the healthcare system by the year 2000 will be basically different from what it is today."[2] Countries like Finland, Germany, the UK, Israel, China, and the United States are intensively investing in AI-related research, and the dynamics of healthcare AI growth are unstable [3]: the USA still a "quantitive champion" with the biggest list of entities with the highest capitalization and broadest trials and researches, China is the one with the highest growth rate in healthcare AI implementation and intensive consumer-oriented approach (for example, Ping An Good Doctor) [4], European countries has advantages in terms of the scope of collected healthcare data and amount of joint researches in different issues of AI using in medicine such as data protection, privacy, ethics vs law, humanity and other. So, there is no single "flagship" till now, and the process of healthcare AI usage is at its starting point.

Going down to definition (its acronym - AI), we almost from the beginning meet some complexities. One of the first broad definitions sounded like "Artificial Intelligence is the study of ideas which enable computers to do the things that make people seem intelligent ... The central goals of Artificial Intelligence are to make computers more useful and to understand the principles which make intelligence possible." [5]. Now we have some "governmental," normative definitions. Thus, European-oriented terminology included in the European Commission's guidance on ethical AI as follows: "Artificial intelligence (AI) systems are software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behavior by analyzing how the environment is affected by their previous actions. [6] However, USA's approach is operating definition of "augmented intelligence," making an accent on the enhanced capabilities of human clinical decision making when coupled with these computational methods and systems." [7] Both approaches have their advantages and level of rationality, but the main two things we should consider are:

1) that AI in current practice is interpreted in three forms, they are: AI as a simple electronic tool without any level of autonomy (like electronic assistant, "calculator"), AI as an entity with some level of autonomy, but under human control, and AI as an entity with broad autonomy, substituting human's activity wholly or partly, and we have to admit that the first one cannot be considered as AI at all in current conditions of science development;
2) description of AI often tends to operate with big technological products like DeepMind (by Google), Watson Health (by IBM), Healthcare's Edison (by General Electric), but in fact, a lot of smaller technologies also use AI in healthcare field – smartphone applications, wearable health devices and other examples of the Internet of Things. We all (the majority of us) are using some assistants with AI technologies inside, and this trend is growing.

We prefer to use a more common category of "Artificial intelligence" rather than "Augmented Intelligence" because the last one, from our point of view, leaves a lot of space for "human supervision" meaning, and that will limit the sense of AI while it will undoubtedly develop in future. So, what is AI in medicine? Simply the AI specialized to medical applications.

At the current stage of development AI in medical practice is existing in three technical forms: software, hardware, and mixed forms.

Software form includes a wide range of implementations in applications from simply fixating and record-keeping to neural network systems designed to generalize data and recommend treatment decisions by predicting their efficiency. Most of its software-based potential AI in healthcare could demonstrate in the following areas: Artificial Intelligence Techniques in Medicine; Data Mining and Knowledge Discovery in Medicine; Medical Expert Systems; Machine Learning-Based Medical Systems; Medical Signal and Image Processing Techniques.

Hardware form is a "world of robotics" [8] that assists in medical treatment, surgeries, rehabilitation, functioning in intelligent prostheses, etc.

The mixed form is a combination of both elements as components of the complex unite system. For this moment,

such a category is not filled with a lot of examples, in fact, we have just a few "almost-proper" examples of such [9].

Health care is faced with two modern problems that could be addressed by using AI, they are the rise of "big data" – huge amounts of data coming from many sources (electronic health records, scientific and practical medical literature, clinical trials and their results, insurance data, pharmacy records, information added by patients via smartphones, wearable devices etc.), and the necessity (and ability) to generalize and to find consistent patterns to enhance healthcare and treatment of patients. These two problems are resulting in one – the necessity of automatization and assistance, and it is curious, but healthcare system, thought being open to technologies, is one of the spheres with the lowest possible automatization rates – only 15% of working hours presumed to be automated till 2030 and only 35% - are potentially automatable at all [10]. Some skepticism is added by evidence-based researches arguably state that "… healthcare has exhibited a dismal record for adopting cutting edge technologies." [11]

How could AI help with this? The primary method of medical science is to establish interconnections through some kind of patterns based on existing data (databases), and here we can presume that statistical method was the core of such a process for a long time before AI. However, AI could be much more effective in that by using three main scientific-statistical approaches – flowchart method, database method, and decision-making method. All of them are useable but they are differently suiting for AI implementation.

"Flowchart method" is grounded on the gathering of established symptoms, thus creating some history record and resulting in probable diagnosis by combining symptoms in one picture. The downsides of such an approach are obvious, they are the necessity to input a lot of data on different symptoms, their characteristics, combinations, connected diseases etc. in order to achieve a trustworthy result; moreover, such an approach is limited because of medical worker's intermediary role – the algorithm cannot "ask" anything in addition except the information provided by the medical worker, cannot achieve any information of the particular patient – 100% "machinery" and inflexible approach. However, it can be useful in appropriate circumstances, for instance, to encode triage protocols for use by nurses [12], patient interviewing [13], for giving therapeutic advice in the acid/base area [14].

"Database method" is based on the principle of self-generalization, self-learning, and in-depth analysis, when AI has to learn how to recognize interconnections and patterns utilizing repetitive algorithm designed to identify how the symptoms or their combinations, visual appearance etc. are manifested. And such systems are effectively working now, for instance, in the relevant issue of COVID-19 diagnostics on the basis of cough sound [15]. Although such data processing techniques have more advance than previous, it could not be implemented in all cases because of some issues: high costs and time spendings of collecting and processing huge databases; problems with the comparison of old data and new data; regional differences of collected data; the possibility of medical exceptions in some types of diseases; lack of explanation and inability to substitute the role of the physician. Such a method can undoubtedly be practically implemented, but the scope of such implementation should not be overestimated.

"Decision-making method" is grounded on the mathematical algorithms of creating decisions under some level of uncertainty, involving prior experience, manifestations, likelihoodness, and outcomes. As P. Szolovits rightly notes, "Besides its rationality, such an approach has some issues regarding obtaining reasonable estimates of probabilities and utilities for a particular analysis. Although techniques such as sensitivity analysis help greatly to indicate which potential inaccuracies are unimportant, the lack of adequate data often forces artificial simplifications of the problem and lowers confidence in the outcome of the analysis". [16] For instance, such an approach could lead to a situation when multiple symptoms are considering as a mix of single diseases (when, in fact, they are a combination leading to one) or vice versa. Additionally, numeric algorithmic representation of the decision-making process obviously differs from that of a real human-physician, which could confuse the patient.

Thus, every single approach is suitable but not universal, moreover, as was mentioned before, despite the fact of the relatively long story of AI, we can admit that it is just a starting point of the technology in general and its use in healthcare in particular. According to recent researches, "While there are widespread questions on what is real in AI in healthcare today, this report looked at 23 applications in use today and provides case studies of 14 applications already in use. These illustrate the full range of areas where AI can have an impact: from apps that help patients manage their care themselves, to online symptom checkers and e-triage AI tools, to virtual agents that can carry out tasks in hospitals, to a bionic pancreas to help patients with diabetes." [3, p. 14]

It is predicted that we will face three main phases of AI in healthcare scaling:

- **low-level technical implementation phase**, when AI will be assisting in repetitive administrative tasks. At this point, AI technology will reduce the accompanying workload (not the main one) of the medical staff of all levels and image-based application of AI in ophthalmology, radiology [17].
- **home-based care phase**, when the assistance of AI will make it possible to switch the model of medical treatment more toward remote monitoring, alerting visual assistance on the basis of AI technology. Additionally, advancing will take place in AI utilization in oncology, cardiology, neurology, where it shows its first forms of implementation these days [18-20] with broader digitalization combinations (by deep learning, NLP, connectivity) and organizational transformation in accompanying existing technologies.
- **clinical trials and decision support phase**, when AI technologies will be implemented in clinical decision

support, embedded in every stage of the healthcare system, from training and learning through clinical trials and treatment to health enhancement end general evaluation of healthcare

Thus, for now, we are far from the real broad implementation of AI in healthcare, so it is the right time to think – what kind of issues will it raise? Are we ready to address them, or (if not) what strategy should we have to minimize the risks? Furthermore, the central concern is grounded on the fact that we are discussing revolutionary modification of healthcare, public health issues, the conflict between public and private interests, law and ethics, technology, and humanity. We have no intention to dive into every single issue of AI implementation in healthcare deeply, and that will be a core of our further researches. So, let's get down to the analysis.

The technology nature. AI, machine learning, and supportive technologies, as we stated above, if we explain them with regard to healthcare, execute the process of obtaining the decision which usually is 1) unexplainable at all, because some of the stages are "presumed" or "skipped"; 2) explainable, but the explanation is justified mechanically but absolutely make no sense from a medical point of view [21]. That is why the term "black box" is widely used when describing the decision-making process within AI technology because the original algorithm could experience modifications on the basis of a massive amount of data analyzed or with changes of data over time. That could be positive when we analyze the perspective of image recognition and early prediction of, for example, skin cancer disease [22], identify disorders in infants on the basis of facial features [23], to recommend of-label use for existing drugs, etc. But medical science and medical treatment must be based on an appropriate level of certainty, so it would be a tough challenge to ensure effectiveness and safety and not interrupt progress, development, and use of AI technology benefits.

Law regulation approach. This issue's core is to ensure the quality, safety, and reliability of IA in healthcare. Regarding the primary status, such bodies as Food and Drug Administration in the USA, relevant Commission in the EU designed to oversee medical devices, but could AI – free-standing algorithms used to make medical decisions (or help make them) – be simply identified as regular medical device? [24, 25] They have many common characteristics, but legislative terms should be modified to strictly cover AI in all its forms. The question of efficiency and safety regarding medical objects always connected with two basic points of scientific reasoning plus understanding and approved by trial efficiency. And with both these demands, there are enormous complexities because understanding and reasoning are unattainable due to the essence ("black-box") of technology, and trials in their classical meaning may not be suitable to AI if the predicted results of AI algorithm isn't general but rather individual and personalized. Furthermore, one of the core features of AI using in healthcare is saving time to achieve the result, thus – trials will interrupt this feature majorly. Thus, the classical approach for premarket evaluation will hardly work for AI in healthcare, and broad premarket control should be changed to stricter and more comprehensive aftermarket monitoring to manage this challenge and to use a collaboration of various entities to create an AI algorithm of the highest quality.

Liability. Healthcare is a field where one can hardly underestimate the meaning of liability because a patient's health and life are at the center of this scope. Using some hi-end technologies in medical practice to enhance treatment is not new, and this kind of model presumes that medical staff is professionally responsible for patient's care and all technical measures used. However, such a strict scheme will not (and in some circumstances should not) work that way when we are talking about AI if, for example, some issues of AI's algorithm caused a mistake in prioritization of patients by the urgency of care or mislead medical worker in some automatically measured figures of patient's state, etc. If AI is a simple electronic instrument under a physician's full supervision and control, it will be understandable case, but with the further increase of automated decision making, there will be an obvious need to clarify the borders and defining where professional responsibility begins and ends. We can now use the starting point of similarization of AI-related liability with the one connected to medical devices, where approach for regulating devices created by national bodies (FDA in USA, Medicines and Healthcare Products Regulatory Agency in UK, etc.). In this situation, the burden of assurance of device effectiveness and safety is fully on the regulatory body, and thus if an AI is used correctly, the physician must not be subject to liability. However, transforming AI from the concept of "supporting the decision" to "making the decision" is a matter of time, and then – should physicians overlook the results of AI activity and be liable for that? If yes – then it will decrease the attractiveness of technology in healthcare because of unnecessary "double-work", if no – how to ensure patient's rights in the right way? Should hospitals, physicians verify and test AI themselves before implementation? What should they do to fulfill their duties in using AI not to become liable? Without clarifying these questions, many physicians and healthcare organizations would be reluctant to introduce or significantly scale up AI applications in healthcare [3]. Liability issues are also connected with the concept of informed consent of the patient regarding treatment using AI technology, namely – how deep should be information that is delivered to the patient regarding AI and (because we a talking about very complex technology) will that information make it possible to such consent be really "informed" in fact.

Privacy. It is a trend of the 21st century, and we cannot overlook this issue regarding AI use in healthcare, and three types of data processing are particularly relevant in this regard: collecting, analysis, and sharing. This data must be firstly loaded by the developers to "train" the AI, and then this data and its combined, generalized, sorted, evaluated, etc., forms are shared with other systems in order to exercise healthcare functions. But such kind of

data is included in the category of highly sensitive data and is covered by special restrictive provisions of General Data Protection Regulation [26], Health Insurance Portability and Accountability Act's (HIPAA's) [27], and other acts and restriction of such information use need further clarification in terms of covered subjects, anonymization and other because machine learning and AI in general do not fully comply with current provisions on privacy. How could be addressed the situation with the right of a person to erase his/her data, if such data is already used, reorganized and "integrated" in a wide range of databases and influenced AI's algorithm and "decision-making"?

There are many other concerns of different nature, from intellectual property rights and commercialization of technology to ethical issues, unemployment concerns and conflict between public and private interests. We will try to address them in ongoing and further researches in this field.

CONCLUSIONS

The conducted analysis makes it possible to admit many pros and cons in the field of AI using in healthcare. Undoubtedly this is a promising area with a lot of gaps and grey zones to fill in. Furthermore, the main challenge is not on the technology itself, which is rapidly growing, evolving, and uncovering new areas of its use, but rather on the legal framework that is clearly lacking appropriate regulations and some political, ethical, and financial transformations. Thus, the core questions regarding this are as follows: is technology by its nature suitable for healthcare at all? Is the current legislative framework looking appropriate to regulate AI in terms of safety, efficiency, premarket, and postmarked monitoring? How the model of liability with connection to AI technology using in healthcare should be constructed? How to ensure privacy without the restriction of AI technology use? Should intellectual property rights prevail over public health concerns? Many questions to address in order to move in line with technology development and to get the benefits of its practical implementation.

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ORIGINAL ARTICLE

DIFFERENTIATION OF CRIMINAL LIABILITY OF MEDICAL PROFESSIONALS

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ABSTRACT

The aim: Determining the need to differentiate the criminal liability of medical workers for damage caused in the course of professional activity.

Materials and methods: This following research is based on an analysis of laws (21 laws), court judgments and case files (108 judgments and 8 case files), judgments of the European Court of Human Rights (4) and the legal doctrine of criminal law. Comparative, systematic, analytic, and empiric methods have been used in this research. During the preparation of this article the results of personal experience of the scientific work (17 years), the experience of advocacy (11 years), and the experience of the Supreme Court's judge have been applied.

Results: The analysis of case files, thoughts of scientists and lawyers-practitioners allowed to propose criteria and indicators influencing increasing or decreasing of social dangerousness of actions committed by medical professionals. It is noted that the necessity of the legislator to consider the close interrelation of professional medical services and influence on the health of persons who demand medical services or need health care during differentiation of criminal liability.

Conclusions: The necessity of differentiating approach to the criminal liability of medical professionals who inflict health damages or death is stated in comparison with the liability of general subjects of a crime.

KEY WORDS: a differentiation of criminal liability, a medical worker, a criminal offense

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INTRODUCTION

Criminal liability for death or bodily injuries cannot be equal. Such damages can have caused by various forms of guilt (intent or negligence), by different aims (vengeance, obtaining profits), under different circumstances (during medical services, as a result of the conflict), to different victims (old people, minors), by different subjects (general or special), etc. Such damage may be caused by persons who are closely related to the provision of professional medical services.

Obviously, the professional activity of medical professionals is engaged with influence upon the health of those who demand medical services or who need health care. That's why there is an increased risk of inflicting health damages or death. Considering this fact, the question arises if it is necessary to differentiate criminal liability between medical professionals and general subjects of crime inflicting the same pecuniary or physical damages.

THE AIM

This research aims to ground the necessity of medical professionals criminal liability differentiation for damages inflicted while performing their professional duties. First of all, the answer is to be found whether in any case of causing damages (pecuniary or physical) medical professionals must bear criminal liability.

MATERIALS AND METHODS

This research is based on philosophical, comparative, analytic, systematic, empiric, and other methods, methods of formal logic, and methods of interpretation. The empiric basement of this research consists of case files (8 case files, which have been the subject of Supreme Court consideration, as well as separate opinions of judges concerning results of these criminal proceedings), 108 trial courts and courts of appeal judgments, conclusions of the Department of Analytical and Legal Work of Supreme Court considering the subject of the analyzed issue, judicial statistics for the period of 2018-2019 provided by the State Judicial Administration of Ukraine, a summary of the judicial practice, made by the Law Department of the Supreme Court, judgments of the European Court of Human Rights (4 judgments). Documents of medical associations (of the USA and Australia) and criminal codes of certain states (Ukraine, Poland, Latvia, and Slovenia) have been analyzed too.

Personal experience of work as a judge has been applied. For instance, the author of the article was the reporting judge during criminal proceedings concerning the accusation of the medical professional whose misconduct caused the death of a minor (case file no. 439/397/17) [1]. This proceeding became the subject of consideration by the Grand Chamber of the Supreme Court, because of the

exclusive legal problem of the possibility of exemption of a medical professional from criminal liability.

RESULTS

Analysis of case files, thoughts of scientists and practical workers allowed to propose criteria and indicators influencing increasing or decreasing of social dangerousness of actions committed by medical professionals. This is said about the necessity of the legislator to consider the close interrelation of professional medical services and influence on the health of persons who demand medical services or need health care during differentiation of criminal liability.

To achieve the principle of justice, the legislator shall differentiate the criminal liability of medical professionals for damages inflicted while performing their professional duties. This is necessary to take into account the permanent risk of damaging health or depriving the life of the patient. At the same time, this is important to consider the special education of a medical professional and his voluntary choice of obligations to provide health care and medical services.

Special grounds or requirements for exemption from criminal liability considering such a feature of special subject of crime as a medical professional shouldn't be provided. These provisions of the general part of criminal law shall be universal without any dependence on special features of the subject of crime.

We suppose that the criminal liability of medical professionals for inflicting intentional physical damage shall be envisaged by general legal norms. At the same time, medical professional who has caused this damage at the patient's demand, shall bear the liability differentiated decreasingly (by prescribing privileged norm).

Criminal liability for negligence causing damages shall be imposed by special norms. Permanent risk of inflicting damage to patients due to the specificity of the professional duties of medical professionals must be taken into account by decreasing the lower limits of sanctions in comparison with sanctions of general norms envisaging criminal liability of the general subject.

At the same time, the criminal liability of a medical professional who has caused physical damage to his patient during the official working time and in a state of alcoholic or drug intoxication shall be differentiated increasingly.

A medical professional cannot be a subject to criminal liability for pecuniary damages. Such damages may be compensated according to civil procedures.

DISCUSSION

The primary role of the differentiation of criminal liability is achieving justice. So, differentiating criminal liability according to the criteria of a character or level of social dangerousness, personal characteristics of guilty one must result in prescribing in the law the borders for providing forms of criminal liability.

Legislators of different states use various means of differentiation of criminal liability. We will not define all the volume of means of criminal liability differentiation. Nevertheless, we will highlight the ones which are connected with the subject of this research. It is said about the exemption from criminal liability, qualified and privileged features of bodies of crime, prescribing special bodies of crime, defining borders of punishment. These means will be analyzed only in part, concerning committing criminal actions by the medical professional.

This is worth to be mentioned, that in some states, the criminal liability of medical professionals is envisaged by general legal norms (Poland, Slovenia). In the other – legislator prescribes special norms (Ukraine, Latvia). Scientists pay much attention to studying of the legislative approaches to the differentiation of medical professionals' criminal liability in the criminal laws of different states. They indicate grounds taken into consideration by national legislators in this process as well [2, 3, 4].

Usually, this is said that medical professionals shall bear stricter level of liability, than the other people who inflicted damage to health or death. However, we suppose that suggestions on increasing strictness of the criminal liability of a medical professional must be made only after considering how often he is at risk of inflicting damage to his patient's health. Regular professional activity of medical professionals is closely connected with providing health care to those who need them or medical services to those who demand.

Peculiarities of professional activities of medical professionals and permanent risk of inflicting damage to health or death of the patient were a separate aspect of research of the exemption from criminal liability problem concerning reconciliation with the victim of crime (case file no. 439/397/17) [1]. In this case, the doctor-anesthesiologist of the anesthesiology and resuscitation department of one of the local hospitals has been charged in inadequate fulfillment of professional duties, negligent medical manipulation (puncture of left collarbone vein by injection needle for mounting catheter). This medical manipulation has been performed contrary to the common technique of catheterization of collarbone vessels. Such action has caused the death of the minor.

102 court judgments have been analyzed while working over the mentioned criminal proceeding [5]. This analysis gives reason to state that in 94% of proceedings, courts have delivered judgments concerning exemption from criminal liability of doctor due to the reconciliation with the family of the deceased patient. Only 7 proceedings are resulting in rejection of the application of a guilty person for exemption from criminal liability. These rejections have been motivated by the impossibility of reconciliation because of the irreversibility of consequences in the form of death, which cannot be compensated to the deceased.

That's why a situation in practice of criminal law application has occurred resulting in the possibility of exemption from criminal liability due to reconciliation with the family of the deceased by most of the medical professionals who have caused negligently death to their patients.

The Grand Chamber of the Supreme Court has stated that the right of reconciliation is personal; it cannot be acquired by another person or delegated to anyone. If death is caused

as the result of a crime (medical as well) then nobody can (even relatives) express the will of the victim for reconciliation with the accused. That's why in such case exemption from criminal liability due to reconciliation is impossible.

It should be stressed that all 16 judges in this proceeding have supported such an approach; there have been no separate opinions or objecting points of view. The mentioned approach has been generally supported by members of the Scientific and Advisory Board of the Supreme Court, who have given their scientific conclusions concerning the exclusive legal problem in this case.

From the stated above it is obvious that it is inappropriate to differentiate grounds and requirements of an exemption from criminal liability basing on the feature of committing a crime by the medical professional. Grounds and requirements of an exemption from criminal liability are to be universal for all subjects of crime.

Prescribing qualified or privileged features, formulation of special bodies of crime, defining borders of punishment are the following means of the differentiation of criminal liability. Criteria decreasing or increasing social dangerousness of crime committed by a medical professional while performing his professional duties shall not be omitted by the legislator. Taking into account the fact that damages inflicted as the result of performing professional duties by medical professionals are widespread it is justified to highlight the necessity to define criteria that provide support for complex differentiation of criminal liability, though this question concerns world medical practice globally.

A medical professional is in the state of permanent risk of causing damage. The essence of the medical profession is tightly interrelated with the necessity to evaluate the state of health of the patient and to provide health care he certainly needs. Traditionally medical professionals use clinic protocol – a framework of medical treatment, which must be applied in any certain clinic situation. However, peculiarities of the human body of a patient, existing illnesses, etc. cause undoubted influence on the general view on medical treatment of any patient. These aspects are sometimes not evident and are not considered by the doctor. By the way, mistakes resulting from the peculiarities of the patient and his body may occur during medical treatment as well as during any other professional activity. As researchers state, each doctor does his/her duties in the wrong way at least once in his/her career [6]. Moreover, following data provided by the World Health Organization, medical mistakes occur in quantity from 8 to 12% of all situations of hospitalization in the states of the European Union [7]. Types of medical mistakes as well as questions of the feasibility of medical professionals' criminal liability are researched by specialists in criminal and medical law [8, 9, 10].

Positive influence on the state of a patient's health is the aim of a medical professional. However, sometimes such positive influence doesn't occur. Or even worse – the state of the patient's health deteriorates, death or bodily injuries happen.

Researching the problem of criminal liability of medical professionals R. Ferner suggests that a medical professional shall bear criminal liability for intentional damage or damage inflicted in the state of inebriation or drug intoxication [11].

Damage by medical professional acting with direct intent can be caused in two situations. First – inflicting damage on patient's demand (for instance euthanasia) or – deliberate damaging the patient's health acting with personal motives (vengeance, mercenary motive, etc.)

In the first of the mentioned situations, when the patient himself asks about inflicting damage to health even causing death motivated by strong pain as the result of illness, incurable illness, we suppose that there are grounds for decreasing the level of criminal liability of a medical professional. The European Court of Human Rights in the case of Pretty v. the United Kingdom (Application no. 2346/02) [12] has stated, that the right to be deprived of life by a third person cannot be interpreted using Article 2 of the Convention. However, in the case concerning the right to access medicine, able to cause the death of the applicant (who has a mental illness), the European Court of Human Rights noted, that state authorities shall obstruct a person to deprive herself life if this decision is not conscious and willful. (Case of Haas v. Switzerland (Application no. 31322/07)). We suggest that the intensity of criminal influence on a guilty person must be substantially decreased if death has been caused by the demand of a patient.

If deliberate inflicting health damages or death are made under the influence of "dirty" motives – the strictness of criminal liability of a medical professional must increase, taking into account that the patient addressed for medical service, but instead received injury. At the same time, such situations are quite rare. That is why strictness of criminal liability can be increased by a court in the process of individualization of criminal liability. Prescribing mentioned aggravating circumstances in the criminal law act is unjustified considering their exclusiveness.

Thus, criminal liability for deliberate causing patient's death or bodily injury by medical professional shall be differentiated only when it is inflicted on patient's demand (by decreasing strictness). When this damage is inflicted under the influence of other motives, then increase of the intensity of means of criminal legal impact can be provided at the stage of imposing punishment by a court (in the process of individualization of criminal liability), without prescribing such an increase in the criminal law act.

Criminal liability of medical professionals for negligent causation while performing professional duties death or health injury is necessary. Court's judgments demonstrate that criminal negligence during medical treatment in many cases is evident and cannot be ignored by the state.

N. Gutorova, O. Zhytniy, and T. Kahanovska aptly observe that in the states where special norms concerning medical negligence are prescribed, sanctions for committing this crime are less strict [2]. In our opinion, a legislator while defining borders of sanction consider the indicator of permanent risk of causing death or bodily injury while performing professional medical treatment. We consider such an approach as justified. Moreover, at the stage of

individualization of criminal liability courts often impose punishments which are not associated with imprisonment.

Such an example is described in the case file no. 447/781/16-к. the doctor has finished with the delivery of a baby, but after a while noticed the woman is bleeding. According to the forensic medical examination conclusion, the doctor has breached the demands of clinic protocols "Obstetric bleeding" and "Hemorrhaging shock"; undiagnosed partial uterus rupture, underestimation of blood loss and total state of the woman in labor, untimely calling anesthesiologist, untimely informing hospital administration and department caused aggrieved hemorrhaging shock, irreversible changes in main parts of the human body, late surgery and death [14]. The court has imposed punishment of 2 years of confinement but exempted guilty person from serving it due to the limitation period ending.

At the same time, analyzing the court judgment the conclusion can be made that there is sufficient difference in social dangerousness between situations when a medical professional acts diligently, use all the possible means to achieve a positive influence on the human body but fails or when a medical professional provides medical treatment in the state of inebriation or leaves the patient without necessary treatment at all.

Damage inflicted by a medical professional in the state of inebriation or drug intoxication must aggravate his liability when this state occurred while working and while being obliged to perform health care or medical services.

Patients' treatment, medical manipulations (as well as surgeries), performing the other professional functions by a medic in the state of inebriation or drug intoxication is an indicator influencing the level of social dangerousness of the committed. The fact of the subject's realization, that his professional activity is connected with medical treatment, so the risk of inflicting damage is high, but ignored this, is the most important factor in such cases.

A medical professional committed himself to qualified medical treatment, provided in time. This approach is recognized worldwide, which can be seen in different legal acts and ethical codes. For instance, article 1.1.6 of the Code of Medical Ethics of AMA (American Medical Association) provides that physicians individually and collectively share the obligation to ensure that the care patients receive is safe, effective, patient centered, timely, efficient, and equitable [15]. This aspect is similarly regulated by the Medical Board of Australia in article 1.4 of A Code of Conduct for Doctors in Australia. Provisions of the mentioned Code state that doctors must make the care of patients their first concern and to practice medicine safely and effectively [16]. In Bases of the legislation of Ukraine on health care declare obligations of the doctor to perform timely and qualified diagnosis and treatment of a patient (part 2 of article 34) [17].

That is why while performing his duties a medical professional must be in such a state that allows him to provide timely and qualified health care. Being in the state of inebriation or drug intoxication while performing professional duties and inflicting deadly bodily injuries of the patient must increase the strictness of the medical professional's criminal liability. Since actions leading to a state of intoxication are accompanied by an understanding of the necessity of performing health care or medical services.

We suggest legislator to differentiate criminal liability of medical professional who caused patients death or health damages directly in the provisions of the Criminal code.

Character and volume of socially dangerous consequences is an indicator that reflect increasing social dangerousness of crime, committed by a medical professional. The legislator usually differentiates criminal liability for consequences in the form of bodily injuries of a certain level of severity or the form of death. Minimal damage resulting in criminal liability of medical professional shall be equal with the level of severity of bodily injury resulting in criminal liability of general subject. Tarasevych T. in her PhD thesis makes similar conclusions. She suggests that consequences shall be directly named in the dispositions of certain articles of the Criminal code instead of the term "heavy consequences" [18].

Taking into consideration that medical professionals provide medical treatment or services, they shall only be incriminated for consequences of death or bodily injury. Inflicting pecuniary damages is indirectly related to the duties of a medical professional and legal relation concerning these duties. That is why we suggest that such damage must be compensated in civil procedure. It is properly said in the literature that criminal intervention considering the damage caused by a medical professional is appropriate when it is really necessary due to the lack of other effective legal mechanisms [19]. There are a lot of examples in court judgments of compensations for pecuniary or non-pecuniary damages inflicted as the result of improper medical treatment or service. For instance, the Supreme Court judged (case file no. 537/4429/15-ц) the hospital to pay non-pecuniary damage for violations during delivery of a baby [20].

In this article, we have analyzed part of the differentiation means of medical professionals' criminal liability. At the same time, it is necessary to research the feasibility of envisaging features influencing the criminal liability of a medical professional in the Criminal Code, such as the age of the victim, the psychological and emotional state of a medical professional during performing medical treatment, a multiplicity of crimes (as well of negligent ones), qualification of the doctor, features of victim's state (state of emergency, life-endangering state, etc.) These questions will be the subject of further studies concerning the differentiation of medical professionals' criminal liability for inflicting damage while performing their professional duties.

CONCLUSIONS

Considering the peculiarities of the medical profession, the permanent influence of treatment and services of medical professionals on such values as life and health, we suggest that there are grounds for differentiation of medical professionals' criminal liability for damages caused

while performing their professional duties. The necessity to differentiate criminal liability of medical professionals alongside general subjects of crime is motivated by such features of the first group of subjects as special education, professional duty and permanent risk to inflict death or health damages. The first two features increase the level of social dangerousness, the last one – decreases. Acting in a state of inebriation or drug intoxication, deliberate causing physical damage on patient's demand are the indicators influencing the level of social dangerousness of a medical professional. Such a differentiating approach helps the legislator to set justified borders of criminal law act application and to provide clear limits for the individualization of criminal liability by a court.

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ORIGINAL ARTICLE

THE PROBLEMS OF CRIMINALIZATION OF THE SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH (ARTICLE 8 OF THE COUNCIL OF EUROPE CONVENTION ON THE COUNTERFEITING OF MEDICAL PRODUCTS AND SIMILAR CRIMES INVOLVING THREATS TO PUBLIC HEALTH)

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ABSTRACT

The aim: Medicrime Convention is a first international treaty against counterfeit medical products and similar crimes involving threats to public health. There are problems in criminalization of those acts that are listed in Art. 8 of the Medicrime Convention because the term of "similar crimes" is absent in the current criminal legislation of Ukraine.

Materials and methods: The conducted study is based on the analysis of the provisions of the Medicrime Convention, the criminal legislation of Ukraine. The following methods: dialectical method; hermeneutic method; system-and-structural method; comparative-and-law method were used.

Results: Comparison of the provisions of the Medicrime Convention allows to state that crimes in its Articles 5-8 that are different from those provided for in Art. 5-7 of this Convention and form independent types of actions, are at least "placing on the market" of medicinal products and medical devices provided in subparagraph "a" of paragraph 1 of Art. 8 and "commercial use of original documents" specified in subparagraph "b" of paragraph 1 of Art. 8.

It's an assumption that Art. 5-8 of the Medicrime Convention provide for such independent types of crimes involving threats to public health as: 1) manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories as well as medicinal products, medical devices, active substances and excipients; 2) the supplying, the offering to supply, the brokering, the trafficking, the keeping in stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories; 3) the making of false documents or the act of tampering with documents; 4) placing on the market of medicinal products, medical devices; 5) the commercial use of false documents.

Conclusions: The term of "similar crimes" in Art. 8 of the Medicrime Convention covers multi-ordinal intentional acts that constitute different types of independent crimes involving threats to public health, as well as special kinds of some of them. These types of crimes are not the same (identical).

KEY WORDS: Elements of crime, Falsified medical products, Medicrime Convention, Health Care, Public Health

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INTRODUCTION

On 28th October 2011, the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (hereinafter referred to as the "Medicrime Convention" [1] was signed on behalf of Ukraine. Medicrime Convention is a first international treaty against counterfeit medical products and similar crimes involving threats to public health. According to Art. 5-8 of the Medicrime Convention, each Party shall take the necessary legislation and other measures to establish as offenses under its domestic law a) the intentional manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories, falsification of medicinal products, medical devices, active substances and excipients (paragraphs 1, 2 of Article 5 of the Medicrime Convention), b) when committed intentionally, the supplying or offering to supply, including brokering, the trafficking, including keeping in stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories (paragraph 1 of Article 6 of the Medicrime Convention), (c) the making of false documents or the act of tampering with documents, when committed intentionally (paragraph 1 of Article 7 of the Medicrime Convention), and (d) the so-called "similar crimes involving threats to public health" (Article 8 of the Medicrime Convention). Crimes provided in Art. 5-7 of the Medicrime Convention are generally referred to as "manufacturing of counterfeits" (Article 5), "the supplying, offering to supply and trafficking in counterfeits" (Article 6) and "falsification of documents" (Article 7) in the names of these articles of the Medicrime Convention.

There are problems in defining the range of those crimes (criminal offenses), which are currently provided for in the Criminal Code of Ukraine (hereinafter referred to as CC), but are similar to those specified in Art. 5-7 of the Medicrime Convention [2, p. 28], as well as the criminal-

ization of those acts that are listed in Art. 8 of the Medicrime Convention because the term of "similar crimes" is absolutely absent in the current criminal legislation of Ukraine. It should be mentioned that provisions of Article 8 (namely par. a(i)) relate to the criminal law protection of intellectual property relations, which is indirectly related to public health issues. [3]

The lack of solutions to these problems not only hinders the fulfilment of the mentioned conditions of the Medicrime Convention, but also makes ineffective mechanisms for preventing crimes related to counterfeiting of medical products and other crimes involving threats to public health. The ineffectiveness of the use of some of these mechanisms was once emphasized in the Concept of implementation of state policy to prevent counterfeiting of medical products, approved by the order of the Cabinet of Ministers of Ukraine of April 3, 2019 No.301-r. At the same time, the solution of these problems in the science of criminal law of Ukraine is mainly to formulate a scientific model of the criminal law mechanism to prevent crimes defined in the Medicrime Convention [4, pp.856-861], the need to ensure clarity of the conceptual apparatus and interpretation of criminal legislation of Ukraine, unity of law enforcement practice and efficiency of realization of norms of the criminal legislation of Ukraine which requires appropriate amendments to the Criminal Code of Ukraine, their justification, scientific confirmation and empirical proof [5, p.6].

THE AIM

An adequate understanding of the term of "similar crimes" should be offered, types of crimes (criminal offenses) provided for in the Criminal Code of Ukraine and are similar to those defined in Art. 5-7 of the Medicrime Convention should be identified, as well as which acts listed in Art. 8 of the Medicrime Convention still not provided for in the CC of Ukraine as crimes (criminal offenses) of certain types and thus "fall out" of criminalization should be found out based on the specifics in Art. 8 of the Convention on Medicrime acts included in the term of "similar crimes involving threats to public health", and taking into account the analysis of the relevant provisions of the CC of Ukraine.

MATERIALS AND METHODS

The conducted study is based on the analysis of the provisions of the Medicrime Convention, the criminal legislation of Ukraine. The following methods: dialectical method – while clarifying the nature of similar crimes involving threats to public health, and determining the content of components of such crimes under the Criminal Code of Ukraine; hermeneutic method – while interpreting of basic terms and their constructions, as well as formulating of offers to improve the norms of the CC; system-and-structural method – while substantiating the systemic criminal law protection of public health; comparative-and-law method – while determining the common and different provisions in the provision of similar crimes involving threats to public health, in the Medicrime Convention and the criminal legislation of Ukraine were used to achieve this purpose.

RESULTS AND DISCUSSION

1. Problems of marking the relevant social-and-legal phenomena with adequate terms and interpretation. The term "Similar crimes involving threats to public health"[6] is used in English in the official text of the Medicrime Convention which in the official Ukrainian-language text of the Convention is translated as "подібні злочини, що загрожують охороні здоров'я" [7]. Thus, when translating the text of the Medicrime Convention, the English term "similar" was translated into Ukrainian as "подібні" and as "схожі" into Russian which cannot be considered an unambiguous and accurate method of legislative technique, especially given the different meanings of these terms.

The English-language term of "similar" should be interpreted taking into account the similarity, the identity of something [8]. However, there is no such unambiguity while interpreting of the Ukrainian-language term of "подібний" because this term is used in two different meanings: 1) the presence of common features, properties with something; 2) sameness.

Thus, a problem of replacing the term of "подібні злочини" in the Ukrainian-language text of the Convention translation with another term (for example, "тотожні злочини") reflecting the ambiguity inherent to the term of "similar" arises. The solution to this problem and the use of the necessary terminology depends on the special-and-legal level of use of the term of "подібні злочини", which can be seen below.

2. Special-and-legal level of solving the problem of using the term of "similar crimes" ("подібні злочини") **in legal acts.**

2.1. The term of "similar crimes" in Art. 8 of the Medicrime Convention **is used to specify** activities committed intentionally, in so far as such an activity is not covered by Articles 5-7 of this Convention as offenses, but have the following types: 1) the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of: medicinal products without authorisation where such authorisation is required under the domestic law of the Party; or medical devices without being in compliance with the conformity requirements, where such conformity is required under the domestic law of the Party; 2) the commercial use of original documents outside their intended use within the legal medical product supply chain, as specified by the domestic law of the Party.

2.2. The following should be considered ***at the ratio*** of the types of "similar crimes" defined in Art. 8 of the Medicrime Convention and the types of those crimes provided in Art. 5-7 of this Convention:

a) "manufacturing" (its subject is medicinal products and medical devices) provided for in subparagraph "a" of paragraph 1 of Art. 8 is ***a special kind*** of "manufacturing", which is specified in paragraph 1 of Art. 5 of the Convention and the subject of which is "counterfeit medical

products, active substances, excipients, parts, materials and accessories", as well as medicinal products, medical devices, active substances, excipients, parts, materials mentioned in paragraph 2 of Art. 5;

b) "the keeping in stock for supply, importing, exporting, supplying, offering to supply" (their subject is medicinal products and medical devices) entrenched in subparagraph "a" of paragraph 1 of Art. 8 is ***a special kind*** of such actions as defined in paragraph 1 of Art. 6 "the supplying or the offering to supply, including brokering, the trafficking, including keeping in stock, importing and exporting" (the subject of these actions is "counterfeit medical products, active substances, excipients, parts, materials and accessories");

c) "placing on the market" of medical products and medical devices should be considered ***an independent type of crime*** which is defined in subparagraph "a" of paragraph 1 of Art. 8 and does not form a special type specified in paragraph 1 of Art. 5 of the Convention "manufacturing";

d) "the commercial use of original documents" provided for in subparagraph "b" of paragraph 1 of Art. 8 in connection with the indication of "outside their intended use" is ***an independent type of crime*** and does not form a special kind of "the making of false documents or the act of tampering with documents" provided for in paragraph 1 of Art. 7.

Thus, a comparison of the mentioned provisions of the Medicrime Convention allows us to state that crimes in its Articles 5-8 that are ***different*** from those provided for in Art. 5-7 of this Convention and form independent types of actions, are at least "placing on the market" of medicinal products and medical devices provided in subparagraph "a" of paragraph 1 of Art. 8 and "commercial use of original documents" specified in subparagraph "b" of paragraph 1 of Art. 8.

Therefore, it should be assumed that Art. 5-8 of the Medicrime Convention provide for such independent types of crimes involving threats to public health as: 1) manufacturing of counterfeit medical products, active substances, excipients, parts, materials and accessories as well as medicinal products, medical devices, active substances and excipients; 2) the supplying, the offering to supply, the brokering, the trafficking, the keeping in stock, importing and exporting of counterfeit medical products, active substances, excipients, parts, materials and accessories; 3) the making of false documents or the act of tampering with documents; 4) placing on the market of medicinal products, medical devices; 5) the commercial use of false documents.

CONCLUSIONS

The term of "similar crimes" in Art. 8 of the Medicrime Convention covers ***multi-ordinal*** intentional acts that constitute ***different types*** of independent crimes involving threats to public health, as well as ***special kinds*** of some of them. These types of crimes are not the same (identical). From this point of view, the use of the Ukrainian-language term "подібні" in the translation of the official text of the Medicrime Convention is quite justified.

2.3. When ***comparing*** these types of crimes under Art. 5-8 of the Medicrime Convention, and their corresponding kinds with the types of crimes defined in the ***Special Part of the CC of Ukraine*** it should be taken into account the following.

1) intentionally illegal production of medicinal products, as well as purchasing, transportation, sending, storage for selling purposes or sale of intentionally illegal medicinal products provided for in Art. 321-1 of the CC of Ukraine, in principle, is consistent with the requirements of Art. 5, 6, 8 of the Medicrime Convention;

2) falsification of documents provided for in Art. 7 of the Medicrime Convention, as well as the commercial use of original documents relating to the falsification of medicinal products referred to in subparagraph "b" of paragraph 1 of Art. 8 of this Convention, are not directly (textually) singled out in the articles of the Special Part of the CC of Ukraine, but may be covered by the relevant provisions of Art. 358 ("Forgery of documents and use of forged documents") and Art. 366 ("Forgery in office") of the CC.

3) the CC of Ukraine does not contain criminalization of the manufacturing, the keeping in stock for supply, importing, exporting, supplying, offering to supply or placing on the market of medical devices, which is specified in subparagraph "a" of paragraph 1 of Art. 8 of the Medicrime Convention

2.4. ***The disadvantage*** of using the term of "similar crimes" ("подібні злочини") in the legal act, which is the source of criminal law of Ukraine, is that it indicates ***an analogy of the application of criminal law, which is prohibited***. That is, the prohibition of the so-called "analogy of law" (*analogia legis*). This prohibition is indicated in part 4 of Art. 3 of the CC of Ukraine. In addition, the legal guidelines for prohibiting the analogy of the application of criminal law are requirements of the definition of criminality and punishment provided for in Part 2 of Art. 4 of the CC of Ukraine, as well as other criminal law consequences of the act only of the CC of Ukraine. Therefore, the norms of the General and Special Parts of the CC, which define a specific type of crime, its individual kinds, types and sizes of punishments and other measures of criminal law nature, cannot be applied to monotypic factual situations which are not provided by these criminal law norms. Thus, the content of the analogy of its application prohibited in the CC of Ukraine is limited and "is narrowed" to its specific norms, which determine the criminality, punishment of the act and its other criminal consequences provided for in part 2 of Art. 4 of the CC of Ukraine.

Prohibition of the application of the criminal law by analogy prevents the "creation" of a new legal (regulatory) basis for determining the criminality and punishment of the act, as well as its other criminal consequences. Only specific norms of the CC are recognized by such basis according to part 2 of Art. 4 of the CC. Instead, if the current CC did not prohibit (allow) analogy in the application of its provisions, there would be at least two legal grounds

on which an act not directly provided for by the CC as a crime would be recognized as a specific type of the crime or its separate kind and entailed the application of a certain type of punishment or other measures of a criminal law character. The first such basis would be the relevant norms of the CC, which defined a particular type of crime or its particular kind and established the type and amount of punishment or other measures of criminal law character for its commission, and the second legal basis would be the relevant provision authorizing the application of the CC by analogy (such provision would in fact mean the possibility of establishing the criminality and punishment of the act, as well as other criminal consequences in monotypic situations, which are not directly provided for "within" the first basis). Thus, the prohibition of analogy in establishing the criminality and punishment of the act and its other criminal consequences should apply both to the norms of the Special Part of the CC and to the provisions of the so-called "regulatory laws" and subordinate legislation, if the norms of the Special Part of the CC have blanket dispositions and provide for the use of the provisions of such "regulatory laws" and subordinate legislation [9, pp. 135-136; 10, p. 51].

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ORIGINAL ARTICLE

MENTAL HEALTH OF A PERSON AS A CRITERION OF PERSONAL PARTICIPATION IN THE TRIAL DURING CRIMINAL PROCEEDINGS

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ABSTRACT

The aim of this work is to identify and analyze the key positions of the ECHR in the context of respect for the right to a fair trial (Article 6 of the European Convention on Human Rights (hereinafter – the Convention)) of a person suffering from mental disorders in criminal proceedings concerning the application of compulsory medical measures (hereinafter referred to as CMM); formulation of scientifically substantiated proposals for determining the restriction legality criteria of the right of a person suffering from a mental disorder to personal participation in the trial.

Materials and methods: During the preparation of the article, the following was processed: scientific research on ensuring the rights of persons suffering from mental disorders in criminal proceedings; provisions of international agreements on the provision of psychiatric care; the legal position of the ECHR on the observance of the right to a fair trial of persons suffering from mental disorders (6 decisions were analyzed in which the ECHR addressed these issues in the context of the requirements of Article 6 of the Convention); criminal procedural legislation of individual states; the results of a survey conducted by the authors of 88 judges (judges of local courts of Ukraine) on key issues of ensuring the participation of a person suffering from a mental disorder in a court hearing.

In the process of research a set of general scientific and special methods of cognition was used (comparative-legal method, systemic-structural method, generalization method, method of analysis and synthesis, method of sociological research, method of expert assessments, etc.).

Results: According to the results of the research: a) the legal positions of the ECHR to ensure the right of a person suffering from a mental disorder to a fair trial are identified and generalized (Article 6 of the Convention); b) criteria for the legality of restricting the right of a person suffering from a mental disorder to personal participation in the trial are proposed.

Conclusions: An analysis of the ECHR's key positions led to the conclusion that there was a violation of a person's right to a fair trial in national case law (Article 6 of the Convention), due in part to the lack of clear criteria for legally restricting a person's right to a trial.

KEY WORDS: mental health, expert opinion, right to a fair trial, mental disorder, ECHR practice

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INTRODUCTION

The current development of the case law of the ECHR shows a fairly high level of appeals to this European institution of persons suffering from mental disorders whose claims are violations of the right to liberty and security (Article 5 § 1 (e) of the Convention) and the right to a fair trial (Article 6 of the Convention). The article will consider the key positions of the ECHR on the personal participation of a person suffering from a mental disorder in the trial from the standpoint of compliance with Art. 6 of the Convention right to a fair trial. We should note that some issues in this area were previously published by the authors of this article together with Olena A. Leiba [see at: 1]. However, in the framework of this study, the authors intend to develop scientific ideas aimed at addressing the issue of personal participation of persons with mental disorders in court proceedings in the context of international standards and legal positions of the ECHR to ensure the right to a fair trial (Art. 6 of the Convention).

THE AIM

The aim of this work is to identify and analyze the key positions of the ECHR in the context of respect for the right to a fair trial (Article 6 of the European Convention on Human Rights (hereinafter – the Convention)) of a person suffering from mental disorders in criminal proceedings concerning the application of compulsory medical measures (hereinafter referred to as CMM); formulation of scientifically substantiated proposals for determining the restriction legality criteria of the right of a person suffering from a mental disorder to personal participation in the trial.

MATERIALS AND METHODS

During the preparation of the article, the following was processed: scientific research on ensuring the rights of persons suffering from mental disorders in criminal proceedings; provisions of international agreements on the provision of psychiatric care; the legal position of the ECHR on the observance of the right to a fair trial of persons suffering from mental disorders (6 decisions were analyzed in which the ECHR addressed these issues in the context of the requirements of Article 6 of the Convention); criminal procedural legislation of individual states; the results of a survey conducted by the authors of 88 judges

(judges of local courts of Ukraine) on key issues of ensuring the participation of a person suffering from a mental disorder in a court hearing.

In the process of research a set of general scientific and special methods of cognition was used (comparative-legal method, systemic-structural method, generalization method, method of analysis and synthesis, method of sociological research, method of expert assessments, etc.).

RESULTS

As it is noted in the special literature, "mental disorder (a term often used in mental health legislation and international literature on mental health tribunals) is recognized as a global health concern and is one that has attracted significant international attention" [2, p. 494]. The World Health Organization demonstrates dangerous statistics – mental disorders are one of the top public health challenges in the WHO European Region, affecting about 25% of the population every year [3]. In the case of committing socially dangerous acts by persons suffering from mental disorders, the legislation of foreign countries provides for a special procedure for criminal proceedings. In general, the peculiarities of the proceedings against persons suffering from mental disorders are embodied at the level of international legal acts, such as: the Convention on Human Rights and Biomedicine of 4 April 1997; United Nations General Assembly Resolution *Principles for the Protection of Persons with Mental Illness and the Improvement of Psychiatric Care*, № 46/119 of 18 February 1992; Recommendation of the Committee of Ministers to member states on the legal protection of persons suffering from mental disorders who are involuntarily detained as patients, № R (83) 2 of 22 February 1983; Recommendation № 1235 on psychiatry and human rights of 01 January 1994, Recommendation 818 on the situation with mental illness of 08 October 1977, etc.

The analysis and generalization of the case law of the ECHR allows singling out certain ECHR approaches to the personal participation of a person suffering from a mental disorder in court proceedings.

1. A person suffering from a mental disorder shall have access to a court and the opportunity to be heard in person or through any form of legal representation (See at: § 71 Case of Shtukaturov v. Russia [4]; § 62 Case of Zagidulina v. Russia [5]; § 39 Case of Gorshkov v. Ukraine [6]). This position of the ECHR embodies the international legal standard provided for in Art. 6 of the Convention – the right to a fair trial. In its decisions on persons suffering from mental disorders, the ECHR has repeatedly recalled that from the very notion of a fair trial, it is clear that a person accused of a crime must be given the right to be present and to participate effectively in the trial (See at: §106 Case of Romanov v. Russia; § 100 Case of Proshkin v. Russia). In addition, the ECHR considers alternative participation in the court hearing of its representatives to be a form of exercising the right to a personal presence in court. Thus, modern criminal procedure legislation of many states provides for double representation of the rights of a person suffering from a mental disorder, in the form of participation of a lawyer and a legal representative (the Criminal Procedure Code of the Russian Federation (Articles 437, 438); the CPC of Ukraine (Articles 512); the CPC of Moldova (Articles 493, 494); the CPC of Belarus (Articles 445, 446); the CPC of Kazakhstan (Articles 512, 513); the CPC of Kyrgyzstan (Articles 467, 468), the CPC of Poland (Articles 76, 79)) and others. Due to the particular vulnerability of a person suffering from a mental disorder, the mandatory participation of their representatives in criminal proceedings (in particular, in court proceedings) is of particular importance. After all, it provides an adequate level of protection of the rights and legitimate interests of a person whose mental disorder does not allow them to exercise their procedural rights independently.

However, at the present stage of development of case law there is a tendency towards *the priority of ensuring personal participation in the trial of a person suffering from a mental disorder*. For example, in Case of Zagidulina v. Russia the applicant was recommended hospitalization, with which Ms. Zagidulina disagreed. On the same day the hospital applied to the court for a sanction for the applicant's involuntary hospitalization. The trial was attended by a prosecutor, a psychiatrist and a representative of a psychiatric hospital, who requested a hearing in the applicant's absence as she could not attend the hearing on medical grounds. The hearing was held in the absence of the applicant and her representative (§ 5-10). The ECHR emphasized that the applicant played a dual role in the proceedings: she was an interested party, and, at the same time, the main object of the court's examination. Therefore, hearing the applicant either in person or through some form of representation was indispensable for a "fair and proper procedure". Taking into consideration the applicant's clear and undisputed refusal to undergo any treatment and the domestic courts' awareness of this fact, which was reflected in their decisions, the need to ensure the applicant's right to be heard was ever more pressing (See at: § 62 of the Case of Zagidulina v. Russia) [5].

It should be noted that the ECHR has categorically stated in some cases that the participation of counsel and legal representative could not compensate for the absence of a person suffering from a mental disorder in the trial. This legal position has been demonstrated in a number of the ECHR cases. For example, in Case of Romanov v. Russia the Court noted that the psychiatrists' findings were identical as to the diagnosis, but differed in the choice of measures to be applied to the applicant: outpatient treatment or placement in a psychiatric hospital. The ECHR emphasized that such disagreement was of particular importance to the applicant's participation in the court hearing. The district court could not rule without a direct assessment of the applicant's testimony, and the presence of the applicant's lawyer could not compensate for his absence (§ 111-112) [7]. In Case of Proshkin v. Russia the ECHR criticized the following circumstances of the case. Thus, the trial court questioned the examination's findings

and therefore considered it appropriate to re-examine the applicant's psychiatric examination. However, not receiving the results of the new examination in time, the court ruled to apply CMM to the applicant (§ 31). In this situation, it was particularly important for the judges to hear the applicant in person and to ascertain his state of health. The court could not rule without a direct assessment of the applicant's conduct and the evidence provided by him. *The presence of the applicant's defense counsel and mother could not compensate for the applicant's inability to present his own arguments in court* (§104) [8].

Thus, the analysis of the above positions of the ECHR allows us to conclude that the ECHR recognizes: a) forms of implementation of the provisions of Art. 6 of the Convention right to a fair trial, personal participation in the trial of a person suffering from a mental disorder and/or the participation of their representatives (defense counsel, legal representative); b) *priority personal participation* in the court hearing of a person suffering from a mental disorder, as the *alternative participation* of their legal representatives is not always able to compensate for the lack of opportunity for the applicant to express their own position in court.

Survey results: Among the judges we interviewed, 99% were in favor of the inexpediency of mandatory participation in the court hearing of the person in respect of whom the issue of applying the CMM to them is being considered. In turn, the same number (99%) of respondents gave an affirmative answer to the question "Do you think that the alternative participation of the defense counsel and the legal representative of the person in respect of whom the application of the CMM is being considered could fully compensate for the absence of such a person in court?". Only one respondent expressed the view that the alternative participation of the defense counsel and the legal representative of the person under consideration of the application of the CMM could not fully compensate for the absence of such a person in the court hearing, and therefore the question of the person's participation in the court hearing should be resolved in each specific case. Thus, the results of the survey show that European approaches today are not always perceived at the level of legal awareness of national law enforcers. In view of this, the implementation of the approaches developed by the ECHR into national law is justified.

2. Establishing the fact of a person's mental illness does not automatically deprive them of their right to personal participation in the trial. This position was expressed in the Case of Proshkin v. Russia, in which the ECHR noted that "although not having an absolute character, the right of being heard enjoys such a prominent place in a democratic society and has such a fundamental value for the protection of an individual against arbitrariness on the part of public authorities, that the mere fact of the individual suffering from a mental illness, as well as his being declared legally incapacitated, cannot automatically lead to the exclusion of the exercise of that right altogether. It is the very weakness of a mentally ill defendant which should enhance the need for supporting his rights. In this context, authorities must show requisite diligence in ensuring the accused's right to be present in an effective manner and must act particularly carefully when infringing upon that right, so as not to place the mentally ill at a disadvantage when compared with other defendants who do enjoy such a right" (§ 102 of the Case of Proshkin v. Russia) [8].

Thus, the established fact of a person's mental disorder cannot automatically deprive them of the right to participate in the trial. However, a fairly illustrative example of violation of this thesis is the Case of Romanov v. Russia, where the ECHR found that the applicant had never taken part in a court hearing on the basis of a mental illness established by a panel of experts, which found that the applicant had: suffered from a psychological disorder in the form of profound dissociative psychopathy; committed the crime in a state of insanity; had a distorted perception of the circumstances surrounding the criminal proceedings, so he could not give adequate evidence (§ 20). At the same time, the ECHR examined two circumstances on the basis of which the district court refused to grant the applicant's request for personal participation in the hearing: a) the remand center does not bring persons suffering from a mental disorder to court (§ 23); b) the testimony of a person who has been declared incompetent is inadmissible evidence (§ 24). Analyzing the above circumstances, the ECHR concluded that "in the present case the authorities failed to take any steps to secure the applicant's attendance at the hearings. There is no indication that the applicant displayed any disturbed behavior or that his physical and mental condition otherwise precluded him from appearing before the court. The District Court's argument that the applicant's presence at the hearing was not required in that the testimony of the applicant as a mentally disturbed person could not be accepted as evidence is striking given that it was for the District Court to determine for the first time whether the applicant had committed the offence in a deranged state of mind and assess whether his mental condition required any compulsory medical care" (§ 109) [7].

At the present stage, the criminal procedure legislation of many states provides for the possibility of restricting the right of a person suffering from a mental disorder to participate in the trial based on the conclusions of forensic psychiatric examination on the nature and extent of their disease (CPC of the Russian Federation (Article 441); CPC of Belarus (Article 445); CPC of Kazakhstan (Article 511); CPC of Moldova (Article 496); CPC of Estonia (Article 400, CPC of Uzbekistan (Article 570)) and others. [1, p. 2448]. However, it should be emphasized that the expert's opinion in criminal proceedings on the CMM actually becomes key evidence. This is due to the fact that the medical aspect is crucial for the court to make both the final decision in the criminal proceedings on the CMM and the interim decision on the possibility of participation in the trial of a person suffering from a mental disorder (Survey results: Among the judges we interviewed, 98% agreed that in proceedings on the application of the CMM, the conclusion of a forensic psychiatric examination is de facto key evidence). At the same time, a balanced approach of judges to the objective assessment of the expert's conclusion (con-

clusions) on the mental state of a person acquires special significance, in particular, when deciding on the possibility of such a person's participation in a court hearing. After all, the case law of the ECHR shows examples of rather abstract conclusions of experts on the mental state of a person, which makes it impossible for them to be present during the trial. Thus, in the Case of Anatoliy Rudenko v. Ukraine the ECHR noted that according to the act at the time of the examination the applicant had suffered from "chronic paranoid personality disorder with delusional inclusions". His mental state was considered to be an impediment to his ability to participate effectively in court hearings. According to the expert's report, the applicant behaved casually and amicably, demonstrating a high level of intelligence, good memory and analytical skills, but also a certain superiority and categorical judgment (§ 31). The ECHR emphasized that *there was no compelling reason* to prevent the applicant from taking part in the proceedings. Thus, the experts did not provide any explanation as to why the applicant's mental state was considered to prevent him from participating effectively in the court hearings (§ 114) [9]. In the Case of Proshkin v. Russia the ECHR stated that it did not see any convincing evidence to substantiate that the applicant's conduct or mental condition prevented him from attending the trial in person (§ 103) [8]. In the Case of Romanov v. Russia the ECHR concluded that "the administration did not take any measures to ensure the applicant's presence at the court hearings. There is no evidence that the applicant behaved inappropriately or that his physical or mental condition in any way prevented him from participating in court" (§ 106) [7].

The ECHR therefore insists on the need for *evidence of the conduct of a person which prevents their personal participation in the trial.* Thus, when deciding on the legality of a trial in the absence of a person suffering from a mental disorder, judges should critically evaluate the conclusions of experts on the mental state of the person, taking into account other circumstances of the criminal proceedings. For example, in assessing whether a person's absence from a court hearing has been justified, the ECHR takes into account concomitant factors such as the nature and complexity of the issues before the national courts, their importance to the applicant, and whether the person's personal presence posed any threat to others or to themselves, etc. (§ 68 of the Case of Shtukaturov v. Russia) [4]. In our opinion, *the danger of a person to themselves and others* should be a criterion for the legitimacy of restricting a person's right to personal participation in court proceedings. Therefore, the conclusions of experts on the mental state of a person, in addition to their diagnosis, should answer the question of the danger degree of a person suffering from a mental disorder.

In the context of this issue, some authors rightly believe that there are various forms of inappropriate behavior that are not covered by the concept of danger, but make it impossible to participate in the trial of a person suffering from a mental disorder. For example, a person gets naked, imitates the voices of animals, etc. Such behavior is incompatible with the observance of the order of the trial and degrades the dignity of the person [10, p. 9]. Agreeing with the above point of view, we believe that in resolving the legality of restricting a person's right to personal participation in the trial, the second criterion is *behavior that degrades the honor and dignity of a person suffering from a mental disorder*.[1] In addition, our survey provides an opportunity to add to the list such a criterion as *the availability/unavailability of a person for verbal contact and communication with the participants of the court hearing.*

Survey results: the answers to the question "If the participation of the person in respect of whom the issue of application of the CMM is considered was not mandatory and this issue would be decided by a judge, then what criteria would be appropriate to take into account when making such a decision?" were divided as follows: only the danger of a person for themselves and others – 22%; the danger of the person for themselves and others and accessibility/unavailability of the person for verbal contact and communication with the participants of the court hearing – 78%. At the same time, in resolving this issue 99% of judges are ready to be guided only by the information reflected in the forensic psychiatric examination and only 1% of judges are ready to take into account not only the expert's position but also their own assessment of the person's visual perception and verbal communication.

3. A person suffering from a mental disorder has a dual role in court proceedings: he or she is an interested person and, at the same time, the main object of judicial investigation. (See at: §72 Case of Shtukaturov v. Russia; § 62 Case of Zagidulina v. Russia, etc.). Explaining the above position in the Case of Shtukaturov v. Russia, the ECHR stated that a person's participation is necessary not only to state their position on a case, but also for a judge to have their own idea of his or her mental state. In the present case, the Court agreed that "the applicant did indeed have psychiatric problems, but on the basis of the case file he was a relatively independent person. In such circumstances, it was absolutely necessary for the judge to have at least a brief visual contact with the applicant, and preferably his interrogation" (§ 72, 73) [4]. Thus, the manual for prosecutors emphasized the thesis that "A judge must determine if the defendant is fit to plead and to stand trial. This is a determination on the balance of probabilities if the defendant raises the issue, or if he contests it then it is for the prosecution to satisfy the court beyond a reasonable doubt" [11, p. 21].

The criminal procedure legislation of Ukraine provides for the obligatory participation in the court proceedings of a person in respect of whom the issue of application of the CMM is being resolved. This legal requirement in modern judicial practice is provided by videoconference between the courtroom and the psychiatric care facility where the person with the mental disorder is actually staying. In fact, in pursuance of the ECHR's position on the need for a judge to form their own assessment of a person's condition as a result of his or her visual perception and

[1] Although this criterion was not supported by the judges who participated in our survey.

verbal communication, videoconferencing allows the legal requirement for such a person to participate in court to be met. However, foreign researchers express the position that "Where a defendant is vulnerable, online and virtual procedures are inappropriate. There is limited opportunity for determining whether the defendant fully understands the nature of the plea he or she is tendering or other procedural aspects for which their instructions are required" [12, p. 59].

DISCUSSION

The issue of personal participation of a person suffering from a mental disorder in the proceedings concerning the application of the CMM from the standpoint of respect for their right to a fair trial (Art. 6 of the Convention) was partially considered by the authors of this article together with Olena A. Leiba [1]. Key aspects of a person's mental health in the context of a fair trial were highlighted in the David Latham's report *Mental Health and Fair Trial* [12]. The practice of applying procedural law to persons suffering from mental disorders has been analyzed in a handbook for prosecutors – *Mental Health Conditions and Disorders: Draft Legal Guidance* [11]. In the article of Penny Cooper and Janet Grace, the issues of application in the judicial system of special measures applicable to persons suffering from mental disorders were considered [13]. The study of ensuring the rights and legitimate interests of persons suffering from mental disorders, in the context of international standards of fair trial was carried out in the work of A.L. Osipov [14]. The problems of personal participation of persons in the trial in criminal proceedings concerning the application of the CMM were analyzed in the work of S.N. Shishkov [10]. At the same time, the review of the works allows us to state that today a number of issues related to ensuring the personal participation of a person with a mental disorder in court remain controversial and require further research in terms of the legitimacy of restricting their rights in the court proceedings. This paper highlights the positions of the ECHR in the context of ensuring the right of persons suffering from mental disorders to a fair trial. However, at the present stage it is necessary to comprehend the compliance of law enforcement practice with the specified case law and international standards in general.

CONCLUSIONS

1. The case law of the ECHR has established certain approaches to the personal participation of a person with a mental disorder in a trial in the context of respect for his or her right to a fair trial: (a) a person suffering from a mental disorder should have access to a court and be heard in person or through any form of legal representation; (b) the establishment of the fact of a person's mental illness does not automatically deprive them of their right to participate personally in the court proceedings; (c) a person suffering from a mental disorder has a dual role in the trial: he or she is the interested person and, at the same time, the main object of the judicial investigation.
2. The ECHR recognizes: a) personal participation in the trial of a person suffering from a mental disorder and/or the participation of their representatives (defense counsel, legal representative) as the forms of implementation of the provisions of Art. 6 of the Convention right to a fair trial; b) *priority personal participation* in the trial of a person suffering from a mental disorder, as the *alternative participation* of their legal representatives is not always able to compensate for the applicant's lack of opportunity to express their position in court.
3. The conducted research allowed to form three criteria of legality of restriction of the right of the person to personal participation in trial: a) danger of the person for itself and others; b) behavior that degrades the honor and dignity of a person suffering from a mental disorder; c) availability/unavailability of the person for verbal contact and communication with the participants of the court hearing.

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ORIGINAL ARTICLE

SUICIDE AS AN INDICATOR OF THE PUBLIC MENTAL HEALTH IN UKRAINE (INCLUDING PERIOD OF COVID-19)

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ABSTRACT

The aim: This article aims to analyze the rates of suicide as an indicator of public mental health, to consider the suicidal map of the territory of Ukraine (including to check the manifestation of such a territorial characteristic as the Albanian paradox); calculate the price of suicide for the socio-economic development of the Ukrainian state, consider the risks of suicide that have arisen as social and criminological consequences of the COVID-19 pandemic.

Materials and methods: The study is based on the analytical materials of the Ministry of Health of Ukraine and the WHO; the information and analytical data of the General Prosecutor's Office of Ukraine, the State Statistics Service of Ukraine and sectoral statistics for the period of 2015-2019, etc. The article is based on dialectical, analytical, synthetic, comparative, statistical, cartographic, and sociological methods of research and the method of potential demography. The theoretical basis of the article is specialized literature on medicine, suicidology, law, sociology, and cartography.

Results: In Ukraine, the death rate from suicide in recent years averages 1.1% of the total number of deaths. The rate of suicide decline in Ukraine has slowed significantly over the past five years, which is an alarming symptom.

There are almost strict proportions between male and female suicide (men commit four out of five suicides). The level of self-harm per 100,000 population of Ukraine remains almost stable, indicating a severe demographic crisis in Ukraine.

Women in Ukraine are less likely to commit suicide than in European countries. In Ukraine in recent years, contrary to European trends, suicide has dominated among the elderly aged 65+. The number of years of potential life loss for male and female suicides in Ukraine is 103 thousand, and the number of working years is almost 100 thousand. The losses for Ukraine from the unlived life of those who died as a result of suicide in 2019 are almost USD 341 billion.

Conclusions: In 2019, suicides accounted for almost 21% of deaths from external causes among Ukraine's population. The most intense suicidal situation is observed in the central part of the country's geographical map along the imaginary vertical axis "North-South" (Kherson, Chernihiv, Cherkasy, Vinnytsia, Zaporizhia, Kirovohrad, Sumy, Poltava, Dnipropetrovsk, Mykolaiv regions).

During the COVID-19 pandemic, many additional factors increase the risk of suicide among individuals who are at heightened risk of suicide or are actively suicidal, and among the general population.

KEY WORDS: public mental health, suicide, vulnerable populations, COVID-19 pandemic

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INTRODUCTION

One of the generally accepted indicators of public mental health, socio-psychological well-being, quality of life of a population or a specific region of the world, or a country or administrative-territorial unit is the indicator of suicide mortality. The level of suicides and their dynamics is also an indirect indicator of the number of people needing urgent treatment and suicidal prevention care [1]. Therefore, the problem of the existence of suicide as a social phenomenon traditionally attracts the attention of the public, church, scientific community, and the state [2, p. 23], because nowadays it acquires immense phenomenological, existential, and philosophical significance.

Suicide is one of the major health problems, and the global suicide mortality rate amounts to 1.4% of all deaths worldwide. Most suicides are related to psychiatric (mental) disease; depression, substance use disorders, and psychosis are the most relevant risk factors [3]. However, anxiety, personality-, eating-, and trauma-related disorders, as well as organic mental disorders, also contribute [4]. That means public health officials are faced with the challenge of identifying people who need help and encouraging them to get the assistance they need [5].

According to the European Regional Office of the World Health Organization's (WHO's), for many years, the top ten European countries in terms of the number of the suicide in various combinations include the six former Soviet republics (Table I). Ukraine is among them. However, Ukraine's suicide situation is reportedly improving (the suicide rate has dropped from 22.6 suicides per 100,000 population in 2005 to 14.8 cases in 2019). But firstly, suicides continue to occur and occupy a leading position among the so-called

Table I. Position of a state in the list of top 10 European states on the rate of suicide [9]

State / Year	Belarus	Kazakhstan	Latvia	Lithuania	Republic of Moldova	Russian Federation	Ukraine
2001	-	4	5	1	-	2	9
2002	3	4	5	1	-	2	8
2003	3	4	7	1	-	2	8
2004	3	4	6	1	-	2	9
2005	3	4	5	1	-	2	8
2006	-	3	6	1	9	2	7
2007	4	2	8	1	-	3	6
2008	3	2	5	1	10	4	8
2009	2	3	5	1	-	4	7
2010	2	3	6	1	7	5	8
2011	4	3	6	1	-	5	7
2012	-	3	4	1	10	5	7
2013	4	2	7	1	8	3	-
2014	4	2	3	1	8	-	5
2015	-	3	4	1	7	-	6
2016	-	-	-	1	3	-	-

unnatural causes of death [6, p. 76], or mortality from external causes [7, p. 78-82], and based on the abovementioned, the WHO qualifies the suicidal situation in our country as unfavorable [8]. And secondly, such modern negative phenomena as suicides among servicemen involving or being involved earlier in the military conflict in eastern Ukraine, cyberbulicide, a wave of child suicides, and more recently the global COVID-19 pandemic, etc. make their adjustments to the state of the suicidal situation in the state.

Thus, since the suicide rate is a kind of indicator of the state's public mental health situation, it simultaneously characterizes the prevalence of mental illness and the presence of disorders in the mental well-being of the population. Besides, the phenomenon of suicide must be analyzed not only in the retrospective view but also given the enormous socio-economic damage caused to society as a result of the premature death of a working-age person who committed suicide. The loss of human resources from suicide has its own value, its own price, which in the universal international payment system is often determined by the years of Years of Potential Life Lost (YPLL) and lost profits by society and the state in gross domestic product.

Of particular note is the problem of suicide mortality during the COVID-19 pandemic, which has changed the pace of life of many people around the world with the introduction of quarantine. After all, it was at this time that the crisis of loneliness worsened, the consequence of a person being in a state of depression, which in turn become one of the causes of suicide [10, p. 42]. Depression at this time is also caused by restrictions associated with lockdown: loss of a job, business, rented housing, financial difficulties, etc.

THE AIM

This article aims to analyze the rates of suicide as an indicator of public mental health, to consider the suicidal map of the territory of Ukraine (including to check the manifestation of such a territorial characteristic as the Albanian paradox); calculate the price of suicide for the socio-economic development of the Ukrainian state, consider the risks of suicide that have arisen as social and criminological consequences of the COVID-19 pandemic.

MATERIALS AND METHODS

The study was conducted in 2020. The source base of this study is: 1) analytical materials of the Ministry of Health of Ukraine and the WHO; 2) the information and analytical data of the General Prosecutor's Office of Ukraine; 3) information from the State Statistics Service of Ukraine and sectoral statistics for the period of 2015-2019, etc. Collected and grouped materials were processed using the technology of descriptive statistics. The article is based on dialectical, analytical, synthetic, comparative, statistical, cartographic, and sociological methods of research and the method of potential demography. Calculations and mapping were performed using computer programs Adobe Photoshop CS6 and QuickMap 2.2, Excel spreadsheets from Microsoft Office 2016. The theoretical basis of the article is specialized literature on medicine, suicidology, law, sociology, and cartography.

RESULTS

Public mental health is the mental health variations of importance exhibited by populations that consist of 'mental health promotion,' 'mental illness prevention', and 'treatment and rehabilitation' [11, p. 12]. WHO's stressed that there is no health without mental health. Mental health is central to the human, social and economic capital of nations and should therefore be considered as an integral and essential part of other public policy areas such as human rights, social care, education, and employment [12, p. 3].

Public mental health consists of a lot of elements. One of them is all issues, which consider suicide. In general, a suicide attempt is a clear indication that something is gravely wrong in a person's life. No matter the person's race or age, how rich or poor they are, it is true that most people who die by suicide have a mental or emotional disorder. The most common underlying disorder is depression, 30% to 70% of suicide victims suffer from major depression or bipolar (manic-depressive) disorder [13].

In Ukraine, the death rate from suicide in recent years averages 1.1% of the total number of deaths [14][1]. This fig-

[1] Footnote. In 2015 the death rate from suicide in Ukraine was 1,3 %, in 2016 – 1,2 %, in 2017 – 1,1 %, in 2018 – 1,1 %, in 2019 – 1,1 %.

Table II. Cases of intentional self-harm were registered in Ukraine in 2015-2019 [14]

Years	Number of reported cases of intentional self-harm that caused the death of a person (suicide)			The level of intentional self-harm that caused the death of a person (suicide) per 100 thousand population of Ukraine			Dynamics of intentional self-harm that caused the death of a person (suicide) (%)		
	Total	Male	Female	Total	Male	Female	Total	Male	Female
2015	7575	6149	1426	17,72	14,38	3,34	-	-	-
2016	6898	5619	1279	16,19	13,19	3,00	-8,94	-8,62	10,31
2017	6488	5327	1161	15,30	12,56	2,74	-5,94	-5,20	-9,15
2018	6279	5172	1107	14,87	12,25	2,62	-3,22	-2,91	-4,65
2019	6190	5112	1078	14,75	12,18	2,57	-1,42	-1,16	-2,62
Total	33430	27379	6051	—	—	—	—	—	—
Average value (abs.,%)	6686 -	5476 (81,9%)	1210 (18,1%)	13,77	12,91	2,85	-4,88	-4,47	-5,68

ure does not go beyond the global: as noted above, suicide mortality in the world is 1.4%. A retrospective analysis of the suicidal situation in Ukraine, conducted based on data on the total number of cases of intentional self-harm resulted in death, by years of observation (2015-2019) and taking into account gender, allows to identify several trends and features of this situation (Table 2), which are as follows:

I. The rate of suicide decline in Ukraine has slowed significantly over the past five years (almost 6.3 times overall and seven and a half times for men), which is an alarming symptom.

II. As before, there are almost strict proportions between male and female suicide (men commit four out of five suicides). Moreover, the risk of suicidal behavior in men is higher in all age groups.

III. In contrast to the apparent decline in the dynamics of this phenomenon, the level of self-harm per 100,000 population of Ukraine remains almost stable, indicating a severe demographic crisis in Ukraine, associated with a sharp decline in the community as a whole.

IV. Compared to the WHO European Region data, women in Ukraine are less likely to commit suicide than in European countries, where this ratio is approximately 3/1 [15]. At the same time, the fact that compared to the mid-90s of the twentieth century now women in Ukraine have become more likely to commit suicide (for example, the ratio of suicidal behavior in men and women in cities was 5.3: 1, and in rural areas - 6.2: 1) [16; 17].

V. In Ukraine in recent years, contrary to European trends, suicide has dominated among the elderly aged 65+ , although 15 years ago it was claimed that among young and middle-aged people, especially men, suicide is a leading cause of death [18, p. 75].

However, it should be noted that there is a distortion of official suicide statistics in Ukraine. This problem is quite common worldwide because, according to the WHO, only 80 Member States (out of 183!) Have high-quality data to assess suicide rates. Given the delicacy of the issue and the illegality of suicide in some countries, it is believed that incomplete reporting and misclassification are likely to be greater problems with suicide than with other causes of death [19]. Nowadays, in Ukraine, we also do not have accurate quantitative characteristics of suicide as a phenomenon because many facts are counted as cases of self-harm with undetermined intent. According to the International Classification of Diseases of the 10th revision, such cases include cases of self-harm, with the exception of poisoning, in the absence of indications of their nature (accidental or intentional) [20]. Thus, there is some unavailability or inadequacy of information to allow relevant experts to determine whether a particular incident is an accident, self-harm, or violence with the intention to kill or injure. In 2019, the number of cases of injuries with undetermined intent (except for alcohol poisoning) in Ukraine amounted to 5,559 [21, pp. 78–82]. The maximum that is done when detecting the fact of suicide is a conclusion about the absence of both the event and the composition of the crime of incitement to suicide that is made based on a few documents and insufficient information [22, p. 1]. By the way, in 2015, 86 cases of suicide were recorded in Ukraine; in 2016 - 133; in 2017 - 109; in 2018 - 114; in 2019 - 109 [23]. The suicidal situation in places of imprisonment is also tense. Thus, according to the WHO Regional Office for Europe, suicide is the cause of 13.5% of all deaths of convicts [24]. Simultaneously, the problem of suicide looks even more complicated concerning children and adolescents because many cases are "attributed" by society to curiosity, risk-taking, low level of life experience, carelessness, and so on. And the problem of adolescent suicide under the influence of communication on the Internet remains significantly undeveloped [25, p. 36]. And if it is almost impossible to hide the facts of adolescent suicide (both due to the natural reaction of parents and through wider communication), then "silence" to hide, in particular, from the public condemnation of suicide of the elderly, especially in rural areas, is quite common [19].

The suicidal map of the territory of Ukraine in 2019, conducted on the basis of official statistics and own calculations, gives grounds to claim that in terms of the intensity of suicide cases, the leading areas are still such regions as Kherson, Cherkasy, Vinnytsia, Zaporizhia, Kirovohrad.

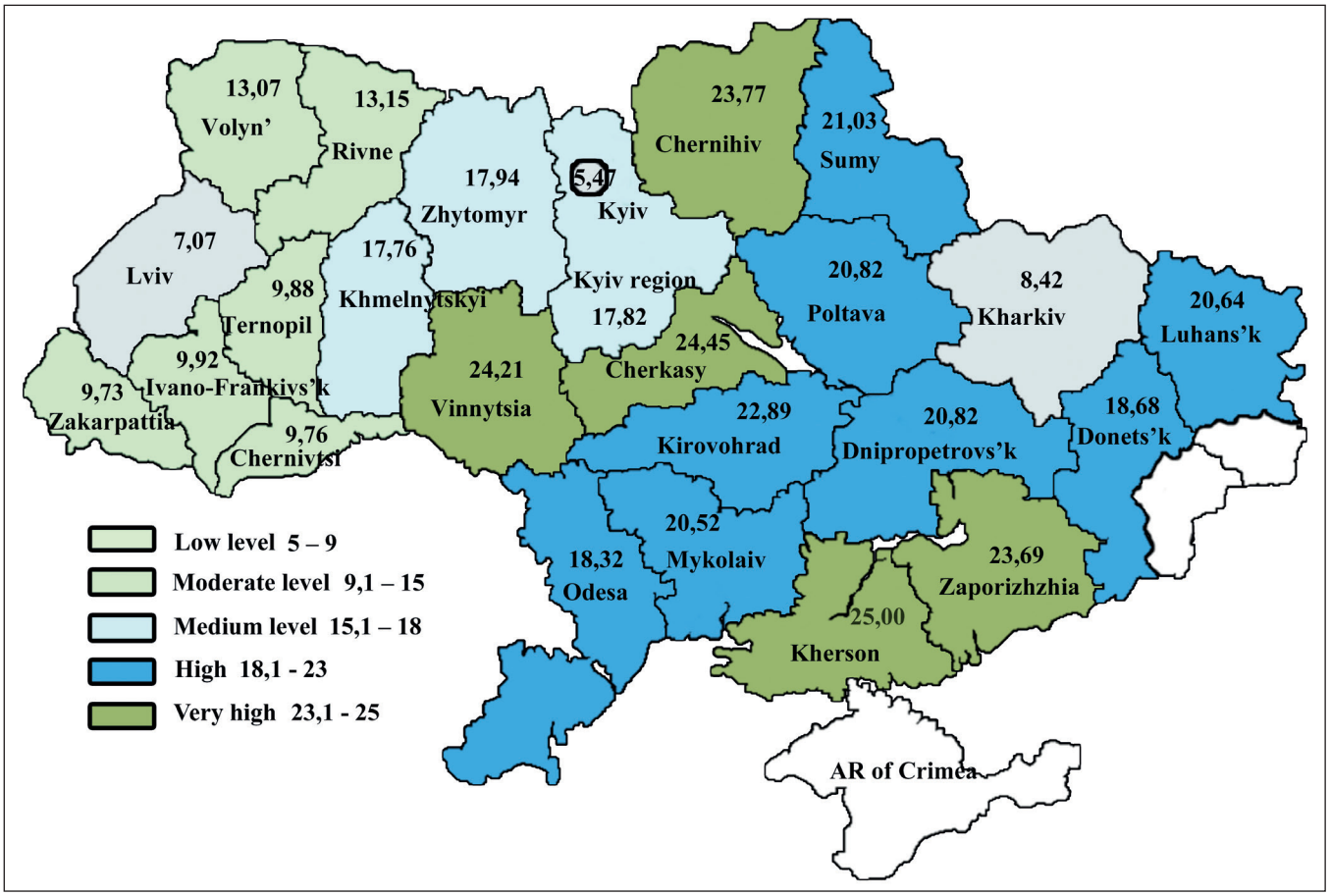

Fig. 1. Geography of suicide intensity in Ukraine per 100 thousand population in 2019.

At the same time, the situation in Chernihiv, Sumy and Poltava region has significantly deteriorated (Fig. 1). In these areas, the intensity of suicides is 20.82-25.0 cases per 100 thousand population.

One of the research problems of modern suicidology is related to the explanation of the uneven distribution of suicide mortality rates on the European continent [26, p. 8] because a long-term analysis of the territorial distribution of suicides in Europe gives ground to argue that there is a certain spatial pattern and it is resulting in the growing number of suicides in the direction from the southwest (the Mediterranean and the British Isles) to the northeast of the continent (central and northeastern regions of Europe). In the specialized literature, this pattern is called the Yugoslav or Albanian paradox [26, p. 8; 27; 28]. In this regard, one of the goals of this study was to address the question: does this pan-European (regional) phenomenon work in Ukraine, as is the case in France, Italy, Russia, Belarus, etc.? (Fig. 1).

The above map clearly shows that the suicidal picture in Ukraine "unfolds" in space in a peculiar way, different from the European trend. The situation in the east of the country, which indicates relative prosperity in terms of suicidal activity in one of the largest regions of Ukraine – Kharkiv region, is interrupted in the central part of Ukraine's map by a vertical axis in the direction of "North-South." This territorial segment of the country (Kherson, Chernihiv, Cherkasy, Vinnytsia, Zaporizhia, Kirovohrad, Sumy, and other regions) that a high and very high level of suicides is observed, which contradicts the principle of the Albanian paradox, the vector of which, as was mentioned before, shows a decrease in suicidal activity in North to South direction in the European part of the continent. In these areas, the saturation of territories by suicide is almost twice as high as the national parameters and three to four times higher than those included in the group of relatively low suicide intensity. At the same time, one cannot fail to note the very tense suicidal situation is in eastern Ukraine, namely in the territory of the Luhansk region controlled by the Ukrainian authorities, which is adjacent to the area of military activity. More than a thousand military conflict participants in the east of our country have committed suicide in a few years. These are mostly young people born in 1995-1998 [28].

The geographically outlined suicidal situation in Ukraine has been observed for at least the last 4-5 years [29]. Before that, there was statistically confirmed information that the difference in suicide rates was observed on the East-West axis and testified to the tense suicidal situation with the highest mortality rate from auto aggression in industrial areas of the country in the East and in Chernobyl-affected areas with its noticeable softening in agricultural regions closer to the western borders of Ukraine [30, p. 30]. Thus, within the territory of individual countries, the Albanian

Table III. Calculation of lost years of life (including able-bodied) for persons who committed self-harm in 2019

Parameters	Distribution of persons by age groups and number of lost years of life													
	5-9	10-14	15-19	20-24	25-29	30-34	35-39	41-44	45-49	50-54	55-59	60-64	65-69	70+
Number of suicides among men	-	14	105	230	346	527	536	487	466	385	523	447	325	721
The average value of unlived years for a certain age group of men	55,3	50,3	45,3	40,3	35,3	30,3	25,3	20,3	15,3	10,3	5,3	0,3	-	-
The actual number of lost years of life for a particular age group of men	-	754,5	4756,5	9269	12213,8	15968,1	13560,8	9886,1	7129,8	3965,5	2771,9	134,1	-	-
The total number of lost years of life in all age groups of men	80 410,1													
The average value of working age for a particular age group of men	49	49	47,5	42,5	37,5	32,5	27,5	22,5	17,5	12,5	7,5	2,5	-	-
The actual number of lost years of ability to work for a particular age group of men	-	686	4987,5	9775	12975	17127,5	14740	10957,5	8155	4812,5	3922,5	1117,5	-	-
The total number of lost years of ability to work for all age groups of men	89256,0													
Number of suicides among women	–	8	36	30	62	86	64	76	73	71	82	79	93	318
The average value of unlived years for a certain age group of women	67,3	62,3	57,3	52,3	47,3	42,3	37,3	32,3	27,3	22,3	17,3	12,3	7,3	2,3
The number of lost years of life for a certain age group of women	-	498,4	2062,8	1569	2932,6	3637,8	2387,2	2454,8	1992,9	1583,3	1416,6	971,7	678,9	731,4
The total number of lost years of life for all age groups of women	22 917,4													
The average value of working age for a particular age group of women	44	44	42,5	37,5	32,5	27,5	22,5	17,5	12,5	7,5	2,5	-	-	-
The actual number of lost years of ability to work for a particular age group of women	-	352	1530	1125	2015	2365	1440	1330	912,5	532,5	205	-	-	-
The total number of lost years of working capacity for all age groups of women	11807													
The total number of lost years of life for all age groups of persons who committed self-harm	103327,5													
The total number of years of incapacity for work lost for all age groups of persons who committed self-harm	101063,0													

paradox can be leveled, as is the case in Ukraine. However, in terms of the area, it is the largest country in Europe, whose territory is entirely within this continent. Probably, such deviation from the European trend is due to the existence of a unique causal complex of many different regional factors (socio-economic, military-political, cultural, environmental, etc.), which affects the suicidal picture and is specific to this country.

Committing suicide is a deliberate shortening of age by a person, reducing the number of potentially lived years. In this regard, it should be emphasized that an essential indicator of the socio-economic dimension of any state's well-being is the preservation of human potential, which can produce a certain amount of gross domestic product at a given time. The indicator of the produced product depends, in particular, on the length of human life and the number of working years of human potential depending on gender.

In WHO's reports, the effects of suicide are expressed in standardized units, namely: in years of potential life loss (YPLL) due to premature death, calculated as the sum of the differences between a predetermined endpoint and the ages of death for those who died before that end point; the two most commonly used end points are age 65 years and average life expectancy [31, pp. 3–33]. To determine the cost of suicide in Ukraine, we calculated the YPLL for any age group of suicides in Ukraine based on the average of the corresponding five-year interval and the average life expectancy for men and women separately. Thus, currently,

Table IV. Unearned GDP for all unlived working life of persons who committed self-harm in 2019

Parameters	Distribution of persons by age groups and unearned GDP for unlived working life													
	5-9	10-14	15-19	20-24	25-29	30-34	35-39	41-44	45-49	50-54	55-59	60-64	65-69	70+
Unearned GDP for all unlived working life for a certain age group of men	-	4875020	71667875	24421750	1227045750	1619747675	1393961800	1036250775	71218350	55118125	370950825	105681975	-	-
Unearned GDP for all unlived working life for all age groups of men (UAH)	8440939920													
Unearned GDP for all unlived working life for a certain age group of women	-	33288640	144692100	106391250	90558550	23658050	36180800	25778100	86295125	0358525	19386850	-	-	-
Unearned GDP for all unlived working life for all age groups of men (UAH)	1116587990													
Unearned GDP for all unlived working life for all age groups of persons who committed self-harm (UAH)	9557527910													

the average life expectancy in Ukraine for men is 62.8 years, for women - 74.8 years [32]. Concerning the calculation of lost years of ability to work, we took into account the number of unlived years to retirement age for each age group, which in our country is 65 years for men and 60 years for women. At the same time, the minimum working age in Ukraine is generally 16 years. It is interesting to note that nowadays, for Ukrainian men, the age at which a person can retire exceeds the average life expectancy (!). Therefore, there is a certain imbalance between YPLL and lost years of employment because the latter's total value exceeds the actual cost of life expectancy by men. In such a situation, there is a severe problem for Ukraine of premature depletion of the labor force to the endpoint of the working-age specified in the national labor legislation. After all, with any sudden death, labor reserves are devastated, investment in people is devalued [33].

Our calculations show that the total number of YPLLs for men who committed suicide in 2019 is 80,410.1 years, and the working-age - 87,838.5. For women, the corresponding figures are 22,917.4 and 11,807, respectively. In total, the number of YPLLs for male and female suicides in Ukraine is 103,327.5, and the number of working years is 101063,0.

When calculating the amount of GDP not received as a result of suicide, we again took into account the number of unlived years for each age group before retirement age and the quantitative indicator of per capita income per year. These losses were calculated at the rate of 94,570 UAH per person (2019) [34]. So, if there were no premature death, then during their working life, men who died from suicide only in 2019 could produce a GDP of UAH 89256,0, which in terms of US dollars is about 313 billion (!) Unearned GDP for all unlived working life of women who committed suicide in the analyzed year reaches UAH 1,116,587,990 (over USD 41 billion). In total, the losses for Ukraine from the unlived life of those who died as a result of suicide in 2019 are equal to UAH 9557527910 (almost USD 354 billion) (Table III). The average damage to the state and society's productive functioning from the death of one person is about 58 thousand US dollars. At the same time, the central part of unearned GDP due to unlived life falls on men who committed suicide at working age or even before reaching that age.

Table IV. Unearned GDP for all unlived working life of persons who committed self-harm in 2019

DISCUSSIONS

About 800,000 people commit suicide each year worldwide. Each suicide affects an average of 135 other people: relatives, friends, acquaintances of the deceased. That's 108 million people a year [35]. The consequences of this interaction are different: from longing for the dead to depression. Information about a person's suicide also affects ordinary citizens, can cause them a state of anxiety, insecurity, etc., which affects not only the prevalence of mental illness but also the state of mental well-being of the population. Therefore, the suicide mortality rate can be defined as a kind of indicator of public mental health in the state.

Identification and analysis of statistical material related to suicide, compared with other social changes, can be an indicator of favorability of social conditions, the level of social tension, and society's functioning as a whole [36, p. 76]. Since December 2019, the world has been affected by gradual (and sometimes abrupt) changes in public life related to the SARS-Cov-2 virus pandemic and the introduction of state measures to stop its spread. This situation also affects those who are prone to suicide.

Suicide is a multifactorial process. In addition to the immediate causes that a person considers to be the impetus for suicide, several risks contribute to suicidal thoughts. The risk factors common across health care settings include mental illness; having previously attempted suicide; recent suicide attempt; suicidal thoughts or behaviors; a family history of suicide or psychiatric illness; on antidepressants; physical health problems, including central nervous system disorders such as traumatic brain injury; diagnosis of delirium or dementia; chronic pain or intense acute pain; poor prognosis or the prospect of certain death; social stressors such as financial strain, unemployment or loss of economic independence; disability; trauma; divorce or other relationship

problems; hopelessness; and substance abuse [37; 38]. Older adults are prone to additional suicide risk factors, including declining health, loneliness, and recent bereavement [38; 39]. In addition to these risks, the COVID-19 pandemic presents new ones or changes existing ones' content. Foreign researchers suggest identifying the following risks of suicide during a COVID-19 pandemic:

1) selective and indicated interventions (target individuals who are at heightened risk of suicide or are actively suicidal): mental illness; experience of suicidal crisis;

2) universal interventions (target the whole population and focus on particular risk factors without identifying specific individuals with those risk factors): financial stressors- domestic violence; alcohol consumption; isolation, entrapment, loneliness, and bereavement; access to means; irresponsible media reporting [40].

The formation of suicidal behavior in vulnerable populations in the COVID-19 era occurs primarily under the influence of factors such as uncertainty, social isolation, and economic problems [41]. The risk of suicide by vulnerable people (including individuals with preexisting psychiatric disorders, low-resilient people, individuals who reside in high COVID-19 prevalence areas, people who have a family member or friend who has died of COVID) increases when these factors affect in combination with exacerbation of preexisting psychiatric disorders, depressive disorders, anxiety disorders, alcohol, and other substance use disorders and other psychiatric conditions [41].

Thus, the study of the suicidal situation during COVID-19 allows concluding the state of public mental health in this period, to make predictions about similar indicators in case of future pandemics and, considering their features, to develop suicide prevention work in the current and comparable possible period.

Regarding the further study of the problem of suicides in Ukraine, it is necessary to deeply research the issue of creating a so-called suicide passport of the regions of Ukraine (VZ Rothschild-Varibrus et al.) [43] to see regional features of the mortality situation in certain areas as a result of suicides, to find out the reasons for possible differences and to develop appropriate suicide prevention strategies at both the state and local levels.

Of particular note is the additional collection of arguments to explain the territorial deviations of the suicidal situation in Ukraine from the pan-European trend of a significant decrease in the number of similar facts in Europe from North to South, called the Albanian paradox.

Studying the specifics of suicide situation (the causes in particular) and developing measures for its prevention, special attention should be paid to a comprehensive study of such a socially dangerous phenomenon as cyberbulicide, which can be a cause of incitement to suicide, especially regarding minors, through the use of Internet technology (S. Bauman et al. (2013), Primack AJ et al. (2017), Hinduja S. et al. (2010), Bychkova AM (2018)) [44; 45; 46; 47] The problem of suicide in the light of the global pandemic COVID-19 as one of its consequences of a social and criminological nature acquires special significance.

CONCLUSIONS

The suicide mortality rate as an indicator of public mental health in Ukraine shows that in our country, suicide mortality does not exceed the global figure (1.1% in Ukraine vs. 1.4% in the world).

At the same time, in 2019, suicides accounted for almost 21% of deaths from external causes among Ukraine's population. The most intense suicidal situation is observed in the central part of the country's geographical map along the imaginary vertical axis "North-South" (Kherson, Chernihiv, Cherkasy, Vinnytsia, Zaporizhia, Kirovohrad, Sumy, Poltava, Dnipropetrovsk, Mykolaiv regions). The situation in the largest country in Europe, whose territory is entirely in the European part of the continent, contradicts the principle of the Albanian paradox described in the literature, according to which the vector of suicidal activity indicates its decline from North to South of the European part of the continent.

People's death as a result of suicide in just one year causes colossal material and human losses to Ukraine. Thus, the number of YPLL due to premature death in 2019 is 103,327.5, and the number of working years – 101063,0. In material terms, the loss from unlived life is almost 354 billion US dollars. The central part of these losses is caused by the death of men of working age.

In addition to the main factors of suicide (mental illness, depressive disorders, etc.) during the COVID-19 pandemic, many additional factors increase the risk of suicide among individuals who are at heightened risk of suicide or are actively suicidal, and among the general population.

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REVIEW ARTICLE

THE STATE AS A GUARANTOR OF THE PROTECTION OF THE RIGHTS OF INDIVIDUALS AND LEGAL ENTITIES IN THE CONDITIONS OF CORONAVIRUS CRISIS OF 2020

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ABSTRACT

The aim of the article is to stimulate discussions about the necessity to improve the legal regulations that guarantee a proper public health policy, as well as to determine the balance between the level of restrictions that may be imposed by State in order to protect both, the public interest of health and the economic development.

Materials and methods: National legislation of Ukraine, United Kingdom and France on public health and health policy, case law of these countries, including high court decisions were used for dialectical, comparative, synthetic and systemic analyses.

Conclusions: As the legality of government officials' actions principle is a fundamental constitutional principle in most European countries, states must establish such legal provisions to avoid short-term and long-term conflicts when the rights of individuals and legal entities are being restricted.

At the legislative level, it is necessary to adopt transparent rules to attract private funding to the health sector. Development of the e-health and telemedicine systems could be boosted through the use of public-private partnership tools.

KEY WORDS: public-private partnership, public health, e-Health, telemedicine

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INTRODUCTION

In the 21st century, public health care has become a primary responsibility of the state. This statement is included in all national constitutions of European countries and universally binding international documents. International legal standards have been developed, being under custody of not only the World Health Organization (WHO) and its strategic governmental and non-governmental partners, such as International Red Cross, but also other institutions and organizations on the regional, national and local levels.

However, the system that was established in the second half of the 20th century by the efforts of many governments, experts, and enthusiasts, and that deemed to be one of the most successful social projects of mankind, is now coming under criticism from various sides in the 21st century.

There are many reasons for this and for the most part they are related to new infectious diseases emerging and spreading beyond their usual endemic regions such as Africa and Asia.

At the national level, most countries appeared not to be ready for the

practical security of people's constitutional guarantees of health protection in a situation that in the expert community is increasingly referred to as a 'coronacrisis'[1].

Legatum Institute, the UK based think tank announced that 'compared to the situation where the Covid-19 pandemic had not hit the country, 440,000 more people were in poverty in Summer 2020 and 690,000 more in Winter 2020'. By Spring 2021 nearly 15,5 mln people in the UK will live in poverty. The original analysis uses the Social Metrics Commission's approach to poverty measurement and the assessment of the likely course of poverty since the start of the crisis, the protective impact of Government action that has already been taken, and choices that still need to be made. [2].

Among the many reasons of a political, social, economic and institutional nature, special focus should be given to the legal assessment of the states actions aimed at the introduction of quarantine measures and their correct implementation, since they are often and sometimes considerably associated with the restriction of basic rights and freedoms of citizens. The balance between public and private interests in such situations can be achieved only partially, as these are not always synchronized with time and value.

THE AIM

The aim of the article is to stimulate discussion about the necessity to improve the role of the state and legal regulations to guarantee proper public health policy, and determine the balance between the amount of restrictions that may be used by the public officials in order to protect public interest for a healthy life and tools for economic development.

This article also describes how the crisis in the health care system in Ukraine influenced the development of electronic health care system (e-Health system) and telemedicine.

MATERIALS AND METHODS

This study was conducted in 2020 and is based on the national legislation of Ukraine, regulatory acts in the field of public health, the practice of the Constitutional Court of Ukraine, legislation of the selected European countries such as the UK and France, case law of these three countries. Dialectical, comparative, synthetic and system analyses research methods were used, including for interpretation purposes.

REVIEW AND DISCUSSION

The global coronavirus pandemic has become a challenge for national health care systems worldwide. Many countries searched for their own response to this challenge, and actions of the governments were not always adequate and effective.

The effectiveness of the measures to ensure the protection of human health security with the Law and state measures can be understood through the analysis of three relatively independent but closely related issues:

1) the establishment and application of proper legal regulation in public health;
2) the establishment of proper cooperation between the state and private business to ensure that all restrictions will not affect human life or health and, at the same time, will minimize the damage to the economic activity of companies to a possible level ;
3) the proper regulation of circumstances surrounding administrative disorder, to ensure the right of the public officials and law enforcement officers to interfere into private business and private territory even if it seems to pose a real damage to his/her personal freedoms and economical interests.

It is important to find out what kind of measures can be considered and the most effective answer to the situation.

In Ukraine, the state's response to the coronavirus epidemic was the introduction of quarantine, a number of restrictions and bans. Thus, on March 11, 2020, the Cabinet of Ministers of Ukraine adopted Decree No. 211 "On the Prevention of the Spread of COVID-19 Coronavirus on the territory of Ukraine". This Decree, in particular, forbade students from visiting educational institutions, and banned all mass gatherings with more than 200 participants, except for events necessary to ensure the operation of public authorities and local governments from March 12 to April 3, 2020 in the whole territory of Ukraine. Sports events could only be held without the participation of the public (fans) [3].

However, already on March 17, the list of restrictions provided by the governmental Degree on the quarantine measures was significantly expanded. The most controversial and important restrictions were the ones for businesses whose activities involve reception of visitors, including catering businesses (restaurants, cafes, etc.), shopping and entertainment centers, other entertainment establishments, fitness centers, cultural institutions, trade and consumer service organizations. In addition, the Decree significantly restricted the freedom of movement of citizens. This included a ban on transportation of passengers by road in suburban and interurban motor service, the carriage of more than 10 passengers at a time in one vehicle in urban electric transport and in buses. Decree No. 211 also banned transportation of passengers by subways in the cities of Kyiv, Kharkiv and Dnipro, as well as the transportation of passengers by any routes of rail transport inside the country.

During 2020, the Decree of the Cabinet of Ministers of Ukraine «On Prevention of the Spread of COVID-19 Coronavirus on the territory of Ukraine» has been amended 17 times.

On May 20, 2020 the Cabinet of Ministers of Ukraine adopted another special Decree No. 392 «On the establishment of quarantine to prevent the spreading of COVID-19 acute respiratory illness caused by the SARS-CoV-2 coronavirus and the mitigation of anti-epidemic measures in Ukraine.» This Decree clarified the list of prohibitions and changed the model of quarantine measures (from all-Ukrainian to adaptive depending on certain indicators) [4].

The epidemic also led to some changes in Ukrainian legislation. Thus, special provisions were introduced into the Labor Code of Ukraine, the Code of Administrative Offenses, the Tax Code of Ukraine, the Law of Ukraine «On Holidays», etc.

It should be noted that the introduction of quarantine on the territory of Ukraine by the Cabinet of Ministers, namely certain significant restrictions on human rights and freedoms introduced by the quarantine, caused discussions in the society and in the experts level. The key points of discussion were the proportionality of the restrictions in regard to the real threats, as well as the Government's authority to introduce prohibitions such as travel bans or restrictions on businesses without amending the law or declaring a state of emergency by the Parliament.

The issue of proportionality of the restrictions became a pressing challenge not only in Ukraine. It was reviewed by many European courts. So, for example, in the decision of the Council of the State of France (Conseild'Etat) of September 06, 2020, in the case involving the issue of liability for not wearing masks, it was noted that in the context of the rule of law, freedom should remain the rule and police restrictions the exception. It follows therefor, that measures, restricting rights and freedoms are lawful only if they meet the three requirements of the principle of proportionality: necessity, adequacy and proportionality. Thus, this measure must be applied first and foremost to prevent a risk to public order, such as a health risk. In the absence of such a risk this measure shall be deemed illegal. Only in such a case can this measure achieve the intended goal, otherwise it will be either inadequate or inappropriate [5].

Based on these arguments, the Council of State partially reversed the interim orders of theadministrative courts of Lyon and Strasbourg, ordering the prefects of Rhône and Bas-Rhinto

review as soon as possible - under penalty of suspension - their decrees imposing the wearing of a protective mask for people aged 11 or over in open public places in the cities of Lyon and Villeurbanne, on the one hand, and in municipalities with more than 10,000 inhabitants in the Eurometropolis of Strasbourg, somewhere else. This half-hearted decision has not prevented the proliferation, since then, of orders of the same type on French territory, although it seems to proceed from a very timid application of the requirement of proportionality.

In this regard, it should be noted that Ukrainian judges also drew attention to these issues. The Supreme Court filed to the Constitutional Court of Ukraine a petition to declare certain provisions of the Decree of the Cabinet of Ministers of Ukraine «On the establishment of quarantine to prevent spreading of COVID-19 acute respiratory illness caused by the SARS-CoV-2 coronavirus and the mitigation of anti-epidemic measures in Ukraine» and some other bylaws as unconstitutional.

The Constitutional Court of Ukraine made reference to Article 64 of the Constitution of Ukraine, according to which the constitutional human rights and freedoms shall not be restricted, except in cases provided by the Constitution of Ukraine; in the state of emergency, including state of defense, certain restrictions on rights and freedoms may be established, with indication of the term of these restrictions; however, the rights and freedoms envisaged in Articles 24, 25, 27, 28, 29, 40, 47, 51, 52, 55, 56, 57, 58, 59, 60, 61, 62, 63 of the Constitution of Ukraine shall not be restricted.

The Constitutional Court of Ukraine also stated that the restriction of constitutional human rights and freedoms is possible in cases specified by the Constitution of Ukraine. Such restrictions shall only be established by law - by an act adopted by the Verkhovna Rada of Ukraine as the only legislative body in Ukraine. Establishing such restrictions with a bylaw contradicts Articles 1, 3, 6, 8, 19, 64 of the Constitution of Ukraine [6].

The debate over the lawfulness of quarantine restrictions is relevant to other countries as well.Given that the principle of legality of actions of government officials is a basic constitutional principle in most European countries, states are obliged to establish such provisions of law so that short-term and long-term conflicts do not arise when applying procedures related to restriction of rights of individuals and legal entities.

In France there is a general principle of legality (principe de légalité) according to which the powers of the French administration are subordinate to the law. This principle has been affirmed in jurisprudence of the Conseil d'Etat (Highest French Court in charge of the administration both before and after the 1958 version of the French Constitution)Prosper Weil says that"all the action of the administrative bodies is governed by the principle of legality. The regulation may be part of the character of the law - by its general and impersonal character - but the case law decides that, emanating from the government, it is an administrative act subject to the principle of legality." [7]

For lawyers and judges the issue about justification of risks and their comprehensive relevance to the scientific data is important when the violation of restrictions of the rights and freedoms is under review.

Professor Jeff King from the University College London and a Legal Adviser to the House of Lords Constitution Committee says:The Health Protection (Coronavirus, Restrictions) (England) Regulations 2020 (Reg 6) and the Health Protection (Coronavirus Restrictions) (Wales) Regulations 2020 (Reg 8) both provide in identical wording that 'During the emergency period, no person may leave the place where they are living without reasonable excuse.' Both also enumerate thirteen exceptions ('reasonable excuses') to the rule.These are the restrictions widely referred to as the 'lockdown.' There is a question at the moment about whether they are so invasive as to be unlawful [8].

The recently adopted Coronavirus Act 2020 does not confer new powers on the UK and Welsh ministers to impose a lockdown on the people of England and Wales. It does confer such powers on Northern Ireland (specifically, the Northern Ireland Department of Health) in Schedule 18; and on Scottish ministers inSchedule 19. Neither Northern Ireland nor Scotland had them previously. The scheme in those two schedules is roughly – and in the case of Northern Ireland almost verbatim – based on the powers accorded to UK and Welsh ministers under the Public Health (Control of Disease) Act 1984. It is there that the source of the powers both now and into the future are to be located in respect of any lockdown. If the present lockdown is found to be outwith the 1984 Act, it would follow that no lockdown is presently permissible anywhere in the country.

In the lockdown regulations cited above, the UK Government has clarified that it is acting under section 45C:

- s.45C(1): 'The appropriate Minister may by regulations make provision for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination in England and Wales (whether from risks originating there or elsewhere).'
- s.45C(2): 'The power in subsection (1) may be exercised–

(a) in relation to infection or contamination generally or in relation to particular forms of infection or contamination, and

(b) so as to make provision of a general nature, to make contingent provision or to make specific provision in response to a particular set of circumstances.'

- s.45C(3)(c): 'Regulations under subsection (1) may in particular include provision… imposing or enabling the imposition of restrictions or requirements on or in relation to persons, things or premises in the event of, or in response to, a threat to public health.'
- s.45C(4)(d): 'The restrictions or requirements mentioned in subsection (3)(c) include in particular…a special restriction or requirement.' [9]

Jeff King is a strong supporter of restrictions and limitation,and he is referring to the opposite minds which are widespread among the UK lawyers.

As the jurist and peer, Lord Anderson, has put the challenge on his blog, '[f]or such a remarkable limitation of personal freedom to be contemplated by statute, one would have expected to find clear words in section 45G(2):

something like "that P be required not to leave the place where P is living, save for specified purposes." That might seem apiece with the idea behind the principle of legality and many other public law cases which are apt to deny that general rather than specific words can permit serious infringements of personal liberty. Relatedly, was it the gist of the Act to deal with something much more limited than a health scare that precipitates a nation-wide lockdown?[8]

In our opinion, and as also reflected in the decision of the Constitutional Court of Ukraine, consideration of the problem of the efficiency and adequacy of the state response to the spread of COVID-19 should be based on the provisions of Article 19 of the Constitution of Ukraine, according to which governmental authorities and local governments and their officials shall only act on the basis, within the powers and in the manner prescribed by the Constitution and laws of Ukraine. Thus, public authorities in Ukraine do not possess as much discretion compared to the respective organs in some other countries, but must explicitly act within the adopted legislation. In view of the above decision of the Constitutional Court, it becomes obvious that this constitutional principle was violated by the highest executive body, as a result of which significant interference with human rights and freedoms was committed and significant losses were caused to business entities. Without assessing the issue of reasonability of restrictions from the medical point of view, it can be argued that from the legal point of view, actions and decisions of the authorities of Ukraine did not meet the requirements of the fundamental law.

Quarantine has had a significant negative impact on business. Some sectors of the economy have experienced a decline, and large numbers of small and medium-sized businesses have been forced to lay off large numbers of workers or completely shut down. We agree with the authors of the scientific report «Ukraine after the coronavirus crisis - the way to recovery» stating that the restrictions had a significant negative impact on the country economy, causing some side effects of the «treatment» of the country from the spread of coronavirus [10].

Next, we will discuss whether the quarantine measures implemented in Ukraine and the crisis caused by the spread of COVID-19 had any positive consequences for the health care system in Ukraine. In this part, two issues should be reviewed: the development of the electronic health care system (eHealth system) and the introduction of telemedicine in the healthcare practice during quarantine.

Article 2 of the Law of Ukraine «On State Financial Guarantees of Medical Care» establishes the definition of the term electronic health care system, which is an information and telecommunications system that automates the accounting of medical services and management of medical information through the creation, post, publication and exchange of information, data and documents in electronic form, which includes a central database and electronic health information systems, with automatic exchange of information, data and documents between these through an open application programming interface (API).

The law states that the access to the patient's data in the electronic health care system is only possible with the consent of the said patient (or his legal representative) provided in writing or in a form that allows to make a conclusion about the consent [11].

The legal framework for the electronic health care system was laid several years before the coronavirus pandemic. The Procedure for operation of the electronic health care system was approved by the Decree of the Cabinet of Ministers of Ukraine No. 411 of April 25, 2018. This legal act was made to define the mechanism of the electronic health care system's functioning and its components, user registration, entry and exchange of information and documents within the electronic health care system. At the same time, the Government established that from the date when this Decree enters into force, the functionality of the electronic health care system shall become gradually introduced to implement state guarantees of medical care at the level of primary health care [12].

Therefore, as can be seen from the above-mentioned legal norms, the electronic health care system had to be introduced step by step. Its full launch involved a large amount of regulatory and technical activities. Thus, the Cabinet of Ministers of Ukraine assigned a number of tasks to the Ministry of Health of Ukraine, including:

- developing a complete design and regulations necessary for the functioning of the electronic health care system in the framework of the state medical care guarantees, at the level of secondary (specialized), tertiary (highly specialized) and other types of medical care, in accordance with the implementation stages of the public healthcare's financial guarantees;
- ensuring the development, operation, and financing of the central database of the electronic health care system and transfer of property rights to the central database software to the National Health Service by January 1, 2019;
- including to the central database of the electronic health care system of the data contained in the electronic system of medical information exchange, created on the basis of the Concept of Healthcare Financing Reform, approved by the Order of the Cabinet of Ministers of Ukraine No. 1013 of November 30, 2016, and the action plan for implementation of the Concept of Healthcare Financing Reform for the period until 2020, approved by the Order of the Cabinet of Ministers of Ukraine No. 821 of November 15, 2017, as well as verification of relevant data;
- creating a comprehensive information security system complying with the central database electronic health care system.

Therefore, practical implementation of the electronic healthcare system established by the law provided for a significant amount of further work at the level of the relevant ministry. This work involved both rule-making activities, detailed elaboration of regulation, as well as solving a large number of technical issues.

As stated by R.V. Vlasenko, the electronic health care system (e-Health) is based on creation and maintenance of a number of electronic registries. However, at this time,

creation and filling of such registries is performed slowly and inconsistently, which causes technical and organizational problems in the functioning of the eHealth system, negative perception of the health care reform in general by patients and health professionals and in general reduces the availability of health services to end users. This situation resulted from a number of systemic problems, first of all:

- gaps in the legislation governing the establishment of health registries;
- unpreparedness of the supporting infrastructure, including incompatibility of the existing health information systems and lack of computer and network equipment in health care facilities, in particular due to lack of funding for the process of digitization of medical data and creation of infrastructure for the provision of high-quality medical services [13].

According to the researcher, despite the National Health Service of Ukraine statements about nearly 85% readiness of Ukrainian medical institutions for autonomization, the Ministry of Statistics shows that only 45% of medical institutions have an Internet connection, and the overall level of computerization of medical institutions is 42.7%. Without launching the main components of eHealth (including electronic medical registries), the effectiveness of the latest innovations in the electronic health care system is significantly reduced, and in some cases even creates new obstacles. Therefore, legislation of Ukraine urges changes in terms of building a consistent policy of implementation and filling of electronic medical registries with allocation of appropriate funding. First of all, it concerns the issue of creating conditions (including material ones) for the functioning of the nosology registers for diseases that cause the highest mortality and disability, and orphan diseases. [13].

Indeed, further completion of electronic medical data registries requires significant investment from the state. And this could be the subject of the active use of public-private partnership. However, despite the fact that the healthcare system in Ukraine is under extreme strain during quarantine, the Parliament has not yet adopted any laws that would create the conditions for effective and transparent involvement of private capital in the healthcare sector.

It should be noted that the coronavirus pandemic became a boon for telemedicine in Ukraine.

The main legislative act regulating the development of telemedicine in Ukraine is the Order of the Ministry of Health No. 681 «On approval of regulations on the use of telemedicine in health care» of October 19, 2015.

This normative act defines that telemedicine is a set of actions, technologies and measures implemented in the provision of medical care using remote means of communication in the form of electronic messaging.

Primary objectives of telemedicine include:

- providing medical care to the patient when the distance is a critical factor in its provision;
- maintaining medical secrecy, confidentiality, and integrity of medical information about the patient's health;
- creating a single medical space;
- promoting the quality of care and optimizing the processes of organization and management of health care;
- developing systemic approaches to the introduction and development of telemedicine in the health care system [14].

Telemedicine is a way to provide help to patients at a distance and in those conditions when they are not able to leave their homes. And hence, the quarantine, introduced in many countries around theworld to prevent the spread of coronavirus disease (COVID-19), further accelerates the pace of development of remote medical care. Thanks to telemedicine, consultations of the best doctors, including highly-specialized physicians, become available in the most remote settlements and distant countryside.

Therefore, while before the pandemic telemedicine was an optional and non-compulsory service for many doctors, it has now become an essential part of providing health services to the population.

The active use of telemedicine technologies in the fight against coronavirus has contributed to its extremely rapid development. In this aspect, it can be noted that free telemedicine services have become available not only to doctors but also to patients. In addition, the area of services offered by medical mobile applications has significantly expanded. The field of telemedicine peer counselling for doctors has also expanded. Now, active peer counselling is available not only for primary-, secondary- and tertiary-level physicians, but also for doctors of specific specialties.

CONCLUSIONS

Most countries are not ready to practically ensure constitutional guarantees of human rights to health care in the context of the spread of COVID-19 on the one hand, and, a balance between restrictions of rights and freedoms, and, economical and social interests of humans and private businesses on the other. Restrictions on the exercise of powers by public authorities, the introduction of quarantine-related subordinate legislation in Ukraine actually violated the constitutional rights of its citizens. Development of the eHealth system and further completion of electronic medical registries, which requires significant financial investment from the state, could be boosted through the use of public-private partnership tools.At the same time, the coronavirus pandemic has become a significant impetus to the development of telemedicine in Ukraine, which contributed to the more rapid provision of medical services to all target groups.

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REVIEW ARTICLE

LEGAL REGULATION OF EPIDEMIC SECURITY UNDER THE COVID-19 PANDEMIC CONDITIONS IN SOME POST-SOVIET COUNTRIES AND POLAND

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ABSTRACT

The aim: To reveal the features of the epidemic safety and security legal regulation in Belarus, Kazakhstan, Moldova, Poland, Russia and Ukraine during the COVID-19 pandemic.
Materials and methods: This study is based on Belarusian, Kazakh, Moldavian, Polish, Russian and Ukrainian regulatory acts as well as national court judgments. Such methods as dialectical, comparative, analytic, synthetic, comprehensive, statistical and generalization approaches have been used in the article.
Conclusions: the study confirmed that the direct impact on the spread and dynamics of morbidity during the COVID-19 pandemic in the countries to be analyzed is determined by: the presence of government agencies and special institutions involved in combating, preventing and monitoring the spread of infectious diseases and their readiness for effective measures in emergency situations caused, in particular, by epidemics; timeliness and duration of quarantine restrictions, their severity and scope; observance of these restrictions by the population; effectiveness of law enforcement responses to violations. The strengthening of administrative and/or criminal liability had no significant impact on the morbidity situation in the country.

KEY WORDS: public health, epidemic security, SARS CoV-2 pandemic, quarantine restrictions, liability

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INTRODUCTION

Epidemic security is an important component of each state's national security. Despite the development of the world, outbreaks of epidemics occur on the regular basis: the rapid pace of people movement across the world leads to the rapid spread of disease. Thus, only in the beginning of the 21st century the world had already experienced a pandemic of influenza A/H1N1 (01.2009-08.2010)[1], epidemics of Severe Acute Respiratory Syndrome (SARS), H5N1 (HPAI A (H5N1), Middle East respiratory syndrome coronavirus (MERS-CoV), Ebola, Zika, etc. Also, as noted in the literature, "Old diseases - Cholera, Plague, Yellow fever among them - often return, and new ones invariably arrive to join them". About 40 outbreaks of cholera alone are reported to WHO every year [1, p. 15], the epidemics of HIV/AIDS and tuberculosis continue to date. The latest pandemic in the world is the COVID-19 coronavirus pandemic (caused by the rapid spread of SARS-Cov-2 virus) has shown how quickly epidemics and pandemics can modify the "face of the world", suspending most of our usual social processes[2]. As rightly noted, "the threat to global health has reached alarming proportions and has exposed a lack of national preparedness and international solidarity" [2, p .1521]. Such situations emphasize the fact that the health of the population is the key to the functioning of all the important areas/processes in each state: from the effective operation of government agencies to the state of the economy. The same provisions are noted by F. Alazzam, K. Aldrou, R. Moiseyenko, V. Mykhalchuk, Y. Radysh, A. Saleh [2, p. 1522; 3, pp. 995].

In response to the threat most countries urgently tightened state control over migration processes, restricted tourism and services to prevent the deterioration of the situation due to foreign visitors, outbreak and spread of

[1] Although the debate initiated by Wolfgang Wodarg regarding the falsity of the decision to declare this pandemic, which was supported by the Parliamentary Assembly of the Council of Europe on October 5, 2010, continues, the WHO did not agree with this criticism [4]. According to the official data, 18,500 people died during the A/H1N1 influenza pandemic, and the diagnosis was laboratory confirmed [5], while researchers suggested that between 151,700 and 575,400 people had died using mathematical simulations [6].

[2] A clear confirmation was achieved: "The sudden influx of large numbers of sick individuals to health facilities stretches the systems' capacity and resources, even more so and more noticeably where resources are already scarce" [1, p. 21]. Since the announcement of the Covid-19 pandemic, people with non-epidemic related health issues have found it more difficult to access health care. The same opinions were expressed in the WHO, noting that "many routine and elective services have been suspended... Disruptions to 24-hour emergency room services for example were affected in 22% of countries, urgent blood transfusions were disrupted in 23% of countries, emergency surgery was affected in 19% of the countries" [7].

COVID-19, as well as to provide conditions and tools for rapid and quality response to their emergence/spread, restricted trade, banned the export of medicines, medical products and equipment, etc. Some countries also increased administrative and/or criminal liability for violating the quarantine regime.

THE AIM

The purpose of this paper is to compare the legal regulation of epidemic security in the Republic of Belarus (hereinafter, RB), the Republic of Kazakhstan (hereinafter, RK), the Republic of Moldova (hereinafter, RM), the Republic of Poland (hereinafter, RP), the Russian Federation (hereinafter, RF) and Ukraine, and also to identify features of such regulations impact on the spread rates of COVID-19 coronavirus infection in these countries.

MATERIALS AND METHODS

This research is based on Belarusian, Kazakh, Moldavian, Polish, Russian and Ukrainian regulatory acts as well as scientific publications. Additionally, statistical data, expert opinions, judicial practices, doctrinal ideas and reviews on this issue has been used. Besides, the article is based on dialectical, comparative, analytic, synthetic, comprehensive, statistical analysis and generalization.

REVIEW AND DISCUSSION

On January 30, 2020, the World Health Organization declared an outbreak of coronavirus 2019-nCoV-2 "Public Health Emergency of International Concern" [8]. On 31 January 2020, WHO issued a "Global Surveillance for Human Infection with Novel Coronavirus (2019-nCoV): Interim Guidance" for Member States, providing recommendations to prevent outbreaks and/or rapid spread of a new infection in their territories [9]. The WHO then issues several other recommendations. All documents are periodically supplemented and adjusted to consider new information, in particular, on March 20, April 16, August 7, etc. [10; 11; 12]. On March 11, 2020, the COVID-19 pandemic was declared [13]. However, to that date each of the countries of the world had different levels of readiness to fight this virus: some are better, others are worse, some countries decided to use an approach to develop collective immunity (for example, Sweden, Japan).

The actions of government agencies and special institutions involved in the fight, prevention and monitoring of the spread of infectious diseases in a given area were one of the indicators of each country's readiness to respond to epidemic threats. During the spread of COVID-19, the need for their existence and proper functioning in each country was obviously demonstrated.

It should be noted that the post-Soviet states partially borrowed the Soviet model of control over epidemic security, which was later reorganized. Thus, in Belarus, Kazakhstan, Moldova, Russia and Ukraine special bodies were created to address such health care issues as: 1) anti-epidemic measures, 2) infection control organization and 3) response to epidemic situations. Over time these bodies were transformed, and the areas of their activities changed. Thus, in Ukraine and Moldova, sanitary and epidemiological services were eliminated, and their functions were transferred to the bodies for which the fight against epidemic threats is not a priority.

In Belarus today, the system of sanitary control bodies is quite extensive and includes: The Hygiene, Epidemiology and Prevention Department of the Ministry of Health (hereinafter, the Ministry of Health); republican, regional centers of hygiene, epidemiology and public health; city, district, zonal hygiene and epidemiology centers in cities; disinfection and sterilization centers [14].

In the Republic of Kazakhstan, to date, the bodies of the sanitary-epidemiological service are: 1) branches of the Scientific and Practical Center for Sanitary-Epidemiological Examination and Monitoring; 2) state organizations involved in sanitary and epidemiological examination at the state border, in territories, transport facilities; 3) state organization that carries out sanitary and epidemiological examination during official events with the participation of state officials; 4) republican research organizations engaged in sanitary and epidemiological well-being activities, and 5) state anti-plague institutions [15].

In the Russian Federation, starting from 2004 till today the structure of control bodies of public health has included the Federal Service for the Oversight of Consumer Protection and Welfare responsible for, inter alia, sanitary and epidemiological supervision and control. Units in the federal subjects, Moscow and St. Petersburg, Hygiene and Epidemiology Centers, Research Institutes, hygiene and epidemiology related authorities, anti-plague institutions, sanitary and epidemiological services of ministries and departments are subordinated to the said Federal Service [16].

In the Republic of Poland, that is oriented towards the Western European countries, the State Sanitary Inspection is the leading body for ensuring the sanitary and epidemiological safety and security of the population, which implements the main functions through the Main Sanitary Supervision Body and the Sanitary and Epidemiological Council [17].

In our opinion, Moldova and Ukraine were among the most unprepared states in terms of combating coronavirus 2019-nCoV-2 due to the lack of a special state body to control the epidemic situation. Thus, in the Moldova, the State Sanitary and Epidemiological Service functioned within the structure of the Ministry of Health, Labor and Social Protection until 2010. However, at the time of the pandemic declaration, a separate body that would ensure the sanitary and epidemiological safety and security of the population was no longer available. Its functions were partly entrusted to the National Public Health Agency that is subjected to the Ministry of Health, Labor and Social Protection and having its own territorial offices. However, after the declaration of an emergency situation in Moldova the Public Health Institution "COVID-19 Center" was established in Chisinau [19].

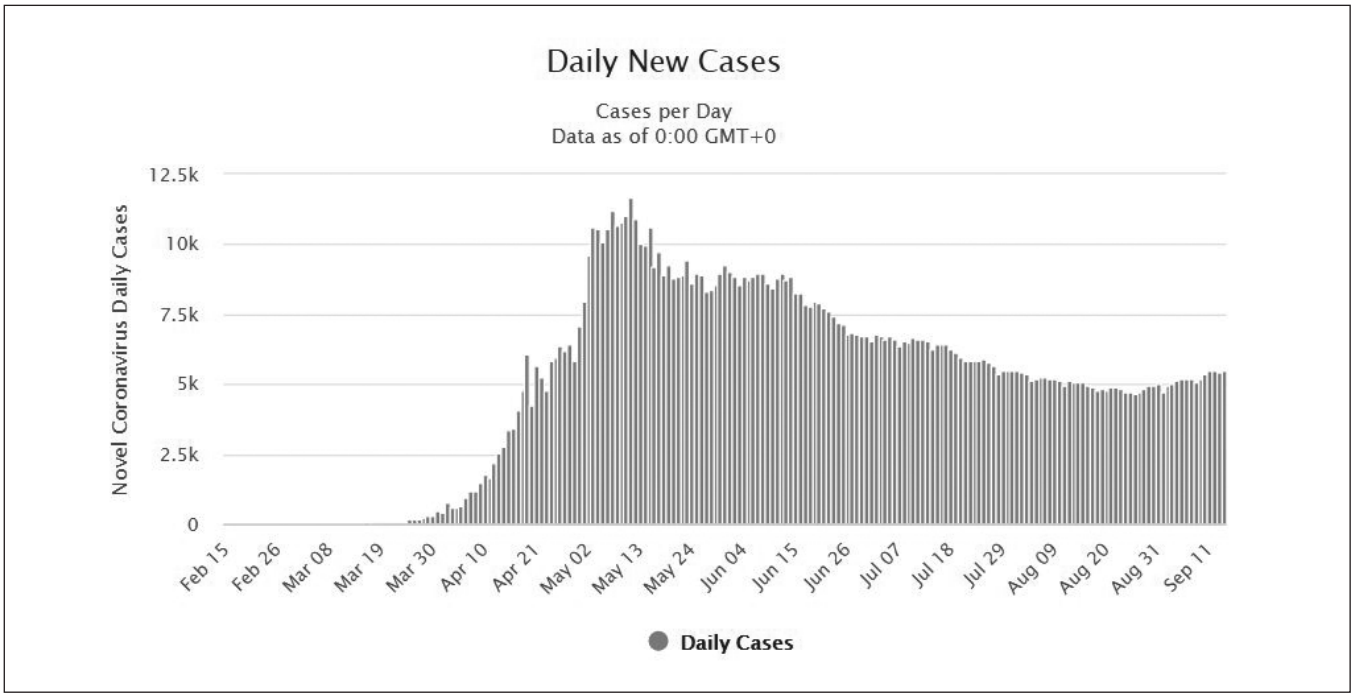

Fig. 1. Daily new cases in Russia.[3]

In Ukraine the functions of the State Sanitary and Epidemiological Service, which had been liquidated in 2017 and existed as a separate central executive body, were transferred to the Ministry of Health, the Ministry of Agrarian Policy and Food of Ukraine and the State Service for Food Safety and Consumer Protection. The dispersion of functions related to the control, prevention and monitoring of the spread of infectious diseases among institutions with other priority areas of activity led to a lack of comprehensive support for the epidemic security of the state. Therefore, on February 26, 2020, the position of Chief Sanitary and Epidemiological Doctor was restored in Ukraine. Today, the creation of a special state body to ensure sanitary and epidemiological security in Ukraine seems to be a cornerstone: the pandemic has shown that anti-epidemic measures, infection control and response to epidemic situations are vital for the effective health care policy in each country. Currently, the Government is considering options for establishing a service within the Ministry of Health. This once again confirms, in our opinion, the erroneousness and hastiness of the State Sanitary and Epidemiological Service elimination of in 2017. As rightly pointed out by Dr. T.A. Ghebreyesus, the WHO Director-General, "COVID-19 should be a lesson to all countries that health is not an 'either-or' equation. We must better prepare for emergencies but also keep investing in health systems that fully respond to people's needs throughout the life course" [7].

In addition to the functioning of special sanitary and epidemiological authorities, the measures implemented by the states to prevent the spread of COVID-19, the time of their implementation and the duration of such measures have also become a key to maintaining a safe (steady) level of morbidity. The red line among all quarantine restrictions imposed in all states is: the obligation of persons arriving from foreign countries within 14 days from the date of arrival to self-quarantine at home (recommended by WHO on February 29, 2020) [20], and the ban on the export of medicines, medical products and equipment.

Russia was the first state to start implementing preventive measures. On January 24, 2020, the Federal Service for the Oversight of Consumer Protection and Welfare issued Resolution № 2 "On Additional Measures to Prevent the Spread of New 2019-nCoV-Coronavirus Infection". On January 29, the Interdepartmental Operational Headquarters was established. Moreover, the first cases of COVID-19 (2 people) were identified on January 31 in Russia. From that day on, due to the spread of coronavirus infection, the state began to gradually close its borders. Thus, on March 16, the Russian Government issued a resolution to close Russia's border with Belarus, the only country with no strict quarantine restrictions in its territory. It was also decided to limit the leisure of the country's population and sports events at all levels.

On March 25, when the number of new cases per day reached a rate of 163 and there were no coronavirus-related deaths [21], the Russian government declared the day-off period from March 30 till April 3 inclusive, which was then extended until April 30. Additionally, all life support structures (banks, shops, transport, pharmacies, medical institutions) and authorities at all levels continued to work. Additionally, by the Executive Order of the President of the Russian Federation dated April 02, 2020 № 239 "On ensuring people's sanitary and epidemiological welfare in view of coronavirus infection spread (COVID-19)", heads of regional administrations of the Russian Federation were given the discretion to impose restrictive measures, including restrictions of movements. Such rather mild quarantine

3 Hereinafter, graphs from the Worldometers web-site [21].

regime seems to have resulted in a lack of positive dynamics in the number of new cases (see Figure 1). For example, on May 11, Russia ranked 3rd in the world by the number of cases (11,656 daily new cases and 94 daily new deaths [21]), due to the eased regime. However, some of the quarantine restrictions continued, in particular: restrictions for the elderly and those suffering from chronic diseases; ban on mass events; prolongation of the powers of the heads of regions to ease or strengthen restrictive measures, etc. This resulted in an improvement of the epidemic situation, partly due to the seasons change (warming), and as at August 31, 2020, there were 4,993 new cases of COVID-19, and 83 people died [21].

It should also be noted that among the measures aimed at combating coronavirus infection, Federal Laws dated April 01, 2020 № 99-FZ and № 100-FZ in the Russian Federation strengthened administrative[4] and criminal liability for the violation of sanitary and epidemiological rules. According to the analysis of judicial practice, during the period from April 01, 2020 till August 31, 2020, Russian courts considered 16 criminal cases under Art. 236 "Violation of Sanitary and Epidemiological Rules" of the Criminal Code (hereinafter, the CC) of the Russian Federation. However, only 3 persons were convicted and imposed with a real sentence. Another 5 people were exempted from criminal liability under Art. 76.2 of the CC with the determination of a criminal law measure (court fine). Five materials of criminal cases were returned to prosecutors by courts. Nothing is known about the progress of 3 more cases. Much wider was the practice of administrative prosecution of persons under Part 2 of Art. 6.3 of the Code of Administrative Offenses (hereinafter, the CAO). In particular, 29, 742 administrative offense reports were issued. Among them, in 6,867 cases, individuals and legal entities were sentenced by the courts of the Russian Federation to an administrative fine, in 1,624 cases the proceedings were closed, in 1,638 cases the protocol was returned to the police, and in 231 cases the case was transferred to proper jurisdiction [22].

On January 26, 2020, the Republic of Kazakhstan strengthened sanitary and epidemiological control at checkpoints across the state border and held training exercises. Medical monitoring of persons arriving from China was also provided, and the 72-hour visa-free stay for Chinese citizens in Kazakhstan was suspended. On January 31, the second stage of strengthening sanitary and epidemiological control began: 150 sanitary and epidemiological service experts were sent to sanitary and quarantine points near the state border, laboratory diagnostics were established, clinical treatment protocols and algorithms of anti-epidemic measures were approved.

On March 13, the first 7cases of COVID-19 were identified and on March 14 there were 4 more, and on March 15 there were 6 more [21]. Therefore, on March 15, a state of emergency was declared in Kazakhstan, which was further extended until May 1. On April 27, the daily rate of new coronavirus cases reached 217 people [21], the authorities of the Republic of Kazakhstan decided to extend the state of emergency until 00:00 of May 11, while deciding to mitigate the quarantine regime in cities and regions. The situation with the spread of the virus was under control.

The easing of quarantine measures led to the announcement of a lockdown regime in Kazakhstan on July 5: all facilities were closed, except for supermarkets, pharmacies, cafes (with social distancing requirements), airports (domestic flights). It was caused by a sharp deterioration of the epidemiological situation and the rapid spread of the disease, as seen in Fig. 2. Such prompt and tough measures had a significant positive effect. Thus, as at August 31, 2020, the number of infected people decreased significantly to reach 111 new cases per day and the downward trend proceeded [21]. Despite the severity of the measures taken by the Government to stop the spread of coronavirus infection in the country, administrative and criminal liability for violating sanitary and epidemiological norms was not increased, due to sufficiency of punishment for such actions, according to the Kazakh legislator[5].

Instead, from January till early March 2020, there were minor ("soft") restrictions on air travel and for persons who are "contact persons" or came from a country where there was an epidemic of coronavirus infection.

On March 2, the Sejm of the Republic of Poland approved the Law "On Special Decisions Related to the Prevention, Counteraction and Control of COVID-19, Other Infectious Diseases and Emergencies Caused by Them" (hereinafter, the Law of March 2, 2020), which entered into force on March 8, 2020. It created the possibility of using administrative, budgetary and anti-epidemic means to combat the spread of coronavirus. This Law also amended the provisions of the Law on Prevention and Control of Infections and Infectious Diseases, after which: a) the Council of Ministers was given the right to declare an epidemic or an epidemiological threat in certain parts of Poland or throughout Poland; b) public authorities have the right to establish 3 different zones (zero level, buffer and danger zones) at the site of the epidemic outbreak, which differ in the level of restrictions associated with the risk of an epidemic in each area [23].

On March 4, the Ministry of Health of the Republic of Poland reported the first case of SARS-CoV-2. After that, the state began to gradually tighten quarantine restrictions. Thus, on March 8, the Chief Sanitary Inspector recommended the cancellation of all mass events involving more than 1,000

[4] Art. 6.3 of the CAO of the RF was supplemented by Part 2, establishing more severe penalties for violations of current sanitary rules and hygiene standards, non-compliance with sanitary and anti-epidemic measures, etc., committed during an emergency or at risk of spreading a disease that poses public danger or during the implementation of restrictive measures (quarantine) in the relevant territory.

[5] The administrative liability under Art. 425 "Violation of the Requirements of the Legislation in the Field of Sanitary and Epidemiological Well-Being of the Population, and also Hygienic Standards" of the CAO of the RK, Art. 476 "Violation of the State of Emergency" of the CAO of the RK and Art. 304 "Violation of Sanitary Rules or Hygienic Standards" of the CC of the RK.

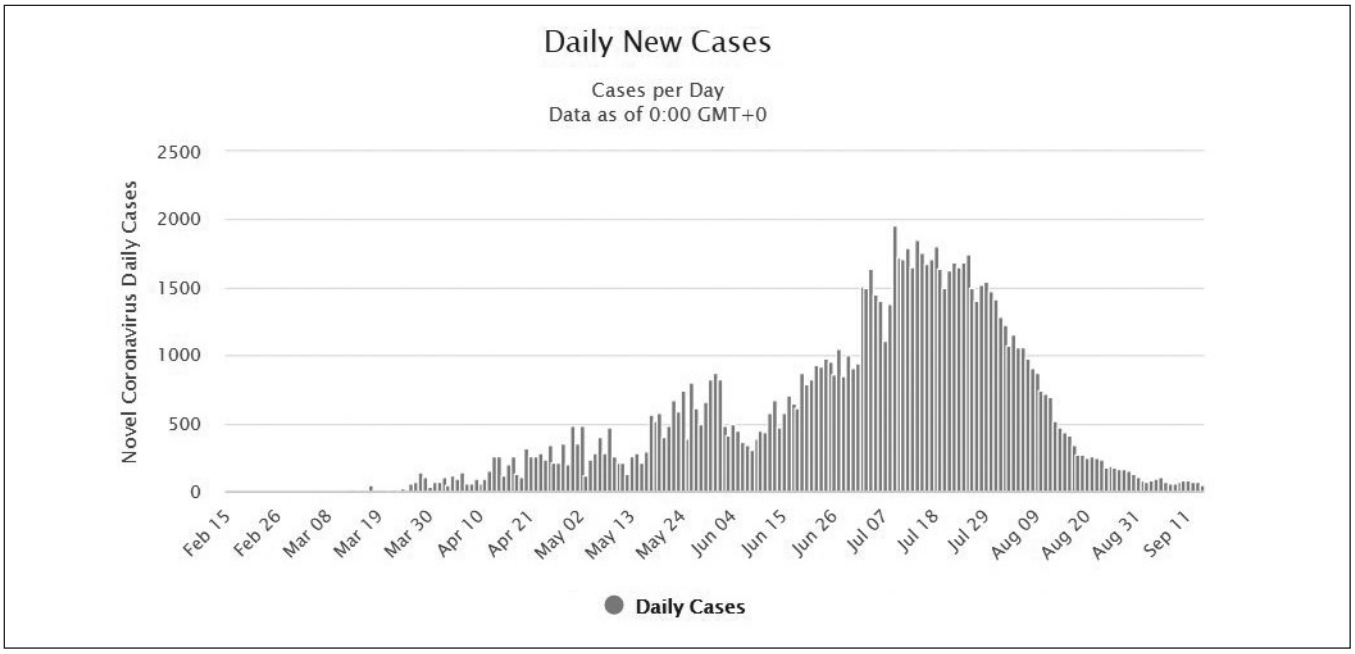

Fig. 2. Daily new cases in Kazakhstan.

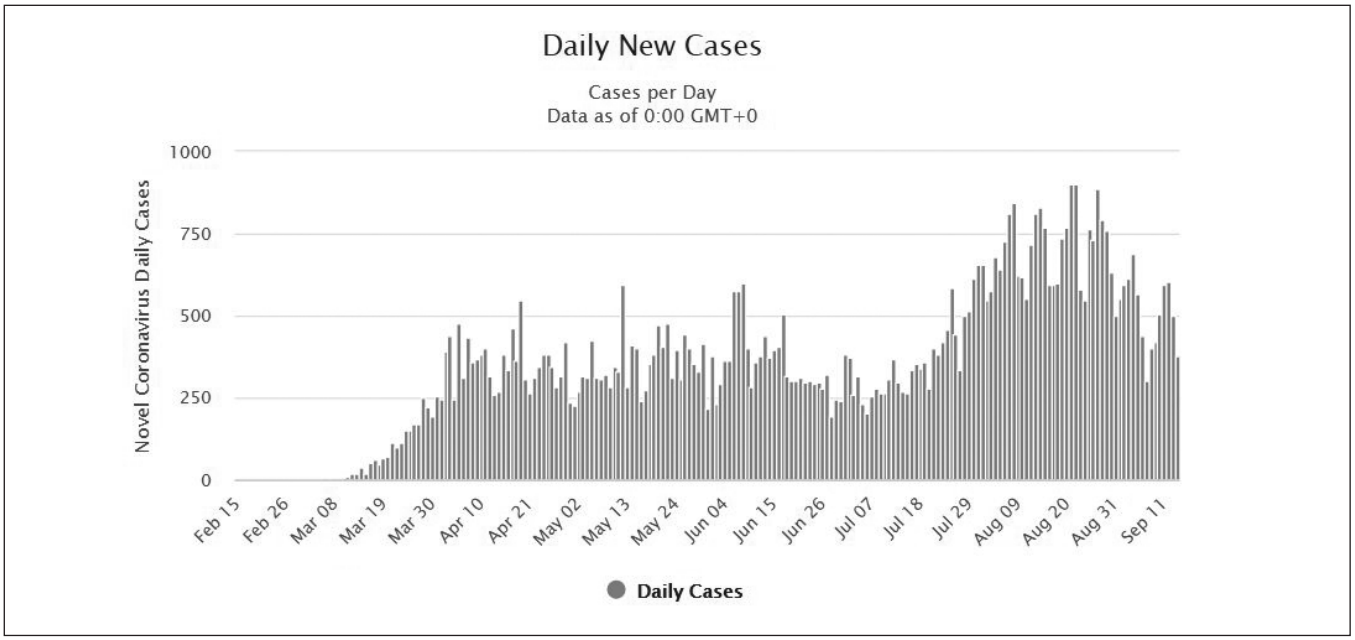

Fig. 3. Daily new cases in Poland.

people indoors. A meeting of the National Security Council on countering the spread of coronavirus in the country was held on March 10, and the Prime Minister of Poland canceled all mass events. On March 11, all schools, kindergartens, nurseries, and secondary schools were closed, except for special schools, institutions for the education of children with special needs and sociotherapy facilities, psychological and pedagogical centers, as well as schools in correctional facilities and prisons (from March 12 until March 25, 2020). An epidemic was officially declared on March 20, and the next day Poland had 111 new cases of COVID-19. From March 24, a lockdown was introduced (152 daily new cases and 2 daily new deaths [21]), which lasted until April 11. However, on March 31, the restrictions became even stricter, since as of March 30, Poland faced 193 daily new cases and 9 daily new deaths. On April 10, there was a slight easing, despite the fact that the rates increased (380 daily new cases and 9 daily new deaths [21]). In general, most restrictions were extended until May 3. Then, as can be seen from Fig. 3, Poland experienced a periodic fluctuation in the number of new cases in-line with increasing/decreasing of restrictive measures in certain areas. In particular, new restrictions are to apply in 19 poviats from August 8, which were related to two zones: yellow and red.

The Republic of Poland also strengthened criminal and administrative liability for violating quarantine restrictions. Thus, the Law of March 31, 2020 "On Amendments to

the Law on Special Decisions Related to the Prevention, Counteraction and Control of COVID-19, Other Infectious Diseases and Crisis Situations Caused by Them and Certain Other Acts" amended Art. 161 of the CC of the Republic of Poland with a new wording. In this case, according to Polish researchers, the changes cause numerous corpus delicti comments [24; 25]. It is noteworthy that, unlike the legislation of other countries to be analyzed, criminal prosecution of a guilty person in Poland for creating a risk of coronavirus infection of one person starts only at the request of the victim (§ 4 of Article 161 of the CC). For such actions the guilty person faces imprisonment for a term of 3 months up to 5 years, while the risk of infecting several people provides imprisonment from 1 up to 10 years, which is the most severe punishment among the countries we analyze[6]. Poland increased administrative liability for violating quarantine restrictions, where fines increased to 30,000 zlotys. The amount of the fine under Art. 116 of the Code of Minor Offenses depends on the agency that imposes these sanctions. If the police "fine on the spot", then fine will be 500 zlotys (for each violator), if the case is passed on to the sanitary services or court, then higher fines are applied [26].

It was the imperfection of the criminal norm and its significant severity that can be explained by the fact that as of August 31, 2020 the courts of Poland did not pass a single conviction under § 2 of Art.161 of the CC [27].

Ukraine faced one of the most difficult situations among the countries under study, due to the fact that at the time of the rapid spread of COVID-19 it did not have a functioning State Sanitary and Epidemiological Service. Moreover, since January, the airlines have gradually canceled flights to countries with a large number of coronavirus cases.

On February 26, the post of Chief Sanitary and Epidemiological Doctor was restored in Ukraine and already on March 3 the first case was found, and since March 10 there was a gradual increase in the number of new cases. On this background, on March 11, the Cabinet of Ministers of Ukraine introduced quarantine from March 12 till April 3, which in fact lasts to this very day. On March 25, due to the steady increase in the number of new cases (43 daily new cases and 2 daily new deaths [21]), the Government introduced a state of emergency throughout Ukraine until April 24, 2020, during which the authorities and civil protection services had to work in an enhanced mode and there was no provision for state intervention in the management of private companies or restrictions on the rights of citizens. On April 6, due to the epidemic situation (as at April 5, 83 daily new cases and 5 daily new deaths were detected [21]), new restrictive quarantine measures were introduced in Ukraine: a ban on visiting parks and recreation areas, mandatory wearing of masks in public places, persons over 60 years old were recommended to stay at home, which were subsequently extended until May 11 without mitigation. Subsequently, the Government presented a 5-stage plan for the country's quarantine, which began to be implemented on May 7[7]. In the summer, the list of quarantine restrictions constantly changed depending on number of new cases. Finally, from August 1, the quarantine rules in Ukraine have been changed: all regions were divided into green, yellow, orange and red zones, each of which provided for a different amount of quarantine restrictions. Such measures, although difficult for society to accept, generally affected, in our view, the containment of the infection. As can be seen from Fig. 4, it was only in autumn that the daily morbidity rates began to grow.

On March 17, Law of Ukraine "On Amendments to Certain Legislative Acts of Ukraine Aimed at Preventing the Occurrence and Spread of Coronavirus Disease (COVID-19)" № 530-IX strengthened criminal liability for the violation of sanitary and epidemiological rules (Art. 325 "Violation of Sanitary Rules and Norms for the Prevention of Infectious Diseases and Mass Poisoning" of the CC), which was also rightly negatively assessed by scientists [28, pp. 101-106; 29, pp. 237-240]. In addition, administrative liability was introduced for such actions: the CAO of Ukraine was supplemented by Art. 44-3 "Violation of the Rules on Quarantine of People", which imposed too severe penalties, and therefore, according to the analysis of case law, in the vast majority of cases judges limited punishment to the announcement of oral warning notice[8].

If we consider the trend of the disease spread in Moldova, which, like Ukraine there, had no special state body to control the epidemic situation, it should be noted that the situation in this small country is even worse and according to official data the percentage of infected persons is the highest. On February 25, 2020, some anti-coronavirus measures were introduced, in particular, persons crossing the border and under suspicion were subject to isolation. The first case of COVID-19 was found on March 7. On March 8, the Emergency National Public Health Commission issued an orange code warning at the national level in the context of the epidemic. The Red Code was announced on March 13, and 11 daily new cases were identified on March 15. As the number of new cases began to increase, on March 17 the Parliament declared a state of emergency throughout Moldova until May 15. Despite these measures, the total number of patients (Total Cases) increased to 109 people on

[6] The most severe criminal punishment, which is established in the criminal laws of Belarus, Moldova and Ukraine, for the spread of coronavirus infection among the population, and sometimes for creating a real threat of its spread, is imprisonment for up to 3 years. The criminal legislation of the RK and the RF provides for up to 2 years of imprisonment.

[7] As of May 6, 2020, 487 daily new cases and 11 daily new deaths were identified.

[8] Thus, the data of the Unified State Register of Court Decisions of Ukraine show that in the period from March18, 2020 till August 31, 2020, 2,370 people were found guilty of committing an administrative offense under Art. 44-3 of the CAO of Ukraine. Analysis of 100 of these resolutions shows that: a) an administrative penalty in the form of a fine was imposed on 26 persons, of which 25 persons were fined in the amount equivalent to UAH 17,000, 1 person was fined in the amount equivalent to UAH 34,000; b) 73 persons were released from administrative liability due to the insignificance of the act with the announcement of oral remarks. Another case was closed [30].

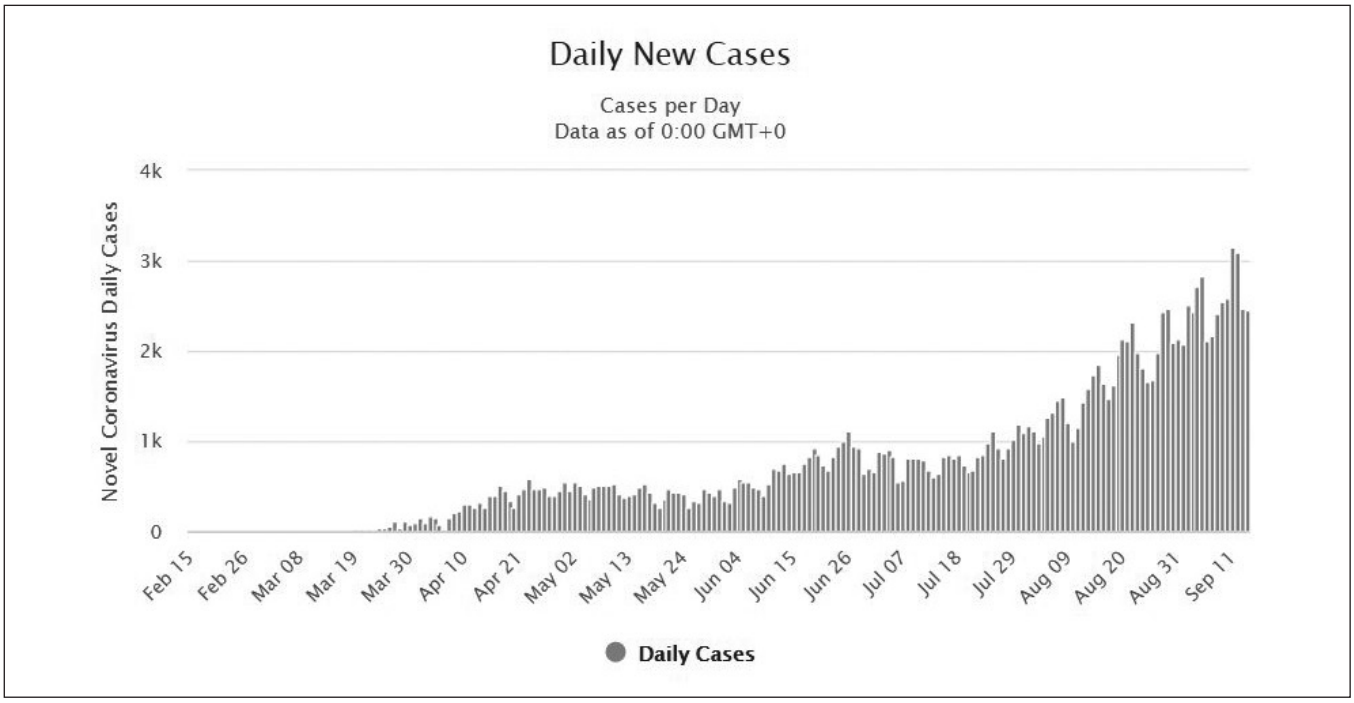

Fig. 4. Daily new cases in Ukraine.

March 23 and to 1,056 cases on April 7 [21]. On April 27, the total number of deaths exceeded 100. A public health emergency was declared in Moldova starting on May 16 and quarantine restrictions were partially decreased, and despite a sharp increase in the number of patients (189 daily new cases and 5 daily new deaths [21]), the authorities did not strengthen quarantine and generally extended the state of emergency until August 31.

In Moldova, Law of March 12, 2020 № 52 "On Amendments to Certain Regulations" also not only strengthened criminal liability for the spread of epidemic diseases (Art. 215 of the CC), but also amended the Code of Offenses of the Republic of Moldova with the Art. 76-1 "Failure to Comply with Measures for the Prevention, Counteraction and/or Control of Epidemic Diseases".

However, all these quarantine restrictions do not seem to have improved the situation (Fig. 5). The reasons for this can be seen, according to E. Goloshchapov, in the fact that people ignore safety measures in the hot weather conditions [31].

Belarus is a special case in terms of the countries studied. Thus, the first case of COVID-19 in Belarus was detected on February 28, 2020. As of March 11, there were 9 cases, and on March 12 there were already 21 cases of coronavirus [21]. But only on March 12, the Council of Ministers decided to limit all cultural, sporting and scientific events with international participation until April 6. From March 13, railway and air transport communication with many foreign countries was suspended. However, these measures could not limit the rapid spread of the infection and as of March 13, 27 Total Cases had already been identified. March 23 was marked by 81 cases, of which only 5 daily new cases [21]. On March 25, the Minister of Health of stated that he would no longer update the map of the spread of coronavirus infection, explaining it by the need to protect the rights of patients. However, fig. 6 clearly shows that the morbidity rates subsequently increased rapidly.

Also, Resolution of the Council of Ministers of March 25, 2020 № 171 defined measures to prevent the spread of infection caused by COVID-19, but these restrictions can be assessed as mild. It is noteworthy that, unlike other states, the authorities did not cancel the May 9 Parade dedicated to the Victory Day, although veterans were urged to stay at home and not to attend mass events. On May 12 in comparison to May 6 the number of cases considerably increased (from 905 to 967 daily new cases [21]).

Generally, when assessing the morbidity rates in Belarus, a remark should be made - they are quite relative. Thus, the National Statistical Committee of Belarus did not publish official data on mortality in the country for the first half of 2020, but based on information provided to the UN, in April-June mortality exceeded the average for the last 5 years by about 5,500 people. [32]. Reasons for such a rapid growth is not specified, but this information suggests that the epidemic of coronavirus infection is also raging in Belarus. However, according to official statistics, as at August 31, 71,843 people got infected with COVID-19 in Belarus [21]; according to Figs. 6, the morbidity rate since July has been consistently low.

Belarus has also become another country where neither administrative nor criminal liability for violating sanitary and epidemiological rules has been strengthened.

The analysis showed that the amount of restrictive measures imposed in all the countries studied was different at over time. It is seen that a number of factors has played a

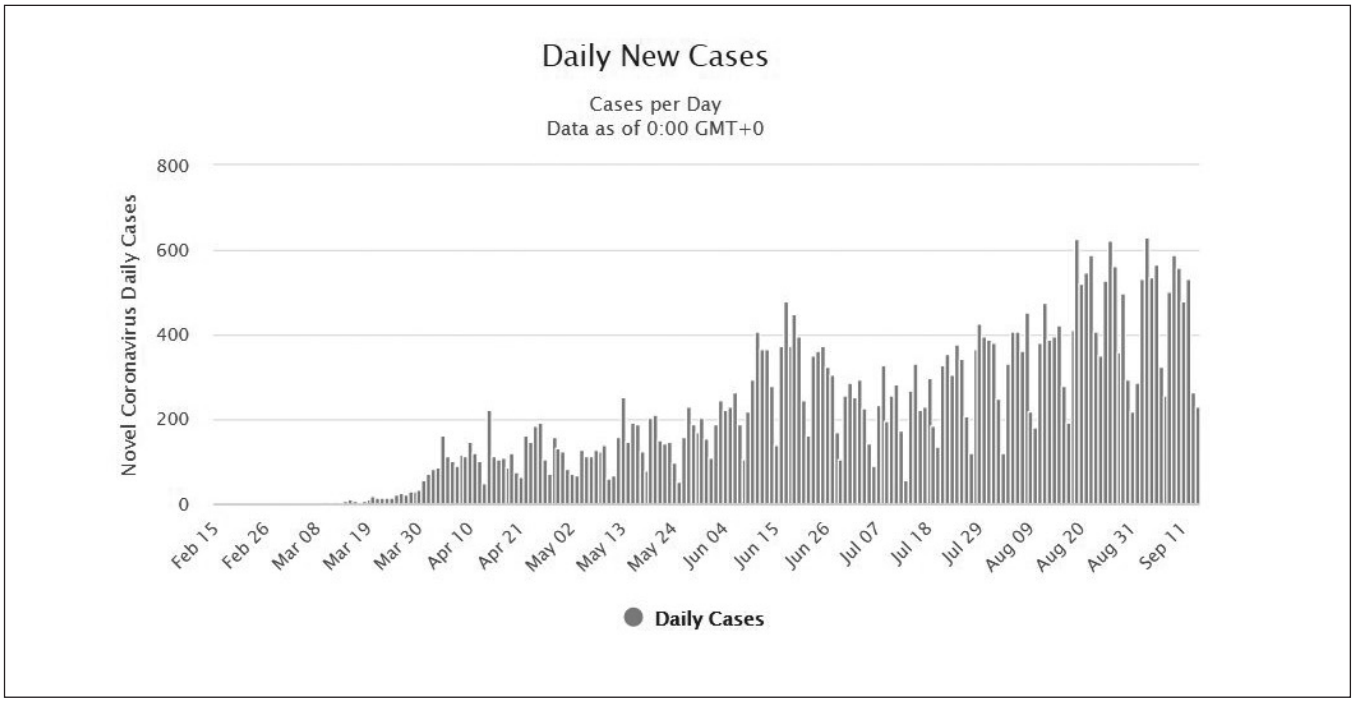

Fig. 5. Daily new cases in Moldova.

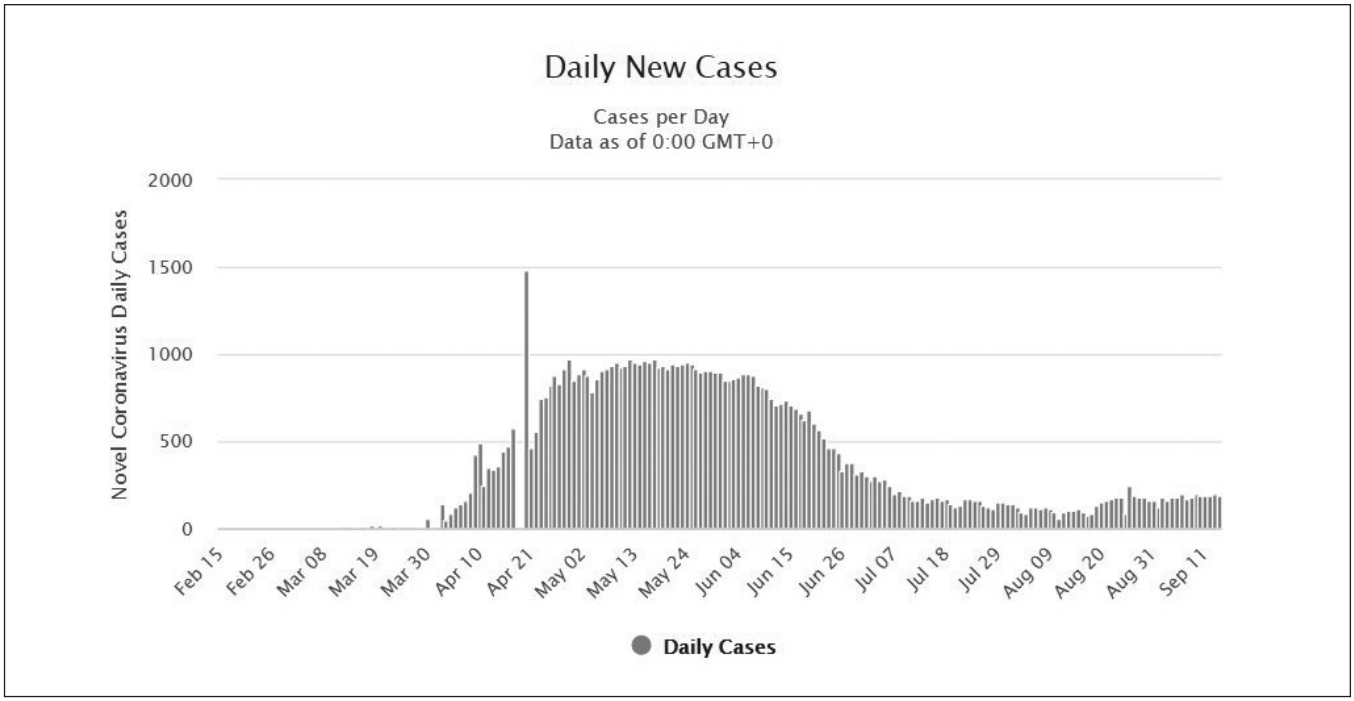

Fig. 6. Daily new cases in Belarus.

role in this process. In particular, the proximity to a country with a high morbidity rate, the COVID-19 spread rate within a certain area, the country's readiness to fight the coronavirus, the availability of places in hospitals, lung ventilators, health workers, protective equipment and others. Moreover, the time to implement these measures, their duration, level of perception and compliance by the population were of importance for the effective counteracting of the spread of coronavirus infection in a certain area. As a result, the quantitative indicators of COVID-19 cases as of August 31, 2020 were different for each of the analyzed countries, as shown in Table I.

These indicators make it clear that as of August 31, 2020 in Belarus 0.76% of the population was infected, of which 0.007% died, these figures were 0.562% and 0.008% in Kazakhstan; 0.916% and 0.025% in Moldova; 0.178% and 0.005% in Poland; 0.682% and 0.012% in Russia and 0.278% and 0.006% in Ukraine, respectively.

Table. I. Indicators COVID-19 cases as of August 31, 2020[9]

Country	Total Cases[1]	Total Deaths	Population
Belarus	71 843	681	9 448 781
Kazakhstan	105 795	1 523	18 814 618
Moldova	36 920	995	4 032 320
Poland	67 372	2 039	37 839 368
Russia	995 319	17 176	145 945 354
Ukraine	121 215	2 557	43 657 291

CONCLUSION

Thus, it should be noted that it will take time for the world to overcome the negative consequences of the SARS-Cov-2 virus. The study showed that the state of epidemic safety and security during the COVID-19 pandemic was significantly affected by: 1) the presence of government agencies and/or special institutions involved in combating, preventing and monitoring the spread of infectious diseases, 2) their readiness to operate effectively in emergencies situations caused, in particular, by epidemics, 3) the severity of the implemented quarantine measures, 4) the level of perception and compliance with security measures by the population, and 5) the effectiveness of law enforcement response to their violations. In addition, restraining the rate of coronavirus infection spread in a particular state depended on the timeliness of such restrictions and the time of their decreasing. It was also found that increased criminal and administrative liability for violating quarantine measures failed to become an effective tool to curb the spread of the disease. This is because the preventive effect is not so much dependent on the severity of punishment, but rather on the inevitability of its application to the perpetrator as well as the attitude of the population to the quarantine restrictions and good faith compliance.

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REVIEW ARTICLE

THE IMPACT OF COVID-19 PANDEMIC ON IMPROVING THE LEGAL REGULATION OF PROTECTION OF HUMAN RIGHT TO HEALTH

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ABSTRACT

The aim: Theoretical and methodological substantiation of the impact of COVID-19 on the implementation of state policy on the protection of human right to health in terms of improving the legal framework in the field of demographic security.

Materials and methods: The main research materials are the norms of the International Covenant on Economic, Social and Cultural Rights, the Conventions for the Protection of Human Rights and Fundamental Freedoms and the legal framework of the countries that have adopted temporary quarantine measures. This research is based on empirical and analytical data from WHO, Bloomberg's financial information provider. During the research, the following methods have been used: statistical, system-structural analysis, content-analysis, comparison, grouping and forecasting.

Conclusions: Under the conditions of pandemic, attention should be paid to strengthening both administrative and criminal liability for violating quarantine, which will serve as a prerequisite for improving the legal mechanism of combating threats to the country's demographic security. The protection of the right to health requires the state to create conditions to prevent the risk of occupational diseases among health care workers and others involved in the response to COVID-19.

KEY WORDS: global health, demographic sphere, state policy, health care

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INTRODUCTION

The determining factor of stable socio-economic development of the state is demographic security, and demographic processes are the prerequisite and the result of qualitative and quantitative changes in the demographic situation in the country. Therefore, the preservation of human resources, as a carrier of the intellectual potential of the nation, requires special attention and, today, acquires not only domestic but also geopolitical significance. It should be noted that the state of demographic security of the country is influenced by external factors, which due to the destructive impact on the demographic system can affect the political, economic, social and spiritual spheres of society, the level of socio-economic development of the state. Demographic security is currently the focus of the issue of depopulation of inhabitants, especially under the conditions of active phase of the COVID-19 pandemic, which requires demographic security as an adaptive system, improvement of state demographic policy in order to respond in a timely manner and counter threats to demographic security.

An important direction in struggle against the COVID-19 pandemic is a proper and timely legal response. The sphere of health care today, more than ever before, requires improvement of the existing and creation of the new strong legal framework, the legal principles of which would meet the international obligations of the state to respond to public health threats.

Scientists such as I. Azemsha, Ye. Podorozhnii, V. Lordkipanidze, A. Malnar, D. Malnar made an invaluable contribution to the study of the influence of the "responsibility" category on the state of demographic processes and, accordingly, the condition of the state's demographic security. However, the scientific work of the scientists focuses on the study of certain aspects of the studied phenomena, while the issue of improving the normative-legal providing of demographic security of the country under the conditions of pandemic becomes actual, namely improving the legal regulation of liability for violating the rules and norms of human quarantine. Thus, the relevance of the research topic determined the aim and the objectives of the study.

THE AIM

Theoretical and methodological justification of COVID-19 impact on the implementation of state policy to ensure the demographic security of the state and the protection of human right to health under the conditions of relevant legal framework improving.

To achieve this aim the following tasks should be solved:

1) to determine the main sources of threats to demographic security under the conditions of COVID-19 pandemic, to determine the main aspects of state policy improving during the pandemic;
2) to study foreign experience in legal regulation of liability for violation of quarantine conditions and the specifics of determining fines;

3) to suggest the approach to increase the response to the negative consequences of the pandemic and to propose key recommendations for counteracting the threats of the pandemic consequences to demographic sphere.

MATERIALS AND METHODS

The main research materials are the norms of the International Covenant on Economic, Social and Cultural Rights, the Convention for the Protection of Human Rights and Fundamental Freedoms and the legal framework of the countries that have adopted temporary quarantine measures. This research is based on empirical and analytical data from the WHO, Bloomberg's financial information provider, in particular on the number of patients in WHO regions, as well as the amount of fines for violating quarantine norms. In this research we used a number of research methods, in particular: the method of processing statistical data to analyze the number of patients in the world; the method of system-structural analysis to study the peculiarities of the application of measures to counteract and prevent possible threats to the demographic sphere; content analysis, method of comparison for the study of state policy of foreign countries related to ensuring the state's demographic security under the conditions of quarantine and the specifics of setting the amount of fine for violation of quarantine; grouping and forecasting to substantiate the conceptual framework of legal regulation of the issue of liability for violations of quarantine conditions and improving the mechanism of protection of human right to health.

REVIEW AND DISCUSSION

Taking into account the importance of the demographic situation, it should be noted that such negative processes of declining birth rates and increasing aging of population can threaten the passage of demographic processes and demographic security in general [1, p. 115].

Studies of the security aspect indicate the priority of demographic development of the state as a determining factor of security, which can serve as an indicator of the security sector and possible changes [2, p. 59]. The prerequisite for these steps should be clarifying the contextual filling of the category "responsibility". Considering legal responsibility as an independent phenomenon, it is advisable to emphasize that it comes from social responsibility, acting as a separate, unique manifestation [3, p. 7].

The opinion of I.B. Azemsha, who emphasizes the social - communicative nature of responsibility, which arises when human behavior is regulated by social norms and carries social significance is essential. In this case, the implementation of social norms is a social value phenomenon, and the actions that violate the rules that are socially significant are considered unacceptable and those that lead to the rupture of social communication causing negative reaction of society in the form of social responsibility [4, p. 54]. Thus, responsibility has a preventive effect, it is a mechanism for stopping illegal behavior and a measure to protect society. Establishing strategic priorities for the development of the demographic sphere will undoubtedly have a significant impact on the development of both society and the state. Therefore, special significance should be given to the process of formation and implementation of effective balanced state demographic policy, especially under the conditions of pandemic. Such policy will improve demographic processes in the country and prevent negative consequences of internal and external threats to demographic security of the country in the global transformational context. Among the main aspects to pay attention to when analyzing the state of demographic security of the country, the following are worth noting:

1) population of the country (population density, proportion of inhabitants of a particular region in the general structure of the population, depopulation, etc.);

2) the structure of population (disparities in gender and age composition of the population, imbalance of rejuvenation and population aging processes);

3) the reproduction of population (life expectancy, the ratio of reproduction and mortality of population);

4) the natural movement of population (natural increase (decline) of the population, birth rate and mortality, number of marriages and divorces);

5) the migration processes (intensification of urbanization processes, disproportions of the territorial location of the population, migratory population growth, growth of amounts of illegal migration).

The active spread of the COVID-19 coronavirus pandemic has caused great concern, forcing the countries to adapt to the new realities. As of August 17, 2020, 21,549,706 confirmed cases of COVID-19 were registered, including 767,158 deaths [5]. According to the World Health Organization, the leading region in the number of confirmed cases of COVID-19 is the United States (11,561,554 cases), followed by Europe (3,754,649 cases), Southeast Asia (3,103,018 cases), Eastern Mediterranean (1,737,027 cases), Africa (945,165 cases), western Pacific (414,606 cases) [5].

The virus is known to be aerosol-transmitted, so social distancing can prevent infection through respiratory drops when sneezing and coughing. Scientific studies suggest that the corona type of SARS-CoV virus can persist on the surface for up to 96 hours [6], while other types of virus - up to 9 days, and the incubation period can last up to 24 days [7], although the basis for conclusions is the state of patients after two weeks of the disease. It should be noted that SARS-CoV-2 infection significantly worsens the course of concomitant chronic diseases, especially diabetes and cardiovascular disease. Therefore, the key recommendation in the struggle against the pandemic is the prohibition of mass gatherings, social distance and timely consultation with a doctor when first symptoms of the disease appear.

The scale and severity of the COVID-19 pandemic is clearly growing to the level of the threat to society as a whole. In a number of countries, the outbreak has demonstrated shortcomings in health and social protection systems, making it difficult to protect at-risk groups and reduce disease transmission. In responding to this crisis, governments must give priority to human rights, including the right to health.

Responding to the challenges of COVID-19, countries are trying to create conditions that would contain the spread of the pandemic. However, each country responds to the same challenges with different measures and deadlines, which ultimately leads to differences in the epidemiological situation. Nevertheless, it is also necessary to take into account that countries have different reporting standards, different approaches to testing. It takes time to properly assess the effectiveness of the implemented measures, so the most informative is the negative experience of regions with early outbreaks - China, South Korea, Singapore and others.

China's approach included strict quarantine; strict restrictions on international and domestic travel; use of QR-health codes for permits to movement around the city; frequent household and street disinfection; testing, admission and treatment of all patients; isolation of suspicious cases, rapid construction of specialized hospitals for the treatment of patients with coronavirus.

In South Korea free and mass testing was conducted for people with symptoms, with suspicious contacts and for travelers. Education was not conducted in schools, it was recommended to work remotely, and large gatherings of people were prohibited.

Taiwanese authorities have been actively identifying patients with severe respiratory symptoms (based on information from the National Health Insurance database), and citizens have been encouraged to report suspicious symptoms or hotline numbers. The authorities monitored infected people and mapped cases. Contact persons were inspected on a large scale, from simple communication with the patient to the inspection of internal surveillance cameras. The location and observance of the rules of self-isolation of people with coronavirus through personal phones were monitored.

Although these early and decisive measures did not eradicate the virus, they helped to delay its spread over time relieving the capacity of the health care system, thus guaranteeing everyone the right to health established by the International Covenant on Economic, Social and Cultural Rights, which stipulates that states must create conditions that provide everyone with medical care and medical assistance in the event of illness [8].

The tendency to increase the number of patients has led to the increase in state budget expenditures to overcome the coronavirus epidemic and eliminate the consequences. Thus, as of April 9, 2020, budget measures totaling more than 8 trillion US dollars have been implemented worldwide [9].

Overcoming the negative consequences of the pandemic requires the implementation of appropriate measures and their realization through the state policy. Thus, a number of countries and health care providers are making concerted, joint efforts to combat the coronavirus. The European Commission has launched the global online donor conference, "Coronavirus Global Response", to combat COVID-19 in response to the World Health Organization's call for cooperation to raise funds to jointly develop and widely implement effective diagnostic, treatment and vaccination tools against the coronavirus, whose participants managed to raise 7.4 billion euros [10].

To reduce losses and overcome the spread of infectious disease, it is extremely important to work ahead, introducing additional unprecedented protection measures, including forced quarantine, curfews, restrictions and / or blocking opportunities to travel, engage in economic activities, lead active social life and more. The Convention for the Protection of Human Rights and Fundamental Freedoms recognizes that in the context of public danger that threatens the life of the nation, including serious threats to public health, such restrictions of rights may be justified [11]. The International Covenant on Economic, Social and Cultural Rights guarantees everyone the right to the highest attainable standard of health and obliges states to take all necessary measures for the prevention, treatment and control of epidemic diseases [12]. The Syracuse Principles determine that in the event of a conflict between human rights and public health needs, states may restrict rights. However, in any case, such actions must be necessary to achieve legitimate goals, based on scientific evidence, to have limited period to be revised [13].

The study of foreign experience in solving this problem revealed that the pandemic contributed to the increase in fines for violating quarantine rules.

For example, in Poland, the amount of the fine imposed by the sanitary-epidemiological service for violating quarantine reaches PLN 30,000. In Latvia, the fine for violating quarantine is 350 euros, but if such violations are found serious or prove the intentional infection of others, the violator faces 3 years of imprisonment [15]. In Saudi Arabia, violation of quarantine is punishable by a fine of $ 53,300 or two years imprisonment [14].

In some countries, criminal liability was immediately imposed for those who did not comply with coronavirus control instructions. For example, in Romania, for ignoring the quarantine requirements a person can be imprisoned for 3 years, for infecting others - up to 5 years, for failure to take measures to combat the epidemic that led to death - up to 15 years of imprisonment [15]. The largest scope of offenses is a public appearance without a protective mask, which is a very serious disregard for one of the basic rules of anti-epidemic safety. The study of the situation regarding quarantine restrictions in the Federal Republic of Germany shows the possibility of slowing down the spread of the virus by 40% due to the establishment of requirements for wearing a protective mask. The basis of this hypothesis was the experience of the German city of Jena, in which the mask regime was among the first to be introduced. After 20 days, the number of new cases in the city decreased by 25%, and later approached almost zero. The results of the study varied depending on the region, but there was a noticeable tendency to reduce the number of reported cases of infection by 2.3-13% within 10 days after wearing the mask became mandatory [16]. Therefore, the use of medical masks, provided they are used properly, is an effective method of preventing the spread of coronavirus.

Equally important task for the states in the context of

ensuring the right to health is to minimize the risk of occupational diseases among healthcare workers and others involved in responding to COVID-19. In the first place, this should be done by providing these people with appropriate protective equipment. In addition to the risk of COVID-19 infection at work, they are forced to overwork, as a result of which they may experience psychological stress and fatigue [17]. Therefore, special training and psychological assistance should be provided for such persons.

The World Health Organization has established strategic and technical advisory group of the World Health Organization on infectious hazards, the main activity of which today includes regular monitoring and risk assessment of the COVID-19 pandemic, as well as the development of practical recommendations to the World Health Organization on measures to counteract and prevent emergencies in healthcare. The active spread of the pandemic and the growing number of patients requires use of self-defense measures. Thus, the World Health Organization's strategic and technical advisory group has developed a number of recommendations to reduce the rate of infection transmission:

1) States should ensure preparedness and strengthen response measures, taking into account possible scenarios for the spread of the virus.

2) In order to strengthen preventive measures, it is necessary to consider the possibility of combining protection measures, in particular: preparation of the health care system for a possible increase in the number of diseases, control and prevention of infections in medical institutions, informing population, active promotion of personal hygiene under the conditions of pandemic.

3) In countries where COVID-19 has not yet been identified or has been detected in a small number of cases, epidemiological surveillance activities should be intensified in order to detect cases of illness in a timely manner and apply preventive measures for further spread among the population. Additional necessary measure to combat the spread of infection is social distancing, which should be observed both indoors and outdoors.

Countries in the WHO region should receive all the necessary financial and technical assistance, including from the World Bank, in particular from the Pandemic Emergency Fund, etc. [18].

4) Scientific researches on gaps in the COVID-19 pandemic study should be strengthened and foreign experience in combating and counteracting the spread of the virus should be implemented.

Taking into account rapid spread of the disease and increase in budget expenditures to combat COVID-19 among members of the world community, we propose to implement best practices in legal enforcement of the COVID-19 pandemic, increasing the responsibility for violating quarantine rules:

administrative liability - by increasing the amount of fines;

criminal liability - by abolishing the possibility of execution of a penalty in the form of a fine, leaving in the sanction of the article only sanctions in the form of arrest, restriction or imprisonment.

CONCLUSIONS

Revenues to the state budget from the payment of fines for violating quarantine norms should be used to finance monetary compensation to those involved in the struggle against the pandemic, in order to form effective state demographic policy to respond to today's challenges.

We emphasize that the proposed aspects of responsibility can serve as a practical recommendation for the formation of foreign countries regulatory framework.

1) Under the conditions of pandemic, attention should be paid to strengthening both administrative and criminal liability for violating quarantine, which will serve as a prerequisite for improving the legal mechanism for countering threats to the country's demographic security by responding to challenges and dangers, creating conditions for socio-economic development and quality progress of society.
2) The protection of the right to health requires states to create conditions to prevent risk of occupational diseases among healthcare workers and other persons involved in response to COVID-19.
3) All countries must commit themselves to quickly respond to challenges and take all necessary health measures, strive to provide adequate and enough funding to contain the virus and protect people. Only global, coordinated, international cooperation can minimize the negative effects of the pandemic.

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REVIEW ARTICLE

ENSURING RESPECT FOR HUMAN RIGHTS AND FREEDOMS IN THE CONTEXT OF STATES' MEASURES INTRODUCTION TO COMBAT THE COVID-19 PANDEMIC: EUROPEAN EXPERIENCE

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ABSTRACT

The aim: To suggest the ways and means for ensuring respect for human rights and freedoms in the context of introduction of states' measures to combat the COVID-19 pandemic based on the generalization of European experience and systematization of recommendations of international and European institutions.

Materials and methods: In thise research we applied a complex of philosophical and ideological approaches, general scientific and special methods of scientific cognition, in particular civilizational and axiological approaches as well as dialectical, comparative legal and statistical methods.

The empirical basis of the study is represented by the statistical data of the healthcare sector of European countries, generalization of the practice of countering the pandemic spread. In this study we used international and European regulatory legal acts and documents in the field of human rights, national legislations of foreign countries.

Conclusions: Derogation from the provisions of the European Convention on Human Rights in the context of introduction of measures to combat the COVID-19 pandemic is a common problem for European countries, which requires emergency measures introduction by the governments of these countries; the measures introduced should be legal, necessary, non-discriminatory, with a certain specific focus and duration; ensuring respect for human rights and freedoms requires deliberate, timely and effective legal, organizational forms and methods of states' activities and international cooperation.

KEY WORDS: respect for human rights, international legal acts, national legislation, COVID-19 pandemic, human rights

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INTRODUCTION

It is indisputable that the spread of the COVID-19 pandemic worldwide has become one of the most difficult and hard-to-predict challenges of our time. The outbreak, which the World Health Organization described as a pandemic, created the global emergency unprecedented for the last century. Under such circumstances, international organizations and national governments are faced with several complex problems and tasks that require significant financial, legal, and organizational resources. The health care system of every country in the world had to meet the challenge of finding effective measures to prevent the spread of the virus, minimize the increase in morbidity, quickly identify and isolate sick people while providing them with competent high-quality care, minimizing mortality and, at the same time, ensuring availability of medical resources for patients suffering from other, more common pathologies and diseases. The economic and social problems are menacing as well, which enforces national governments to support entrepreneurship and develop social sphere in order to cover the most vulnerable society segments (unemployed, migrants, refugees, displaced persons, homeless people, etc.). The pandemic situation exacerbates the problems of public administration in all sectors and encourages national states, supranational institutions and bodies to perform effectively and efficiently, to take reasonable and coordinated actions.

The COVID-19 pandemic has affected all countries worldwide without exception, forcing their governments to take measures aimed at minimizing the spread of the virus and reducing the incidence of people's infection. The orders issued by governments of national states are characterized by various degrees of categoricity and proportionality, up to the emergency state introduction, which entails restrictions of some human and civil rights, and freedoms. Based on the fundamentality and inviolability of human rights, principles of the rule of law and democracy, international human rights bodies and institutions are directing their efforts to develop effective mechanisms of minimization of unjustified restrictions on human rights and, at the same time, to counter the spread of the pandemic.

THE AIM

To suggest the ways and means for ensuring respect for human rights and freedoms in the context of introduction of states' measures to combat the COVID-19 pandemic based on the generalization of European experience and

systematization of recommendations of international and European institutions.

MATERIALS AND METHODS

In this research, we applied a complex of philosophical and ideological approaches, general scientific and special methods of scientific cognition, civilizational and axiological approaches as well as dialectical, comparative legal and statistical methods. Civilizational and axiological methods were used in the research process for justifying the importance of human rights, their universality and particularity; a dialectical method– when identifying the relationship between international, European and national legislations in the field of human rights; a comparative legal approach – for analysing foreign experience in ensuring respect for human rights and freedoms in the context of introduction of measures by states to combat the COVID-19 pandemic, as well as systematization, analysis, and synthesis.

The empirical basis of the study is represented by the statistical data of the healthcare sector of European countries, generalization of the practice of countering the pandemic spread. In the study, we used international and European regulatory legal acts and documents in the field of human rights, namely the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social and Cultural Rights, the European Convention for Protection of Human Rights and Fundamental Freedoms, the Universal Health Coverage: Moving Together to Build a Healthier World as well as national legislations of foreign countries.

REVIEW AND DISCUSSION

The fundamental international document that proclaims and enshrines inalienable human rights and freedoms is certainly the Universal Declaration of Human Rights adopted and proclaimed by the United Nations General Assembly on 10 December 1948. Article 29 of this document says that "…everyone has duties to the community in which alone the free and full development of his personality is possible. 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" [1].

Similar provisions are included in other international standards for human rights protection. The International Covenant on Civil and Political Rights adopted by the United Nations on 16 December 1966 declares that the right to liberty of movement and freedom to choose residence (Article 12), the right to freedom of thought, conscience and religion as well as the right to freedom of expression of one's views (Articles 18-19), the right to peaceful assembly (Article 21), and the right to freedom of association with others (Article 22) may be subject to certain restrictions provided for by law that are necessary to protect national security, public order, public health or morals [2]. The International Covenant on Economic, Social and Cultural Rights adopted by the UN General Assembly on 16 December, 1966 contains similar provisions saying that the State may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society [3].

In situation of public emergency, the States Parties to the International Covenant on Civil and Political Rights shall immediately inform the other States Parties to the Covenant through the intermediary of the Secretary-General of the United Nations, in accordance with their legal obligations. The measures, which place restrictions on exercise of human rights, shall be strictly required by the exigencies of the situation and the scale of threat, and shall not involve discrimination. This means that such restrictions on human rights shall have a specific focus and time frame, with the most lenient approach to public health to be applied.

In the European space, the main document is the European Convention for the Protection of Human Rights and Fundamental Freedoms signed on 4 November 1950 in accordance with the Universal Declaration of Human Rights in order for the member states of the Council of Europe to respect and ensure human rights and fundamental freedoms in their territories. The fundamental rights and freedoms provided for in this international treaty include: the right to life; prohibition of torture, slavery and forced labour; the right to liberty and security of person; the right to a fair trial; and the right to respect for private and family life; freedom of thought, conscience and religion, expression of views; freedom of assembly and association. Article 15 of this document contains a provision that in time of war or other public emergency threatening the life of the nation any signatory to the Convention may take measures derogating from its obligations under this Convention to the extent strictly required by the exigencies of the situation, provided that such measures are not inconsistent with its other obligations under international law [4]. The above-mentioned public emergency can be applied to harmful consequences of the COVID-19 pandemic as well. The procedure for derogating from obligations in order to narrow the scope of certain rights and freedoms involves keeping the Secretary-General of the Council of Europe informed of the measures taken and restrictions imposed. It is also necessary to indicate the time when such measures have ceased to operate, and the provisions of the Convention are being fully executed again. Emergency powers should be exercised solely for legitimate purposes in the area of public healthcare. The human right to life is not subject to narrowing or restriction, and the use of torture and slavery as well as use of legal liability and punishments in circumvention of national legislation are always unacceptable. The restrictions in order to counter pluralism of opinions and oppositional views must not be imposed as well.

Moreover, in order to achieve universal coverage of the population with health services, on 10 October 2019, the UN General Assembly adopted a high-level political declaration "Universal Health Coverage: Moving Together to

Build a Healthier World", following its approval by world leaders in September. The declaration recognizes that health contributes to the promotion and protection of human rights and makes a commitment to covering one billion additional people by 2023 with quality essential health services, with a view to covering all people by 2030. The declaration stresses that strong and resilient health systems, capable of reaching people in vulnerable situations, can ensure pandemic preparedness and effective responses to any outbreak [5]. Despite the fact that civil society representatives assessed the declaration ambiguously and expressed their concern that it leaves too much discretion to governments in deciding on the degree of universal health coverage referring to "nationally determined sets", "in line with national contexts and priorities", difficulties with funding, the declaration consolidated the attention and need for efforts of state governments in health systems [6].

To date, 10 states of the European Union have exercised their right of derogation from the provisions of the Convention: Serbia, San Marino, Romania, the Republic of Moldova, North Macedonia, Latvia, Georgia, Estonia, Armenia and Albania [7]. These states are obliged to inform the population about emergency measures, the territory of their application and the time frame for their introduction and extension. Response measures should be taken in accordance with the needs that arise at different stages of the crisis situation caused by the pandemic. The states should update this information regularly and make it widely available. Also, when the epidemic situation has improved, as soon as it is feasible, the national governments should ensure that citizens return to life as normal.

Summarizing the current experience of the measures implementation by the governments of European countries to halt the pandemic spread proves that the following human rights and freedoms are among most restrictive: the right to liberty (treatment of COVID-19 patients in isolation); the right to freedom of movement (border closures, introduction of a state of emergency, restrictions on transport services, creation of quarantine zones, control over person's movement outside his residence); the right to freedom of peaceful assembly (the obligation to maintain social distancing and self-isolation regime, prohibition of holding mass events); the right to healthcare (cancellation of planned operations and medical interventions in the event of non-urgency for the patient, difficult access to healthcare due to overloaded healthcare facilities); the right to education (educational institutions' work in remote mode can complicate the access of pupils and students to educational services); the right to freedom of religion (prohibition of religious events and restriction on religious rites); the right to business activities (temporary suspension of work of entertainment and catering facilities, overall difficulties faced by entrepreneurs during the pandemic).

Having analysed the statistics of the COVID-19 incidence, we identified the "record holding" countries within the European Union. The situation is constantly changing but in general the highest number of confirmed cases of infection is observed in the following countries: Spain, France, Italy and Germany. The United Kingdom is also on the list; it is no longer part of the EU but is included in the European statistical reports [8]. Malta, Iceland, Latvia, Cyprus and Liechtenstein enjoy the lowest figures of registered cases, which is due to the territorial remoteness of these states and small population numbers. The measures taken by the governments of these countries to restrict and halt the spread of the COVID-19 pandemic are stipulated by many factors, namely economic, legal, political and social ones. The thing they have in common is the need to strike a balance between public safety and human rights.

The process of such a complex task implementation has different characteristics in each country. Thus, Spain is currently introducing quarantine measures in the entire metropolitan region due to an increase in the incidence. In Madrid and 9 surrounding cities, the movement of citizens is restricted and control over compliance with the quarantine restrictions is being strengthened. Only those who have a valid reason (a trip to work, hospital or school, shopping, etc.) can enter this zone and leave it. The number of guests in hotels and visitors in public catering facilities cannot exceed 50% of the maximum capacity. The regulations provide for the penalties from €100 up to €30,000 for quarantine restrictions violation; resistance and disobedience to law enforcement officers in an emergency situation are also punishable by penalties of up to €600 thousand- or one-year's imprisonment [9]. The Spanish police are authorised to check the identity of persons in the street and find out the purpose of their movement. Quarantine measures are not unanimously supported by the population; there are protests demanding to ease the restrictions. Also, the government is allocating funds to support entrepreneurship (€200 billion) [10].

Italy was the country that suffered most from the COVID-19 in the spring of 2020; therefore, the measures to fight off the pandemic are more drastic and applicable in all spheres of life. The government appointed a special commissioner for emergency response to counter the spread of the pandemic, and the emergency state was introduced on the territory of the country. In the adopted Decree on the measures to combat the pandemic, it is stipulated that the state of emergency in Italy gives special powers to governors. In other words, local authorities will be able to create "red zones" or isolation areas on the territories of the COVID-19 outbreak. Wearing a mask and social distancing are mandatory – the Italian population is responsible for protecting against infection by meeting these requirements. Quarantine violators are subject to a fine of € 206- or three-months' imprisonment. The strict general quarantine lasted in Italy from the beginning of March to the beginning of May and was characterized by a ban on entry for foreigners, restrictions on movement between settlements, closure of educational and entertainment venues, and a ban on mass events such as weddings and funerals. Since then, such strict quarantine restrictions have been relaxed and sometimes introduced locally. To maintain a stable economic situation, the government has allocated extra € 25 billion [11].

In France, no strict restrictions have been imposed since the outbreak of the COVID-19 pandemic. However, with an increased incidence of the virus, the restrictions were imposed on mass events, and gatherings of more than 10 people were banned. Public facilities such as bars, swimming pools and coffee shops were closed. There is a restriction on entry into the territory of the country of persons who are not citizens of the European Union member states. The French government has provided a €100 billion stimulus package to boost the economy affected by the global healthcare crisis. As well, the authorities have provided a €207 million stimulus package for aid during the COVID-19 outbreak to boost the economy affected by the global health crisis [12].

Among other European countries, Germany is quite successful in countering the spread of the COVID-19 virus, which is proved by the emergency measures taken by the government [13]. In the world ranking of the safest countries, Germany ranks second after Israel, according to the results of the London study conducted by experts of the Deep Knowledge Group Foundation [14]. This result is associated with a high-quality organization of response in the healthcare system. German hospitals have qualified staff and enough beds to receive patients, and if the disease is suspected, COVID-19 testing is carried out promptly. The state did not impose a strict quarantine, but entertainment and sports facilities, as well as educational institutions, were closed for some time. Religious rites were banned. Despite the threat of infection, local elections were held in Bavaria, providing all citizens with disinfection products. Violation of the quarantine rules is punishable by a penalty of up to €450 thousand or imprisonment of up to 2 years. The German Chancellor Angela Merkel is engaged in supporting business and announced the allocation of €550 billion for government loans.

The situation analysis and assessment of measures to counteract the pandemic spread in Germany shows that the government has taken a fairly objective, balanced and timely approach to the application of comprehensive measures, making the escalation of the epidemiological situation impossible. An unprecedented package of support for business activity and social assistance to citizens was also aimed at ensuring respect for human rights and freedoms when the state introduced the measures to combat the pandemic.

The UK also introduced the restrictive measures designed to counteract an increase in the number of COVID-19 patients. The first restriction was the introduction of self-isolation for the most vulnerable population group – people of the age group over 70. All other citizens were advised to reduce the number of social contacts and, if possible, telecommute. "The government's strategy for fighting coronavirus is aimed at achieving 'herd immunity' so that the health system can withstand the pressure" [15]. For violators of the established requirements and restrictions, there are significant penalties – from £200 for individuals for non-wearing a mask to £ 10 thousand for violations by legal entities. The compliance with the requirements will be checked not only by the police with an increased number of patrols, but also by the military forces, who will be involved in security measures. Currently, the opening hours of entertainment and public catering facilities are limited, with social distance between their visitors to be observed. Mass events are prohibited in the country and there are restrictions on the movement of public transport. Local elections, which were supposed to be held in May 2020, were postponed to May 2021. The British government also promised to allocate £ 330 billion to support businesses – these funds will be used to support the most vulnerable categories of the population and self-employed, whose incomes may decrease. £ 1.3 billion have already been allocated for the distribution of free personal protective equipment to healthcare and social services, public pharmacies and public sector organizations [16]. It is planned to allocate one-time grants of up to £ 25 thousand to entrepreneurs engaged in economic activities in the entertainment and catering sectors in order to prevent their bankruptcy. For common people experiencing financial difficulties, there is also a benefit – a three-month deferral of payment on mortgage loans. It should be noted that in this country, state subsidies are allocated to the private sector and through the social security system for the first time.

In the field of ensuring human rights in the UK, human rights defenders and scientists express concern and call for countering domestic violence, which has increased significantly: "Given the rise in domestic abuse during the pandemic, the UK, Scottish and Welsh Governments should ensure that survivors of domestic abuse and other forms of violence against women and girls receive appropriate protection and support, regardless of immigration status. They should also ensure that services are adequately funded and supported to address all forms of abuse, both during and after the coronavirus pandemic" [17].

The analysis of the UK's experience in fighting COVID-19 shows that the measures to counteract the pandemic spread are less effective due to several factors, namely: late response; a low level of citizens' responsibility; insufficient provision of medical equipment; limited statistical data on patients.

International organizations support the introduction of restrictive measures, as without them it will not be possible to reduce the COVID-19 incidence. They give recommendations with regard to reduction of the traumatic impact on human rights and freedoms and ensuring the population's interests during implementation of such restrictions. The United Nations emphasizes on the following actions: ensuring maximum accessibility of healthcare for every person; emergency measures introduction, including a state of emergency, should be legal, necessary and non-discriminatory, with a certain specific focus and duration, applied in the least intrusive way possible for the population; maintaining jobs, wages and housing through targeted economic programs; provision of paid medical certificates and unemployment benefits; support for employers and entrepreneurship; counteraction to corruption risks and ensuring free dissemination of information; combating dis-

crimination; countering domestic abuse [18]. It is proposed to take measures to ensure universalization of healthcare, cooperate in the development of vaccines and treatment procedures as well as to accelerate the trade and transfer of necessary medical supplies and equipment, including personal protective equipment for health-care providers who are primarily facing infection.

The World Health Organization also issues recommendations related to the observance of human rights. In particular, attention is focused on the following: countering stigmatizing and discriminatory behaviour and practices; supporting gender equality and preventing violence against women; supporting vulnerable segments of the population (namely, disabled, homeless people, refugees, migrants and people in detention); respect for people's rights in accordance with international standards during introduction of quarantine or restrictive measures; solving the problem of shortage of materials and equipment for patients' treatment; providing international assistance and cooperation. It is noted that the WHO plays a crucial role in supporting member states so that they meet the challenges of our time and develop an integrated approach to the COVID-19 [19]. The recognition of human rights as an integral part of a quality health system not only will ensure the ethics of restrictions for the population, but also create the basis for response to possible healthcare crises in the future.

The Council of Europe has also issued the guidance presented in the form of toolkit "Respecting democracy, rule of law and human rights in the framework of the COVID-19 sanitary crisis" [20]. It says that the derogation from the provisions of the European Convention on human rights will be assessed by the European Court of Human Rights. Emphasis is placed on the following provisions: ensuring the right to life (availability of medical procedures and medicines, especially for patients of vulnerable groups, such as people with disabilities or elderly persons); the right to liberty and security (strict sanctions for violating anti-epidemic measures should only be imposed in accordance with the regulated procedures, it is necessary to maintain a balance between coercion and prevention); development of effective counteraction to crime and protection of victims of crime (in the context of the pandemic, such offenses as domestic abuse, human trafficking and fraud have become more relevant); confidentiality and data protection (through a widespread use of electronic resources). It is noted that all the Council of Europe institutions are mobilised and will spare no effort to use tools and resources to exchange information, good practices and experience gained from all stakeholders, including authorities, civil society and citizens in order to find common responses to the challenges posed by the pandemic. The Council of Europe will make every effort to assist its member states during the current crisis and to overcome its consequences.

In the context of the pandemic spread and introduction of quarantine measures, despite the differences in the health systems of the countries, measures introduced by the governments, different economic resources, there are similar problems arising in the field of human rights and their provision, since "the violations we are now observing, including discriminatory policies and disturbing discussions about medical rationing and "rejection" or sacrifice of the elderly for the economy sake contradict the foundations of human rights that recognize the equality and dignity of all people" [21]. Scientists from different countries, experts, politicians and officials pay special attention to problems of security of certain citizen categories (persons obliged to contact a large number of people [22], children, women, elderly persons, convicts, refugees and migrants), mental health of the population, justice, anti-corruption in the healthcare sector. We should consider the warning by Joseph Stiglitz, Professor of Columbia University and Nobel Prize winner in economics, who emphasises on the fact that "COVID-19 has not been an equal opportunity virus: it goes after people in poor health and those whose daily lives expose them to greater contact with others. And this means it goes disproportionately after the poor, especially in poor countries and in advanced economies like the United States where access to health care is not guaranteed" [23, p. 19]. That is why ensuring human rights requires governments to develop and implement national strategies to counter the spread of the pandemic in a timely manner, considering the unequal opportunities of their citizens. In the international context, the spread of the pandemic causes, among other things, an aggravation of inequality between countries, since less developed countries do not have enough resources to overcome the economic consequences of the pandemic.

Summarizing and systematizing the provisions set out in the UN, CoE and WHO program documents, we determined the following important provisions and recommendations of international and European institutions for ensuring human rights in the context of countering the spread of the COVID-19 pandemic:

- freedom of expression and access to information (the state should provide its citizens with access to statistical information about the state of morbidity and at the same time refute false information about the methods of treatment and prevention);
- ensuring maximum access to health resources (especially for vulnerable groups – elderly persons and people with disabilities, people with low incomes);
- ensuring compliance of restrictive measures with inalienable human rights (restrictions for reasons of public health or a state of emergency in the country must comply with the regulatory legal acts, be necessary and proportionate; the sanctions must have a certain appeal procedure);
- creating the safest working conditions possible for healthcare professionals and providing them with necessary means to perform their duties effectively;
- providing economic support (subsidies and benefits) for persons suffering losses due to restrictive measures (both legal entities and entrepreneurs as well as individuals – migrants, low-income and unemployed persons);
- combating discrimination and violence based on race, age, gender (through supportive measures, educational activities);

- ensuring access to education (introduction of distance technologies);
- ensuring international cooperation and effective work of supranational institutions both to disseminate medical information, develop vaccination, new treatment methods and to provide economic and organizational support for the measures to combat the pandemic consequences.

It is also necessary to consider the fact that the national legislations of European countries guarantee human rights and their judicial protection, including applying to the European Court of Human Rights. Scholars have repeatedly emphasized that violation of human rights in the context of introducing measures by states to combat the COVID-19 pandemic can expose national states to the risk of numerous appeals from citizens to the ECHR and corresponding legal consequences [24, 25]. According to Dainius Pūras, "…the COVID-19 crisis cannot be resolved through public health and emergency measures alone; all other human rights must also be covered. The global spread of COVID-19 and the impact of measures to curb it clearly demonstrate the interdependence, interconnectedness and indivisibility of all human rights" [26].

CONCLUSION

Generalized foreign experience in ensuring human rights and freedoms in the context of introduction of states' measures to combat the COVID-19 pandemic and recommendations of international organizations (UNO, CoU, WHO) provide grounds for the following conclusions: derogation from the provisions of the European Convention on Human Rights in the context of the introduction of measures to combat the COVID-19 pandemic is a common problem for European countries and requires special attention from the ECHR; implementation of emergency measures should be legal, necessary, non-discriminatory, with a certain specific focus and duration; ensuring respect for human rights and freedoms in the context of introduction of measures to combat the COVID-19 pandemic requires deliberate, reasonable, timely and effective legal, organizational (regulating, economic, monitoring) forms and methods of state activities; the first priority is to ensure the right to life (availability of medical procedures and medicines, especially for patients of vulnerable groups); the right to liberty and security (strict sanctions for violating anti-epidemic measures should only be imposed in accordance with the regulated procedures); the right to work (provides for maintaining jobs, wages, provision of paid medical certificates and unemployment benefits). In order to ensure the respect for human rights and freedoms, it is essential to provide free dissemination of information; counteraction to crime, primarily, domestic violence and protection of victims of crime; confidentiality and data protection. A complex approach to the problem of ensuring human rights in the field of European and international activities to counter the spread of the COVID-19 pandemic is of extreme importance.

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REVIEW ARTICLE

REALIZATION OF THE RIGHT TO HEALTHCARE OF CONVICTED WITH SERIOUS ILLNESS

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ABSTRACT

The aim of the study is to analyze the features of realization mechanism of the rights of convicted persons suffering from a serious illness to release from serving a sentence in order to receive the necessary treatment.

Materials and methods: this study uses a set of methods of scientific knowledge. The empirical basis of the study is the statistics of the State Judicial Administration of Ukraine for 2015-2019 on convicts released from punishment due to their serious illness, statistical materials and case law of Turkey, Georgia, Great Britain, Germany and Greece, generalization of judicial practice of Ukraine, and the personal experience of one of the co-authors of more than 20 years as a lawyer and for 3 years as a judge of the Supreme Court.

Conclusions: in order to protect the persons; interests serving sentences and suffering from serious illness, government mechanisms should provide flexibility in the approach to assessing the health of each person, and not just the detection of disease; the authorities assessing the convict's state of health must be independent, and a prisoner must be able to choose physicians not only for treatment but also for assessment of his/her state of health.

KEY WORDS: serious illness; exemption from punishment for illness; the right to life and health; protection of the rights of persons in captivity; criminal-legal jurisdictional mechanism of protection

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INTRODUCTION

The European context for the humanization of criminal policy provides for the protection of the rights of every person suffering from a serious illness and serving a sentence in a prison. After all, the release of a convict due to illness ensures the realization of the human right to health care and the creation of conditions for effective treatment and recovery. The introduction of the institution of exemption from serving a sentence due to a serious illness in different countries has its own features that allow to study and identify trends, as well as best practices for creating effective mechanisms, both to achieve the goals of criminal justice and to protect the right to life and health care.

THE AIM

The aim of the study is to analyze the features of the realization mechanism of convicts' rights who have fallen ill with a serious illness, to release from serving a sentence in order to receive the necessary treatment.

MATERIALS AND METHODS

This study uses a set of methods of scientific knowledge. The empirical basis of the study is the statistics of the State Judicial Administration of Ukraine for 2015-2019 on convicts released from punishment due to serious illness, statistical materials and case law of Turkey, Georgia, Great Britain, Germany and Greece, generalization of Ukrainian case law. This study also used the personal experience of one of the co-authors as a lawyer for more than 20 years and for 3 years as a judge of the Supreme Court.

REVIEW

In Ukraine, release from punishment for illness was introduced in 2001 with the adoption of the current Criminal Code of Ukraine (hereinafter - the Criminal Code of Ukraine) [1] and is one of the grounds for early release of a person from further imprisonment.

Analysis of statistical data indicates that in Ukraine in 2015, 49.5% of applications for release from punishment due to illness were granted, in 2016 - 49%, in 2017 - 52%, in 2018 - 41%, in 2019 - 42.2%, i.e. in most cases, the person is not exempt from punishment for illness [2].

In addition, according to the Prosecutor General's Office of Ukraine, 510 prisoners died in penitentiary institutions in 2015, 523 in 2016, 568 in 2017, 484 in 2018, and 517 in 2019, respectively. And we observe such statistics despite the fact that the number of prisoners is constantly decreasing (for the period 2015 - 2019 – from 70 000 to 52.9 thousand, respectively). In addition, as of January 1, 2020,

1,300 people with disabilities were held in penitentiary institutions in Ukraine [3].

In European countries, statistics on the functioning of exemptions due to illness are rather limited. Thus, in 2017, 9 people were discharged in Georgia; 1 person [4] in Moldova. In the 2018 report, only Lithuania provided information on 5 people released due to serious illness [5].

It should be noted that the high mortality rate in penitentiary institutions of Ukraine is primarily due to inadequate conditions of detention, untimely diagnosis and inadequate medical care provided to convicts, as evidenced by numerous decisions of the European Court of Human Rights (ECHR), which indicate violations Art. 3 of the Convention for the Protection of Human Rights and Fundamental Freedoms (hereinafter - the Convention) (Pokhlebin v. Ukraine, no. 35581/06 [6], Logvinenko v. Ukraine, no. 13448/07 [7], Petukhov v. Ukraine (No. 2), no. 41216/13 [8] and others).

The analysis of our sources allowed us to identify two main approaches to defining the concept of serious diseases, notably: 1) normative definition of the list of serious diseases; 2) determination of the serious illness signs a and its impact on the person at the law level.

The authors' own experience of law enforcement activity and analysis of judicial practice in Ukraine shows that in the case of an application for release from punishment due to illness filed by a convict or his/her lawyer, in accordance with the requirements of Part 1 of Art. 539 of the Criminal Procedure Code of Ukraine (hereinafter - CPC of Ukraine) [9] most often the court refuses to grant the petition precisely because of the lack of opinion of the medical advisory commission, which cannot be obtained without the Head Penitentiary's participation. For example, in case № 1-в / 367/1159/2016, the convict applied to the court with a request to resolve the issue of his release from serving a sentence as having suffered a serious illness, but did not attach to it the opinion of a special medical commission. The court granted the prosecutor's request and ordered the Special Medical Commission at the State Penitentiary Service in Kyiv and Kyiv Oblast to conduct a medical examination of the convict and provide the court with a written opinion on the basis for his release from serving a sentence due to serious illness [10].

It has been proved that in Ukraine the assessment of a prisoner's health state is carried out in the health care institutions of penitentiary system, which deprives the convict of the right to choose a physician who will examine him/her. At the same time, it is argued that the procedure for release from punishment and imprisonment should be based on protecting the rights of prisoners to free access to effective medical care and preventing such treatment as harassment or torture.

DISCUSSION

Problematic issues of release from serving a sentence due to the fact that the convicted person has a serious illness or reached an old age are permanently the subject of research by both Ukrainian [11,12] and foreign scholars [13-16]. Exemption from serving a sentence due to illness, as scientists note, is one of the manifestations of criminal responsibility humanization. The idea of achieving the objectives of criminal justice through the mitigation of repression and the use of alternatives to imprisonment is directly linked to the task of ensuring the prisoner's right to health care. At the same time, the issue of prisoner's health care is considered both in terms of ensuring free access of prisoners to medical care, and in terms of creating appropriate detention conditions [17].

The Parliamentary Assembly of the Council of Europe (hereinafter – PACE), taking care of the plight of seriously ill prisoners, in Resolution 2082 (2015) recommends the wider introduction of exemption from imprisonment for prisoners suffering from serious illness, it cannot always be provided by penitentiary institutions [18].

ECHR rulings show that the state of penitentiary system in many European countries cannot protect and guarantee the rights of prisoners to adequate medical care. In particular, in the case of Gülay Cetin v. Turkey [19] concerning the non-release of a prisoner with terminal cancer or in the case of Contrada (no. 2) v. Italy [20], in relation to the detention of a person whose state of health was incompatible with detention, a violation of Art. 3 of the Convention regarding the prohibition of inhuman and degrading treatment [21].

In view of the above, the EU Committee of Ministers has developed recommendations requiring States to release persons suffering from serious illnesses as soon as possible, taking into account medical and social criteria [22].

As for the essence or definition of the term "serious illness" of the Criminal Code of Ukraine, unfortunately, it is limited only to the definition of "serious illness of a convict that prevents serving a sentence". Although, in our opinion, it is not the disease itself that is significant, but the consequences it has for the state of health of the convict.

At the same time, Ukraine uses the normatively established List of Diseases as a basis for release from further imprisonment [23], which is mandatory for medical professionals in preparing an appropriate opinion on the prisoner's health.

It should be noted that the definition of serious diseases by approving the official list is not unique in European practice. Thus, in Georgia, the list of serious and incurable diseases, the presence of which is the basis for dismissal, is approved by the Minister of Labor, Health and Social Protection of Georgia, according to Article 39 of the Criminal Code of Georgia [24]. A similar situation is observed in Greece, where a list of serious diseases has also been approved [25].

Another approach is to determine the signs of a serious illness and its impact on the person at the law level, which should be investigated when making appropriate decisions, and medical professionals should only give a reasonable assessment of whether a person's health meets these signs. For example, in Germany there is no such list of diseases, but at the same time there are conditions that must be met by the person's state of health claiming exemption from

the disease [26]. A similar approach is observed in Poland, Netherlands, France and other countries.

According to Mr. Andreas Gross, this gives grounds for concluding that the assessment of the medical criterion of exemption from serving a sentence due to a serious illness should be based on an individual approach and, in particular, answer the question: does further imprisonment poses threat to the prisoner's health or life, his/her dignity? Whether the treatment and proper conditions can be provided to incarcerated, considering their state of health?

And in general - does the further presence of a person, taking into account the conditions and medical indications, meet the purpose of punishment? [27].

The effectiveness of assessing a prisoner's compliance with medical criteria also depends on the institutional mechanism that ensures that a prisoner has access to the professional care of health professionals who are called upon to draw appropriate conclusions about his/her health. The above-mentioned PACE recommendations and the Guidelines for the Treatment of Prisoners [28] emphasize that prisoners with a serious illness vitally need both unimpeded access to legal aid and access to medical care equivalent to that which they may receive at large. After all, one of the fundamental rights of the patient is the right to choose a doctor and the restriction of this right must be justified by necessity.

In Ukraine medical examination of convicted persons is carried out by the Medical Advisory Commission of health care institutions of State Criminal-Executive Service of Ukraine (hereinafter - SCES). Taking into account the results of the mentioned medical examination, an opinion is immediately drawn up on the convict's medical examination for the presence of a disease determined by the List of Diseases, which is the basis for submitting materials on release of the convict from further serving the sentence to the court.

A similar situation is observed in many other countries. Thus, in Turkey, according to the Law on Execution of Punishments and Security Measures, a medical opinion is drawn up only by the relevant commissions of the Institute of Forensic Medicine, which reports to the Ministry of Justice [29].

Given that limiting the range of facilities and doctors who can conduct the Medical Advisory Commissions creates risks of bias on their part, as well as restricts the rights of the patient prisoner, it seems appropriate to recommend mechanisms for involving independent doctors in the medical examination of prisoners and drawing appropriate conclusions.

Exemption from serving a sentence in Ukraine generally corresponds to European practice and is carried out by the court at the place of serving the sentence on the basis of assessment of both medical (nature, severity of illness) and legal criteria (gravity of the criminal offense, identity of the convict and other circumstances).

However, it should be emphasized that the conclusion of the Medical Advisory Commissions is not binding to the court, because according to Part 2 of Art. 84 of the Criminal Code of Ukraine in resolving this issue the court considers the crime gravity, the disease nature, the identity of the convict and other circumstances of the case, and therefore, despite the positive conclusion of the commission, the prosecutor's refusal.

Thus, in case № 367/762/14-k the court refused to satisfy the request to the head of the Bucha Correctional Colony № 85 for release from serving the sentence of the convict as having fallen ill with a serious illness. At the hospital, the convict received medical care, but his/her condition deteriorated, a meeting of a special medical commission was held, which, studying the dynamics of the disease, concluded that the diagnosis sentenced the patient to a serious illness, which is the basis for lawsuits materials on the release of convicts from further imprisonment. At the same time, the court argued its refusal as follows: the person was sentenced to 11 years in prison for committing a grave crime; did not admit guilt in the committed crime; served less than half of the sentence; at the court hearing, the doctor did not prove that the convict's illnesses prevented them from serving his/her sentence [30].

Currently, in Ukraine, the court examines such circumstances as behavior during the sentence, compliance with the regime, attitude to work, discipline, degree of correction, evasion of treatment and so on. Other circumstances that may be taken into account by the court include the length of imprisonment, lack of permanent residence and relatives at large, lack of funds, intentional infliction of harm to the convict, which led to illness, and so on.

In fact, the presence of even a fatal illness is not a necessary basis for exempting a person from punishment due to illness. For example, in the case № 11кр / 818/1429/19 the appellate court granted the prosecutor's complaint and denied the request for exemption from punishment due to illness, although the convict also suffered from a serious illness, namely: HIV infection, the 4-th clinical stage. However, the medical report states that the patient's condition is defined as relatively satisfactory, stable, the course of the patients' disease have a slight positive tendency. In addition, the appellate court additionally took into account the gravity of the crime and the convict's identity, who had been convicted several times before, was released from serving his sentence, but did not take the path of correction, but continued to commit crimes [31].

In general, it should be concluded that the decision to release from punishment due to illness should be provided by an impartial body. In this case, the prisoner in person, his/her representative or their lawyer should be invited to represent their interests and be able to provide evidence, including alternative medical opinions.

CONCLUSIONS

The rights of prisoners should be limited to the extent that the purpose of punishment is achieved, but States should refrain from violating the inalienable rights of prisoners to life and health. Given the state of the penitentiary system and the systemic problems identified in ECHR decisions,

special attention should be paid to the prevention of torture and ill-treatment of prisoners, in particular those in need of adequate medical care. States should implement recommendations for statistical monitoring of the release of prisoners, summarize information on the number of requests for release and the results of their consideration, timing of their consideration, the list and nature of diseases that caused them, and so on. In order to protect the interests of persons serving sentences and suffering from a serious illness, and therefore requiring release from serving a sentence, state mechanisms should provide flexibility in the approach to assessing the state of health of each person; authorities assessing the convict's state of health must be independent, and the prisoner must be able to choose doctors not only for treatment but also for the assessment of his/her state of health.

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REVIEW ARTICLE

MEDICAL ASPECTS OF VIOLATION OF THE RIGHT TO LIFE IN THE CONTEXT OF THE EUROPEN COURT OF HUMAN RIGHTS CASE LAW

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ABSTRACT

The aim: The purpose of the paper is to raise awareness of the medical services subjects in the issues of establishment of the relationship between their activities and harm to patients, analysis of the case law of the ECHR and provision of practical recommendations for the prevention of violations of Art. 2 of the Convention with subsequent compensation for non-pecuniary and pecuniary damage.

Materials and methods: The authors used the judgements of the European Court of Human Rights (ECHR) on medical research, international regulatory acts, publications of scholars in the field of medical law and legal doctrine in terms of liability of medical services providers for the violation of Art. 2 of the Convention.

Conclusions: Aiming to ensure proper legal protection of the rights and legitimate interests of subjects of medical care, the authors have developed recommendations on how to prevent cases of violation of the right to life during the provision of medical services.

KEY WORDS: balance of doctors' and patients' interests, the "open door" mode, patient

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INTRODUCTION

Art. 2 of the Convention for the Protection of Human Rights and Fundamental Freedoms (hereinafter - the Convention) defines the everyone's right to life shall be protected by law. [1] The inviolability of the right to life is also guaranteed in Article 3 of the Universal Declaration of Human Rights, which states that "everyone has the right to life" [2]. At the same time, the list of actions that are defined in the Convention and are admissible in matters of deprivation of life and are not qualified as a violation of this article creates a protective "barrier" for persons who commit acts of self-defense against violence or oppose illegal actions of persons who are detained, etc. This approach of lawmakers gives grounds to claim that the only group of persons who can be released from liability (subject to the condition of the exclusively necessary use of force) for violation of the right to life in the performance of professional duties are law enforcement officials.

From the point of view of legal risks, the provision of medical services is the most vulnerable in terms of ensuring proper conditions for the observance of the right to life of a human in the provision of qualified medical care. This thesis is due to the fact that human rights in the field of health complement bioethics, but at the same time cover a set of generally accepted standards and procedures that allow to draw conclusions about violations in the context of health care and provide protection against such violations [3, p.1.1]. the Harmonization of national legislation with European Union standards is among the most common ways to improve the legal regulation of health care in the member states of the European Union. The implementation of international law into domestic law is a constant practice in Great Britain, Bulgaria, Poland, etc.

It is beyond argument that the adaptation of national legislation to "uniform" standards is made in such a way as to provide leverage to influence the behavior of the subjects of relations devoid of ambiguity in the interpretation of their application. This approach is self-sufficient in terms of ensuring the interests of the state as a subject of regulation of social relations. However, compliance with the requirement to balance the interests of patient and doctor is possible only when the analysis of judicial practice for the effectiveness of a rule of law that governs the relationships in the provision of medical services.

THE AIM

The purpose of the paper is to raise awareness of the medical services subjects in the issues of establishment of the relationship between their activities and harm to patients, analysis of the case law of the ECHR and provision of practical recommendations for the prevention of violations of Art. 2 of the Convention with subsequent compensation for non-pecuniary and pecuniary damage.

MATERIALS AND METHODS

The paper is devoted to the analysis of the ECHR case law and legal doctrine on liability of medical services provid-

ers for the violation of Art. 2 of the Convention during the performance of professional duties. We used the dialectical method to formulate conclusions regarding the understanding of the content of Art. 2 of the Convention in the context of ECHR decisions; the analytical method was used in determining the trends of the case law of the ECHR on the outlined subject; the method of synthesis was used to create conclusions and recommendations for the prevention of violations of Art. 2 of the Convention.

REVIEW AND DISCUSSION

The provisions of the Convention are general in nature. Their significance in all the variety of meaningful manifestations is revealed in the case law of the European Court of Human Rights (hereinafter - the ECHR). According to Art. 32 of the Convention, the ECHR is the authority empowered to interpret the provisions of the Convention and its Protocols. And specifically, this international judicial institution determines the correct version of the understanding and content of the norms and legal concepts enshrined in the Convention. [4, p.5] Thus, the decisions of the ECHR as an international judicial body whose jurisdiction covers all member states of the Council of Europe are binding and unprecedentedly oblige the respondent State to comply with such a decision.

Analytical activities with the subsequent development of appropriate legal recommendations are useful in the field of private and public medical assistance. In particular, analytical methods will provide an opportunity to outline a range of additional criteria and standards with their subsequent enshrinement in local acts regulating the activities of employees of medical institutions. Such measures are preventive in nature and are designed to prevent litigations aimed at recognition of the activities of a doctor (hospital) as such that appeared to be a result of a violation of patients' rights.

The Report of the ECHR in 2019 confirmed the existence of deficiencies in the mechanisms of medical care and the functioning of medical institutions, which led to a violation of the right to life of patients, in the cases of violations of Art. 2 of the Convention. [5] Among the reasons for the existence of the outlined issues, case law determines the violation of the balance of mutual interests of doctor and patient. This introduction of doctrinal views seems positive, as it is taken into account in further ways to address the causes of violations of the right to life in the provision of medical care.

G. Lianning noted that in modern conditions of development and improvement of the health care system, doctors and patients should cooperate to make joint decisions on diagnosis and treatment [6]. The interaction of the patient and the doctor is a key factor not only in making a correct diagnosis and carrying out of further treatment but also in recognizing the actions of doctors as such that violate the right to life in the context of ensuring the mutual interests of these parties. V. Flis believes that the liability of doctors and medical institutions is thus based solely on negligence and on each of its degrees. In case of the civil liability of a doctor, unlike in criminal liability, slight negligence, which is assessed as an objective category, with objective criteria for negligence, is sufficient.[7, p.74] Therefore, compliance with mutual interests and taking into account case law will provide an opportunity to prevent the commission of acts of medical negligence or error, and so on.

Given the practical significance, it is worth considering the position of the ECHR in the decision of June 27, 2017 "Gard and Others v. The United Kingdom". In this case the ECHR considered the aspect of compliance with the positive obligations under Art. 2 (right to life) of the Convention and concluded that the application for the decision to cancel the artificial maintenance of vital functions of a child suffering from a fatal genetic disease was unacceptable. [8, p.51]

The complexity of the case was that the applicants complained about the hospital's actions to block access to artificial maintenance of patients' vital functions. An additional factor of complexity was the fact that the dispute concerned an infant suffering from a fatal genetic disease. The applicants, in turn, demanded from the hospital to allow undergoing experimental treatment in the United States. Instead, the domestic courts concluded that the cessation of the infant's artificial maintenance could be lawful, as the child could suffer serious damage if the suffering from the symptoms of the disease were continued without the prospect of positive dynamics from the experimental treatment.

It is noteworthy that the practice of the ECHR in these categories of cases on the interests of patients and hospitals shall meet the following three criteria: 1. The existence of an appropriate legal basis consistent with the provisions of the Council of Europe Convention on Human Rights (on the issue of experimental treatment abroad); 2. Taking into account the wishes previously expressed by the patient, close relatives and medical staff; 3. The possibility of appealing against the actions of employees of the medical institution in court.

In the case above, the patient was an infant who was not able to express his wishes due to mental development. It should be noted that the activities of the medical institution fully met the requirement for the second criterion, namely:

A) The child's parents were involved and their opinion was taken into account when making decisions on providing medical care to the child; among others, the possibility to provide instructions to their expert in the field of qualified medical care was ensured.

B) The court provided evidence of the involvement of a group of specialists to advise and make a collective decision on effective treatments and the possibility of providing experimental treatment abroad.

Such approach made it impossible to recognize the involvement of a medical institution in the violation of the right to life on grounds of non-compliance with the requirements of the patient's (patient representatives) involvement and taking into account their will in the treatment process.

Another decision of the European Court of Human Rights of March 28, 2017, in the case of Fernandes De Oliveira v. Portugal is interesting in terms of justifying the admission of guilt of a medical institution in terms of violation of the right to life. This case can be considered exemplary in meeting mutual interests of the patient and the hospital, complicated by the specifics of the treatment regimen. According to the circumstances of the case, the applicant's son was taken to a

state psychiatric hospital for treatment after a suicide attempt. Previously, the young man had already been hospitalized several times in the same hospital due to his mental health (on the grounds of unsuccessful suicide attempts). In view of the above, the ECHR noted that the hospital staff had reasons to assume that he could try to commit suicide again. Besides, it was possible in the view of his diagnosis to foresee another attempt to escape with the possibility of fatal consequence since he had escaped from the hospital earlier. [9]

Thus, the ECHR obliges employees of the medical institution to take actions based on anticipation provided that the patient's actions are systematic. By this case the ECHR explained that in the categories of such actions, for example, medical staff should more often carry out control measures to ensure the presence of the patient in the hospital. The court also noted that one of the causes of death for the patient was the ineffectiveness of the mechanism of the medical institution's response to the absence of the missing patient. In particular, it was noted that in the case of a mentally ill patient who had recently attempted suicide and was prone to escape, hospital staff should have been expected to take safeguarding measures on a more regular basis to ensure that he did not leave the hospital. [9]

The ECHR also noted that there were increased risks in this case due to the "open door" regime. The possibility of treating mentally ill patients (according to the indications) without complete isolation from society and with access to public places is positive in terms of the dynamics of recovery. However, this type of treatment does not release the subject of medical care from the obligation to protect mentally ill patients from the risks, which they create for themselves.

It is also specific that in this situation, a recommendation is given referring to the need to establish a balance between the responsibilities of the medical institution according to Art. 2 of the Convention during "open door" treatment regimen and the patient's personal needs through enhanced surveillance of suicidal patients. The indicated warning should be applied by medical institutions regardless of the method of placing the patient in a medical institution. That is, when ensuring a balance of interests, it is not necessary to distinguish between voluntary and involuntary hospitalization. The level of control measures for this category of patients should be based on the criteria of personal characteristics of the patient taking into account the systematic implementation of suicide attempts.

Another exemplary case is Lopes De Sousa Fernandes v. Portugal regarding violation of the requirements of mutual patient-doctor interests, which was qualified as medical negligence on the side of the physician in the decision of December 19, 2017 [10]. As a result of the surgery for the removal of nasal polyps, the applicant's husband suffered from bacterial meningitis, which was detected two days after his discharge. As a result of the repeated treatment, the man was hospitalized and underwent medical interventions as part of medical care. This happened several times, as a result of which the man died from the effects of septicemia caused by peritonitis and perforation of the internal cavity. Following the examination of the case file, the ECHR provided a distinction between the qualification of doctors' actions and the distinction between cases concerning the negligence of doctors and the case of denial of access to emergency rescue care.

In order for a case to fall into the latter category, the following factors must be considered together: 1. The actions and omissions of health professionals should go beyond the simple error or negligence of doctors. J. Anderson notes that health workers, in breach of their professional responsibilities, refuse emergency care, even though they are fully aware that a person's life is in danger if treatment is not provided. [11] The concept of **awareness** implies **a set of factors that include both the qualifications of the doctor and experience in providing similar medical care and the severity (stage) of the disease**.

The next criterion is the dysfunction of hospital services. 2. The dysfunction should be objective and recognizable as systematic or structural, and should not include cases where something could be dysfunctional in the sense of misconduct of a person or functioning. [10] In this criterion, the ECHR classifies two actions of the subjects of medical care, which are covered by signs of systematic nature and misconduct.

Misconduct of a person (doctor) must have a subjective basis, i.e. it should be based on actions caused by personal factors that lead to the provision of low-quality services. Systematicity is a criterion that involves the performance of duties by an employee of a medical institution in a certain order by analogy with previous cases of qualified care in such cases.

Misconduct of a person implies a situation where a health professional provides qualified care in violation of the requirements of clinical protocols, which should be based on the regulatory standards of such care. In this situation, the doctor is legally liable if the patient is damaged or injured due to the fact that the subject of medical services has deviated from the quality of care that is usually expected in similar situations. [12] In the context of misconduct, the inaction of doctors in providing medical care is also recognized. In the decision of the ECHR of July 18, 2017, in the case of Nina Kutsenko v. Ukraine, inaction is equaled to the category of "refusal to provide medical care" [13], except in cases of such a refusal by a doctor on legal grounds.

It is noteworthy that the actions that qualify the ECHR as wrongful acts of a medical professional in most cases are associated with consequences that entail violations not only of Article 2 of the Convention, but also of Art. 3.

To continue the previous thesis (in case of incorrect actions of a medical worker) it is necessary to pay attention to the decision of the European Court of Human Rights of 15.05.2012 in the case of Kaverzin v. Ukraine.[14] The applicant's total loss of sight and his first group of disabilities were equated with the consequences of the doctors' inaction and a violation of Article 3 of the Convention. The same position is supported by the decision of 08.09.2011 in the case of the European Court of Human Rights "Oshurko v. Ukraine". The same position is supported by the decision of 08.09.2011 in the case of Oshurko v. Ukraine, in which the provision of inadequate medical care was understood in the context of doctors' actions to provide unqualified treatment ("no systemic treatment") and refusal to provide inpatient treatment.[15]

3. There must be a link between the dysfunction of the healthcare provider and the harm caused to the patient. It

is important to note that in civil proceedings the burden of proving the existence of such a connection rests with the persons who address with the claim about compensation of the harm caused.

4. The last combined criterion is the lack of statutory prescription of the implementation of the activities of the medical services subjects according to their functional compliance.

The case Lopes De Sousa Fernandes v. Portugal is exemplary in terms of the necessity of imposing responsibilities on the state on fixing of procedures for the provision of medical services by hospitals at the legislative level. In case of absence of such fixation, medical workers of medical institutions are not responsible for violation of Art. 2 of the Convention subject to the comprehensive availability of the above criteria.

CONCLUSIONS

1. In view of the above, it is stated that the key factor in providing quality medical care is the mutual cooperation of doctor and patient. Moreover, the effectiveness of achieving a positive result in certain categories of diseases is possible through the application by the medical institution of the so-called preventive measures that should be applied by the medical institution to prevent violations of the right to life of patients.
2. In the field of providing treatment to mentally ill patients it is recommended to take into account the following factors (in order to prevent the recognition of the actions of medical staff as violating the patient's right to life): a) history of mental illness; b) the severity of mental illness; c) previous attempts to commit suicide or self-harm; d) suicidal thoughts or threats. In the presence of at least one of the above circumstances, three precautionary measures must be taken: daily schedule with control of the patient's presence; emergency procedure (in case of inpatient treatment in institutions with "open" doors, it is recommended to use a "restrictive procedure").
3. A set of the following factors should be considered as a criteria for distinguishing the refusal of emergency medical care from medical negligence: the behavior of a health professional, which is not qualified as medical negligence or error; dysfunction of hospital services, the causal link between damage and dysfunction; lack of statutory prescription of requirements for the functioning of the medical institution at the regulatory level.

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REVIEW ARTICLE

CHILD'S HEALTH CARE: LEGAL FRAMEWORK AND ONGOING CHALLENGES

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ABSTRACT

The aim: Is to analyze the development of the modern legal framework for child's health care, to clarify the benefits of a human rights-based approach, which is now is mainstreaming for understanding the right of children to health and means of its protection.

Materials and methods: To achieve this goal, as well as taking into account the specifics of the topic, the following research methods became relevant: the application of a dialectical approach and historical method made it possible to understand the patterns of formation and development of ideas of children's rights and health within the international community and national states; formal-legal method was used when studying legal texts (international law acts, both of universal and regional level, interpretation and clarification of human rights treaty bodies, expert reports and research, case law), and comparative-legal was used to compare different approaches on health protection in various international human rights mechanisms (US Supreme Court, Council of Europe).

Conclusions: Today, perceptions of children's rights at the doctrinal and jurisprudential levels are quite developed due to a broad understanding and openness to progressive interpretation. In particular, the inclusion into the legal context such determinants as the inviolability of the dignity and private life of the child, proper understanding of the stages of adulthood, and an assessment of the child's developmental environment has made modern international law and national legal systems to become more viable in sense of protection of child's well-being in today's world.

KEY WORDS: health, children, human rights, obligations, child welfare, protection

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INTRODUCTION

It is not difficult to see that children's health and well-being are the number one target when it comes to violations of children's rights. Just look at some of the examples. According to UNICEF, today more than 230 million children (almost every tenth child in the world!) live in countries or areas affected by armed conflict, of which there are now about 20 [1]. Armed conflicts cause extreme harm to children, the scale of which is difficult to assess, from killings and mutilations to the extermination of the whole generations. This is exactly the trend in Nigeria, where many children have been recruited by the Boko Haram military group, among which dozens of children have been held in military custody for months or years. In addition to the torture and ill-treatment of children, lack of medical care has resulted in the deaths of many children. [2] .

In the context of the spread of the COVID-2019 pandemic, the situation with children's health is in a critical condition. For example, in his most recent report, the Special Representative of the Secretary-General for Children and Armed Conflict reported on the horrific use of quarantine and the reduction in the number of humanitarian missions in conflict-affected regions for military purposes: in particular, Ebola and other diseases treatment centers were attacked by armed groups and looted in order to prevent the provision of medical care. Isolation regime increased risk of sexual and regular violence regarding children and adolescents because of increased presence of military and armed groups in towns and villages; boys and girls, experienced violation, lost the opportunity to obtain immediate and specialized medical and psychological care [3].

Under conditions of relative safety of children's health, however, it is exposed to dangers and fatal effects. Thus, according to State of Global Air estimates, in 2019, 476,000 infants died in the first month of life from health effects associated with air pollution [4] .

All these examples only fragmentarily outline the issue of protecting the health and well-being of children. At first glance, such cases seem completely unacceptable in the 21st century, when human rights and dignity have the status of the highest value, and the integration of the world's states into international discourse and cooperation is significant. A deeper analysis leads to the conclusion that it is the institutionalization of human rights that has made it possible to identify situations of human rights violations and address these challenges appropriately.

THE AIM

The aim of this article is to analyze the development of the modern legal framework for protection of children's health, to clarify the benefits of a human rights-based approach,

which is now the basis for understanding children's right to health and its protection .

MATERIALS AND METHODS

In order to achieve this aim, taking into account the peculiarities of the topic, the relevant research methods were used: the application of a dialectical approach and historical method made it possible to understand the patterns of formation and development of children's rights idea within of the international community and national states; the formal-legal method was used while studying legal texts, and the comparative-legal method was used to compare different approaches to health protection in different international human rights mechanisms.

The study is based mainly on acts of international law, both of universal and regional levels, interpretation and clarification of human rights treaty bodies, expert reports and research, case law (decisions of the European Court of Human Rights, decisions of the US Supreme Court, decisions of the European Social Rights Committee), relevant scientific literature.

REVIEW AND DISCUSSION

Childhood is a period of life when people are most vulnerable and are dependent in decision-making on parents or other caregivers. However, the vulnerability of children in no way means that children are perceived as inferior in the exercise of their rights and interests compared to adults. But that was not always in such a way. The evolution of the child's rights took place in the range between the status of the child as an object of parental ownership until the recognition of the child's right to self-determination. Until the first quarter of the XIX century corporal punishment of children and the use of child labor, mostly by parents, were considered to be norm, and infant mortality was high, with one in four births dying. That movement against labor exploitation led to transformation of the concept of childhood, according to which the recognized value of physical, moral and intellectual welfare of the child [5, p. 11]. The first efforts at the international level was made by the League of Nations, which created a special committee to consider matters relating to the protection of children, and adopted conventions prohibiting women and children trafficking (1921) and slavery (1926). In 1924 Geneva Declaration of the Rights of the Child proclaimed an obligation of all adults of the world to provide safety and well-being to children. Three of the five articles of the Declaration dealt with the well-being and health of the child. In Art. 2 adults proclaimed duty to feed hungry children, to nurse a sick child, to help a child who is backward; also in Art. 3 and 4 it was highlighted the need to assist children primarily during disasters and distress, and to ban any of forms of exploitation of children [6]. Later in the 1959 UN Declaration of the Rights of the Child it was declared a duty of parents, men and women both as individuals, as well as public organization and national governments take all measures, including, legislative in order for children to have a happy childhood and be able to exercise their rights and freedoms, in particular those that contribute to the child's health – the right to special protection of physical, mental and social development of the child, the right to adequate nutrition and medical services, the right to special treatment when a child has physical or mental disabilities [7].

The 1948 UN Universal Declaration of Human Rights (UNDHR) proclaimed human rights are to be equally concerned children and adults, with the exception of Art. 25 recognizing that "motherhood and childhood are entitled to special is the care and assistance" and Art. 26, which deals with the prior right of parents in choosing the type of education for their young children". It is also important that the UNDHR is the first international instrument to appeal to human health. Art. 25 of the UNDHR establishes the right of everyone to a standard of living, including medical care and medical care, which is necessary for the maintenance of one's health and well-being of family; it also proclaims the right to security in case of illness [8].

1966 International Covenant on Economic, Social and Cultural Rights (ICESCR) in its Art. 12 imposes on States obligations to fully support "the right of everyone to the highest attainable standard of physical and mental health" and identifies steps that states must take to ensure "achieving progressively the full realization of the rights" to the maximum of its available resources, including through reducing of "the stillbirth-rate and infant mortality" providing "healthy development of the child", "improving of all aspects of environmental and industrial hygiene", preventing of epidemic, endemic, occupational and other diseases, creation "conditions which would assure to all medical service and medical attention in the event of sickness".

It seems there are three features of ICESCR in terms of child: 1) the family as a unit of society is responsible for "dependent children" (par. 1. Art. 10); 2) for the first time a prohibition of discrimination was in the provision of special measures of protection and assistance to children and adolescents, as well as a ban on the use of children in work that is harmful to their health (par. 3 of Article 10); 3) it was recognized special protection not only of childhood but also of motherhood, namely protection of mothers during a reasonable period before and after childbirth by providing the necessary social security and paid dismissal (par. 2 of Article 10)[9] .

During the second half of the 20th century the rights and legal status of the child have become the subject of philosophical, legal, biological research, the essence of which was mainly to answer the question of how to find a balance between the treatment of children as vulnerable subjects that are in need of special protection and assistance and self-dependent subject, whose rights and status do not differ in any way from that of adults. The authors of the British publication dedicated to children's right to vote and participate in decisions indicated in the work that international recognition of children's rights was based on the notion of children or both of passive, weak and vulnerable beings who need protection, or as recalcitrant

and menacing, who need control [10]. This approach is called "paternalist" and it is based on the assumption that children are not rational agents and are not able to make their own decisions, are not responsible for errors and vulnerabilities, so it justifies the control and intervention of adults in children's lives. Thus parents, society and state must provide or protect emotional, psychological or physical well-being of children including children's rights to health care, freedom from strict penalties and providing food and clothing. In contrast to the paternalistic liberal approach, based on the children's right to self-determination, recognizes their freedom of choice and thought on issues that concern them: religion or belief, the right to privacy, choice of friends or entertaining, right to express their opinion when they are accused of misconduct [11].

Several decisions of the US Supreme Court deserve to be presented as an example of a liberal approach. In *Haley v. Ohio* case, which concerned detention of adolescent and his stay in the police when it was granted police used a proof manner contrary to law, the Court noted that "Neither man nor child can be allowed to stand condemned by methods which flout constitutional requirements of due process of law" [12]. Another case in which the Court analyzed the content of children's right to freedom of expression in schools noted that public schools may not be "enclaves of totalitarianism" and school officials have no absolute power over their students. The Court stressed that children at school and outside are "persons" under the US Constitution, are entitled to fundamental rights that the State must respect as they themselves must respect their obligations to the state, but students cannot be seen as being forced to communicate on what the state has decided [13]. Soon after, the US Supreme Court reiterated its full understanding of children as bearers of human rights: "constitutional rights do not mature and come into being magically only when one attains the state-defined age of majority. Minors, as well as adults, are protected by the Constitution, and possess constitutional rights" [14].

It turned ironically out that it is the United States to be the only country in the world that has not ratified the Convention on the Rights of the Child (CRC), the adoption of which in 1989 was the turning point in development of children's rights, including health rights [15]. Since its unanimous adoption in 1989 and entry into force in 1990 CRC has become the most widely ratified treaty on human rights, which indicates the willingness of states to adopt comprehensive rules that protect the rights of children, regardless of race, sex, religion, ethnic origin, agency and other, that confirms once again the recognition by all of nations the principle of indivisibility of fundamental rights and duties [16]. The Convention combines modern understanding of human rights, the status of the child and the progressive understanding of the concept of "human health", that is all called "human rights-based approach to health", that is accepted and implemented by World Health Organization together with the Office of the High Commissioner for Human Rights. This approach, implemented in the field of health care, is based on seven key principles: accessibility, acceptability and quality of facilities and services, participation, equality and non-discrimination, accountability, which are expressed in the relevant positive obligations of the state. A "holistic" approach is taken to the understanding of health , according to which the right to health includes timely and appropriate medical care, as well as the main factors that determine its condition – safe and pure water, sanitation, information and education, related to health, and gender equality [17]. Finally, it should be noted that the CRC provisions have become a kind of reconciliation of conflicting theories about the status of the child, as it recognized children as "rational agents" that have the right to participate in decisions affecting their interests, to receive the necessary information (Art. 12, 13), but also considers their "physical and mental immaturity" which requires special safeguards and care (Preambula). The basis for such a compromise concepts of "best interests of the child" and "evolving capacities" (Art. 5).

In its Art. 24 of CRC it was for the first time that the child's right to "the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health" was institutionalized, and states shall strive to ensure that no child is deprived of his or her right of access to such health care services. This wording draws attention to the socio-economic nature of the right proclaimed in Art. 24, which means that its implementation is closely related to the financial capacity of the state . From this point of view, Art. 26 of CRC fulfills this idea, pointing out to the duty of the state to ensure to every child the right to benefit from social security, including social insurance, and to take all necessary steps to achieve the full realization of this right under national law, taking into account available resources and capabilities of the child and the persons responsible for their. Such an approach is extremely important in terms of practical sphere, particularly in terms yof justiciability of these rights, which deserves special attention and study.

Art. 24 lists specific steps by which the state can promote the full realization of the child's right to the enjoyment of the highest attainable standard of health:

(a) to diminish infant and child mortality;

(b) to ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;

(c) to combat disease and malnutrition, including within the framework of primary health care, through, inter alia, the application of readily available technology and through the provision of adequate nutritious foods and clean drinking-water, taking into consideration the dangers and risks of environmental pollution;

(d) to ensure appropriate pre-natal and post-natal health care for mothers;

(e) to ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents;

(f) to develop preventive health care, guidance for parents and family planning education and services.

However, given one of the key principles of CRC – the principle of non-discrimination (art. 2) , and advanced approach to understanding the health of the child – it seems that Art. 24 is not only one to outline the range of remedies of health and welfare of the child proposed by CRC. At least it worth to talk about another four articles: Art. 23, mentally or physically disabled child should enjoy a full and decent life, in conditions which ensure dignity, promote self-reliance and facilitate the child's active participation in the community; Art. 25, which proclaims the right of a child who has been placed by the competent authorities for the purposes of care, protection or treatment of his or her physical or mental health, to a periodic review of the treatment provided to the child and all other circumstances relevant to his or her placement; Art. 27, that proclaims the state responsible to recognize the right of every child to a standard of living adequate for the child's physical, mental, spiritual, moral and social development; Art. 6, which proclaims child 's right to life, survival and healthy development.

The Committee on the Rights of the Child (Committee), established by the Convention, issued General Comments in 2013 [18], where it provided a detailed reading of the right proclaimed in Art. 24 of the Convention, taking into account all trends and challenges for almost 25 years after the adoption of CRC. It is possible to highlight the main theses and messages of this document.

1. A child is treated as a person under the age of 18 in accordance with Article 1 of the Convention, and childhood is a period of continuous growth from birth to infancy, through the preschool age to adolescence. The stages of the child's development are cumulative and each stage has an impact on subsequent phases, influencing the children's health, potential, risks and opportunities. Understanding the life course is essential in order to appreciate how health problems in childhood affect public health in general. In particular, as to the rights of new-born, the Committee stresses the duty of the state and health care providers to maximize the promotion and support of breastfeeding.

With regard to school-age children and adolescents, the Committee notes the following challenges and approaches to address them:

a) increasing cases of mental diseases within to school-age children and adolescents, like eating disorders, psychologic injuries, suicides that demand primary care to be developed to early detect and treat such illnesses;

b) obesity is a cause of premature death in children, which requires restricting of influence of “fast-food” that are high in fat, sugar or salt, micronutrient-poor and as well as drinks ontaining high levels of caffeine or other potentially harmful substances, ensuring for all schoolers access to daily nutrition and creating a school environment that promotes healthy lifestyles ;

(c) given the high rate of adolescent pregnancy, states should work to ensure that girls can make independent and informed decisions about their reproductive health, including abortion; discrimination on the ground of teenage pregnancy such as expulsion from school is inadmissible.

(d) Adolescents in particular need education and training in health care, especially sexual and reproductive education, and have access to all necessary information relating to their health and health services. Article 12 of the Convention emphasizes the importance of children's participation in ensuring that children express their views and take them seriously, in accordance with their age and maturity. States are encouraged to conduct regular participatory consultations that adapt to the child's age and maturity, as well as to conduct research with children and do so separately with parents to learn about their health problems, needs and developmental expectations as a contribution to effective interventions and health programs.

f) gender-sensitive approach, which provides full political participation of young women; expansion of social and economic opportunities; recognition of equal rights in sexual and reproductive health; equal access to information, education, justice and security, including the elimination of all forms of sexual and gender-based violence.

2. The best interests of the child are closely linked to the protection of child's privacy. The Committee believes that children should have access to confidential counseling and advice without the consent of a parent or legal guardian, as well as to certain interventions, such as HIV/AIDS testing, sexual and reproductive health services, including education and recommendations for sexual health, contraception and safe abortion, if it assessed by professionals working with the child, in accordance with the best for the child.

By the way, it should be noted that in 2014, the Optional Protocol to the Convention allowed children to file complaints directly to the Committee on the Rights of the Child, which is an unprecedented decision that strengthened the foundations of children's rights [19].

The broad approach to children's rights reflected in the Convention resulted in relevant trends at the level of regional human rights protection systems. Thus, in accordance with the European Social Charter of the Council of Europe, children and adolescents have the right to special protection against the physical and moral risks to which they are exposed (p. 7 Part 1), have the right to adequate social, legal and economic protection (Art.11); states should guarantee to children and adolescents, taking into account the rights and duties of their parents, necessary care, assistance, education and training, in particular through the creation or maintenance of institutions and services sufficient and adequate to achieve this goal (p. 17 Part 1). Furthermore, the European Social Committee considered the complaint of the international human rights center INTERIGHTS against Croatia, in which it acknowledged that the fact that Croatian schools do not provide comprehensive or adequate education on sexual and reproductive health for children and youth, and educational materials used in Croatian schools contain some discriminatory statements, it is a violation of Article 11, 16 and 17 of the European Social Charter [20].

The European Convention on Human Rights, the Coun-

cil of Europe main document on civil and political rights, does not contain references to health rights. However, due to the fact that the European Court of Human Rights often uses an "integrated approach" in interpreting the rights enshrined in the European Convention, it had an opportunity to examine some aspects of health rights, mainly within Art . 2 (right to life) and Art. 8 (right to respect for private and family life). This approach is based on the indivisibility of all human rights and recognizes that, on the one hand, the realization of civil and political rights requires respect for and promotion of social rights, and on the other hand, social rights are not secondary to civil and political rights . That opens doors for creative opportunities to reconceptualize the contours of social rights, including the right to health [21, p. 713]. Let's look at just a few examples of decisions of the European Court of Human Rights. In case of *A. R. and L.R. v. Switzerland (admissibility decision*) concerned the refusal of the primary school to exempt the applicant's seven-year-old daughter from sex education lessons, due to the applicant's doubts about the usefulness of sex education at the kindergarten and primary school stages. The Court did not regard this as an interference with the applicant's child's privacy (under Article 8 of the European Convention), finding that sex education in primary school had legitimate aims and was, moreover, optional and not systematic; teachers simply "responded to children's questions and actions" [22] .

In case of *P. and S. v. Poland* 14-year-old rape victim wanted to terminate the pregnancy, but the local government hospital refused to have an abortion and published a press release which confirmed its decision. After that applicants experienced serious pressure from various groups, including medical professionals, journalists, priests and activists against abortion. After appealing the situation in the ministry, she was invited to a secret abortion per 500 km. from her house. The court concluded that Poland had violated its obligations to prevent inhuman and degrading treatment (Art. 3 of the European Convention), as well as its obligations under Art . 8 through the disclosure of personal and medical data of the girl and the creation of barriers in the practical implementation of her right to legal abortion [23] .

Despite significant progress in developing the idea of children's rights and children's health, many challenges lie ahead today. Today's Sustainable Development Agenda prioritizes reducing of infant mortality and under-5 mortality, fighting female genital mutilation and child abuse, which is now very common in the world. The concept of sustainable development of pays much attention, and the children themselves recognized as a basis for all sustainability dimensions, whose health and education the key to the progressive development of societies [24].

CONCLUSIONS

The study of the development of the modern legal framework for the protection of the child's health, conducted in this article, allowed us to note a change in approaches to understanding the status of the child and, consequently, to the scope of its rights and opportunities. In the early 20th century the protection of children's interests was limited by the principles contained in the declarative documents. The post-war world has made a significant leap towards the development of safeguards to protect children, recognizing their dignity and respect for fundamental rights. This took place in parallel with the formation of understanding of human health, the actualization of special human needs depending on age and the formation of understanding of the special needs of children.

Inclusive approach that was first embodied in the Convention on the Rights of the Child and the activities of UN Committee on the Rights of the Child, was supplemented in 2014 by creating for children the opportunity to address complaints directly to the Committee. This has not wiped out all cases of injustice and disorder, and a significant number of challenges to the health and well-being of children are facing us all today. But it is the human rights-based approach that underpins children's health and demonstrates ability to address these challenges.

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REVIEW ARTICLE

EVIDENCE-BASED MEDICINE AS PATIENT'S PROTECTION MEASURE IN JUDICIAL PRACTICE

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ABSTRACT

The aim: To identify the role of evidence-based medicine, its principles and approaches to patients' rights protection and the provision of medical service optimization, the skills of medical staff improvement, increasing the objectivity of court decisions in cases of non-providing quality care or death.

Materials and methods: The authors used the decisions by the European Court of Human Rights (ECtHR) on the statements of victims of unprofessional actions by doctors, international and domestic regulations on patients' rights, statistics on the results of criminal proceedings on violations of patients' rights over the past 5 years, case law of criminal and civil jurisdiction in this category of cases, the results of surveys of prosecutors, as well as the results of research by scientists in the field of medical law and criminalistics. The research is carried out on the basis of a harmonious combination of philosophical approaches, general scientific and special methods of scientific knowledge, the complex of which is chosen taking into account the goals and objectives, object and subject of research.

Conclusions: In order to implement the patients' rights by legal means in accordance with the Convention for the Protection of Human Rights and Fundamental Freedoms, the European Charter of Patients' Rights and other international regulations in the field of medicine, the authors argue the need for greater implementation of evidence-based medicine into the practice of medical institutions as a means of improving the level of medical care and an obvious source of relevant information for litigation to protect the rights of patients and doctors. For patients' rights protection in the diagnosis and treatment of diseases, it is proposed to regulate a set of such measures: 1) to include in the educational programs of pharmacy and medicine such disciplines as «Evidence-Based Medicine» and «Rights of the patient and medical worker's rights»; 2) to oblige the doctor to explain to the patient or to his/her representative the differences of treatment protocols, to provide information to patients about official sources, which contain information on unified and updated treatment protocols and diagnosis of certain diseases, to obtain informed consent by the patient (his/her representative) on certain medical guideline; 3) to recognize medical guidelines as sources of law in criminal and civil proceedings as a kind of benchmarks for clarifying and assessing the facts of non-performance or improper performance of professional duties by a medical or pharmaceutical worker, violation of patients' rights, as well as means for doctors' legal protection and etc.

KEY WORDS: health care, patient's rights, medical law, clinical protocols, medical standards

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INTRODUCTION

A few international health care legal acts have been adopted in recent decades, in particular: Universal Declaration of Human Rights; Convention for the Protection of Human Rights and Fundamental Freedoms; International Covenant on Civil and Political Rights; International Covenant on Economic, Social and Cultural Rights; European Social Charter (revised) (ETS N 163); Declaration of Lisbon on the Rights of the Patient, etc. Their norms are included in the legislation of many countries around the world, including Ukraine. Thus, some provisions of these regulations are contained in the Constitution of Ukraine, Civil, Family and Criminal Codes of Ukraine, laws of Ukraine «Grounds of Ukrainian legislation on health care», «On ensuring the sanitary and epidemiological well-being of population», «On the personal data protection», protocols, standards and other legal acts in the field of health care. Article 5 of the European Charter of Patients' Rights states that «Each individual has the right to freely choose from among different treatment procedures and providers on the basis of adequate information». The right to freedom of choice in health care is enshrined in the Civil Code of Ukraine (Part 2 of Article 284, Article 633), in the laws of Ukraine «Grounds of the legislation of Ukraine on health care» (clause «d» of Article 6, part 2 Article 34, Article 36, Article 38), «On Consumer's Rights Protection» (Article 21).

The right to consent to medical intervention and the right to refuse medical intervention are enshrined in Article 4 of the European Charter of Patients' Rights. Also, this right is enshrined in the Constitution of Ukraine (Part 3 of Article 28, Part 1 of Article 29), the Civil Code of Ukraine (Parts 3, 4, 5 of Article 284, Part 4 of Article 286, Article 289), Law of Ukraine «Grounds of the legislation of Ukraine on health care» (Articles 42, 43, 44).

In view of the above, it is important for Ukraine to actively take the necessary organizational and legal measures aimed at improving the quality of medical services, protecting the rights of patients from unprofessional actions by doctors, including by appealing to the courts.

THE AIM

To show the advantages of evidence-based medicine, to argue the need for more active implementation in medical practice of unified and local clinical protocols developed and approved on the basis of evidence-based medicine and existing international standards, which should be considered in judicial practice as benchmarks to compare doctors' activities while providing medical care for the treatment of one or another disease. To identify factors that hinder or prevent the implementation of clinical protocols in medical practice as a means of realizing the patient's and doctor's right to a fair and effective justice. To assess the impact of the absence of such protocols on the objectivity of a court decision on non-provision or improper provision of medical care. To propose a set of measures that will help to the patients' rights protection.

MATERIALS AND METHODS

In order to achieve the objectives of the study, 25 judgments of the European Court of Human Rights on applications of victims of improper provision of professional duties by a medical or pharmaceutical worker, statistics on the results of criminal proceedings on violations of patients' rights over the past 5 years, the results of questionnaire of 128 prosecutors, 195 criminal court verdicts and 275 decisions and rulings by civil courts were analyzed. They were accessed through the official websites of the European Court of Human Rights (ECtHR) and the Judicial Administration of Ukraine. In particular, the decision of the European Court of Human Rights «Case of Arska v. Ukraine» of 5 December 2013 on application №45076/05 (violation of Article 2 of the Convention - inconsistency with the clinical protocols of doctors' actions to establish the patient's mental health and his/her ability to make decisions independently) [1]; decision on application № 4605/05 «Case of Petrova v. Latvia» of 24 June 2014 (violation of Article 8 of the Convention - transplantation of organs (kidneys and spleen) without the consent of the mother of the deceased in a traffic accident, his mother learned eight months after the death of her son about the fact of transplantation) [2]; decision on application №10060/07 «Case of Bataliny v. Russia» of 23 June 2015 (violation of Article 3 of the Convention - testing of a new medicinal product on a patient without one's consent) [3] and others.

In addition, international and Ukrainian legal acts were studied and analyzed (Universal Declaration of Human Rights, Convention for the Protection of Human Rights and Fundamental Freedoms, International Covenant on Civil and Political Rights, International Covenant on Economic, Social and Cultural Rights, Declaration on Physician Independence and Professional Freedom, European Charter of Patients' Rights, International Code of Medical Ethics, Constitution of Ukraine, Criminal and Civil Codes of Ukraine, Laws of Ukraine «Grounds of Ukrainian Legislation on Health Care» and «About Consumers' Rights Protection», Decree of the President of Ukraine «About doctor's oath», orders of the Ministry of Health of Ukraine, etc.), which regulate legal relations in the field of medical services provision.

The methods of theoretical analysis and synthesis were used while studying the content of legal norms and concepts contained in international legal acts, Criminal and Civil Codes of Ukraine, the Law of Ukraine «Grounds of Ukrainian legislation on health care», in scientific papers by foreign and domestic researchers, in verdicts, decisions and court rulings on cases of violations of patients' rights. The method of systematic analysis was used to determine the content of the human right to health care, the right to consent to medical intervention (application of diagnostic, prevention or treatment methods) and the right to refuse medical intervention and determining ways to implement it in Ukraine.

Formal-legal analysis of international and Ukrainian legislation on health care and patients' rights protection gave an ability to identify the inherent shortcomings and contradictions of legal acts and to formulate proposals to improve legal regulation, in particular, on the need for establishing a regulation on strict compliance with treatment recommendations which are contained in clinical protocols approved on the basis of the principles of evidence-based medicine. By using the comparative-legal method, the experience of certain countries in implementing and exercising the principles of evidence-based medicine was studied. Other separate scientific methods of cognition, in particular formal-logical (for typification of medical errors and their consequences), functional (while identifying the influence of local clinical protocols on process of collecting and an estimation of the facts of non-performance or improper performance of professional duties by medical or pharmaceutical worker, violation of patients' rights), sociological (while analyzing the results of activities by monitoring groups to identify facts of non-performance or improper performance of professional duties by a medical or pharmaceutical worker, assessing the level of latency of such offenses), etc.

REVIEW AND DISCUSSION

Life and health of every person is the main asset of mankind. Healthy nation problems have not only socio-political but also economic significance. Thus, Belarusian economists have calculated the economic damage caused to the state by the death of a person of working age. In particular, the annual contribution to the GDP of a person of working age is about 10,000 US dollars. If a person dies at an early working age and does not live to retire about 10-15 years, loss of income of the state is 100 000-150 000 US dollars. The direct expected economic losses from mortality in working age are millions of dollars [4]. It should be noted that until 1980, physicians around the world while selecting the meds for the treatment of patients relied solely on their own experience or on the recommendations of the most recognized experts in the field of medicine. Such an approach to doctors' choice of treatment methods has often led to negative and sometimes tragic consequences. As Juan E. Méndez notes, medical professionals today

receive a comprehensive education that includes the practice and ethics of modern medicine, but blatant violations of physical integrity and human dignity come from the hands of those professionals and "in the name of medicine" worldwide [5].

In 1979, the famous English epidemiologist Archie Cochrane for the first time in the world justified the need to use in practical medicine only those data that could be obtained in the process of properly organized and proven scientific research. He suggested writing scientific medical reviews based on the systematic collection and analysis of facts with regular new data updating [6]. These ideas have found their supporters and since 1980 in the diagnosis and treatment of diseases spread the technology of collection, analysis, synthesis and application of scientific medical information, which allows to make optimal clinical decisions that provide quality medical care to the patient considering its economic efficiency (financial and time spending reduction on patient's treatment). Such scientifically justified medical practice in 1990 at the suggestion of Canadian scientists from McMaster University was called «evidence-based medicine», which involves in everyday medical practice (in diagnosis, treatment and prevention) the usage of medical technologies and drugs, which effectiveness has been proven in pharmacological studies using mathematical estimates of the probability of success and risk [7].

According to M.P. Skakun, evidence-based medicine is a strategic direction of modern medical science and practice, which is based on impeccable scientific information and focused on improving the level of scientific research, significantly improving the diagnosis, prevention, treatment and prognosis of human diseases, optimizing the state health care system [8]. Despite a relatively short period of existence, evidence-based medicine has achieved significant results, which are as follows:

- evidence-based medicine covers the world experience of internal diseases diagnosis and treatment and is based on medical information, the reliability of which is undoubtable. Thus, John R. Buscombe points out that laboratory studies to determine the effectiveness of radionuclide therapy in the treatment of tumors have been carried out for 15 years and only when a positive result is obtained in 80% of patients, the appropriate treatment protocol was adopted [9];
- evidence-based medicine, as a type of medical practice, differs in the consistent and conscious usage of only those interventions in the patient's treatment, the usefulness of which has been proven in benign studies. It should be noted that due to over-reliance on clinical results published by well-known physicians and medical scholars in various medical publications, physicians may make incorrect diagnostic or therapeutic decisions and thus endanger the health or even life of the patient. Therefore, according to Margaret MacDougall, Helen S. Cameron and Simon R. J. Maxwell, to make a correct diagnosis and to avoid errors in treatment, health professionals should be guided by evidence-based medicine, based on long-term research using a large amount of empirical material [10];
- evidence-based medicine is aimed at releasing medical science and medical practice from outdated and ineffective methods of diagnosis and treatment. Analyzing the negative impact of numerous doctors' errors on patients' health, Canadian medical scientist Allan S. Detsky argues that medical errors have become more common today due to the complexity of treatment methods and to the lack of clinical protocols unification. The evidence-based medicine usage, multidisciplinary approaches, cooperation with patients and the use of electronic systems to support clinical decision-making should facilitate the timely detection and prevention of medical errors in the future [11];
- evidence-based medicine allows to create individual treatment programs for the disease at any level of medical care provision;
- evidence-based medicine ensures the achievement of the maximum effect of treatment with minimal use of pharmaceuticals. According to Hans-IkoHuppertz, the application of effective approaches and avoidance of ineffective medical recommendations will cause the quality of medical services improvement [12];
- evidence-based medicine is aimed at reducing the influence of subjective factors on the choice of criteria for diagnosis and treatment of a particular patient in accordance with the recommended algorithms.

Thus, evidence-based medicine could be defined as the faithfully, accurate and meaningful use of the best results of clinical studies to choose a method of treatment for a particular patient [13]. It is a kind of approach, the concept of a new modern clinical thinking, based on the collection, analysis, generalization and interpretation of information for the choice of methods and treatment recommendations, which are or will be obtained as a result of clinical experiments on human beings [14]. While doing so the development and selection of optimal criteria for diagnosing diseases of patients is a key component of evidence-based medicine, where special attention should be paid to the development of a standardized set of indicators based on the results of clinical testing [15]. Therefore, the inclusion into the pharmacy and medicine educational program of evidence-based information is appropriate and extremely important in the permanent growing role and responsibility of physicians and pharmacists to meet the needs of patients in the use of drugs in compliance with one's rights [16].

In 1992, a world organization, named in honor of Archibald Cochrane - the Cochrane Collaboration, was established. Its primary task is to systematize information for periodicals and analyze the results of research in medical science and treatment practice. Today, doctors, researchers, and representatives of consumer organizations from around the world prepare systematic reviews and analyzes of clinical studies at the research centers of the Cochrane Collaboration. The results of their activities are publicly available in an electronic evidence-based database called The Cochrane Library, which contains systematic

reviews, abstracts and research in all areas of medicine and healthcare. Summaries of examinations are available free of charge, as well as a self-search on the server is available, which is a significant asset of medicine [17]. In view of the above, we consider it appropriate to join the opinion of scientists and practitioners on the need to open a Ukrainian branch of the Cochrane Collaboration and its' electronic library [18].

The degree of evidence of certain clinical studies is determined jointly by the Cochrane Collaboration, the World Health Organization, the Society for Critical Care Medicine and the British Medical Journal. Guidelines for doctors in the form of certain standards and protocols are created on the basis of reliable scientific evidence.

It should be emphasized that the use in clinical practice of clinical protocols and clinical guidelines as documents containing requirements and recommendations for methods of medical care should be considered as one of the most important ways to implement evidence-based medicine. The main order regulating the introduction of evidence-based medicine in Ukraine is the Order of the Ministry of Healthcare of Ukraine № 751 «On the creation and implementation of medical-technological documents for standardization of medical care of the Ministry of Healthcare of Ukraine» of 28.09.2012. In addition, order of the Ministry of Healthcare of Ukraine № 1422 of December 29, 2016, which allows Ukrainian doctors to use international clinical protocols in their work, came into force. The mentioned protocols are, first of all, a clear algorithm of actions for practicing doctors. The implementation of international protocols would contribute coherence in the provision of medical care to patients at all levels, as well as ensures that each patient receives a high level of medical care.

According to the Law of Ukraine «Grounds of the Legislation of Ukraine on Health Care», a clinical protocol is a unified document that defines the requirements for diagnostic, treatment, prevention and rehabilitation methods of medical care and their sequence. A clinical recommendation, according to the Order of the Ministry of Healthcare of Ukraine № 751 of 28.09.2012, is defined as a document containing systematic provisions on medical and medical-social care, developed using evidence-based medicine methodology on the basis on confirmation of their reliability and credibility, and is aimed at providing assisting the doctor and the patient in making a rational decision in different clinical situations.

There are several types of clinical protocols: 1) international clinical protocols; 2) unified protocols approved by the Ministry of Healthcare of Ukraine on the basis of guidelines for the various diseases treatment; 3) local protocols (routes), which are developed on the basis of unified and approved by the relevant officials (usually these protocols are approved by the Department of Healthcare of the regional state administration and are approved by an order of the chief physician of the health care institution). They could be supplemented by appropriate additions, for example, «Information card of the main actions in the case of anaphylaxis», which further detailed the algorithm of actions of the doctor in the selection and implementation of treatment measures is prescribed; 4) new clinical protocols, which are created according to the initiative of a particular doctor on the basis of international clinical protocols and other guidelines for the treatment of various diseases and approved by the relevant internal order of the health care institution.

The special literature drew attention to certain shortcomings of the existing unified and local clinical protocols and the procedures for their development and approval. In particular, unified clinical protocols may contain trade names of drugs, which lead to lobbying the interests of certain manufacturers of pharmaceutical products. In some cases, unified protocols are developed according on the «personal experience» of the members of the working group and on the outdated, non-evidence base. Unified and local clinical protocols are mainly prepared according to the capabilities of the healthcare system, and not to the needs of patients. It violates the right of patients to access the information about modern treatments methods. Moreover, despite the methodology of development of unified protocols approved by the Order of the Ministry of Healthcare of Ukraine No. 751, which meets European standards, the end result is far from them in practice. Since 2012, only 123 unified protocols have been created in Ukraine, covering a small percentage of diseases. Therefore, the permission to use new clinical protocols really provides access to world standards of almost all diseases treatment, without waiting for the working groups in Ukraine to complete the development of unified protocols [19].

Evidence-based medicine also provides a greater opportunity for the doctor to choose the optimal method of treatment at his/her discretion. Thus, if at the same time there is a unified clinical protocol and a new clinical protocol, then according to the decision by the doctor a new clinical protocol could be applied. In this case, the doctor should explain the differences in treatment protocols and obligatory to obtain the patient's informed consent (in certain situations the decision is made by a legal representative). When a new protocol is used, the doctor is relieved of the obligation to use a unified protocol.

Unified clinical protocols remain mandatory if the health care facility does not approve new clinical protocols or the patient has not given an informed consent. Healthcare institutions have the right to independently select and translate international protocols, with their subsequent approval by the relevant internal order. Such protocols are allowed to be used only in the work of still that particular healthcare institution. While doing so, doctors, other subjects of medical services, regardless of their educational-qualification level and position (paramedic, nurse, etc.) have to access these protocols verifying this fact by the signature and to strictly adhere to their provisions while the medical care provision. According to Michelle Robson and co-authors, healthcare professionals must adhere to clinical protocols and be aware of certain risks when choosing patient treatments. Otherwise, the doctor may face professional disci-

plinary punishment, prohibition or restriction on medical activities, loss of professional reputation [20].

Contacts with various international institutions and organizations facilitate the process of intensifying the access by medical workers to clinical protocols based on evidence-based medicine. Thus, thanks to the cooperation of the Ministry of Healthcare of Ukraine with the company of the Finnish medical-scientific society Duodecim Medical Publications Ltd., which specializes in integrated solutions in the field of evidence-based medicine, an online platform for primary care physicians was created and introduced. Modern clinical protocols based on evidence-based medicine could be found there and accordingly, it is possible to deepen physicians' professional knowledge [19]. In addition, the protocols approved by the Ministry of Healthcare of Ukraine on the basis of guidelines for the various diseases' treatment are now collected for convenience on the website of the Ukrainian Medical Journal [21]. The NGO «Foundation of Medical Law and Bioethics of Ukraine» also joined the implementation of these ideas [22].

It is also interesting that one of the options for checking the quality of a scientific publication in the field of medicine is its «blind» (anonymous, independent) peer review by three or more specialists in this field. Not only doctors but also patients could check the quality and effectiveness of any treatment methods at the same time. On this issue, Martin Bientzle and co-authors rightly believe that the choice of pharmacological or surgical treatment methods for patients should be made jointly by physicians and patients, which will help the patient to make informed decisions about optimal treatments based on factual data analysis obtained due to the evidence-based medicine measures [23]. Steffen Häfner and co-authors emphasize that physicians should perceive the patient as a person, who makes decision on the way of his/her treatment, and not the one who agrees with the physician's opinion on that issue in advance [24]. A reasonably well way to protect patients' rights has been proposed by US doctors, who have set up an online communication system at three medical centers with patients who have visited doctors and received records in their medical cards describing symptoms, medical diagnosis and treatment suggested. Analysis and summarization of the survey of 1,400 patients allowed to find that in 25% of cases, medical records contained significant inaccuracies that could potentially lead to a deterioration in patients' health status. The most common types of potential inaccuracies included a description of symptoms (21%), previous medical problems (21%), prescribed meds (18%), and important additional information about chronic diseases and patient health conditions (15%). Inaccuracies in the medical records were subsequently corrected and medical appointments were adjusted. The authors of the idea believe that the cooperation of doctors with patients will help protect their rights and increase the effectiveness of treatment [25]. In other words, evidence-based medicine helps to establish a dialogue between doctors and patients who, according to Dainius Puras, should participate in decision-making regarding future diagnostic and therapeutic interventions [26].

Thus, in modern conditions, due to global informatization, patients' rights are expanding. Healthcare professionals are no longer the only source of information about the symptoms and diagnosis of diseases, methods and protocols for their treatment, modern medicines and medical equipment, treatment options for certain diseases in medical clinics around the world, possible risks and causes of negative results of healthcare provision. That is why medical and pharmaceutical workers generally try not to violate the rights of the patient, as they are constantly under close control by the state, society, law enforcement bodies, patients themselves and their relatives.

In the context of the considered issues, the statement that clinical protocols should be developed and approved only on the basis of unambiguous medical information based on the results of scientific research and clinical observations, should be axiomatic. It also applies to the emergence of new, unknown diseases, which are of a mass character, having intensive for widespreading and require immediate response by the relevant government agencies. Coronavirus disease COVID-19 could be considered as such. In the context of the COVID-19 pandemic conditions, pharmacological studies on the effectiveness of treatment of this disease based on the approaches of evidence-based medicine have become especially relevant. Clinical treatment protocols for COVID-19 treatment are constantly changing and supplemented. In order to achieve the most coordinated possible approach to obtaining the results of medicines testing in the European Union, the document «Guidance on the management of clinical trials during the covid-19 (coronavirus) pandemic» was published [27]. In addition, most countries around the world are conducting research to develop protocols for early diagnosis of this disease, establishing the stages of the disease and the degree of risk to the patient's life. Depending on the presence of associated comorbidities, treatment methods and their effectiveness are analyzed. Thus, in the United Kingdom, a group of scientists analyzed the effectiveness of treatment of 22,361 patients for the period from May 21, 2020 to June 29, 2020, who were observed by doctors at least for four weeks. The results of these studies were immediately published in the public access on the Internet [28]. That is why rather hasty statements about the completion of vaccine development from COVID-19 (as one that has not been properly researched) cause some concern.

The introduction of evidence-based clinical protocols is intended not only to optimize the provision of medical services, but also to facilitate the collection of evidence of the guilt or innocence of doctors in criminal and civil proceedings. At the same time, the protocols themselves should be considered as sources of law, as a kind of guide in clarifying and assessing the facts of non-performance or improper performance of professional duties by a medical or pharmaceutical worker, violation of patients' rights, as well as measures for doctor's legal protection.

It should be noted that there are different approaches to resolving conflicts that arise between doctors and patients in world practice. Thus, in the United States, the United Kingdom, Canada, New Zealand, South African Republic and other countries, disputes arising from harm to the life

and health of patients while performing of their professional duties by healthcare workers are mainly resolved by methods of civil law regulation. Criminal measures are applied only in special cases. Whereas in Japan, Saudi Arabia, Belarus, Russia, Kazakhstan, Armenia, and Latvia, medical workers are primarily criminally liable for the results of their professional activities under general rules that provide for liability for harm to life and health. In particular, according the Criminal code of the Russian Federation it is possible to bring the doctor to criminal responsibility under several articles: Art. 109 (causing death by negligence), Art. 118 (causing grievous bodily harm through negligence), Art. 124 (non-providing care to the patient), Art. 235 (illegal medical or pharmaceutical activities) [29]. According to the data by Investigative Committee of Russia, only 10% of criminal cases investigated against doctors go to court, in 90% of cases investigators prove their innocence. Only those doctors who have committed gross violations of treatment standards and protocols are prosecuted in Russia [30].

According to the results of the analysis of the statistics of the pre-trial investigation bodies (see Table 1), it was established that the corpus delicti provided for in Art. 140 of the Criminal Code of Ukraine (Improper performance of professional duties by a medical or pharmaceutical worker), is the most widespread among crimes against life and health of a person, the subjects of which are medical workers. Thus, from January 2016 to September 2020, 3182 such criminal offenses were registered. At the same time, only in 11 (0,35%) criminal proceedings medical workers were given a notice of suspicion, and only 8 (0,25%) proceedings were sent to court with prosecuting acts. At the same time, a significant part of criminal proceedings (1608 or 50,53%) was subsequently closed by the pre-trial investigation bodies, primarily due to the absence of a criminal offense or the absence of a corpus delicti.

For the same period under the Article 141 «Violation of the patient's rights», the suspicion was not handed over to any doctor, 3 proceedings were closed, and no decision was made at all on the other two.

In view of the above, among the main problems of the investigation of «medical crimes» there are the following:
- the lack of investigator's medical knowledge, and hence the need to involve relevant experts, medical and pharmaceutical workers as specialists in the conduct of investigative (searching) actions;
- the lack of proper experience and practice of investigating criminal offenses of this category. For example, out of 128 interviewed prosecutors, only 31 (26,3%) indicated that they had faced with proceedings concerning the improper performance of professional duties by a medical or pharmaceutical worker in practice;
- the need to quickly obtain the decision of the investigating judge on temporary access to things and medical documents, which leads to a situation where due to delays in obtaining such a decision, the medical institution manages to destroy the evidence in practice;
- mutual help of medical workers, which consists in evidence destroying (medical card data, test results, etc.);
- the desire to attribute any unsuccessful manipulation or surgical intervention that led to serious consequences solely to a medical error;
- covering up by the heads of medical institutions of their subordinates, active opposition to the investigation;
- difficulty in distinguishing negligence from accident, medical error and justified medical risk.

In turn, the analysis of case law shows that the courts are guided primarily by the provisions of clinical protocols in making a decision on the guilt of a particular medical worker [32; 33; 34]. Clinical protocols are also the basis for acquittals of doctors. Thus, during the court hearing it was found out that the doctor had no reason to believe that the patient had a disorder in the body regarding thrombosis, which later led to her death. He made recommendations for the treatment of the patient with the exception of certain laboratory tests, the absence of which could not affect the course of the disease [35].

Clinical protocols as sources of evidentiary information are also used by courts of civil jurisdiction while clarifying the circumstances of providing the appropriate level of medical care and making decisions on compensation for material and moral damage caused by deteriorating health [36; 37; 38]. At the same time, well-founded court decisions, which not only state the fact of existing errors in the diagnosis and treatment of the disease, but also determine the amount of compensation to the patient, emphasizes Maya Peled-Raz, contribute to the realization of one's rights to appropriate medical care [39]. National human rights organizations also pay attention to this fact in their reports [40].

CONCLUSIONS

Appropriate medical care is the provision of medical care by a healthcare professional in accordance with current clinical protocols and guidelines based on evidence-based medicine, considering the clinical situation and respecting patients' rights, especially – with the informed consent of the patient on medical intervention.

The introduction into medical practice of the principles and approaches of evidence-based medicine should be seen as a significant step towards reforming the medical field, improving the medical services provision, and the patients' rights protection. Created on the basis of medical information, the reliability of which is undoubtable, clinical protocols are rightly considered as an effective tool for improving the efficiency of medical professionals. In addition, in court-investigative practice, they serve as an informative means of proving the guilt or innocence of medical workers for non-performance or improper performance of their professional duties.

While creating guidelines that serve as the basis for the development and approval of clinical protocols, it is necessary to use those methods of diagnosis and treatment, the effectiveness of which has been proven in clinical studies in hundreds of thousands of patients.

To implement the rights of the patient in the diagnosis and treatment of diseases, it is necessary to regulate a set of such measures:

Table 1. Information on the results of criminal proceedings in Ukraine by article 140 of the Criminal Code of Ukraine «Improper performance of professional duties by a medical or pharmaceutical worker» (from January 2016 to September 2020) [31].

Year	Criminal offenses registered	Notices of suspicion given	Criminal proceedings sent to court	Criminal offences where proceedings were closed	Criminal offences without any decision to the end of the review period
2016	642	2 (0,31%)	1 (0,16%)	208 (32,39%)	641 (99,84%)
2017	725	2 (0,27%)	2 (0,27%)	234 (32,27%)	723 (99,72%)
2018	655	3 (0,45%)	3 (0,45%)	251 (38,32%)	652 (99,54%)
2019	669	2 (0,28%)	1 (0,15%)	296 (44,24%)	668 (99,85%)
January-September 2020	492	2 (0,41%)	1 (0,20%)	203 (41,26%)	490 (99,59%)

Table 2. Information on the results of criminal proceedings in Ukraine under Article 141 of the Criminal Code of Ukraine «Violation of the patient's rights» (from January 2016 to September 2020) [31].

Year	Criminal offences in the review period included	Criminal offences where notices of suspicion given	Criminal offences where proceedings were closed	Criminal offences without any decision to the end of the review period
2016	1	0	1 (100%)	0
2017	1	0	1 (100%)	0
2018	1	0	1 (100%)	0
2019	1	0	0	1 (100%)
January-September 2020	1	0	0	1 (100%)

1. To include in the curricula of pharmacy and medicine such disciplines as «Evidence-based medicine» and «Medical worker's and patient's rights».
2. Oblige the physician to explain to the patient or his/her representative the differences of treatment protocols, provide information to patients about official sources that contain information on unified and updated protocols on treatment and diagnosing of certain diseases, to obtain informed consent from the patient (or his/her representative) about a specific guideline.
3. Recognize guidelines as sources of law in criminal and civil proceedings as a kind of benchmarks in clarifying and assessing the facts of non-performance or improper performance of professional duties by a medical or pharmaceutical worker, violation of patients' rights, as well as means of doctor's legal protection etc.

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REVIEW ARTICLE

LEGAL REGULATION OF BIOETHICAL ISSUES IN THE LIGHT OF MEDICAL SCIENCE ACHIEVEMENTS

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ABSTRACT

The aim: To identify issues of legal support for the use of genetics' advances in medicine, reproductive technologies, etc. and to identify criteria for admissibility of safe and ethical implementation of scientific results.

Materials and methods: The analysis of international acts, legislation of European countries, scientific reports on the results of achievements in medicine, in particular, the study and modification of DNA. Decisions of the European Court of Human Rights and a sample survey were used. The study is based on a combination of philosophical approaches, theoretical (dialectical, logical, historical, analysis and synthesis), specific legal and sociological methods of scientific knowledge.

Conclusions: It is necessary to adopt at the UN level the Convention on the Control of Genetic Programming, to clearly define international cooperation in the field of prevention and counteraction to experiments on editing the genome of the "best man". Governments should adopt regulations based on certain standards of "preservation of human genetic identity", to establish the order of location of laboratories or other institutions on the territory of the states conducting research with genetic material.

KEY WORDS: germ cells, DNA, genome

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INTRODUCTION

Today's rapid development of medicine and scientific advances in physiology, genetics, molecular biology, pharmacology makes it possible to effectively treat acquired serious diseases, congenital genetic defects, positively solve the problems of human reproductive functions. At the same time, such studies and application of their results should not be deprived of control, legal regulation, as well as biosafety and ethics. The coronavirus pandemic has clearly demonstrated the need for transparency in the results of scientific laboratories, legitimacy of certain experiments, to protect humanity from the risks of leaking unauthorized and unsuccessful scientific products of scientific experiments, which also leads to negative economic consequences and diplomatic complications. (in particular, the statement of D. Trump "kung fu flu").

It is obvious that science is created and lives in a closed space, in a laboratory, but the subject of its research must be known to society, proven in an accessible form, especially in medicine. Science satisfies the desire of scientist to go beyond the known, but the result is used by society, which decides on the safety and usefulness, limitation or further prohibition of implementation of scientific result. The discovery itself, which is undoubtedly extremely necessary, sometimes arouses suspicion and opposition from citizens, as there were no discussions on the issue, no indication of research subjects, sources of funding, customers. So far, conspiracy theories have emerged about chipping citizens under the guise of vaccination against COVID-19 only on the grounds that Bill Gates joined in funding the search for the vaccine. This is due to the public's ignorance that the Bill and Melinda Gates Foundation is sponsoring medical research not only now, but that such assistance has been provided on an ongoing basis. For example, in 2010, the Foundation's funds were used to implement the idea of transforming DNA-cleaving enzymes into something like a diagnostic tool for detecting human-specific RNA molecules, including Dengue fever and yellow fever.

Public relations, regardless of the field, need legal regulation - from the legality of location of scientific laboratories (including foreign ones), infrastructure (locations considering environmental and other biological risks) and transparency of research to conduct experiments. However, currently such normative acts not adopted at the national or the international levels, legal policy does not correspond to the rapid development of science. This year, the Nobel Prizes in Medicine are awarded (almost every tenth for achievements in the field of immunology - in 2018, James Allison (James Patrick Allison), Tasuku Honjo for discovering the mechanism that inhibits the activity of T-lymphocytes, immune cells-killers of cancer cells, however, the agenda of meetings of international organizations and parliaments of the states are rarely addressed issues of regulation of these issues.

THE AIM

Identify problematic issues of legal support for the use in medicine of advances in genetics, reproductive technolo-

gies, etc. and identify criteria for admissibility of safe and ethical implementation of scientific results.

MATERIALS AND METHODS

The study is based on the analysis of international law on human rights and biomedicine (6 conventions and additional protocols to the conventions was analyzed); legislation of Ukraine; scientific reports on the results of advances in medicine, in particular, on the study and modification of DNA in the United States; judgments of the European Court of Human Rights. The empirical basis of the manuscript was the results of a sample survey conducted in December 2019 – January 2020 by 54 doctors and other health professionals (ranked depending on place of residence, level of clinic, specialization, work experience, degree, etc.). The article uses philosophical approaches to scientific knowledge and a set of methods of scientific research: theoretical (dialectical, logical, historical, analysis and synthesis), specific legal (comparative legal, formal legal), sociological (questionnaire).

REVIEW AND DISCUSSION

What is the first thing that prevails - medicine or law? Is it possible to combine and harmonize them for the people service? A person has an inalienable natural right to life, the right to health care, and in the event of encroachment, a legal mechanism is activated. Can scientific medical experiments in search of a cure for the disease be harmful to human health? What should be the actions of lawyers to prevent and counteract the negative consequences? What is the scale of regulations – national or international – to protect humanity from biological threats? These issues arise periodically and are addressed in the international legal acts of the World Health Organization, established at the UN in 1946, the World Medical Association, established in 1947, which, in particular, adopted the Declaration of Human Rights and Freedom of Health Workers (1985), Declaration on Euthanasia (1987), Declaration of Helsinki, Recommendation for Physicians Conducting Biomedical Research on Humans (1964), Declaration on Human Organ Transplantation (1987), Statement on Trafficking in Living Organs (1985), etc.

Council of Europe Convention on the Protection of Human Rights and Dignity of the Human Being with regard to Biology and Medicine: The Convention on Human Rights and Biomedicine of 1997 April, 4 was adopted with the recognition that biology and medicine are evolving rapidly, that will threaten human dignity; that progress in biology and medicine must be used for the benefit of present and future generations; that international cooperation is necessary for all mankind to be able to use the achievements of biology and medicine [1].

Directive № 2010/45/EU of the European Parliament and of the Council of Europe on standards of quality and safety of human organs intended for transplantation of 7 July 2010 drew the attention of states to the need for international control over transplantation, as such operations are performed by medical institutions or specialists from different jurisdictions. There are significant differences between varied EU Member States as to their requirements for the quality and safety of transplantation. In view of these facts, there is a need to develop common standards for preparation, transport and use of organs at European Union level. These standards are designed to facilitate the exchange of organs for the benefit of thousands of European patients who need this medical care every year. European Union legislation must ensure that bodies comply with recognized quality and safety standards. These standards should reassure the public that bodies trained in other countries have the same quality and safety guarantees as bodies trained in their own countries.

The practice of organ donation and transplantation, which involves the illegal transportation of organs, is considered unacceptable. In certain cases, this practice involves the illicit transport of persons for the purpose of removing organs, which is a serious violation of inalienable human rights and, in particular, the human right to respect for one's dignity and physical integrity. Although the main objective of this Directive is the safety and quality of organs, it is also directly aimed at the illicit transport of organs. This goal is achieved by creating competent authorities to issue permits for the establishment of organ transplant centers, creating conditions for the training of organs and monitoring systems for this process [2]. This Directive does not address the risk of human organ transplantation, the scope of standards is limited to EU countries, which allows to address these issues in some way (territorially and in time) but does not solve the problem as a whole.

Scientific advances in cell and molecular technology have led to the development of advanced therapies, such as gene therapy, somatic cell therapy and tissue engineering. This new field of biological medicine offers new opportunities for the treatment of diseases and disorders of the human body, the relevant Regulation (EU) N 1394/2007 of the European Parliament and of the Council "On advanced therapy medicinal products" amending Directive 2001/83/EU and to Regulation (EU) No 726/2004 "This Regulation lays down specific rules concerning the authorization, pharmacovigilance and control of advanced therapy medicinal products [3].

The CIS has adopted a Model Law on the Protection and Dignity of Man in Biomedical Research in the CIS Member States, which applies to all types of biomedical research involving humans, including in vivo embryos, but excluding in vitro embryo research. (Article 2). It is noteworthy that this law draws attention to biomedical research involving vulnerable groups, which include minors, persons with mental disorders, pregnant women and nursing mothers, persons serving sentences in penitentiary institutions, servicemen, migrants, as well as individuals and communities of people who are in different conditions of financial, administrative, national, religious, racial and other dependence. When conducting biomedical research with the participation of a vulnerable contingent, special

procedures are taken into account, which take into account the factors of age, intellectual, mental or social immaturity of the research participant (Article 24). It should be noted that, in accordance with Art. 28, epidemiological and social studies, combined with minimal risks for study participants or those that do not foresee such consequences, may be conducted without directly informing and obtaining the consent of potential study participants, but subject to independent ethical expertise and with the consent of authorized state body established by law. The principle of confidentiality and liability insurance in accordance with state law must be observed.

As stated in Art. 29, when conducting any biomedical research that involves obtaining information about the genetic data of the research participant, it is necessary: to provide the ethics committee with reliable and convincing data on feasibility of such studies, their usefulness or potential benefits of scientific data for research participants or others; obtain separate informed consent; ensure all necessary confidentiality measures; not to discriminate on the basis of obtaining genetic information; to ensure compliance with the requirements for such a procedure by law, as well as by generally accepted principles and norms of international law [4].

Ukraine has not yet adopted relevant legislation, and it must be acknowledged that the Convention on Human Rights and Biomedicine, which deals with transplantation of organs and tissues of human origin, and the Additional Protocol to the Convention on Human Rights and Biomedicine, which relates to biomedical research, have not yet been ratified, despite the fact that the Ministry of Health of Ukraine on 22.05.2007 the order on preparation for ratification of specified documents was approved.

In order to clarify the problematic issues of legal regulation of bioethical problems, we surveyed 54 doctors and other health professionals. Thus, according to the results of generalization of obtained data, it was found that the vast majority of health professionals are well acquainted with current bioethical problems (93%), in particular, 29% indicated the problems of organ and tissue transplantation in humans; 15% drew attention to the unregulated euthanasia, 19% –recognition of the embryo as a person from conception; 7% – the right of the mother (pregnant) to determine the fate of the embryo (without the partner's consent); 13% focused on surrogacy; 3% – conducting research on germ cells; 8% – biological research on DNA, viruses; 3% – location of biological foreign laboratories on the territory of Ukraine; 3% – editing the genes of patients for treatment.

For example, the results of the work of Professor Jennifer Anne Doudna (https://doudnalab.org/), who developed the method of genome editing, were known only to doctors who conduct research, and this is 4 people out of 54 respondents. Nevertheless, 84% of respondents justify the use of genome editing methods for therapeutic purposes, but categorically against gene editing of future children.

At the same time, 97% of the surveyed doctors opposed the consolidation of euthanasia (religious, social and moral-psychological factors) at the legislative level in Ukraine. 43% believe that it is appropriate at the regulatory level to determine that a pregnant woman has the right to use fertilized cells for childbirth, despite the partner's objections. The analysis of the survey shows that doctors need to raise awareness of the legal regulation of these issues in the European Union, the United States and other countries; Physicians face risks of violating bioethical principles, as there is legal uncertainty at national and international levels of certain issues (research).

Scientists N.P. Dubinin and Yu.G. Shevchenko in 1976 predicted that "… scientific and technological revolution brings humanity to enter the era of… biology" [5]. They pointed to the possibility of the next 20-30 years due to the achievements of genetics to eradicate hunger, overcome infectious diseases, cancer, cardiovascular disease, and organ transplantation will be ensured by the success of immunogenetics. At the same time, scientists have warned against hasty attempts to create a genetically better person, as this will have socially unpredictable consequences. At the same time, they did not deny that over time, the need for biological improvement will inevitably arise before science in connection with qualitatively new living conditions, habitats, which may be caused by cosmic or terrestrial factors.

In 1990, with the support of the US Department of Energy, the United Kingdom, France, Japan, China and Germany, the Human Genome Project was launched under the leadership of Francis Collins, head of the International Human Genome Sequencing Consortium. Scientists set themselves the following tasks: identification of 20-30 thousand DNA genes; establishing the sequence of 3 billion pairs of chemical bases that make up human DNA and storing this information in a database; improvement of devices for data analysis; introduction of the latest technologies in the sphere of private use; research on ethical, legal and social issues that arise during the decoding of the genome To solve the problem it was spent more than $ 3 billion, and in 2001 it was published the result of a scientific search. The process of DNA and genome sequencing later became available, and scientists were able to identify more than 4,000 types of DNA mutations that cause genetic diseases. The results of the research helped scientists to establish links between multiple gene variants and human physical and behavioral traits.

In this regard, Francis Fukuyama noted that the scientific offensive in all these areas has potentially political consequences, because they expand our knowledge of the brain, the source of human behavior, and consequently – the ability to control it "[6].

The open method of genome sequencing was exclusively a diagnostic tool, not a method of treatment. The challenge for scientists was to find a way to influence the correction of a defective gene. Scientists have discovered that viruses are able to embed new genetic information in the DNA of bacterial cells. Viruses were used as a vehicle to deliver a given content, as a vector or, in the words of scientists, a "Trojan horse". The so-called gene targeting process was used to correct mutations in the genome. In 2007, Capekki,

Smithis, and Evans received the Nobel Prize in Physiology or Medicine, in which they succeeded in deriving a live mouse with simulated changes as a result of gene targeting in mouse embryonic cells.

In 2012, the results of the CRISPR study were published, which emphasized the usefulness of a programmable enzyme capable of cleaving DNA for genome editing. As Jennifer Dudna points out, "when you gain power over the code of life, it comes with a certain level of responsibility that we are not ready for. Weighing the risks of technology like CRISPR against the responsibility to use its power to benefit humanity and the planet will be an unprecedented challenge. And still we have to go through it. Given the stakes, we simply have no choice. "[7]

According to scientists, we are on the threshold of a new era in the history of life on Earth - an era when humans have gained an unprecedented level of control over the genetic makeup of species that coexist with them. The use of the open method has a double effect, on the one hand it is aimed at improving treatment methods (use of modified bone marrow of the patient without transplantation), correction of visual impairment in infants, etc., on the other hand uncontrolled use can have negative unpredictable consequences.

The analysis of scientific reports allowed grouping the application of the following methods in the following areas:

1) cultivation of genetically modified plants (slow maturation, adaptation to certain climatic conditions, resistance to natural disasters, protection against insects, etc.);

2) breeding of genetically modified animals (create human diseases in animals for more accurate detection and development of treatment methods - monkeys for autism, pigs for Parkinson's, ferrets for influenza). Researchers are humanizing various pig genes for xenotransplantation - transplantation of organs grown in animals to human recipients. These gene editing technologies are used to create designer animals;

3) restoration of the ecological balance disturbed by human intervention in nature, namely restoration, return to life of extinct animal species through cloning and genetic engineering. It should be noted that scientists recognize that CRISPR technology can be used to destroy (extinct) unwanted species.

Emmanuel Charpentier and Jennifer Dudna were awarded the Nobel Prize in Chemistry in 2020 for the discovery of so-called "genomic surgery". According to J. Dudna, there must be an ethical justification for an outright ban on cell modification, just as she does not believe that states have the right to prohibit parents from using modern genetic technology to give birth to a healthy child, the scientist cites Charles Sabina's justification [8].

Scientists in medicine and biology have asked lawyers and politicians about the legitimacy of the use of advanced methods of gene therapy, in particular, it is a question of which cells can be directed to a new discovery – somatic or germinal? Somatic cells are the general name for all cells of multicellular organisms (heart cells, muscle cells, liver cells, etc.). Germinatives are any cells that can be inherited by future generations. According to scientists, embryo editing is the best way to demonstrate the therapeutic potential of CRISPR technology, by correcting a genetic defect in the embryo at an early stage of development.

According to Art. 1 of the Universal Declaration of the Human Genome and Human Rights, adopted by the United Nations on 11 November 1997, the human genome is the basis for the commonality of all members of the human race, as well as the recognition of their inherent dignity and diversity. The human genome marks the dignity of humanity. Therefore, as stated in the Preamble, Recognizing that scientific research on the human genome and the practical application of its results offer unlimited prospects for improving the person's health and of humanity as a whole, emphasizing that such research must be based on comprehensive respect for dignity, freedoms and human rights, as well as the prohibition of any form of discrimination on the grounds of genetic characteristics [9].

UNESCO now indicates in its documents that, although technologies such as CRISPR should be used to prevent the risk of life-threatening diseases, if such an intervention would affect offspring, it would jeopardize the inalienable, equal dignity of all human beings and restore eugenics, disguised as the realization of desire for a better, improved life [10]. Some scientists are also wary of the use of such methods, in particular, G. Annas warns that editing the human genome can significantly change the very concept of "being human", and this change in the gene pool will have detrimental unpredictable consequences [11].

Medical scientists are debating how to draw the line between the use of new methods for treatment (getting rid of diseases) and the improvement of the human species; lawyers are questioning the mechanism of control over these processes. The threat lies in the emergence of genetic discrimination, which is based on financial ability of families to turn to specialists to form a unique individual at the embryo level.

Professor V.Z. Tarantul, who participated in the Human Genome Project, does not rule out that in the future the courts will consider the results of genetic analysis when passing sentence. V.Z. Tarantul cites a case in which the killer's lawyers in a U.S. court helped his client avoid the death penalty by using the results of a genetic examination, findings of which confirmed the hereditary predisposition to the accused to violence. Given this, there is a threat of the return of eugenics, the science of control and influence on hereditary qualities [12]. In scientific discussions, scientists suggest not to use the term "eugenics", replacing it with the word "derivation" (F. Fukuyama), or "liberal eugenics" (Y. Habermas). Obviously, given this opportunity, states will not force parents to edit the genes of future children, however, the prevailing opinion is that giving such a right to the parents themselves is still appropriate.

In some countries, clinical interventions in human germ cells are prohibited, criminal penalties are provided by law (Austria, Brazil, Canada, Germany, France), and in some countries such restrictions do not exist. Scientists are drawing attention to the quality of regulations, which currently do not correspond to clarity and predictability,

as legal terminology does not reflect the essence of genetic interventions. Thus, in the European Union, "clinical trials of gene therapy which result in modification of the genetic identity of human germ cells" are prohibited [13]. The interpretation of "genetic identity" is quite broad. In France, actions that "violate the integrity of the human species" are prohibited, as are any "eugenic practices aimed at organizing the selection of people." In Mexico, instructions for dealing with human germ cells are limited to the purpose: all purposes except "eradication of serious diseases or defects or alleviation of disease" are prohibited.

According to the analysis of the case law of the European Court of Human Rights, the issue of the person's right to withdraw their consent to the preservation and use of embryos needs additional regulation [14].

CONCLUSIONS

Given the available technology to influence the human genome, determine the hereditary qualities of offspring, it is advisable to hold international interdisciplinary conferences with geneticists, biologists, ecologists, lawyers, government officials to understand the opportunities, challenges and threats. Based on professional counseling (to avoid terminological differences), it is necessary to adopt at the UN level Convention on the Control of Genetic Programming to clearly define international cooperation in the field of prevention and counteraction to experiments on editing the genome of "best person". Governments should adopt regulations based on certain standards of "preservation of human genetic identity", establish the order of location in the territory of laboratories or other institutions that conduct research with genetic material; provide criminal liability for collection of genetic material, embryos for unlicensed experiments at the legislative level; establish a regime of transparency of foreign laboratories on the territory of states (bacteriological and other). States that do not ratify international conventions and do not implement the standard of protection against genetic inequality set by the international community should be subject to severe sanctions and require access by international experts to the activities of questionable laboratories.

In Ukraine, public unrest is caused by the uncontrolled distribution of advertisements for the purchase of women's eggs (certain characteristics), surrogacy, significant funds are offered as payment, but advertisements do not meet the requirements of the law (no printing, customer, circulation), no clinic address (only price and phone). And there are fears on the basisof this about conducting informal experiments on human embryos, selling babies for scientific experiments, and so on. In a context of COVID-19 there was a discussion in the media about the legality of the presence of foreign laboratories on Ukraine's territory, where scientists from other countries work on issues unknown to society. Prohibition of genetic and biological research on the territory of some states does not solve the problem and only poses a threat of uncontrollability, which will be a threatening consequence.

In order to accelerate legal international harmonization and settlement by introducing strict control over the editing of germ cells, it is necessary to realize that scientific research does not stop for a moment. Procrastination can create a greater risk. The challenge must be accepted. For, as Herbert Wells noted in The Eating of the Gods, "The old scientist's disappointment was so deep and painful that he closed his eyes with his hands and was afraid to open them so as not to see his fears, which had already come true." [15].

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REVIEW ARTICLE

GENDER INEQUALITY IN HEALTHCARE IN TERMS OF EMPLOYMENT AND REMUNERATION: LEGAL MEANS OF OVERCOMING THE PROBLEM

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ABSTRACT

The aim: To determine the nature of gender inequalities in the field of healthcare according to the criteria of employment and remuneration and to outline legal means to overcome this problem.

Materials and methods: Reports of international organizations (World Health Organization, International Labour Organization, Organization for Economic Cooperation and Development); Ukrainian non-governmental organizations' reports and statistics of the State Statistics Service of Ukraine. The study is based on theoretical and empirical methods.

Conclusions: To overcome the problems associated with gender inequality in healthcare, we need to use legal means intended to implement the concept of decent work for women who work in the medical profession. This concept should include: removing barriers of women's employment in healthcare, support to women's careers and gender parity on management positions at healthcare facilities; establishing the minimum wage of healthcare employees at the level of the average wage in the country; creation of a specific entity (e.g. commission) to consider cases of gender discrimination against women in the healthcare sector; establishing salary bonuses for women-healthcare employees who have children, and other legal mechanisms.

KEY WORDS: healthcare employees, women, gender inequality, employment, remuneration

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INTRODUCTION

The World Health Organization assumes that there will be a global shortage of healthcare employees (about 18 million people) by 2030 due to number of demographic and economic transformations [1]. According to the World Health Organization, this shortage can be mitigated by initiatives to establish gender equality in healthcare [2]. The implementation of such initiatives should be carried out through the establishment of legal means aimed to eliminate the factors that produce gender inequality in the field of healthcare. Especially such factors can be identified on the criteria of the level of employment and remuneration of women who hold medical positions. The scientific attention of such researchers and authors as V. Pashkov, V. Tatsiy, N. Gutorova [3], A. Hempenstall, J. Tomlinson, M. Bismark [4], S. Ludwig, C. Kurmeyer, M. Gross [5], D. Barr [6], E. Spencer, A. Deal, N. Pruthi [7], L. Willett, A. Halvorsen, S. Chaudhry [8], S. Read, R. Butkus, A. Weissman [9] was drawn to the importance of these and adjacent issues. The outcomes of their studies revealed gender inequality in the field of healthcare, which confirms the relevance of this article, which aims to outline the most problematic issues of gender inequalities in the field of healthcare and to outline legal means to overcome this problem.

THE AIM

The article is to define problems of gender inequalities in healthcare in terms of employment and remuneration and to outline legal means to overcome this problem
.

MATERIALS AND METHODS

The study conducted on the basis of analysis of reports of international organizations (World Health Organization, International Labour Organization, Organization for Economic Cooperation and Development), reports of Ukrainian non-governmental organizations and statistical data of the State Statistics Service of Ukraine. The data that reports on gender inequalities in healthcare covers 104 countries and the period between 1993 and 2020. To identify comparable characteristics of gender inequality in healthcare, the following medical professions were considered: physicians and nurses. To assess gender issues the following indicators were used: the distribution of health employees by gender, age, position, nature of employment (employment in the private or public healthcare sector) and wages.

The study is based on theoretical and empirical methods. Theoretical methods included content analysis of the data from the reports of international organizations and scientific literature. Empirical methods related to processing

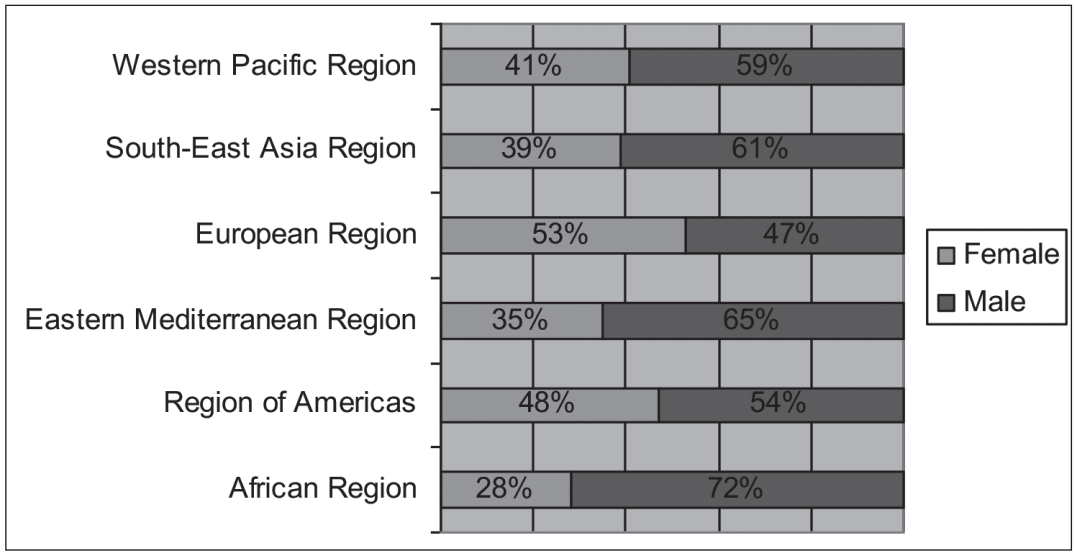

Fig. 1. Distribution of physicians by gender. Source: Data from National Health Workforce Accounts

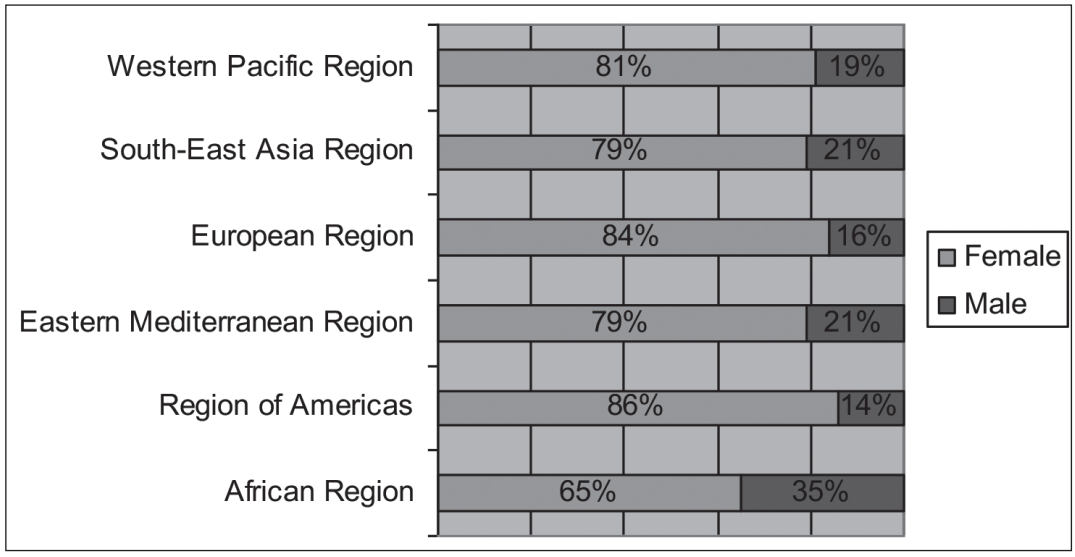

Fig. 2. Distribution of nurses by gender. Source: Data from National Health Workforce Accounts

statistics that demonstrate the nature of gender inequality in healthcare in terms of employment and remuneration.

REVIEW AND DISCUSSION

Totally, there are 234 million healthcare employees around the world [10], and the share of women's employment in healthcare is 67% of the total number of healthcare employees around the world [11]. In 2017 almost half of all physicians in countries of the Organization for Economic Cooperation and Development were women [12].

The World Health Organization (WHO) conducted a study [13] on gender and job differentiation in healthcare which had to show occupational segregation in the branch of medicine.

According to the graphs (Fig. 1 and Fig. 2), it's noticeable that in majority of regions, male healthcare employees make up the majority of physicians. Instead of that, women make up the majority of employees as nurses.

In the majority of countries, healthcare employees earn below the average wage in the country, and the wages of low-skilled employees in healthcare often have a basic minimum amount [14]. In 2018 the International Labour Organization (ILO) presented an analysis of the average wage in the healthcare sector in the report "Global wage report 2018/19" [15]. The results of the report showed significant gender gaps relating to wages, working hours and gender discrimination in the branch of medicine.

The analysis (Fig. 3) shows that, in general, women who works in healthcare sector earn 28% less than men. Working during the same working hours, but in different positions, women earn 21% less than men. Doing the same job during the same working hours, women earn 11% less than men in the healthcare sector.

Imbalance of employment and remuneration in the public or private healthcare sector is also highly indicative [16]. In private healthcare sector men are more likely than

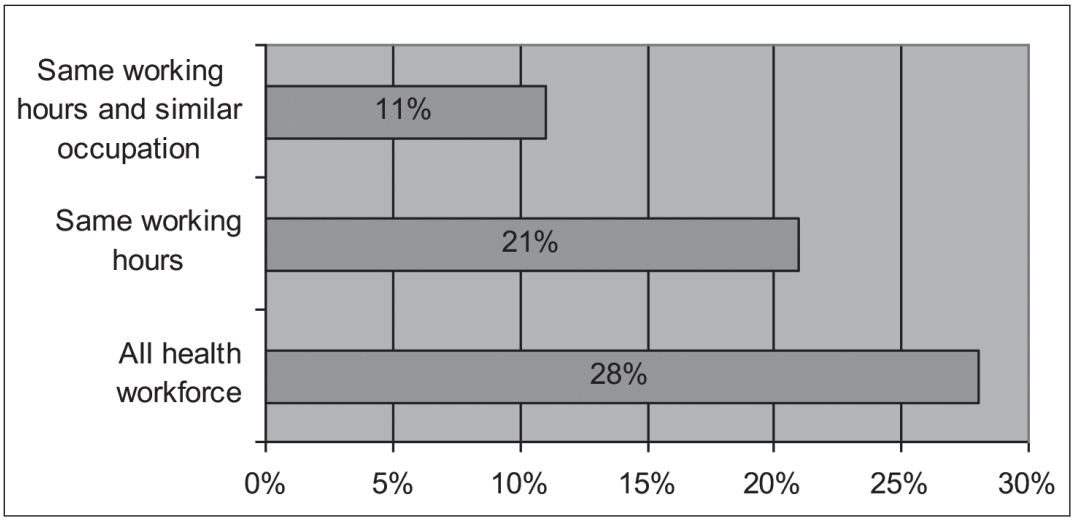

Fig. 3. Gender remuneration gap among healthcare employees as a percentage of men's wages. Source: Data from ILO. Global wage report 2018/19

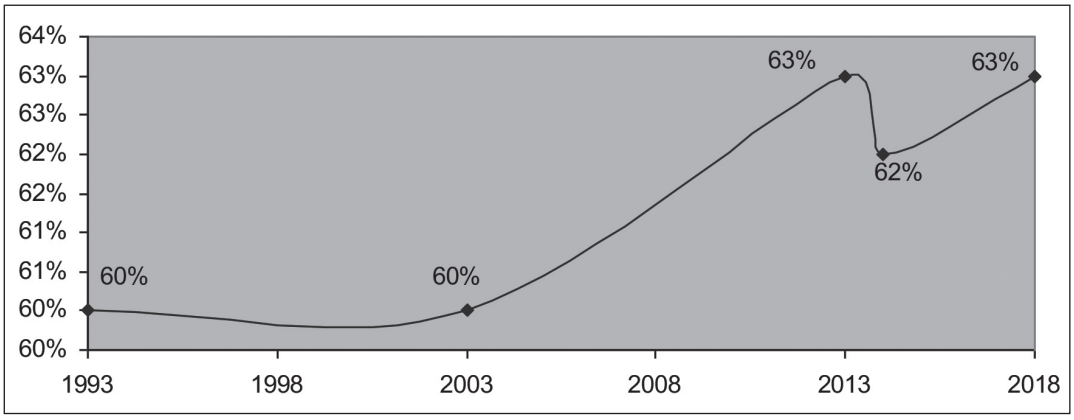

Fig. 4. Distribution of physicians by gender in Ukraine, 1993/2018, %. Source: Data from State Statistics Service of Ukraine.

women work as physicians (49.2% and 39.2% respectively), that creates a pay gap. Instead of that, women are often employed in the private healthcare sector as nurses (81.8% and 53% respectively) and mostly earn less than men.

As a member of the world medical community, Ukraine has similar trends related to gender imbalance in healthcare which can be observed taking into account some national characteristics.

In 2018 the most (around two thirds – 63%) of physician positions in Ukraine were occupied by women (Fig. 4), that exceeds the global rate (40%) of women's representation on such positions. The number of female nurses also exceeds the global rate (79%) and was 94% in 2018 (Fig. 5). At the same time, the structure of physicians and nurses by gender has not changed since 1993. 51% of managers positions at healthcare institutions occupied by women [17].

Given the quantative advantage of women in Ukrainian healthcare, the wages of women and men in the branch of medicine differ in the direction of gender inequality. However, according to the reports of the State Statistics Service of Ukraine, we can note the positive dynamics of women wages over the last decade.

The indicators (Fig. 6) illustrate that the difference between the wages of women and men in the branch of medicine in Ukraine is less than the world's average. In 2018 the correlation of the average wage of women and men in this sector was 28% around the world and 9.3% in Ukraine. Moreover, the dynamics of levelling Ukrainian indicators of the average wage of women and men in healthcare is positive (from 2003 to 2020 the gap in the wages amount of women and men in the of healthcare decreased by 7.3%). At the same time, it does not prove real gender equality in Ukrainian healthcare sector. In the first quarter of 2020, the average monthly wage in the healthcare sector of Ukraine was 7901 Ukrainian hryvnia, which is about 290 EUR. This amount is less than twice exceeding the amount of minimum wage which is guaranteed by Ukraine and payed for unqualified work. We can assume, that mainly for such reason, men who have medical education or certification often prefer private practice or strive work in private healthcare facilities (unfortunately, we do not possess statistical data on this issue). Hence, because of such situation, not all positions of medical employees at Ukrainian state healthcare institutions are occupied and there is a lack of professionals in state healthcare sector.

The conducted study confirmed the hypothesis that employment in the medical branch is predominantly female. At the same time, there is a significant gender gap in

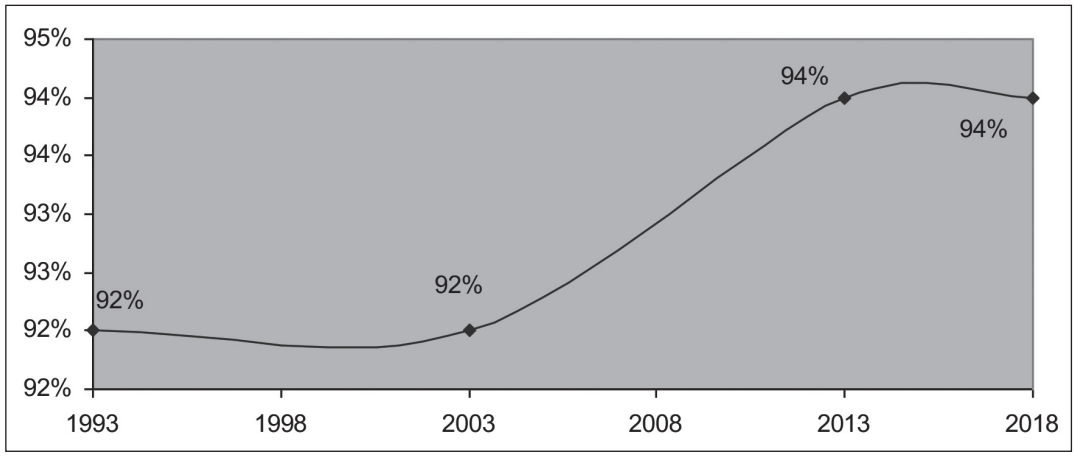

Fig. 5. Distribution of nurses by gender in Ukraine, 1993/2018, %. Source: Data from State Statistics Service of Ukraine.

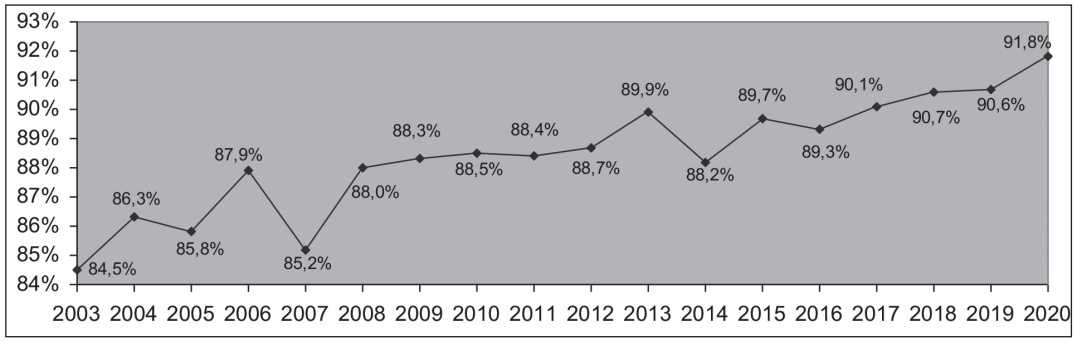

Fig. 6. Correlation of the average salary of the women and men in healthcare sphere, 2003/2020, %. Source: Data from State Statistics Service of Ukraine.

women's attitudes towards employment in medicine. Men make up the majority of physicians and women make up the majority of nurses. Men have higher potential career opportunities to get a job in the private healthcare sector at the level of qualified medical professionals, and women have more risks to get low-paid medical jobs in the private sector, which are usually fixed-term.

The global pay gap among healthcare employees can be explained by several reasons:

1) different duration of work for men and women (women are less likely than men being full-time employed: among physicians, women work 4.2 hours per week less than men; among nurses – 3.5 hours per week less than men in same positions; women-dentists – 3.7 hours per week less than men [16]). This is primarily connected with women's family duties and housework in addition to their professional responsibilities. 82% of women-physicians name work and family life balance as a major challenge in the branch of medicine. 71% of women who are working in healthcare sector indicate that their careers limit the duration of time which they can spend with their families. As a result, women from healthcare sector have great difficulty with work-life balance, therefore women more likely than men move to part-time jobs, refuse to take part in certification trainings or quit their jobs to take care about their families;

2) occupational differentiation between men and women as well as a set of other factors related to underestimation of women holding management positions (twice as many management positions in healthcare are held by male physicians than women), less chances of career promotion (male physicians are more likely have higher level of qualification than women). 70% of men who are employees in healthcare sector believe that their gender opportunities are the same as for women. At the same time, only 49% of women feel the same. Women are much more likely to consider their career opportunities worse than men's (49% of women versus 13% of men).

3) gender discrimination, especially the cases of sexual harassment of women in the healthcare sector. 12% of women reported that they had never encountered any form of sexual harassment while they are working in the medical branch versus 38% of men. Only 7% of women say that the employees in healthcare sector do not have problems with sexual harassment. Another factor that confirms gender discrimination in the medical branch is the different perceptions of women and men in healthcare. 69% of men believe that women and men are treated equally at healthcare facilities, but only 34% of women agree with this fact. 63% of women believe that men are respected more than women. 87% of women health professionals believe that patients treat them differently than men [18].

The Ukrainian healthcare sector might be called "women's", which is explained by the next reasons. The length of life of women is seven years longer than the life of men in Ukraine. Such situation has a serious impact on employment in healthcare sector, where the common practice to

continue working after retirement age exists in case with female healthcare employees (25% of physicians and more than 10% of nurses are retired employees) [19]. However, the most obvious indicator is not the age structure of women's employment in healthcare, but the amounts of their wages.

In Ukraine wages of women in healthcare are only 11% lower than of men. However, this dynamic is a formal outline of progress in ensuring gender equality in Ukrainian healthcare sector. In fact, given the predominant representation of women physicians and nurses among all employees, a minority of women generally receive higher wages than men. Such discrepancy exists primarily because of the very high representation of women at lower-paid positions, e.g. nurses. Maintaining the quantative advantage of women and small correlation between women's and men's wages in the medical branch does not guarantee them decent employment opportunities and wages.

For such reasons, the progressive indicators of gender equality in Ukraine in terms of the number of positions occupied by healthcare employees and the level of their remuneration are illusory. Conversely, they discourage women to work in healthcare sector reducing their economic and social status. As we may see, the global trend of low remuneration in healthcare which reduces the socio-economic status of healthcare employees and produce gender inequality and sets the risks associated with the effective provision of health care and the shortage of qualified professionals in the branch of medicine has being implemented in Ukraine.

Lowering the prestige of work of women in healthcare and segregation in terms of profession means that the gender gap in remuneration and wages in this sector is significant. Given the large number of women employed in healthcare sector, it also has a strong impact on the gender pay gap in the economy generally. Reduction of male employment in healthcare sector is associated with the attitudes in society about "women's" skills and the stereotype that women can sell their workforce for less reward. In Europe the most low-paid positions are occupied by women and scientific researches show that only the fact of employment in a female-dominated profession can reduce wages by 9% [20]. The wages which are paid in healthcare are the evidences of the overall low cost and low prestige of work in healthcare sector. Moreover, they create the preconditions for significant gender inequality in this sphere.

The availability of medical services and quality of future workforce in healthcare sector significantly depend on increased wages. Instead of this, the current trends of low wages in healthcare produce a significant shortage of qualified medical personnel. In 2019 the shortage of physicians and nurses at Ukrainian public healthcare institutions was 88% and 93% respectively [19]. It is estimated that the global shortage of healthcare employees by 2030 will be up to 18 million of physicians and nurses [1]. At the same time, more favourable working conditions and a decent level of remuneration will contribute to the prestige and attractiveness of work in the medical sphere.

CONCLUSIONS

1. According to global and Ukrainian indicators, the healthcare sector mainly consists of women in the structure of employees. Women are mostly employed on nursing positions. The majority of physicians are men. There is another trend in Ukraine when women predominate among physicians. The wide representation of women in healthcare does not prevent the presence of gender inequality among healthcare employees, in particular, in terms of employment and remuneration. The main reasons causing gender inequality in healthcare are: different duration of work for men and women; family responsibilities as an addition to women professional activities; occupational differentiation between men and women due to underestimation of women on management positions; less opportunities for career promotion and certificate trainings; gender discrimination (in particular, sexual harassment, different perceptions of professionals).
2. In order to effectively reduce gender inequalities in healthcare, the following legal means should be established and implemented both in international and national law: 1) remove barriers to full-time employment of women, support women's career growth and gender parity on management positions in healthcare; 2) establish a minimum wage for healthcare employees which will be equal to the average wage in the country and will increase depending on the qualifications and productivity of healthcare employees; 3) establish the minimum wage of healthcare employees in rural areas and healthcare facilities that are experiencing a shortage of staff, twice as much as the average wage in the region; 4) establish a specific entity (e.g. commission) to consider cases of gender discrimination against women in healthcare; 5) introduce an audit of gender equality in healthcare; 6) establish bonuses for women-healthcare employees who have children or other dependants; 7) develop recommendations to national governments to increase the number of legal norms that will guarantee equal rights and opportunities for women and men in healthcare sector, indicating the specific terms of their fixing in collective agreements, as well as develop and make proposals to increase the number of relevant norms in the Sectoral Agreement in healthcare sector.

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REVIEW ARTICLE

CONSENT TO TREATMENT AND OTHER MEDICAL INTERVENTIONS: LEGISLATIVE AND SCIENTIFIC APPROACHES

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ABSTRACT

The aim: To research approaches to maintaining balance between social and personal interests in the sphere of human right to consent to medical interventions.

Materials and methods: The research is conducted with help of both general and special juridical methods of investigation. The empirical basis: an international legal acts; domestic laws of EU countries, the USA and other states; courts' decisions; statistics; juridical and medical articles.

Conclusions: Consent to medical interventions is an absolute right of mentally capable adults and restriction of this right is never too necessary for social interest except for limiting measures due to pandemic or psychiatric disorders threaten. Next of kin or guardian has the right to consent for minors or mentally disabled in their best interests.

KEY WORDS: consent to treatment; patient's rights; restriction of patient's rights

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INTRODUCTION

Right to health and life are amongst the main natural rights of the human being. It is of great importance to come to convergence in the legislation of all democratic states in approaches for respect to human right to life and health. In today's circumstances of globalization and people's travelling, everyone has the right to be aware of his/her basic rights and relevant risks.

According to the main international acts in medical law sphere (Declaration of Lisbon on the rights of the patient [1]; European Charter of Patient's Rights [2]; International Code of Medical Ethics [3], Convention on Human Rights and Biomedicine [4]), every patient has right to information about his/her health; right to informed consent to medical treatment and other medical interventions; right to free choice of the possible methods and measures of treatment. Despite these principles, exists question of maintaining balance between social interests and personal rights. For example, coerced children vaccination, organ donation under presumption of consent, forced sterilization, psychiatric clinic placement by force etc.

THE AIM

The main goal is to research the main legislative and scientific approaches to the consent to treatment and other medical interventions all over the world and the main conflicts of social and personal interests in medical sphere that have different points on necessity of consent to treatment and medical invasions. Either, we aim to find out the main legal gaps and infringements of human right to consent.

MATERIALS AND METHODS

The legal basis of the study: The International Covenant on Civil and Political Rights (1966); European Charter of Patient's Rights (2002); Declaration of Lisbon on the rights of the patient (1993); Declaration of Oslo Statement on Therapeutic Abortion (1970); 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 (Ovideo Convention, 1997); International Code of Medical Ethics (1949) and some domestic laws of Spain, Poland, United Kingdom (UK), Ukraine and other countries.

The following methods of scientific research are used in this research: comparative legal method; formal-logical (dogmatic) method; statistical method; methods of analysis and synthesis.

REVIEW AND DISCUSSION

Health right is highly connected with right to true, entire and correct information about state of patient's health, the diagnosis, methods of treatment, medical prognosis etc. Based on this information, patient may give his consent to treatment, which often calls "informed consent to treatment". Some countries allow physicians to hide such information from both adult and minor patients when they have a reasonable position that it may aggravate their state and worsen the process of treatment and its results (Art. 285 of Civil Code of Ukraine [5]). Taking into account knowledges about placebo effect, getting aware of hard diagnosis usually leads to depression, thus aggravating of

health. Nevertheless, hiding information about patient's health and methods of treatment leads to breaking one of the main rights of the patient in the medical law – right to consent or disconsent to medical treatment.

A mentally competent adult patient has an absolute right to reject medical treatment or other medical intervention for any reason, doesn't matter rational or irrational, even in case when the decision may lead to his/her death. Sometimes, compulsory medical measures may be avoided of medical interventions and be connected with freedom deprivation. It is very relevant due to Covid-19. In difficult epidemic and pandemic cases states usually implement measures to arrest the spread, however, such measures as quarantine or isolation often conflict with civil liberties [6]. Conrad Nyamutata (2020) admits that "even traditional democratic states mimic authoritarian regimes" [7]. Democratic countries have liabilities under international treaties to use principle of proportionality in applying any kind of liberty-limiting interventions. Such measures shouldn't include forced medical invasions, only some restrictions in movements. Full deprivation of liberty into specialized medical institutions may be applied only under the court's decision (tuberculosis dispensary or psychiatric clinic placement by force).

The International Covenant on Civil and Political Rights (1966) [8], in Art. 9 states that restriction of human freedom in any form is possible only by court's decision. Nevertheless, pre-trial freedom deprivation is being practicing in many countries. However, European Court of Human Rights admits that when person is detained as a result of aggressive behaviour it may be acceptable to apply compulsory hospitalization, but it is necessary to obtain medical conclusion on psychiatric disorder after a proper examination immediately after the deprivation [9]. Not all psychiatric disorders are the basis to apply liberty deprivation but only those, which are combined with a threat to society or patient itself [10].

Patients of psychiatric clinics are deprived of right to sue by themselves after some period of their compulsory hospitalization and also have no right to choose another doctor, clinic or an alternative point of view about the treatment measures. That's because they are presumed to be mentally disordered, but it is also the reason why they often suffer of ill treatment and application of too much of sedative drugs, which poses obstacle to their recovery.

There are special norms for consent to treatment concerning children under the domestic law. The most commonly used age with absolute capability of making decisions of health care is 18 years as in most European Union (EU) countries and some Canadian provinces. Some states use an alternative demarcations, such as 16 years (eg. Ukraine, Scotland) or 19 years (eg. a few Canadian provinces: British Columbia, Labrador and others). Various European countries have adopted a system in which health-care specialists have competence to evaluate maturity of the minor on a case-by-case basis [11], without specification of the age. In other states additional conditions about consent to some definite medical measures (eg. in Quebec (Canada) consent can be given by patient of 14 years but parents should be informed about definite kinds of medical procedures). An opposite example, countries, which demand dual consent from both parent and the minor (Poland) [12]. In most countries, it is enough for doctors to obtain consent for definite medical treatment from one of the parents, but in case of disagreement physician may ask court for consent if such measures are not urgent. In Spain, the opinion of the minor should also be taken into account at least from the age of 12. It is preferably when domestic law anticipates requirement to inform parents about all serious risks and interventions about minor of any age and to take into account their opinion.

In Ukraine plenty of medical invasions may be done for minors even from 14 years old, for example, an abortion. Nevertheless, medicals have no obligation to inform parents about such medical invasion. That's a negative approach, because parents still bear responsibility for health and welfare of their children. On the other hand, in some countries parents or guardians have the right to give consent for sterilization of minors and incapable adults despite of their volition. In our opinion, such decisions should be adjudicated only by courts in cases of serious psychiatric deceases; such procedure shouldn't be applicable for minors at all. The same position is supported by other scientists (V. Iemelianenko, A. Gornostay, A. Ivantsova, 2019) [13].

United Nations Committee on Human Rights recognizes forced sterilization as a kind of torture and ill-treatment, also any other medical treatment or intervention without person's consent is a violation of human rights. However, the United States, Russia and China excluded themselves from the jurisdiction of the International Criminal Court. For example, in the USA court's decisions with compulsory sterilization still happen. Failure in paying money for raising children because of lack of profit became the ground for court's orders on forced sterilization in Virginia and Ohio in 2014. [14*]. EU accepted that forced sterilization can't be a kind of punishment, but in our opinion forced sterilization may in some cases be a kind of prevention to giving birth to badly sick infants with hereditary deceases or disabilities (persons with hereditary hard psychiatric sicknesses and chronic alcohol and drug addicted persons) after obtaining both guardians' and court's permission.*

Forced abortion isn't allowed even in cases when there is a medical reason, because adult capable woman has the right to decide and the possibility to take care of afflicted child, on the contrary incapable adults wouldn't be able to do so. Surely, only intellectual disability may be the ground for forced abortion. Still it is better to apply one medical invasion – sterilization then every time to operate abortions to intellectually disabled women. A horrible practice was recently leading and still happens in China, for example Feng Jianmei was forcibly made an abort to 7-month old fetus because of failure of paying fine for breaching one-child policy (June 2012) [15].

Another question appears from what period fetus has the right to life. Legislation doesn't give strict answer to this ques-

tion. However, there is a maximum term in which woman has the right to apply for an abortion without any medical reason. The most spread time-limit in EU is 12 months of pregnancy (Austria, Belgium, Bulgaria, Czech Republic, France, Greece, Hungary, Italy, Latvia, Lithuania, Luxemburg, Poland, Portugal, Slovakia). There are also other limits like in Sweden – 18 months, in Germany – 22 months, in Netherlands and UK – 24 months. Currently, UK is in the process of adoption the limits for abortions in line with the majority of EU countries. It's worth to say that even in the term of 12 weeks of pregnancy fetus is a formed human creature with heart beating and electrical brainwaves. Some countries recognize right to life of fetus, for example, in Ukraine artificial abortion may be performed under medical grounds only till 24 weeks of pregnancy, the third trimester is prohibited for abortion even under threaten to the woman's life. This is quite reasonable, because an abortion at such a late term is similar with childbirth and the vitality of such babies is quite high, so it may be premature childbirth induced artificially, thus it is a criminal offence to mortify a newborn.

Question about abortions and "fetal rights" should be regulated in the legislation. Joanna N. Erdman (2017) admitted: "rather than eliminate the moral and ethical questions of later abortion, the law reassigns them to physicians in the guise of professional judgment" [16]. Physicians set their own conditions on the legislative norms, which merely allow abortion until the gestation of 24 weeks, but do not require its availability. Late abortion is available only for women with hard fetal or women's diagnosis, but inappropriate age and financial constraint may also be considered.

Under the European Convention on Human Rights (Art. 8), the European Court recognizes that regulation of abortion and decision to become a parent should not engage a woman's right for private and family life [17]. Under the Declaration of Oslo Statement on Therapeutic Abortion (1970) decision on abortion is to be made by women themselves without coerce and permission of husband or father of the fetus, because pregnancy and childbirth are connected with woman's right to patient autonomy and right to privacy [18].

One of the most ambiguous question connected with parents' consent to medical interventions and social interest is the problem of coerced vaccination. In certain countries vaccination is a coercive measure of infectious diseases' prevention (Australia, Belgium, Italy, Serbia, Slovenia, the USA, France, Ukraine, Russia). At the same time, in all EU countries and in Canada vaccination is only recommended, but not coerced [19]. Legislative norms of those countries which enshrined coerced vaccination vary for many cases: 1) amount of compulsory vaccines (Russia and Ukraine have the biggest amount of mandatory vaccines – more then 10); 2) fines for evasion of vaccination; 3) range of reasons of exemption of the vaccination. For example, in some states of the USA there is an exceptions which allow to refuse vaccination due to medical, religious or ideological reasons [20], but mainly countries with the conception of coerced vaccination allow only medical reasons for vaccination rejection.

In our opinion, there is a difference between coerced and forced vaccination, disconsent to coerced one provides some negative consequences to parents like fines or/and impossibility for child to attend preschool or school institutions. The other situation with forced vaccination which performs without parent's consent and even without make them informed about such medical intervention which was usual in the USSR. Herd immunity is of great importance, nevertheless, immunized people have no threat from those who are not immunized, that's the essence of vaccination. So, should be vaccination imposed for safe of those part of society who refuse it? The balance is between the artificial threat to the children's life and their health (vaccine's aftereffect of death and different prolonged health issues) and potential possibility to obtain some infectious disease and transmit it to others. We shouldn't forget about possibility of pharmaceutical lobby and insufficient researches in this sphere which may influence on enacting a coercive vaccination policy. All states anticipate a compensation for adverse effects from the vaccination, but the trouble is to prove connection between the vaccination and death or any health afflictions. Nevertheless, even low percentage of proved deaths as a result of vaccination doesn't give an ethical right to forced vaccination. There are also plenty other adverse prolonged effects like paresis after polio vaccines. Age and sex have also to be considered, eg. diphtheria-tetanus pertussis vaccines are associated with higher mortality of females [21].

The other question connected with conflict of social interests and right to consent is an organ removal for transplantation. The first trouble is how to regulate accurate diagnosis of human death. For example, in accordance with Art. 2 and 15 of the Venezuelan Law "On transplantation of organs and anatomical materials of the person" death should be established on the basis of traditional criteria of clinical death (cardiac and respiratory arrest, absence of reaction to external stimuli) or complete cessation of the electrical activity of the brain for 30 minutes (people with vegetative state whose vitality are maintained artificially) [22]. Under the Non-heart beating organ donation protocols in the USA (so-called controlled NHBD protocols) when the ventilator is stopped and heartbeat and breathing stops transplant team has the right to remove the organs for just 2 to 5 minutes after the person was declared dead. That's despite the fact that Dr. Michael DeVita, one of the inventors of NHBD protocol, has admitted the possibility of brain recovery for at least 15 minutes [23].

According to Mental Capacity Act of UK, 2003 [24] not only consent of next of kin but either court's decision is needed in case of withdrawal of nutrition and hydration from a person who's in the permanent vegetative state or minimally conscious state. Ronald E. Cranford (2002) persists that no one can say for sure at what point the transient state becomes permanent one. But minimally conscious state shouldn't be the ground for withdrawal of nutrition and ventilator for at least statistically defined period of time when vegetative state becomes permanent: 3 months for patients with anoxicischemic injuries of the brain and 12

months for patients with traumatic injuries. [25]. But this scientifically defined periods of time are not enshrined in the legislation. To minimize a possibility of acting not in best interests of the patient Ovideo Convention states that there is to be no financial gain from the organ donation for relatives/guardians of the donors.

There are also legislative propositions to allow to take off organs before the statement of the death in case of withdrawal of the ventilator in so-called "hopeless" patients' cases when they still have a heart-beating and breathing after ventilator withdrawal, because it is presumed that they will die in any case, but after some time of dying their organs will be unsuitable for donation [26]. Juridical question of obtaining consent to organ transplantation from next of kin may be solved before the declaration of death or after it. Legislation doesn't anticipate compulsory norms to obtain consent to other actions to support organs in optimal state like catheterization and heart-lung bypass etc. Logically, that such pre-mortal interventions are not ethical, since they have no benefit to the patient and may cause suffer due to insufficient analgesia. Nevertheless, there are propositions to use organ donation euthanasia [26]. It is also presumed that in such case the process of death would be less connected with suffering because of applying of full anesthetic doses.

Euthanasia is prohibited in many countries in any version. Those countries who allow euthanasia (Switzerland, Netherlands, Belgium, Luxemburg, Canada, Australia, several states of the USA) have very different approaches to its regulation. Switzerland allows euthanasia for both residents and non-residents. There are also many strict conditions which should be fulfilled for the euthanasia to be applied, among them are the following: 1) incurable sickness or/and unbearable suffering; 2) age of the patient (Netherland allows euthanasia from 12 years old with parental consent); 3) period of suffering or predicted period of life (6 months in Australia); 4) a few alternative doctors' points of view about termination of the sickness. Some countries allow both euthanasia and assisted suicide without medics (Belgium). In any case to evade human's right abuse it is worth to establish an obligatory participation of an independent side and notary or equally subsidiary documented consent of the patient and parents if needed.

Every person has the right to health not only for itself but either for his/her relatives health especially children, this right is connected with right to family autonomy. The persons' right to health of their relatives is reinforced in the legal norms of different countries, for example "weak" model for expressed consent for organ removal anticipates obligatory permission of such procedure by relatives of the deceased even if there is a notarized volition of the deceased on the donation of organs (United Kingdom, Japan and Lebanon) [27]. Surely, that almost all countries which have legalized system of expressed consent for organ removal anticipated "strong" version of consent, that means none of the relatives of the deceased person may change his/her volition to remove organs (Argentina, Australia, Denmark, Norway, the Philippines, Romania, Slovenia, Venezuela) [28].

But, what the legislation states about making decisions of application of an alternative therapeutic methods and measures when an adult person is out of consciousness? Legislative acts of most countries provide that adult people give consent to treatment by themselves if they are mentally capable. In case of some mental health conditions (schizophrenia, bipolar disorder, dementia, intoxication caused by alcohol misuse etc.) members of patient's family can make decisions concerning treatment even if mental health is diminished temporarily. When person is out of consciousness, such decisions can be made by members of patient's family or by physician when such decisions are urgent for life saving. The 'weak' place of relatives' right to family autonomy in most countries is an absence of legislative norms on obligation to inform relatives by hospital servicers about patient's health.

CONCLUSIONS

Human life, health and freedom are the highest democratic values. And it is of great importance to adopt legislative norms with the highest standards of protection of these rights. In our opinion, this research shows that restriction of patient's rights in meaning of forced medical interventions are never too necessary for social interest, except for some cases related to mentally disordered persons and proportional applying of liberty-limiting interventions due to pandemic threaten. Consent or disconsent to treatment and other medical interventions should be adhered for mentally competent adults under any circumstances. In case of controversial issues about interests of minors and mentally disordered adults when there is no mutual vision about their best interests between a physician and a guardian, the court has to solve the dispute. Next of kin has the right to consent instead of his relatives unless adult ones previously made a notarized or other authorized volition about definite health-care interventions.

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REVIEW ARTICLE

THE IMPACT OF A SALARY LEVEL AND THE LEGAL MECHANISM FOR ITS REGULATION ON THE WORK EFFICIENCY OF HEALTH CARE WORKERS

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ABSTRACT

The aim: To determine the impact of the salary level and the legal mechanism for its regulation on the work efficiency of health care workers.

Materials and methods: The research materials cover the reports of international organizations, global and national statistical data and collective agreements. The research results and conclusions are based on the combined use of theoretical and empirical methods.

Conclusions: The legal mechanism for regulating the remuneration of health care workers should be reformed on the basis of the concept of their work efficiency.

KEY WORDS: health care workers, salaries, work efficiency, legal mechanisms, labor law, medical law

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INTRODUCTION

The health care sector is an extremely important social sphere, whose level of development can be used to draw the conclusions about the level of the development of the whole country and to create effective mechanisms (including legal ones) for satisfying the needs of the people in decent medical services. We believe that health care professionals are at the heart of the entire health care sector, whose task is to provide qualified medical care and support patients in a state of illness, which includes, in particular, psychological assistance and regular human support.

Health care workers, while providing qualified medical care as medical professionals and, at the same time, supporting patients in their health assistance as socioeconomic professionals, experience several risks associated with the continuing influence of negative factors in the professional environment. Systematic stress has a negative impact on the health of medical professionals themselves. This is confirmed, for example, by the significant role of health care workers during the COVID-19 pandemic, when they were in the front line of fire to combat the dangerous virus and got infected themselves. The vulnerability of health care workers is linked to the functioning of appropriate legal and institutional mechanisms that minimize and compensate for the impact of these risks and provide appropriate incentives for them to remain in health care sector and provide effective services.

One such mechanism in the field of health care is to use the remuneration systems that can attract and retain the best professionals in the field, encourage them to perform their duties effectively, which combines the quality and intensity of health care workers with the understanding of the need for continuous self-education. Some issues relating to medical remuneration have been considered by A. Eltorai, C. Fuentes, W. Durand [1], S. Fayer, A. Watson [2], S. Hayes, J. Noseworthy, G. Farrugia [3], M. Menacker [4], J. Bisco, C. Cole, K. Bradley [5], D. Kumar, S. Sohal [6].

These researchers focused their attention on specific indicators in the field of healthcare, without taking into account the established legal remuneration mechanisms in the medical field. On the contrary, it is important to draw our attention to the interdependence of the salaries of health care workers and the legal mechanism for regulating remunerations in health care sector. First, we are talking about creating a legal mechanism that would ensure a decent level of remuneration for health care workers. This legal mechanism should, in our opinion, be calculated on the basis of the understanding of the importance of the social function of health care workers and achieving the highest possible level of efficiency in their work.

THE AIM

The purpose of our study is to determine the impact of the salary level and the legal mechanism for its regulation on the efficiency of health care workers.

MATERIALS AND METHODS

The study is based on the reports of the International Organization for Migration, the International Trade Union

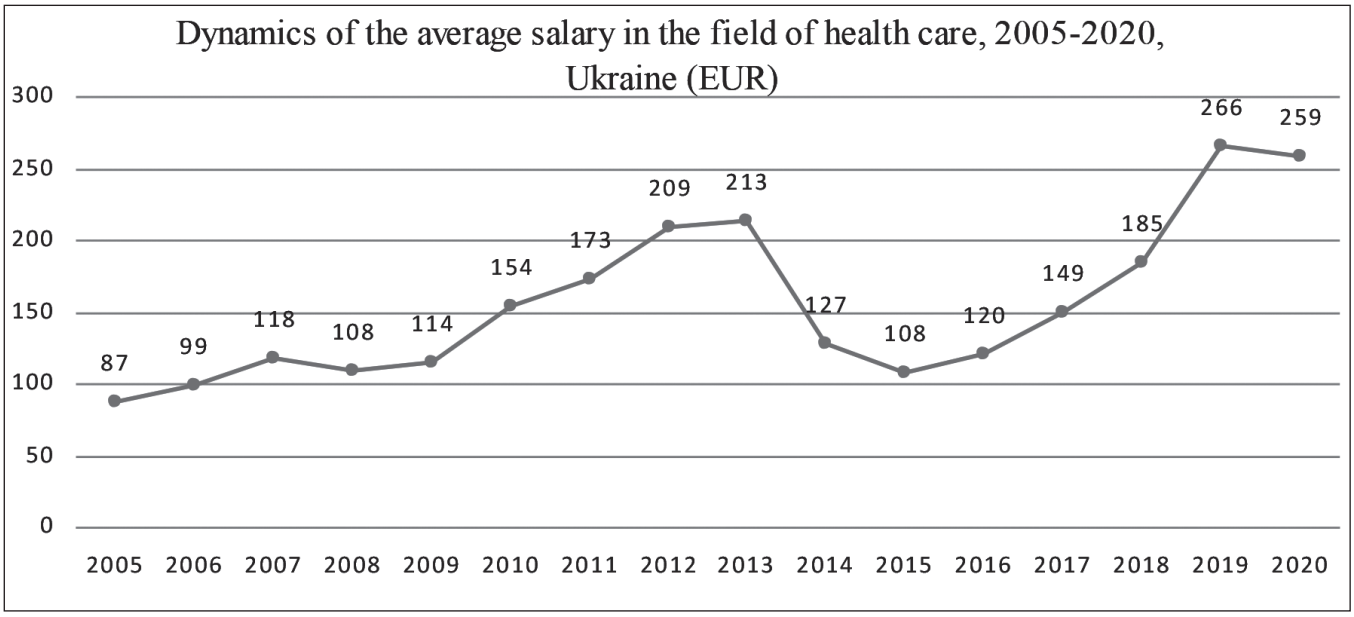

Fig. 1. The ratio of the average salary in the state and the average salary in the field of health care and social work activities, 2005-2020, Ukraine (EUR). Source: Data from State service of the statistics of Ukraine

Table 1. Number of health care workers in Ukraine and regions. Source: Data from State service of the statistics of Ukraine

	Number of Health care workers (Ukraine, regions)							
	Number of doctors of all specialties				Number of nursing staff			
	total, thousand		per 10 000 persons		total, thousand		per 10 000 persons	
	2005	2019	2005	2019	2005	2019	2005	2019
Ukraine	224	187,9	47,9	45,04	496	331,8	106,2	79,51
Kharkiv Region	15,8	13,8	56,1	52,53	28,7	20,8	102,0	79,0
Vinnytsia Region	8,3	7,7	48,9	50,2	18,9	13,0	111,7	84,85
Zakarpattia	5,2	4,4	42,1	35,4	12,9	8,8	104,1	70,55

Confederation, statistics collected by Eurostat, the Ministry of Health of Ukraine, the State Service of Statistics of Ukraine and its regional branches, the State Statistical Service of the Republic of Poland. The study material included regulations, jurisprudence of national courts of Ukraine, collective agreements of Kharkiv hospitals.

The statistical indicators used in the study reflect the data between 2005 and 2020. The relationship between the level of salaries and the legal mechanism of their regulation to the effectiveness of health care workers was examined on the basis of indicators of salary dynamics and the amount of the service and standardization of work established by the regulatory acts.

The research results and conclusions are based on the combined application of theoretical and empirical methods. Among the theoretical methods, the comparative, normative-logical and prognostic methods have been used. The empirical methods have been used in the study for processing the statistics, comparing and summarizing.

REVIEW AND DISCUSSION

The study of the level of health care workers remuneration covers the period from 2005 to 2020. We found out that the dynamics of the salaries of health care workers for the selected period has positive growth indicators (except for the period from 2014 to 2018). In relation to the average salary in the state, the salaries of health care workers traditionally remain lower, despite the medical reform.

According to the State Statistics Service of Ukraine, since the second quarter of 2020, the average monthly salary of full-time health care workers has been 7,720 UAH (259 €), which is 70.7% of the average salary in the country – 10,928 UAH (366 €). In terms of the average monthly salary, this area has the 23rd rank out of 26 [7].

As we can see, the efficiency of health care workers depends not only on the amount of the salary, but also on the work load of such an employee and on the interdependence and the ratio of the salary to the work load. That's why we are turning to the study of the dynamics of the work load, which is best demonstrated by the dynamics of changes in the number of health care workers.

According to the reference book "Medical Personnel and the Network of Health care Institutions of the Ministry of Health of Ukraine for 2018-2019", prepared by the workers of the State Institution "Center for Medical Statistics of the Ministry of Health of Ukraine" in 2019, there are 18,797,275 full-time medical positions in Ukraine 16,328,175 – occupied medical positions, and the number of individual physicians is 154,265

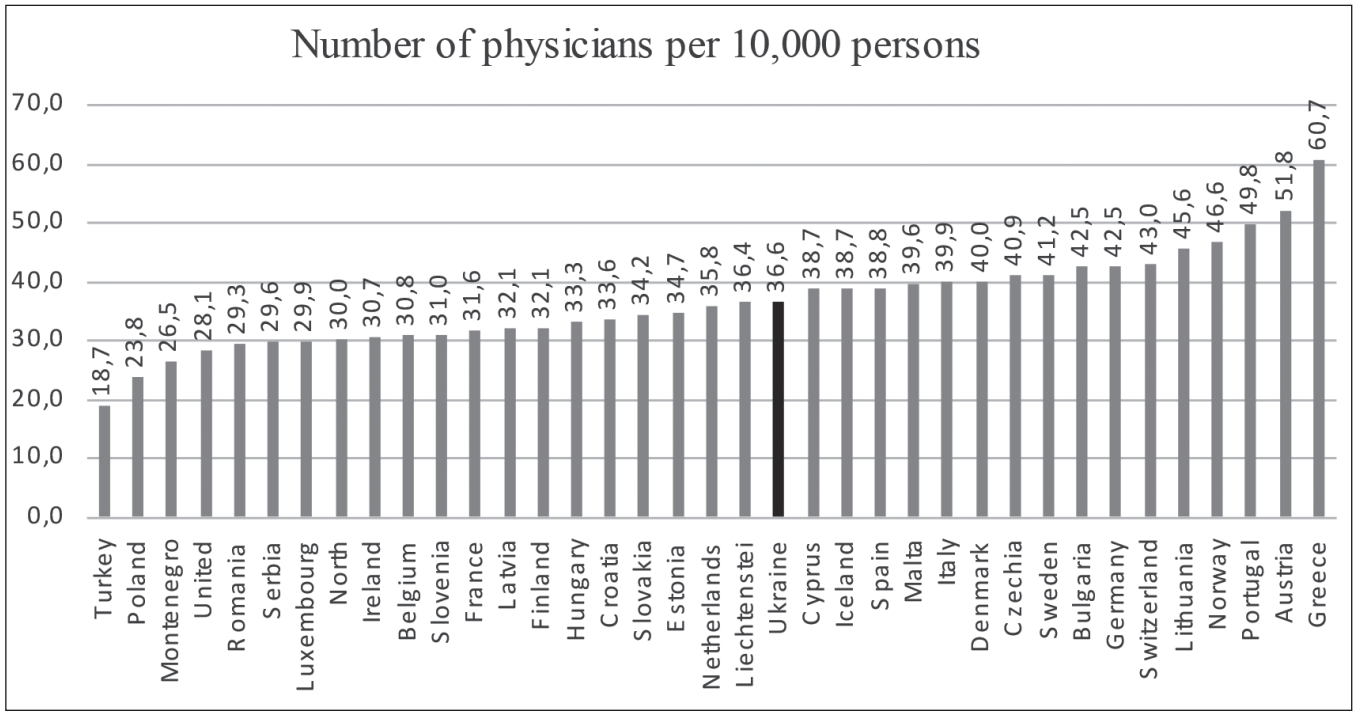

Fig. 2. Number of physicians per 10,000 persons. Source: Data from Eurostat

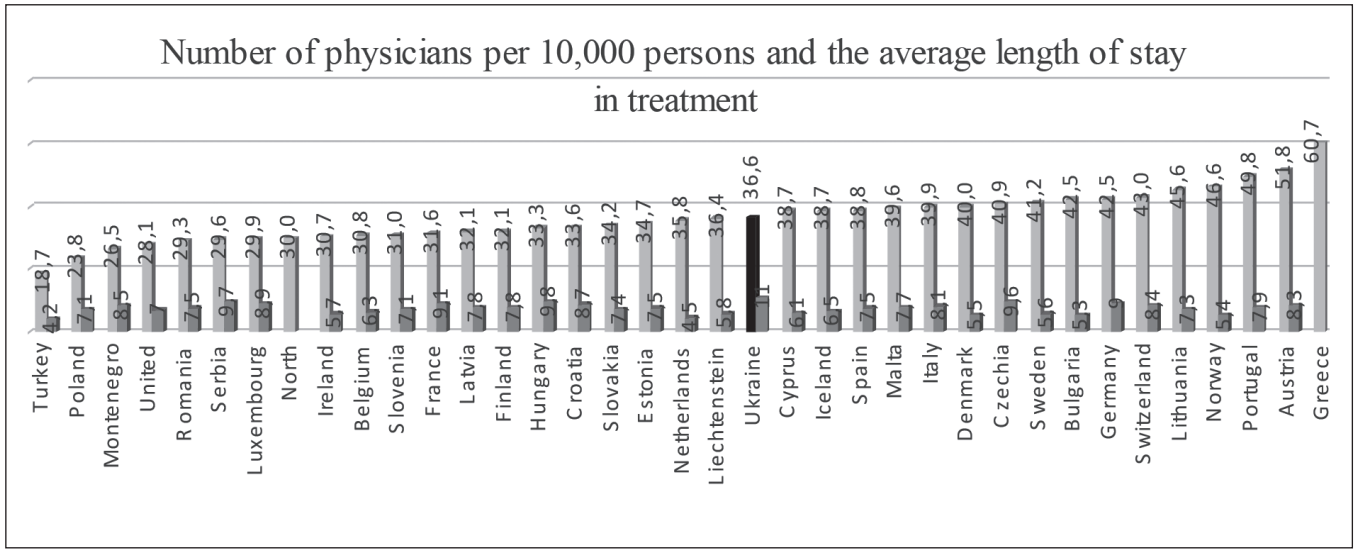

Fig. 3. Number of physicians per 10,000 persons and the average length of stay in treatment. Source: Data from Eurostat.

[8]. For the correct analysis, we should point out that the above indicators (Table 1) show the number of full-time medical positions, but not the number of doctors.

Our figures show that during the selected period there was a reduction in the number of physicians and the nursing staff in both absolute and relative numbers. The relative number of physicians (per 10,000 persons) in Ukraine decreased by 5.97% and the number of the nursing staff – by 25.13%. There was a 25.13% increase in the workload of the nursing staff, which may lead to an increase in the workload of doctors, who, with a shortage of the necessary number of nurses, will have to perform their duties as well. The dynamics of changes in the number of physicians is uneven through the regions: a decrease in Kharkiv Region – by 6.36%, in Zakarpattia – by 15.91%, but in Vinnytsia there is an increase of 2.66%. The dynamics of changes in the number of average medical staff is less polarized. The attention should also be paid to the difference in the dynamics of reduction in the relative number of physicians (5.97%) and the nursing staff (25.13%). At the same time, according to the Eurostat report, the number of physicians per 10,000 inhabitants in the European Union varies between 18.6 (in Turkey) and 60.6 (in Greece), with an average of 36.4. Between 2012 and 2017, the number of physicians increased in all EU countries (9).

At the same time, we can observe the following situation in Ukraine: the amount of work, calculated for 187,972 full-time health care workers, is actually performed by 154,265 health care workers. The real availability of physicians in Ukraine is

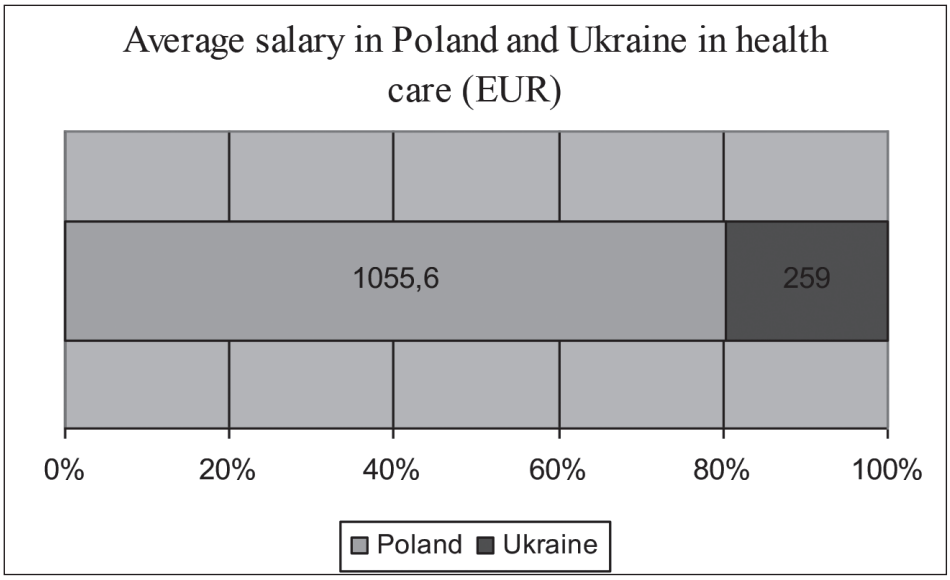

Fig. 4. Average salary in Poland and Ukraine in health care (EUR). Source: Data from Rocznik Statystyczny Pracy and State service of the statistics of Ukraine

36.96 per 10,000 persons and there are 270 patients per a physician (222 patients per a doctor are planned for the number of full-time positions). Thus, the physician's workload is 21.6% more than planned. According to the regional indicators (Table 1), the workload of physicians in Kharkiv Region is 48.3% higher than in Zakarpattia (in 2005 that difference was 33.2%). At the same time, the average monthly salary in the field of health care in Kharkiv Region as of June 2020 is only 12.7% higher [10].

We believe that the imperfect regulation of the remuneration of health care workers poses a significant risk of their migration to the European Union, particularly to Poland.

If to compare the dynamics of migration from Ukraine we can see that in the peak years of the reduction in the number of healthcare workers, there were the highest rates of migration. According to the report of the International Organization for Migration, from 2008 to 2018 the number of first issued residence permits for Ukrainian citizens in the EU countries increased almost 5 times [11]. During this period Poland became the main destination country for the labor migrants from Ukraine (their number increased five times) [11]. One of the industries that attracted Ukrainian citizens was the health care sector. In 2018, the average salary in the health care sector in Poland was 1,015.2 EUR, which is 96.2% of the average salary in the country – 1,055.6 EUR. In terms of the average monthly salary, this sector ranks 10 out of 18 [12].

The number of physicians per 10, 000 inhabitants is 23.7 in Poland and 36.96 in Ukraine respectively. The doctor's workload in Poland is 55% higher than in Ukraine, and the salary is 425% higher. The number of physicians in Poland is increasing [9], the workload of physicians is decreasing, while in Ukraine the opposite trend is observed. At the same time, in 2019, the deficit of medical staff in established positions of doctors was 12% and the deficit of nurses was 7% [13].

In order to understand the prerequisites of the considered negative trends in the remuneration of health care workers, we will turn to the analysis of the current system of the remuneration of health care workers in Ukraine. It should be noted that the current system of payment for health care workers was formed in 2005. Since then, the payment for health care workers has been regulated by the Order of the Ministry of Labor and Social Policy of Ukraine, the Ministry of Health of Ukraine № 308/519, which approved the "The terms of the regulation of labor remuneration of health care facilities and institutions of social protection".

The remuneration system does not provide an automatic increase in the physician's salary in connection with the increase in the number of patients. Instead of that, it provides some additional payments for the expansion of the service area or an increase in the scope of work, which is up to 50 per cent of an employee's official salary. These extra payments are set for the workers if they are working with a smaller number of workers than the established standards require. The state does not establish the criteria for the dependency of the extra payments on the expansion of the scope of services.

In our opinion, in this aspect the system of calculating salaries of workers did not meet the requirements of the Law "On Remuneration of Labor" for years and was much smaller. This fact was recognized by the state only in 2016, when the current approach to calculating salaries was declared to be illegal. That is why it cannot be considered that such a surcharge really compensated for the increase in the workload [14; 15]. In the current tariff system of remuneration of health care workers, the salaries (tariff rates) from January 1, 2017 are calculated based on the salary (tariff rate) of the employee of the 1st tariff category, set at the subsistence level for able-bodied persons on January,1 of the calendar year. However, it cannot be considered to be fair, as the state itself recognizes that the subsistence level is not the subsistence level [16].

As a result of the medical reform in Ukraine, the system of remuneration of health care workers has not changed. Funds that can increase the salaries are transferred to hospitals. The legislator and the Ministry of Health of Ukraine have not established new criteria for calculating salaries in the framework of medical reform. In this situation, there are two parts of the

salaries of health care workers, which are already included in the reform: one is mandatory, regulated by "The terms of the regulation of labor remuneration of health care facilities and institutions of social protection", and the second – variable (bonus) – regulated by a collective agreement, the regulation on bonuses and the order of the chief physician.

The specific amount of the premium is set monthly by the order of the chief medical officer of the health care institution "taking into account the personal contribution of the employee to the overall result of the work". The regulation of the remuneration by the order of the chief medical officer leads to the situation where the amount of the bonus has been set at 12%, 15%, and 25% of the amount of the funding of the declarations made with the doctor on the same basis positions in various hospitals. Then the situation is as follows: the basic salary is 2.5 times less than the "bonus". For example, a family doctor of the highest category has 14 tariff classes and the tariff coefficient 2.42 is used to calculate the salary. The tariff rate for such a doctor is 5,086 UAH (156 EUR) and the monthly bonus is 12,734 UAH (391 EUR). So, we can state that the variable part of the salary, which is regulated by the acts of the social dialogue and the order of the chief medical officer, is the main one. However, the powers of the chief medical officer to determine the amount of the bonus are limited by the possibility of influencing the staff of the health care institution on the size of the latter by concluding a collective agreement. However, according to the Global Index of Workers' Rights, compiled by the International Confederation of Trade Unions, due to the almost complete absence of independent unions, Ukraine has a rating of 5 (worst - 5+) [17]. Therefore, it is questionable whether to use social dialogue to effectively regulate the remuneration of health care workers in Ukraine.

On this basis, as part of the medical reform, there is a situation of unjustified differentiation of salaries at the expense of bonuses. Health care workers who are out of the reform receive a fixed salary that is linked to the labor standards, and a bonus is awarded only as an additional remuneration (optional). Health care workers in the reform area also receive a fixed basic salary, but in addition they receive a bonus (obligatory), the amount of which depends on the will of the chief medical officer but not on the work efficiency.

In our opinion, in order to improve the situation with the salaries in the health care sector in Ukraine, it is necessary to reform the medical sector based on the efficiency of work and create appropriate legal support. After all, in today's environment, if health care workers simply receive higher salaries than a competitive market, it will involve containing costs in this sector while maintaining the current quality level [18]. Health care workers often report that low salaries are a barrier to efficiency, but there is little evidence that the higher salaries actually bring better results. Therefore, the benefit of the efficiency-based salary is that it aligns the bonuses and remuneration of health care workers with the specific goals of the district or the facility, where the health care workers employed. This motivates health workers to pursue their goals in order to receive additional compensation for achieving the goals.

We must emphasize that it is important to differentiate between the salaries based on the concept of efficiency and effectiveness, i.e. based on concluding contracts with a certain number of potential patients (in Ukraine – declarations) and cured patients. In the latter case, the heads of health care institutions usually have a very high degree of freedom in recruiting workers and paying compensation (bonuses) for their results achieved. There are numerous potential gaps in performance-based remuneration: the risk of unnecessary care; the risk of increasing medical care costs; and bonuses based on the improved productivity or quality of care, regardless of who is receiving the help and who really needs it.

We believe that the main impulse for efficiency-oriented remuneration is to increase the efficiency of health care workers (e.g., work efficiency, service quality) in order to improve the quality of medical care and, finally, the health status of citizens. For this purpose, it is necessary: 1) to transfer the right to hire health workers to non-governmental organizations on fixed-term contracts for a maximum of five years; 2) to give non-governmental organizations the right to monitor the salaries of health workers throughout the country and regions; 3) to establish a certain number of claims made to patients with territorially differentiated and resolute medical treatment; 4) to set the minimum salary of a health care employee at the level of the average salary in the country; 5) to combine individual (pay on the basis of the performance of the doctor in particular issue) and collective tools to stimulate effective work (premiums depending on the size of the services, labor intensity, etc.). Individual incentives are allowed by non-governmental organizations and collective incentives by health care providers.

This legal mechanism must be carefully designed. For example, their implementation in the practice of health care workers in Cambodia has shown that the incentives focused on labor productivity were too low to have a significant impact on health care workers' activities. In Romania, incentives to encourage doctors to work in rural areas did not work because they were too small and illegal. Poorly designed incentives can lead to socially undesirable results. In China, the bonuses aimed at improving doctors' efficiency have increased the provision of unnecessary services and medicines and in some cases reduced the productivity [19]. Therefore, when developing an approach based on the efficiency of health care professionals, it is necessary to examine carefully the potentially beneficial and harmful consequences.

CONCLUSIONS

Despite the ongoing medical reform, the salaries in the health care service in Ukraine remain among the lowest in the state economy. The current level of salaries does not allow an effective performance of medical assistance and does not create incentives for the recruitment, retention, development and quality performance of health care workers.

Formal increases in the salaries of health care workers are not the right strategy, as it involves an increase in the cost of health care without any guarantee of improvement. Pay rises are more effective in terms of productivity objectives.

The payment based on the achievement of efficiency objectives for health workers is linked to the development of a legal mechanism. This mechanism should include

the granting of lease rights under fixed-term contracts to non-governmental organizations which will monitor the health care salaries; the setting of a minimum salary for health care workers should not be less than the national averages salary taking into account regional variations; and a combination of individual and collective incentives for the effective work of health care workers.

All elements of the recast mechanism for regulating the remuneration of health workers should be thoroughly examined and tested in separate regions.

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REVIEW ARTICLE

CHALLENGES OF HEALTH CARE PROFESSIONALS' DISCIPLINARY AND CRIMINAL PROSECUTION

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ABSTRACT

The aim of the research is to study the peculiarities of the legislative consolidation of criminal and disciplinary liability for offenses of health care professionals in Ukraine and other states.

Materials and methods: Criminal legislation of Ukraine, international acts, decisions of the European Court of Human Rights (hereinafter - ECHR), data of the Integrated State Register of Judgments, as well as criminal legislation of Germany, the French Republic, the Kingdom of Denmark, the Republic of Belarus, Kazakhstan and many other countries. A set of general and special scientific methods of scientific knowledge was the methodological basis. The use of the comparative law method has become useful in the analysis of Ukrainian legislation and the legislation of other states.

Conclusions: the article examined the features of the legislative consolidation of criminal and disciplinary liability for offenses of health care professionals in Ukraine and other countries. A comparative legal analysis of the legal enshrinement of the corpus delicti in the form of non-performance or misconduct of professional duties by a health care or pharmaceutical worker was carried out on the example of Ukraine and many other countries; types of penalties for medical crimes, which are established for this type of offense, were identified; sanctions for committing a disciplinary misconduct by a health care professional were determined on the example of the legislation of different countries.

KEY WORDS: medical crimes, failure to perform duties, punishment, disciplinary offence, doctor, patient

"If the doctor can't help, do no harm."
Hippocrates

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INTRODUCTION

Relations in the field of medical care and responsibility for such actions were in the sphere of customs and morals. For the first time, the issue of prosecuting health care workers for improper performance of their professional duties was raised in the Hammurabi Laws. Thus, §218 defined the responsibility of a doctor (for professional activity) — cutting off his fingers for causing death or injury to a human eye. Regulations from Ancient Rome that provided for liability for the improper performance of their professional duties by medical staff have come down to us. Note that such liability was mostly limited to criminal one.

Currently there are different legal traditions in the world regarding the issue of prosecuting health care professionals for improper performance of their duties. Thus, some countries mostly use the practice of civil law settlement of the conflict between a doctor and a patient. These are, in particular, the countries of the Anglo-Saxon legal system – the United Kingdom, the United States, Canada, New Zealand, and many others. It should be noted that in these countries the means of criminal and legal settlement of the conflict are used in exceptional cases, and the means of civil-law nature remain predominant. Other countries use the means of criminal law as a basis for resolving conflicts of this kind and only in exceptional cases they use methods of the other branches of law. Such countries include the post-Soviet countries, as well as Japan, Saudi Arabia and others. The third group of countries combines civil and criminal law when regulating the issue of prosecuting health care professionals for improper performance of their professional duties. This group includes the countries of the Romano-Germanic legal system, in particular, Germany, the Italian Republic, the French Republic and others.

THE AIM

The aim to study the features of the legislative consolidation of criminal and disciplinary liability for offenses of health care workers on the example of Ukraine and other countries.

MATERIALS AND METHODS

Criminal legislation of Ukraine, international acts, decisions of the European Court of Human Rights (hereinafter - ECHR), data of the Integrated State Register of Judgments, as well as criminal legislation of Germany, the French Republic, the Kingdom of Denmark, the Republic of Belarus,

Kazakhstan and many other countries became a material for research. A set of general and special scientific methods was the methodological basis. The use of the comparative law method has become useful in the analysis of Ukrainian legislation and the legislation of other states.

REVIEW AND DISCUSSION

As defined by the Convention for the Protection of Human Rights and Fundamental Freedoms, "everyone's right to life is protected by law" (Article 2). The state must guarantee this right to everyone, including when it comes to protecting the right to life of patients. In interpreting this article the ECtHR states in its judgment in Arskaya v. Ukraine (2014) (application no. 45076/05): "… the principles embodied in Art. 2 of the Convention, are applied in the field of public health. The positive responsibilities of the State embodied in this article require States to enact appropriate legislation that would compel public and private health care facilities to take appropriate measures to protect the lives of their patients. These principles also require the establishment of an effective and independent judiciary so that the cause of death of patients due to the actions of health professionals in the public or private sector is established and the perpetrators are held accountable. In the field of medical care, refusal of certain treatment can inevitably lead to a fatal consequence, but treatment carried out without the consent of a mentally competent adult patient will indicate an interference with the physical integrity of the person in a way that affects the rights under Art. 8 of the Convention. However, Art. 2 of the Convention embodies the principle of sanctity (inviolability) of human life, which is evident in the case of a doctor who uses his skills to save lives, and must act in the best interests of the patient… " [1]. Also in its judgment in Csoma v. Romania (2013) (application № 8759/05), the European Court of Human Rights stated: "The Court reiterates that countries that have ratified the Convention "to adopt rules that will oblige both private and public health facilities to take adequate measures to protect the lives of patients"[2]. Such positions of the ECtHR show that the issues of health care workers prosecution are among the issues concerning the observance of fundamental human rights and freedoms and need to be analysed in detail.

Thus, in case of violation of human rights and fundamental freedoms, state coercive measures must be applied to the perpetrators. Such measures of state coercion are legal responsibility. As noted above, different legal measures may be applied in different countries. In Ukraine, criminal, disciplinary, civil and administrative liability can be applied to health care workers.

Let's start the study by analysing the issue of health care workers criminal liability. According to scientists, criminal liability is one of the guarantees of professional performance of their functions by health care workers [3, p. 91]. Quite often crimes in the field of violation of health care legislation are called "medical" crimes.

According to the criminal legislation of Ukraine most medical crimes are concentrated in Section II of the Criminal Code of Ukraine "Crimes against life and health". These include, in particular: improper performance of professional duties, which led to the infection of a person with human immunodeficiency virus or other incurable infectious disease (Article 131 of the Criminal Code of Ukraine); disclosure of information on conducting a medical examination to detect infection with human immunodeficiency virus or other incurable infectious disease (Article 132 of the Criminal Code of Ukraine); illegal abortion (Article 134 of the Criminal Code of Ukraine); illegal medical activity (Article 138 of the Criminal Code of Ukraine); failure to provide care to the patient by a health care worker (Article 139 of the Criminal Code of Ukraine); improper performance of professional duties by a health care or pharmaceutical worker (Article 140 of the Criminal Code of Ukraine); violation of the patient's rights (Article 141 of the Criminal Code of Ukraine); illegal conduct of experiments on humans (Article 142 of the Criminal Code of Ukraine); violation of the procedure for transplantation of human organs or tissues established by law (Article 143 of the Criminal Code of Ukraine); forced donation (Article 144 of the Criminal Code of Ukraine); illegal disclosure of medical secrets (Article 145 of the Criminal Code of Ukraine).

Given the limited scope of the article, as well as the need for comparative analysis, we will try to consider only one of the components of crimes in the field of health care. Thus, narrowing the subject of the study, we will analyse improper performance of professional duties by a health care worker in detail. In Ukraine, the responsibility for such acts is established by Art. 140 of the Criminal Code of Ukraine. The choice of this norm of criminal law is due to the fact that, according to experts, "in fact, this is the only article in Ukrainian law, which is used in 90-95% of cases of any criminal proceedings against health care workers" [4].

Analysis of regulations of other countries and scientific sources of the relevant sphere shows that some of them, such as the Republic of Belgium, the Republic of Bulgaria, the Kingdom of Denmark, the French Republic, do not criminalize improper performance of professional duties by a health care worker in a separate clause, but establish responsibility for careless professional behaviour that harms the life and health of a person. Some countries do not enshrine special rules for prosecuting health care workers in the relevant regulations and establish only liability for crimes against life and health [5] (see Table 1 "Consolidation of criminal liability for medical offenses in different countries").

The conducted scientific research on the issue of criminal prosecution in Ukraine shows the following statistics: in 2018, 654 criminal proceedings were registered under Art. 140 of the Criminal Code of Ukraine, 3 of them were transferred to the court with an indictment, of which only 2 people were convicted. To some extent, this is due to the fact that the results of treatment, unfavourable for a patient, are not always causally related to the actions or inaction of health care professionals, and therefore within the pre-trial investigation in many cases it turns out that there are no grounds for criminal liability [6, p. 12]. We should also add that, in our opinion, such a difference in the number of registered proceedings and actually convicted persons (652) is explained by the fact that practically there are difficulties in applying criminal law, in qualifying the act and gathering evidence, sometimes there is no procedural activity by the victim (or his close relatives or family members). Also one of the reasons is "medical solidarity" by means of which it is possible to hide traces of offenses.

According to the criminal legislation of Ukraine, improper performance of professional medical duties as a part of a criminal offense belongs to crimes against life and health of a person. The actus reus of the crime is characterized by an act or omission, namely non-performance or improper performance by a heath care or pharmaceutical worker of his or her professional duties due to negligent or dishonest treatment; consequences in the form of severe consequences for the patient; the causal link between these actions and the consequences.

Failure to perform professional duties is a failure to perform actions (complete inaction) by a health care or pharmaceutical professional, while according to the law he was obliged to perform them. Improper performance of professional duties is the performance of one's duties partially, superficially, without complying with the existing requirements for professional activity. These provisions suggest that in fact the regulations do not explain the specific content of this offense. The disposition of the article under consideration is blanket, i.e. when qualifying the committed act it is necessary to establish in each case which professional duties were assigned to the perpetrator and which of them were not performed at all or performed improperly, as well as the requirements of which regulations (orders, instructions, rules, directives, etc.). This is also due to the fact that the profession of a health care worker, including a doctor, is associated with extraordinary situations, each time with new circumstances. In some ways, the current situation complicates law enforcement, and it is impossible to state unequivocally the presence or absence of an offense. Cases from medical practice, at first glance, may seem like medical crimes, and only a full and objective investigation of all the circumstances of the case will help to establish the truth. The above is one of the reasons why the number of proceedings registered and brought to court differs significantly.

According to Ukrainian law, the effect of committing a crime of improper performance of duties by a health care worker is serious consequences for the patient — causing the victim's death, suicide, causing severe or intermediate severe bodily injury, disability or other complication of the disease, causing iatrogenic disease.

Criminal law of Japan, the Kingdom of Belgium, the Netherlands, the French Republic, Romania, the Swiss Confederation considers death or personal injury as a consequences of the crime; in the Republic of Korea — death or physical injury; in the Kingdom of Thailand, the Republic of Albania, Bulgaria, the Kingdom of Denmark, Germany, and the Republic of Poland — death; in the Kingdom of Sweden — bodily injury or disease [5] (see Table 2 "Legislative consolidation of the consequences of committing a crime by a health care worker in different countries").

The conducted analysis gives grounds to claim that in Ukraine there is the widest list of possible consequences of improper performance of professional duties by a health care worker. Note that the existence of such an extended list does not always give the expected results in terms of prosecution. For example, establishing a causal link between a person's suicide and a professional's failure or improper performance of a health care worker's professional duties seems extremely difficult. At present, no cases of proven suicide of a person due to a crime committed by a health care worker have been established in Ukraine.

Returning to the consideration of the elements of criminal offense under Art. 140 of the Criminal Code of Ukraine, it should be emphasized that the object of this criminal encroachment is human life and health, the established procedure for health care and pharmaceutical workers to perform their professional duties.

There is a special subject of the crime— a health care worker, i.e. persons who have the appropriate special education and meet the unified qualification requirements (doctors regardless of profile, paramedics, etc.), as well as persons engaged in private medical practice. To be qualified under Art. 140 it does not matter which category of physicians the perpetrator belongs to — whether he is directly selected by the patient or appointed by the head of a health care institution (subdivision of this institution). That is, in this criminal offense it must be established that the subject of the crime is a health care worker, the crime is committed in the "doctor-patient" system, and, accordingly, the subject is a health care professional, the victim is a patient and the wronged person is a patient or his family.

Similar provisions are contained in the legislation of other countries. The subject of crimes in the majority of criminal codes is a person engaged in relevant professional activities (Republic of Korea, Spanish Republic of Pakistan, Kingdom of Thailand, Republic of Turkey, and Japan).

Here it is necessary to make a small digression and explain that the victim of the crime and the victim in criminal proceedings are not always the same person. This is especially true to a medical crime, one of the components of which is the occurrence of serious consequences: causing the death of the victim, his suicide, causing him severe or intermediate severe bodily injury. Yes, the victim of a crime is a person who has suffered direct damage from a criminal offense, i.e. his life and health have been illegally encroached upon. The victim in criminal proceedings may be an individual who has suffered moral, physical or property damage by a criminal offense, as well as a legal entity who has suffered property damage by a criminal offense (Part 1 of Article 55 of the Criminal Procedure Code of Ukraine). In this case, if a person has died as a result of a criminal offense or the person is in a condition that makes it impossible for him to submit a relevant application, the procedural status of the victim extends to close relatives or family members of such person. The victim is a person among close relatives or family members who filed an application to be involved in the proceedings as a victim, and several persons may be recognized as victims at their request (Part 6 of Article 55 of the Criminal Procedure Code of Ukraine). In conclusion, it should be noted that quite often there are cases when a victim dies as a result of a crime, and a close relative or family member of such person can be referred to as a victim. Thus, in accordance with the legislation of Ukraine, the procedural status of a victim passes to close relatives or family members. A slightly different approach is used in the Criminal Procedure Code of the Republic of Armenia, according to which in case of death of the victim or loss of opportunity to express their will a separate participant in criminal proceedings is introduced — the victim's successor (Article 80) [7].

Continuing to consider the corpus delicti provided for by Art. 140 of the Criminal Code of Ukraine, it should be noted that mens rea of a crime is determined by the mental attitude to socially dangerous consequences and is characterized by negligence (criminal arrogance or criminal negligence). In general, the analysis of law enforcement practice confirms that intentional crimes in the activities of health care workers are extremely rare, more often negligent ones occur [8, p. 205].

If a person did not foresee the possibility of socially dangerous consequences, and taking into account the specific situation, could not and should not have foreseen them, the responsibility under Art. 140 is excluded. In this case, there is an accident (incident), an innocent medical error, which cannot be avoided even with the most conscientious attitude to one's professional duties and which can be caused, for example, by the difficulty of diagnosing an unusual disease, anatomical or physiological abnormalities, atypical development of the disease, unexpected allergic reaction, lack of specific (inherent only in cancer) symptoms of early forms of malignant neoplasms [9, p. 329 - 330].

An analysis of the criminal law of other countries shows that the mens rea of this type of crime in other countries is also characterized by negligence.

The sanction of Article 140 of the Criminal Code of Ukraine provides for deprivation of the right to hold certain positions or be engaged in certain activities for up to five years or correctional labour for up to two years, or restriction of liberty for up to two years, or imprisonment for the same term.

Examining the criminal law of other countries we can identify the following sanctions that can be applied to persons guilty of "medical" crime: a fine (legislation of the Republic of Albania, the Kingdom of Denmark, Germany, the Swiss Confederation, the Kingdom of Sweden, the Netherlands, the French Republic, the Kingdom of Spain, Romania, the Republic of Belarus, the Republic of Armenia, the Republic of Kazakhstan, the Republic of Latvia, the Kyrgyz Republic, the Republic of Tajikistan), imprisonment (or incarceration) (legislation of the Republic of Albania, the Kingdom of Spain, the Netherlands, the French Republic, the Republic of Poland, The Kingdom of Sweden, Germany, the Kingdom of Norway, Romania, the Republic of Latvia, the Republic of Tajikistan, the Republic of Lithuania), deprivation of the right to hold certain positions or be engaged in certain activities (legislation of the Republic of Kazakhstan, the Russian Federation, the Republic of Tajikistan); mandatory labour (180 to 240 hours) (legislation of the Republic of Tajikistan); correctional labour to (legislation of the Russian Federation, the Republic of Turkmenistan, the Republic of Belarus, the Republic of Uzbekistan) (see Table 3 "Types of penalties for improper performance of professional duties by a health care worker in different countries").

The above analysis shows that the punishment in the form of deprivation of the right to hold certain positions and correctional labour exist exclusively in the post-Soviet countries. It is also interesting to note that such punishment as a fine is quite common in other countries, but in Ukraine it is not applied to persons guilty of committing a crime under Art. 140 of the Criminal Code of Ukraine.

In addition to criminal liability, medical staff may be subject to disciplinary action for a breach of a duty. If we compare criminal and disciplinary types of liability, then disciplinary liability is a less severe type.

Disciplinary liability of a health care worker is a separate type of legal liability that arises in case of a disciplinary misconduct by a health care worker. Disciplinary liability of health care professionals occurs not only for disciplinary misconduct, but also for violation of moral and ethical norms since workers of this category must comply with the requirements of professional ethics, respect for honour and dignity of citizens (patients). This understanding of disciplinary responsibility is common for a Ukrainian reader. Note the interesting fact that such understanding of disciplinary responsibility is not common to all states. Taking into account the limited scope of the study, it should be noted that we found similar interpretations of disciplinary liability in scientific and regulatory sources of Kazakhstan, Georgia, Armenia, etc.

In general, a disciplinary offence is an unlawful act or omission, which is expressed in non-performance or improper performance of duties and other requirements imposed on the employee under labour law, other special regulations, for violation of which there will be a disciplinary action. Like any offense, a disciplinary offense is characterized by a set of objective and subjective features, called the set of elements of an offense: the subject, the subjective side, the object, the objective side.

Unlawful violations can be defined as a violation of any employment obligations specified in an employment contract, a contract, acts of public authority, instructions of managers adopted within their powers, orders and instructions of the head, if they are legal in nature, and other legal rules. Failure to perform or improper performance of his duties by a health care worker must not only be wrongful, but also consistent with the job function of this employee: the range of rights and responsibilities must be defined in the employment contract, job description, internal labour regulations. Violations of labour discipline established by Ukrainian legislation include:

- Failure to comply with the rules and regulations of technological discipline (violation of instructions for work on medical equipment);
- Systematic violation of labour discipline;
- Absence from work without a good reason;
- Appearing at work in the state of intoxication.

Signs of disciplinary offence are: 1) the fault of an employee (employer); 2) illegality of actions (inaction), which are manifested in non-performance or improper performance of labour duties or excess of official authority; 3) the causal link between illegal actions (inaction) and harmful consequences. Failure to prove at least one of these elements excludes the availability of a disciplinary offense [10, p. 552].

For violation of labour discipline according to Art. 147 of the Labour Code of Ukraine, an employee can be subject to only one of the following measures of punishment: reprimand and dismissal. As you can see, the types of sanctions for committing a disciplinary offense under the laws of Ukraine, do not differ in their diversity.

In terms of the implementation of comparative law research, we note that in accordance with Art. 223 of the Labour Code of the Republic of Armenia, for violation of labour discipline the following disciplinary sanctions as reprimand, severe rep-

rimand, termination of employment contract may be applied. In addition, other disciplinary sanctions may be imposed by law on certain categories of employees.

In the Republic of Kazakhstan, such penalties include reprimand, severe admonition, termination of the employment contract at the initiative of the employer. The application of disciplinary sanctions not provided for by the Labour Code and other laws of the Republic of Kazakhstan is not allowed.

In the Labour Code of Georgia there are no references to the definition of disciplinary misconduct and the types of penalties that may be imposed for its commission.

According to Art. 198 of the Labour Code of the Republic of Belarus for committing a disciplinary offense, an employer may apply to the employee the following measures of disciplinary action: reprimand, admonition, and dismissal.

It should be noted that disciplinary action against a health care worker under the law of the above countries may be applied by the body granted the right to hire and dismiss these workers, i.e. the head of the health care facility or a body authorized by him. The right of the head to apply disciplinary sanctions is also enshrined in numerous Regulations on health care institutions and health care staff. For example, in some European countries and the United States there are so-called "professional associations" whose powers are to impose disciplinary sanctions, reprimand, admonition, impose fines, suspend or deprive of the right to practice medicine. We are talking about medical chambers or associations. In almost all European countries health care practitioners, both private and public, are required to be members of the city's health care chamber (association). In the absence of such membership they are not allowed to practice medicine. All members of the chamber (association) make an annual payment. But the main thing is that the members of the chamber must adhere to the Code of Professional Ethics of a doctor, for violation of which disciplinary liability is provided — admonition, warning, fine or expulsion from the chamber (association), which entails the possibility of terminating medical practice. In some countries (Belgium, France, Germany, Switzerland) the provisions of the Code of the doctors' Professional Ethics quite strictly regulate such areas as advertising of medical services, the relationship with the patient, failure to care for the patient, relationships with colleagues. Medical orders (chambers) are non-governmental non-profit organizations that do not provide health care services. Their main function is to represent the interests of doctors and health care organizations, protect the rights of both patients and doctors, and monitor the observance of the Code of Professional Ethics. Chambers (associations) are created on the basis of law, in contrast to public associations, they are associations of public law. In this regard, the European Court of Human Rights in a number of its decisions recognized mandatory membership in the relevant organizations as inconsistent with Art. 11 of the European Convention. The doctor's appeal against the decision of the health care chamber to disciplinary prosecution can be considered by the European Court of Human Rights [11, p. 78-80].

Returning to the Ukrainian legislation we note that, in addition to disciplinary liability, health care workers, in accordance with Art. 130 of the Labour Code of Ukraine are materially liable for damage caused to a health care institution as a result of violation of their duties.

If the necessary grounds and conditions are met then material liability may be imposed regardless of the employee's disciplinary, administrative or criminal liability.

The responsibility for the damage caused to the patient by a health care worker while performing his professional duties rests entirely with the health care institution, regardless of ownership. In turn, a health care institution that is liable as a result of illegal actions of an employed health care professional has the right, in recourse, to file claims against him and prosecute in accordance with labour legislation.

CONCLUSIONS

Aiming to investigate the peculiarities of the legislative consolidation of criminal and disciplinary liability for offenses of health care professionals in the legislation of Ukraine and other countries we conducted a comparative legal analysis of the crime in the form of non-performance or improper performance of duties by a health care or pharmaceutical worker in Ukraine and other countries; identified types of penalties for medical crimes, which are set by law in different countries; the content and sanctions for committing a disciplinary offense by a health care worker on the example of the legislation of Ukraine and other countries. In particular, it has been established that not every state enshrines the corpus delicti in the form of improper performance of professional duties by a health care or pharmaceutical worker in their law, as did Ukraine, the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, Uzbekistan. Thus, some countries criminalize negligent professional conduct that harms the life and health of a person (Kingdom of Belgium, the Republic of Bulgaria, the Kingdom of Denmark, the French Republic, the Republic of Lithuania). Also, some countries do not provide for liability for improper performance of professional duties by a health care or pharmaceutical worker in a separate article and prosecution is carried out for crimes against life and health (Azerbaijan, Estonia, Georgia, the Republic of Moldova, the Republic of India). Also, on the basis of a comparative legal analysis, the possible consequences of the crime of improper performance of duties by a health care worker were identified. In Ukraine, it is the infliction of death on the victim, his suicide, and infliction of severe or intermediate bodily injuries, disability or other complication of the disease, infliction of iatrogenic disease, in Japan, the Kingdom of Belgium, the Netherlands, the French Republic, Romania or Switzerland — death or bodily injury; in the Republic of Korea — death or physical injury; death in the Kingdom of Thailand, the Republic of Albania, Bulgaria, the Kingdom of Denmark, Germany, and the Republic of Poland; in the Kingdom of Sweden — bodily injury or disease. When considering possible sanctions that could be applied to those guilty of "medical" crime it was found that different countries use their own set of sanctions, in particular, fines (Criminal Codes of the Republic of Albania, the Kingdom of Denmark, Germany, the Swiss Confederation, Sweden, The Netherlands, the French Republic, the Kingdom of Spain, Romania, the Republic of Belarus, the Republic of Armenia, the Republic of Kazakhstan, the Republic of Latvia, the Kyr-

gyz Republic, the Republic of Tajikistan), imprisonment (or incarceration) (Criminal Codes of the Republic of Albania, Kingdom of Spain, The Netherlands, the French Republic, the Republic of Poland, the Kingdom of Denmark, the Kingdom of Sweden, Germany, the Kingdom of Norway, Romania, the Republic of Latvia, the Republic of Tajikistan, the Republic of Lithuania), deprivation of the right to hold certain positions or be engaged in certain activities; mandatory work; corrective works (Criminal Code of the Russian Federation, the Republic of Turkmenistan, the Republic of Belarus, the Republic of Uzbekistan), etc. The above analysis shows that the punishment in the form of deprivation of the right to hold certain positions and correctional work exist exclusively in the post-Soviet countries. It is also interesting to note that fine is quite common in other countries, but in Ukraine it is not applied to persons guilty of committing a crime under Art. 140 of the Criminal Code of Ukraine.

The study and analysis of international law, as well as the case law of the European Court of Human Rights on health care workers to disciplinary prosecution leads to the conclusion that a major shortcoming of current Ukrainian law is that health care workers, whose proper activities influences on lives and health of people, are subject only to the general rules of labour law. We consider it appropriate to improve the regulations concerning disciplinary liability for improper performance of professional duties of health care workers. Such acts, in our opinion, may be the Statutes or Regulations on the discipline of health care personnel of public, municipal and private health care institutions, which could supplement the existing regulations, as well as the types of penalties provided for in Art. 147 of the Labour Code of Ukraine, such as - reprimand, suspension, etc.

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REVIEW ARTICLE

PECULIARITIES OF LEGAL RESPONSIBILITY FOR OFFENSES IN THE FIELD OF CLINICAL TRIALS OF MEDICINES

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ABSTRACT

The aim: Is to determine the features of legal liability for violations in the field of clinical trials of medicine remedies and justification of proposals to strengthen the protection of participants' interests in clinical trials through the use of various types of such liability.

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

Conclusions: In order to properly ensure the legal protection of public interests, as well as the rights and interests of research subjects and other entities involved in their implementation, the authors argue the need to use different types of legal liability.

KEY WORDS: researcher, clinical trial, research subject, offense, liability

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INTRODUCTION

The relevance of clinical trials has increased during pandemic, which necessitated the development of vaccines and their clinical trials as quickly as possible. At the same time, there are many reports of side effects of such medicines, which are observed in different countries. It raises the issue of improving the protection of the rights and interests of study subjects, including through the institution of legal liability. The essence of clinical trials is associated with risks for persons involved in clinical trial, as such trials are an innovative research activity to verify (confirm) the effectiveness of unregistered medicine remedies, which requires regulatory effective protection of interests of various subjects involved in clinical trial, as well as public interests, using various types of legal liability.

The legal regulation of legal liability and sanctions for offenses in the field of clinical trials should, above all, take into account the nature of clinical trial, the procedure for its conduct and the legal status of subjects and various participants in clinical trial.

The shortcomings of legal regulation of legal liability, in particular criminal law, reduce the effectiveness of legal protection of public and private interests in this area, which, given the increased risks of harm, requires special attention to basis for such liability and appropriate sanctions.

Not enough attention is paid to these issues in the scientific literature. In view of this, the issues of legal liability for offenses in the field of clinical trials require comprehensive doctrinal elaboration.

THE AIM

The purpose of the study is to determine the features of legal liability for violations in the field of clinical trials of medicines and justification of proposals to strengthen the protection of participants' interests in clinical trials through the use of various types of such liability.

MATERIALS AND METHODS

To achieve the objectives of the study, statistics in terms of quantity of clinical trials in different countries were analyzed. The study also used statistical data on initiation of criminal proceedings for offenses related to clinical trials in Ukraine.

The decisions of the European Court of Human Rights (hereinafter - the ECHR) in cases concerning the use of unregistered methods of treatment are analyzed. In addition, international and national regulations have been studied, which define the general provisions of legal liability in the field of clinical trials, as well as establish sanctions for offenses during their conduct.

The relevance of this study was established by studying and analyzing the publications of foreign and domestic researchers on legal liability for offenses in the field of clinical trials.

The methods of theoretical analysis and synthesis were used in the study of the content of legal norms and concepts contained in international and national regulations on legal liability in the field of clinical trials. Some issues required an application of the method of systematic analysis, in particular, during systematization of different types of offenses and identification of the ratio of different types of legal liability for them.

Formal legal analysis of international and national law was used to study the differences in the application of criminal liability for various offenses that may be committed during clinical trials, and formulate proposals to improve the legal regulation of liability for such offenses in accordance with their public danger and harm. The comparative legal method was used in the analysis of legal consequences regulation for harm to legitimate interests in terms of justified risk to achieve a significant socially useful goal.

The formal-logical (to clarify the characteristics of criminal liability for involvement in clinical trial of the subject with a violation of procedure for obtaining informed consent), functional (in establishing the effectiveness of certain types of legal liability for violation during conducting such tests) methods was also used along with some others.

REVIEW AND DISCUSSION

In the European Community, approximately 4,000 authorizations for clinical trials are issued each year with an average of two Member States involved in each trial. Allmost 61% of clinical trials are sponsored by the pharmaceutical industry and 39% - by non-profit sponsors [1].

The leader among European countries in the number of registered clinical trials is Germany (24.22%), the United Kingdom is in the second place (22.83%), in the third place there is France (19.74%). Ukraine ranks the 23rd in this list of European countries, having 2.57% of the total number of clinical trials registered in Europe. In 2018, 395 clinical trials were registered in Ukraine, in 2019 – there were 391 trials. For comparison: in Germany in 2018, 3116 tests were registered, in 2019 – 2900 ones [2].

One of the principles set out in the Integrated Supplement to ICH E6 (R1) "Guidelines for Good Clinical Practice E6 (R2)" of 9 November 2016, an international ethical and scientific standard for the design and conduct of clinical trials involving human beings as a subject, is the prevalence of the rights, security and well-being of the subject of research over the interests of science and society (paragraph 2.3.) [3]. Adherence to this standard is a guarantee to society that the rights, safety and well-being of the research subjects will be protected, and the test results will be reliable, which is at the same time necessary to ensure the public interest in health care.

An example of resolving a dispute between the state and a patient over the use of an experimental medicinal drug based on balancing private and public interests is the case of Christosov and Others v. Bulgaria, heard by the European Court of Human Rights (ECHR). In this case the reason for the complaint was not inadequate treatment itself but the denial of access to a life-saving treatment, the safety and effectiveness of which were still in doubt. The applicants' interest was defined as "the freedom to choose untried treatment as a means of extreme necessity, which may entail risks but is considered by the applicants and their physicians as appropriate in their situation, in order to save their own lives". The compensatory public interest consisted of three parts: 1) to protect patients from the risks of unauthorized treatment; 2) make it impossible to circumvent the regulatory framework governing the provision of illicit medicinal drugs; 3) ensure that the development of new medicinal drugs is not jeopardized, for example, by reducing patient participation in clinical trials. The ECHR has noted that health policy issues usually lie within the discretion of States. Despite the clear tendency in states to authorize the use of illicit medicines, there is no general agreement on the specific way to regulate neither this issue, nor the established legislative principles in this regard. The ECHR concluded that the balance achieved in national law, whether that balance could be fairer, did not go beyond the discretion afforded to the State. The Court considered the fact that Bulgaria has regulations governing access to illicit medicines in cases where standard treatments are insufficient, and the State (Bulgaria) has the right to deny access to a life-saving treatment, the safety and effectiveness of which are still in doubt [4, p. 56-57].

In the cases of "A.M. and A. K. v. Hungary" The ECHR, in its Decision of 4 April 2017, took into account the data of clinical trials, which showed negative results in medicines ' application for which the applicants tried to obtain an individual permit from the state [5].

Guarantees of observance of inalienable natural rights of the research subject are laid down as in the order of carrying out clinical researches (creation of independent ethical committees for protection and defend of the rights and safety of research subjects, obligation to inform the sponsor and regulatory body of all undesirable phenomena during testing, development of standard operating procedures indicating safety measures, continuous monitoring of testing, suspension or termination of testing in case of a certain level of threats), which is regulated by international ethical and scientific standards, as well as national legislation and legal liability for violation of this procedure, laid down at the level of national legislation. Since it is a question of protection of such personal non-property rights as life and health of the research subject, it is, first, provided by measures of criminal responsibility.

Also, Proper clinical practice (paragraph 2.7) defines the principle of responsibility for medical care provided to the subject of the study, as well as medical decisions. In this case, the researcher is responsible for: proper clinical research (paragraphs 1.34, 4.1.1); all medical decisions made in relation to the subject of the study within the test (4.3.1.); accounting of investigational medicinal product in the research center (paragraph 4.6.1.). The sponsor is responsible for the proper organization of clinical trial (paragraph 1.53), for the researcher's choice (paragraph 5.6.1.), as well as for the quality and completeness of the

data obtained as trial (paragraph 5.2.1). The sponsor's standard procedures should consider the reimbursement of the cost of treatment of clinical trial participant in the event of harm to health in connection with the study procedure in accordance with regulatory requirements (paragraph 5.8.2).

This corresponds to paragraph 15 of the Nuremberg Code of 1947 [6], according to which the physician is always responsible for the subjects of the study, and the subject of the study is never responsible, despite the latter's consent to participate in the study.

Harmonization of Clinical Trials procedure in Ukraine to international requirements, compliance with the GCP standard is a guarantee that the rights of subjects – patients and healthy volunteers are protected, confidentiality is maintained, and the data obtained during the study are reliable information [7, p. 7].

Art. 76 of Regulation (EU) № 536/2014 [8] provides that Member States are required to provide for compensation systems for any damage caused to the subject by participation in clinical trial conducted on their territory in the form of insurance, guarantees or similar measures equivalent in nature and degree of risk. Under Art. 94 of this Regulation, Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. Imposed punishments must be effective, proportionate and dissuasive. Under Art. 95 of the Regulation, it does not limit national and union law in the civil and criminal liability of the sponsor and the researcher. In this case, if required by applicable regulations, the sponsor must provide insurance or guarantee legal and financial support to the researcher (organization) in case of claims related to the study, except for those claims that arose as a result of intent or carelessness (clause 5.8.1).

These requirements comply with paragraph 14 of Part 2 of the European Charter of Patients' Rights [9], according to which everyone has the right to receive adequate compensation within a reasonably short period of time in the event of physical or moral and psychological harm.

Compensation for the damage caused to the subjects of the study is provided by insurance (mainly - the sponsor's liability for damage caused in connection with participation in the trial, and in Ukraine - life and health insurance of the subject). In this case, the subject of the study is the beneficiary of the insurance contract concluded by the sponsor.

Damage caused during a clinical trial by a sponsor, research center, researcher is reimbursed in accordance with the rules of civil law, as well as the provisions concluded between these parties to the contract.

The sponsor of a clinical trial has the right to use the civil liability specified in the contract for violation of clinical trials' procedure by an executor for conducting clinical trials. The subject of the study may use such methods of civil protection as compensation for property and moral damage caused by the violation of his rights. The latter may apply disciplinary measures to a physician as an employee of the hospital.

It should be noted that in Ukraine, public law protection of the rights of research subjects is provided mainly through criminal liability (Articles 137, 139-142, 145, 321-2 of the Criminal Code of Ukraine [10], (hereinafter - the Criminal Code of Ukraine).

The Code of Administrative Offenses of Ukraine [11] does not provide for administrative liability for violations in the field of clinical trials. Only Article 44-2 of this Code stipulates liability for violation of restrictions imposed on medical and pharmaceutical workers in the course of their professional activities.

Such restrictions are normatively defined in the Article 78-1 of the Law of Ukraine "Fundamentals of the Legislation of Ukraine on Health Care" [12], among which, in particular, the prohibition to receive from business entities engaged in the production and (or sale) of medicines, products medical purposes, their representatives an improper benefit.

It should be noted that the ban on receiving from business entities engaged in the production and (or) sale of medicines, medical devices, their representatives any samples of medicines, medical devices for use in professional activities does not apply to cases related to conducting clinical trials of medicinal products or clinical trials of medical devices in accordance with contracts.

Analysis of violations that may occur during clinical trials and lead to the application of criminal liability shows their diversity. In view of this, the study of criminal law protection of rights and legally protected interests in the field of clinical trials should be carried out comprehensively and taking into account the nature of clinical trials and the legal status of persons involved: researchers, sponsors, contract research organizations, management organizations research centers, research coordinators, research subjects, etc.

Based on the analysis of criminal law on liability for offenses in the field of clinical trials, the latter can be divided into the following groups:

1. Offenses against life and health.

As it stated in paragraph 11 of Regulation (EC) №536 / 2014, the risk to the safety of the subject in clinical trial has mainly two sources: the investigational medicinal product and the intervention. Many clinical trials, however, carry only minimal additional risk to the safety of the subject compared to normal clinical practice.

However, the threat to human rights to life and health, as well as the actual harm, may result from: being involved in a clinical trial in violation of the informed consent procedure; violation of the trial protocol for the use of investigational medicinal product, failure to provide or untimely provision of medical care to the subject of the study.

Normative regulation in Ukrainian legislation of criminal liability for damage caused as a result of involvement in clinical trial of a research subject in violation of the procedure for obtaining informed consent (Article 141 of the Criminal Code of Ukraine) has been criticized in the scientific literature. Among the shortcomings of this article: 1) the content of Article 141 of this Code does not correspond to its title, violation of patient rights is a much

broader concept than violation of the rules of clinical trials of medicines, and covers a number of provisions defined in Articles 139,140,142,145 of the Criminal Code; 2) the victim of clinical trials of medicinal products without their own written (informed) consent, or written (informed) consent of the representative, may be only an adult person who has been subjected to such trials. The other two categories of victims should be recognized as such regardless of the written consent of them and their representatives, which is unreasonable and contrary to the Convention on Human Rights and Biomedicine, as well as the Procedure for clinical trials of medicines that allow clinical trials and the involvement of minors; 3) criminal liability is provided for conducting clinical trials without written informed consent, but it may, under certain conditions, be provided orally; 4) there is no consideration that informed consent can be given on certain grounds not only by the legal representative, but also by a close relative [13, p. 5, 67-68,100-103].

When deciding on the qualification of actions that violate the rights to life and health of the subject, it should be borne in mind that such protection is ensured by several components of the crime, between which there may be competition.

Thus, there is a separate liability for murder, infliction of bodily injuries of varying severity, as well as for failure to provide to the patient a medical professional who is obliged, according to established rules, to provide such assistance without apropriate reason, if he/she knows that it may have serious consequences for the patient, non-performance or improper performance of their professional duties by a medical or pharmaceutical worker due to negligent or dishonest treatment, if this caused serious consequences for the patient, conducting clinical trials of medicines without the written consent of a patient or his/her legal representative, if these actions caused the death of a patient or other serious consequences, illegal conduct of medical-biological, psychological or other experiments on a person, if it endangered their life or health, intentional illegal disclosure of medical secrets, if such an act caused serious consequences.

It should be borne in mind that in the presence of special corpus delicti in the field of clinical trials, they should be used in the classification of crimes in this area.

It is also important to note that clinical trials are research and innovation activities in the field of medicine, not medical care. Its essence is to study an unregistered drug to establish or confirm its effectiveness and safety. Therefore, causing harm during such tests should be carried out according to the rules of justified risk (act related to risk - Article 42 of the Criminal Code of Ukraine [10], Article 27 of the Criminal Code of the Republic of Poland [14]).

The Ukrainian legislator establishes that an act (action or omission) that has harmed law enforcement interests is not a crime if this act was committed in conditions of justified risk to achieve a significant socially useful goal. In this case, such a goal can be determined by the presence of real or potential danger, the need to obtain new knowledge (at research risk) [15, p. 168, 169],

Obviously, the study of an unregistered medicinal product to establish or confirm its effectiveness and safety is fully consistent with the purpose set by law. But in addition to the goal, it is necessary to comply with certain other conditions, namely: 1) this goal could not be achieved in this situation by action (inaction), not associated with risk; 2) the person who took the risk reasonably expected that the measures taken by him/her were sufficient to prevent harm to law enforcement interests. It seems that the first condition for the study of an unregistered medicine is performed a priori, because this study is carried out precisely to prove the safety of a new medicine, to learn about anything else (other than testing) is not possible at all. The second condition must be assessed on a case-by-case basis, depending on availability and effectiveness of the means chosen by the physicians conducting the tests to prevent harm to the subject. It should be recalled that the subject' human rights differ from the patient's human rights in the provision of medical care. Both groups of rights belong to human rights in the field of health care [16, p. 2470]. It is important for the assessment of the object and the objective side of a certain crime in the qualification of the actions of subjects of clinical trials, if the conditions of justified risk are not met.

It should also be noted that Chapter 3 of the General Part of the Criminal Code of the Republic of Poland "Exemption from Criminal Liability" contains Art. 27, according to which a person who acts, in particular, for the purpose of conducting a cognitive or medical experiment, does not commit a crime, if the expected benefit has significant cognitive, medical significance, and the expected achievements, expediency and method of experiment are justified in the light of modern knowledge. The experiment is not allowed without the consent of the participant, where it is conducted, duly informed about the expected benefits and negative consequences that threaten him/her, and the likelihood of their occurrence, as well as the ability to terminate the experiment at any stage [14, p. 13]).

As you can see, The Polish legislator establishes the same conditions for the legality of clinical trials of medicinal products as the Ukrainian one: the goal generally coincides, but the fact that the Criminal Code of Ukraine states that "the reasonable calculation of measures taken to prevent harm" the method of experiment was justified "in the light of modern knowledge."

2. Offenses against public health.

Thus, certain violations committed during clinical trials may not pose a threat to the subject's life or health (which is inherent in the offense of the first group), but may pose a serious threat to public health, for example, in the case of falsification study data, in particular, by hiding the negative effects of the study medicine on the human body.

It should be agreed that not any, even intentional, violation of the established procedure for preclinical studies, clinical trials and state registration of medicines is socially dangerous and indicates falsification and impossibility of further state registration of the drug and its admission to use. For example, if the date or signature of the authorized

person was not affixed to any document during the clinical trial, it is a violation of the relevant procedure, but it would not be rational to prosecute the perpetrator [17].

Establishing the same criminal liability for violating the order of clinical trials with varying degrees of threat to public safety provokes reasonable criticism from the pharmaceutical industry. Thus, the European Business Association notes that the prediction for procedural violations during a clinical trial of criminal liability instead of administrative pressure on physicians, pharmaceutical companies, specialists in the examination of registration materials, as well as materials of preclinical studies and clinical trials, the quality of which depends on availability medicines and the country's image in the field of science-intensive clinical research projects [18].

For example, the Criminal Code of Ukraine (Article 321-2) provides for criminal liability for violation of procedure of conducting a clinical trial.

The main feature of this paper is that criminal liability under part one of this article is provided even in the absence of specific harm caused by phisician-researcher or other participant in clinical trials to the state, hospital, subject, sponsor, etc. or its real threat, although for such actions a rather severe punishment is applied - imprisonment for a term of three to five years with deprivation of the right to hold certain positions or engage in certain activities for a term of one to three years. That is, for any violation of clinical trials' order, even those that do not endanger the life, health, safety of the subjects of study, do not threaten the integrity and reliability of the study data, there is no alternative to imprisonment. In addition, this paper does not determine independently the list of criminally punishable acts but refers to the relevant regulations.

It should be emphasized that criminal liability is the most severe type of legal liability of medical workers for offenses committed by them in the course of their professional activities. The Ukrainian legislator has unjustifiably refused to protect private and public interests in the field of clinical trials by establishing of administrative liability, although its introduction could help differentiate legal liability depending on the nature of the clinical trial violation and the negative consequences of such a violation.

There is no criminal liability for unintentional violation of the clinical trial procedure, except for conducting clinical trials without obtaining the informed consent of the subject, if these actions resulted in the death of a patient or other serious consequence. For such actions, a separate criminal liability is provided by Article 141 of the Criminal Code of Ukraine, which does not provide for the intent of such actions. This article aims to ensure the protection of the right to a conscious decision to participate in a clinical trial of a viable person.

According to official statistics, under this article in 2019, 26 criminal proceedings were registered, of which 6 were closed and 2 were sent to court. At the same time, in the first 5 months of 2020, 13 proceedings were registered, none of which has yet been closed or sent to court. Sentences under this article were not published in the public domain. For comparison - for conducting a clinical trial without the informed consent of the patient, which led to serious consequences, in 2019 and 2020, one criminal case was registered [19].

Under Art. 141 of the Criminal Code of Ukraine for the period from 2013 to August 2020, only 6 criminal proceedings were registered but no person was prosecuted [20].

Based on the analysis of the Unified State Register of Judgments, it should be noted that Ukrainian courts have not prosecuted persons under Article 141 and Article 321-2 of the Criminal Code of Ukraine.

This also confirms the ineffectiveness of the legislator's use of criminal liability for these actions, which in practice does not lead to the application of criminal liability by the court to violators.

1. Offenses in the field of official activity.

Such violations may be committed by officials of health care facilities.

For example, concluding a contract for a clinical trial by a head of health care facility may be, under certain circumstances, qualified by law enforcement agencies as an abuse by an official of his/her powers for the purpose of perception of improper advantage for theirselves or others, use against the interests of legal entity, if this has caused significant damage to the interests of health care institution protected by law, or in addition to state interests, if the relevant hospital belongs to state ownership.

The criminal qualification of such actions of health care institution' head is relevant for those states in which it is allowed to conclude along with the contract for clinical trial between the trial client and the hospital, separate agreements with researchers, co-researchers, research coordinators, which they perform in their free time, work in the hospital. The first contracts usually indicate the consent of the hospital to enter into a separate contract with these persons, who are also employees of the hospital. In case of coincidence of functions of hospital and other executors (researchers, co-researchers, coordinators of test) in contracts, there is a situation when the researcher will receive means for the actions which he carries out in the working hours and which are at the same time a contract of the test customer and hospital. This situation can be considered by law enforcement agencies as a result of a deliberate conspiracy of the head of the hospital and staff to reduce the flow of funds to the hospital budget for the personal enrichment of these persons.

The qualification of such actions of officials is related to rule application on the procedure for registration of legal relations of participants in clinical trials, which have differences in different countries.

1. Offenses in the field of economic activity (which includes conducting clinical trials), regarding taxation.

Because clinical trials of medicinal products are paid for, entities that receive funding for services and work performed as part of clinical trials must declare them and pay income taxes on such activities.

The peculiarities of taxation of profits received from non-resident customers for services (works) should be con-

sidered while determining the tax liabilities of a participant in clinical trials, as well as correctly assess the nature of those services that were provided to such entities tax regime.

Persons involved in clinical trials may provide services for certain medical procedures or laboratory tests that do not have any scientific load, as well as provide consulting services, create intellectual property, the profits of which are usually have features of taxation.

In practice, there are cases of criminal prosecution for a set of criminal offenses belonging to the sphere of both official and economic activities [21].

CONCLUSIONS

The study demonstrates the need for a systematic approach to the settlement and enforcement of liability for violations related to clinical trials. In addition, the protection of public and private interests may be provided by other legal institutions, in particular, insurance, as well as compensation for property and moral damage. As for the insurance institute in the world practice, clinical trials mainly use the liability insurance of the research sponsor, while the Ukrainian legislation provides for life and health insurance of the subject of the study.

Particular attention needs to be paid to the standardization of criminal liability for offenses in this area, which are quite heterogeneous, and the correct legal qualification of certain actions requires knowledge of special legislation in the field of clinical trials, including international rules and ethics.

In addition, it is important to consider the legal nature of clinical trials that are outwardly similar to conventional medical practice, which they are not, as it differs in the purpose and nature of actions related to compliance with the trial protocol of an unregistered medicinal product to determine its effectiveness. and security. Clinical trials are scientific and innovative activities in the field of medicine, the essence of which is to study an unregistered medicine drug to establish (confirm) its effectiveness and safety. Therefore, causing harm during such tests must be carried out according to the rules of justified risk.

The diversity of violations that may be committed by different entities involved in the clinical trial makes it impossible to combine the relevant components of criminal offenses in a separate section of the legal act establishing criminal liability.

Resolving the issue of criminalization of certain offenses that may be committed by subjects involved in a clinical trial, it is advisable to consider their social danger and harm. Thus, it is controversial to introduce criminal liability for any violation of clinical trial order, regardless of its harmfulness.

When ensuring the protection of the rights and interests of research subjects and public interests in the field of health care, it is advisable to apply other types of legal liability (civil, administrative, disciplinary), taking into account the degree of harmfulness of the offenses under consideration.

When settling liability for a clinical trial in violation of the informed consent procedure, it should be considered that such consent may in some cases be given orally and not only by the subject or his/her legal representative, but also by close relatives.

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REVIEW ARTICLE

CONTRACTUAL REGISTRATION OF ORGANIZATIONAL AND LEGAL RELATIONS BETWEEN SUBJECTS INVOLVED IN THE CONDUCT OF CLINICAL TRIALS OF MEDICINAL PRODUCTS

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ABSTRACT

The aim: Determination of features of contractual registration of organizational and legal relations between the subjects involved in carrying out clinical trials of medicinal products; justification of proposals on improvement of law enforcement practice in this field.

Materials and methods: This research is based on the analysis of the norms of international law and legislation of particular states, practice of contractual registration of organizational and legal relations between the subjects of clinical trials of medicinal products. The research was carried out using the methods of dialectical and formal logic, general scientific and special legal research methods.

Conclusions: Two models of contractual registration of organizational and legal relations between the subjects involved in clinical trials of medicinal products were justified, and law enforcement recommendations for the contractual registration of such relationships, ensuring that the clinical trial is in compliance with international regulations and ethics in this field, were given.

KEY WORDS: sponsor, hospital, CRO, SMO, researcher

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INTRODUCTION

The issue of regulatory support for clinical trials of medicinal products (hereinafter -clinical trials) is becoming increasingly important given the significant societal threats that have recently emerged in healthcare. The announcement by the World Health Organization of the COVID-19 pandemic due to the outbreak of the new SARS-CoV-2 virus has affected the area of clinical trials – a need for additional standardization of vaccine testing for this disease (at the legislative level), as well as organizational changes in testing other medicinal products (at the local level, in particular, in standard operating procedures, orders for the organization of clinical trials in a pandemic and quarantine), has been raised. Besides, relevant orders and guidelines are developed by national regulators, such as the FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency [1].

The epidemic situation and the restrictions imposed by the states create additional difficulties in the implementation of the trial protocol, in strict adherence to the schedule of visits, procedures and surveys, which creates additional risks for the reliability of the data obtained during the trials. Customers and performers of clinical trials face additional organizational issues due to the need to ensure maximum protection of study subjects and the research team, as well as to minimize the impact on the integrity of clinical trial data.

Proper organization of the trial protocol execution process, first of all, is ensured by the proper construction of relations between the various subjects involved in the conduct of clinical trials, and their appropriate contractual registration. There is no coincidence that the contractual registration of the relations of the subjects involved in the conduct of clinical trials is one of the preconditions for their realization.

The issue of contractual registration of organizational and legal relations between the subjects involved in clinical trials is underresearched in scientific literature, however these issues require proper scientific investigation.

THE AIM

The purpose of the research is to determine the features of the contractual registration of organizational and legal relations between the subjects involved in the clinical trials, substantiation of proposals to improve law enforcement practice on the issue.

MATERIALS AND METHODS

To achieve the objectives of the research, statistical data on the number of clinical trials worldwide were analyzed, global and local trends in the field of such trials were considered.

The peculiarities of normative regulation of organizational and legal relations between the subjects involved in conducting clinical trials in different states were analyzed, including the international normative acts, as well as normative acts of particular states on the subject of research, the agreements on conducting clinical trials and provision of services related to their implementation, in particular, more than a hundred of agreements between foreign sponsors and Ukrainian performers of clinical trials were analyzed.

The methods of theoretical analysis and synthesis were used in the research during the study of the content of legal norms and concepts contained in regulations and ethical norms. The method of system analysis was used to differentiate the functions of subjects involved in clinical trials. Formal and legal analysis of regulatory requirements on organizational and legal relations between subjects involved in clinical trials create possibility to reveal disadvantages in law enforcement practice and to formulate proposals to avoid them by delimiting the functions of these subjects.

The comparative method was used in the analysis of the peculiarities of regulation of organizational and legal relations between the subjects involved in clinical trials in different countries. In solving the research problems other methods have been used, such as formal-logical (to identify differences between the subjects of contracts made with different subjects involved in clinical trials), functional (in establishing the impact of the legal status of the subject on the content of services provided), sociological (when identifying factors affecting the dynamics of the number of registered clinical trials) and some others.

REVIEW AND DISCUSSION

Statistics data show that the number of clinical trials is growing differently in different regions. For example, in the regions of Europe, North and South America and the western part of the Pacific Ocean, it has recently grown much faster than in other areas of the world. Thus, in 2019 the number of registered researches in the western Pacific (16,675) was 23 times higher than the number of trials in Africa (716). Since 2016 the West Pacific region became the region with the largest number of registered trials per year due to the registration of a large number of trials in the People's Republic of China (hereinafter - the PRC) and Japan. Also, the number of registered new surveys is growing much faster in high-income countries. For example, in 2019 the number of registered surveys in high-income countries (27,461) was 84 times higher than the number of surveys in low-income countries (326) [2].

In Ukraine for the period from 1999 to 2019, 4,203 clinical trials were registered, which is 2.57% of the total number of trials registered during this time in Europe. For example, in the Republic of Turkey – 7,008 trials, in the Republic of Poland – 12,072, in the Islamic Republic of Iran – 22,897, in the Italian Republic – 23,097, in Canada – 27,185, in the Republic of India – 27,638, in the Federal Republic of Germany (hereinafter - Germany) – 39,580, in the PRC – 46,149, in Japan – 45,856, in the United States of America – 134,516 [2].

Legislation in the field of clinical trials is represented by the international acts, besides, by EU acts, and also by the national legislation of each state. The stage of development of each particular state's legislation was actively studied, including compliance with EU acts respectively [3-5].

The legislation regulates mainly public-law relations concerning clinical trials (in particular, the procedure for their state registration, assessment of moral, ethical and legal aspects, monitoring, etc.), and the contract is a regulator of private-law relations arising between the customer of the clinical trial (hereinafter - the sponsor) and its executors and other subjects involved in its realization (determines, in particular, the rights and obligations of the parties, the procedure and amount of payment for relevant services and works, conditions for ensuring the confidentiality of research data, protection of personal data and rights to intellectual property used or created as a result of testing, issue of storage of research documentation, use of its materials, interaction with regulatory authorities and other people involved in its implementation).

The clinical trial is preceded by a stage of contractual registration of relations with the subjects involved in its execution, in particular, with the contract research organizations (further - CRO), its executors (in particular, research centers - health care institutions, scientific institutions, medical universities and also researchers, co-researchers, research coordinators, laboratories), science center management organizations (hereinafter - SMO).

When conducting clinical trials, the sponsor often uses an intermediary model of relationships with other trial participants, involving the CRO, which deals with pre-contractual and contractual work with performers and other trial participants. According to paragraph 1.20, the ICH GCP CRO is the organization to which the sponsor officially delegates one or more of its responsibilities and functions for conducting a clinical trial [6].

If in the early 1970s there were about 50 CRO in the world, in 1980 there were 150, in the mid-90s of the 20th century there were 1,500 and now there are about 2,500 of them worldwide, among which 500 are in the United States, 200 in the United Kingdom, 150 in France, 100 in Germany. Today, CRO has become an important element of the clinical trial system. For example, most Japanese pharmaceutical companies conduct clinical trials abroad only through CRO [7, p. 118, 119].

At the same time, some researchers claim that CROs complicate the process of negotiating contracts with the subjects of the research [8, p. 549].

The most common model of building organizational and legal relations between the subjects involved in clinical trials is the sponsor' ordering (CRO on behalf of the sponsor) to complete the clinical trial in the health care institution (hereinafter - the hospital), which conducts such research.

Normative regulations on the organization of clinical trials in different countries have otherness that affects the contractual registration of such legal relations.

For example, in the Republic of Finland, such a contract sets out the rights and responsibilities of the researcher as

Fig. 1. Model of linear relations of clinical trials participants.

a hospital employee. The British legislation stipulates that the researcher is an employee of the institution responsible for the organization and payment of his work, and if the researcher is not an employee of the institution, this institution undertakes to determine the issue of payment with its direct employer [9, p. 149].

Therefore, in the latter case, the executor of the clinical trial (hospital) independently involves, if necessary, another organization, whose employees will be researchers, while remaining responsible to the sponsor for the implementation of the contract. Such a model of organizational and legal relations of the participants of the clinical trial can be conditionally named the model of linear relations (Fig. 1).

The second model of organizational and legal relations between the subjects involved in clinical trials (it is common, in particular, in Ukraine and some other post-Soviet countries), can be provisionally named as model of parallel relations (Fig. 2), is characterized by making a contract with (by the sponsor (CRO)) :

1) a hospital in which the place of the trial conduct is determined (hereinafter - PCT), as well as a higher medical educational institution (hereinafter -HMEI) or a scientific institution (hereinafter - SI), if they are involved in the clinical trial;

2) researcher, co-researchers, trial coordinator, institutions involved in laboratory and (or) diagnostic tests that cannot be performed in the hospital.

Thus, the peculiarity of this model of contractual regulation of organizational and legal relations in the field of clinical trials is that in case of need to involve other (then hospital) person to perform a clinical trial or provide related support services, the sponsor enters into particular contracts with such subjects.

In Ukraine the first model is used in private hospitals, and the second one is used in state and municipal hospitals, which is explained by the peculiarities of the legal regime of state and communal property, the legal personality of such hospitals for entering into contracts and regulatory requirements on giving wages to their employees.

The possibility of entering into a contract with a researcher by the sponsor is provided, for example, in the Rules of Good Clinical Practice of the Eurasian Union 2016, which states: financial issues of the study should be reflected in the contract between the sponsor and the researcher (medical institution) (subparagraph 4.9.6 and paragraph 5.9.); entering into a contract between the sponsor and the researcher (medical institution) or any other part participating in the clinical trial (subparagraph 5.1.4.), in particular, between the sponsor and the CRO, and if necessary – between the researcher (medical institution) and the relevant authority (subparagraph 8.2.6) [10]. Similar norms are contained in the National Standard of the Russian Federation "Appropriate Clinical Practice" [11].

The organization of a clinical trial in the second model may be accompanied by entering into a contract on:

1. conducting a clinical trial: between a sponsor (CRO) and a hospital (where the PCT is defined) or between a sponsor (CRO), a hospital and HMEI or SI, if they are involved in conducting a clinical trial on a hospital basis;
2. the provision of additional services and (or) the performance of work related to clinical trials between the sponsor (CRO) and the researcher and (or) other subjects involved in the clinical trial (in particular, with the trial coordinator);
3. provision of laboratory or medical diagnostic services (eg. computer tomography) by the sponsor (CRO), if such services cannot be provided by the hospital where the PCT is defined. In the first model, such contract is not made by the sponsor, but by the hospital;
4. cooperation between the hospital and HMEI or SI, if the clinical study involves a researcher - an employee of the department of HMEI or SI, which do not have their own clinical base;
5. cooperation between the hospital and the researcher, other subjects involved in the clinical trial, provided that the sponsor (CRO) makes a contract with such persons for the provision of services and (or) performance of work related to the trial.

It should be noted that the subjects of the contract made by the sponsor (CRO) with different entities are different.

The subject of the sponsor's contract (CRO) with the hospital (HMEI or SI) is the implementation of clinical trials. The hospital provides these services with the help of its available material and technical base and its employees (doctors, other medical staff).

In this case, the researcher does not have the status of a contract party (hospital holds this status), and performs actions as a hospital employee. The relationship between the hospital and the researcher is regulated by labor legislation. Ukrainian legislation stipulates that the hospital conducts the main activities of clinical trials (patients treatment, observation, etc.), as it defines the PCT [12].

Therefore, the sponsor's contract (CRO) with the hospital cannot be considered as an agreement on the use of only material and technical resources of this institution. The hospital is a participant, that is an entity that conducts a clinical trial (but not the area of its conduction, a set of buildings, equipment and facilities).

So, the conduct of clinical trial protocol procedures related to medical decision-making should be specified in

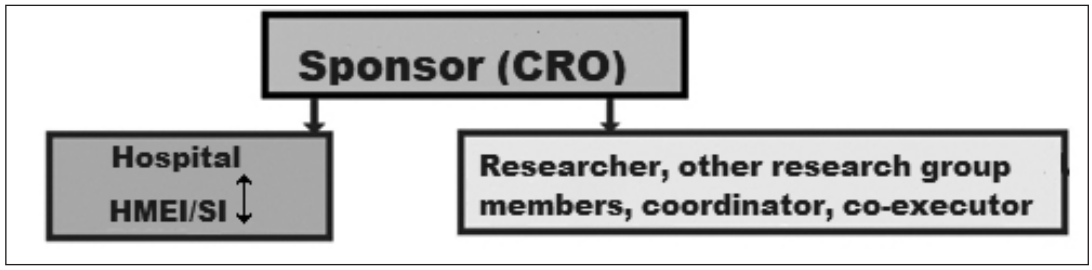

Fig. 2. Model of parallel relations of clinical trials participants

the contract with the hospital, and if the latter is not able to conduct a specific diagnostic or laboratory research, in the contract with other institutions involved in providing relevant services (work implementation).

The contract with the researcher, as well as with other subjects involved in clinical trials, includes those works (services) that are additional (to the "medical part" of the clinical trial protocol) and, mainly, intellectual and organizational by the nature.

Entering into the particular contract with a researcher (another member of the research team) occurs when, within a clinical trial, he is assigned responsibilities that he does not perform within his duties in the hospital during working hours. This occurs because the relevant work or service is not covered by the doctor's job function in the hospital, or because the contract, made by the sponsor (CRO) with the hospital, does not provide relevant work or service.

Based on a separate contract, the sponsor (CRO) may order information from the researcher, in particular, consulting services, information and methodological support for clinical trials, services for organizing the trial process and (or) the process of attracting subjects, creating intellectual property objects, management, supervision and coordinating the research team, supporting the monitoring and audit of testing, generating, quality assurance, collecting, processing, compiling and transmitting research data to its sponsor.

Works (services) ordered by the sponsor (CRO) from the researcher are paid for in favor of the latter. For the work performed by the researcher during the working hours in the hospital, the funds are received by the hospital, which personally decides on the payment of its employee.

Analysis of the content of a large number of agreements concluded between these persons within the second model of contractual relations of clinical trial participants in Ukraine, shows a mostly formal approach to determining the terms of these agreements, which leads to similarity (sometimes identity) of the content of agreements between the sponsor (CRO) and the hospital with the content of the agreements between the sponsor (CRO) and the researchers (co-researchers, coordinators) and the lack of specification of the responsibilities of the hospital and the researcher as separate participants of the clinical trial.

This is partly because it is based mainly on agreements developed in other countries (using the first model of contractual regulation of relevant relations), which try to formally adapt to the legislation of the PCT. Usually, it leads to the use of legal constructions that do not comply with the PCT legislation. Similar draft contracts are tried to be used in the registration of contractual relations with the researcher (co-researchers) for additional services (works), often replacing only the hospital data with the data of the researcher (co-researcher). It is common to specify in the draft contract that the researcher is given the responsibilities of the hospital, and in the contracts with the hospital that is given the responsibilities of the researcher as its employee, and not the hospital as a party to the contract.

Incorrect or unclear definition of the subject and other contract terms between subjects involved in the clinical trial reduces the effectiveness of its conduction; depersonalizes responsibility for conducting clinical trials; raises issues about the fairness of payment for the services of the hospital and the researcher; can affect researchers' income taxation.

The agreement with the researcher may contain terms for the sponsor's (CRO) reimbursement of the latter's costs for the patient's participation in the clinical trial (in particular, reimbursement of transportation costs for the visits to the hospital).

There are two options for payment of the compensation:

1) the researcher spends his own money to cover the patient's transportation costs. In this case, the sponsor (CRO) does reimburse the researcher for the money spent. The payment of such compensation is usually related to the researcher's invoices, which indicate the amount of money spent and the impersonal data of the patients whom such compensation was paid out;
2) the sponsor (CRO) allocates funds in advance to cover the transport costs of patients, transferring them to the researcher, who transfers these funds to patients. In practice, such costs are not separated from the payment received by the researcher from the sponsor (CRO).

EU regulations allow compensation for costs incurred by research subjects in connection with participation in the trial [13, p. 189].

In the EU these issues are covered by Regulation (EU) №536 / 2014 [14], which prohibits the provision of material reward or financial incentives (other than compensation) for minors and incapacitated persons. The Regulation (EU) provides the possibility to pay compensation not only for damage to their life or health, but also for costs incurred in connection with the trial for vulnerable research groups of subjects.

Organization of compensation of expenses of subjects for participation in a clinical trial is a service of the spon-

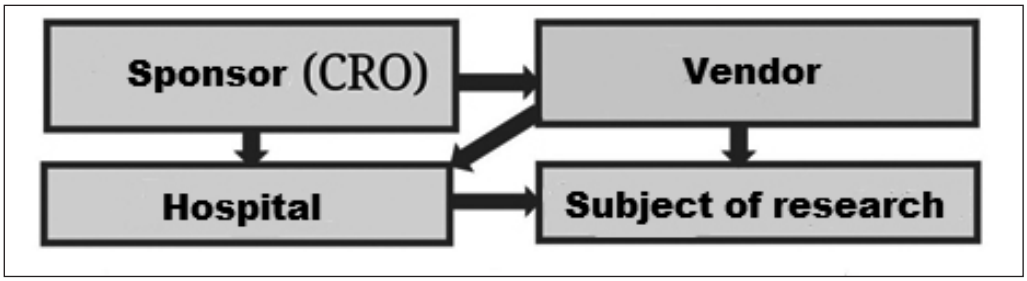

Fig. 3. Organizational and legal relations between participants of the relationship on payment of the research subject's participation in the clinical trial

sor's researcher, provided at the expense of the latter, and the funds provided in the contract with the researcher as reimbursement of patients' visits are not paid for services (works) of the researcher. They may be considered by the researcher's costs related to the services provided to him if the latter include the organization of such visits.

Payments of compensation and (or) rewards to research subjects for participation in a clinical trial should be mentioned in contracts with the researcher or with other subjects that provide services for organizational support of such payments to patients if such payments are agreed upon in the prescribed manner.

The relationship between the hospital and the researcher (co-researcher, coordinator) as a separate entity involved in conducting a clinical trial on the basis of the hospital, regardless of whether he is a hospital employee (HMEI or SI), may be regulated in the cooperation agreement with the hospital. It is also advisable to regulate the interaction of such subjects during the provision of services (implementation of work) related to the trial in the sponsor's contract (CRO) with the hospital to conduct the trial.

If during the clinical trial there is a need to involve staff to perform work (services) not related to medical decision-making (coordination and logistics of patient visits to the hospital, accounting for trial materials and investigational medicinal products, technical support and providing some research procedures, filling out individual registration forms, cooperating with the hospital ethics commission, maintaining a quality control system, preparing reports, ensuring proper paperwork, etc.), research coordinators, data entry specialists, quality specialists, pharmacists may be involved in their implementation.

Thus, it is common in the world practice of conducting clinical trials to appoint a researcher in the PCT Study Coordinator, Clinical Research Coordinator, who is a specially trained person who will assist the researcher in organizing the clinical trial, besides, will deal with the logistics of research materials, laboratories, visits subjects of research, control over the maintenance of primary medical records, filling out individual registration forms. The responsible researcher may delegate his / her responsibilities to the Study Coordinator, except for medical decisions and general control over the implementation of the study in the PCT [15].

If specified duties are not included in the scope of responsibilities of the hospital (HMEI, SI), defined in the contract for the clinical trial, the sponsor (CRO) or the researcher in agreement with the sponsor (CRO) enters into a separate contract with the coordinator for relevant services (work), because the participation of the coordinator cannot be provided in this case by delegation – the researcher cannot delegate more powers than he has.

Also, during the clinical trial a co-researcher doctor or nurse (for laboratory and analytical work in the local laboratory, preparation of tests for the central laboratory, etc.), pharmacist (for acceptance, registration, accounting, preparation, issuance to the researcher of the study medicinal product, temperature register, maintaining documentation related to the medicinal product), narrow specialists (radiologist, bacteriologist, endoscopist, infectious disease specialist, ultrasound diagnostician, neurologist, etc.) may be involved [16, p. 24-25]. If their activities are covered by a hospital contract with a sponsor, the sponsor (CRO) does not enter into separate agreements with them.

In general, the list of persons who can be involved in a clinical trial is not legally limited, the range of these persons and their responsibilities are determined by the sponsor (CRO), or in each particular trial, taking into account the protocol and design of the trial, and also the number of subjects under this trial.

The second model of organizational and legal relations in conducting clinical trials, is characterized by the entering into contracts by the sponsor with both the hospital and the researcher, other persons who provide services (perform work) related to clinical trials that are additional to the hospital services, is strictly prohibited in the legislation of some states. For example, in the UK, some financial arrangements between the sponsor (CRO) and any other hospital unit (including pharmacies) or the university where the researcher works are prohibited (financial issues must be settled between the hospital and the relevant entities) [9, p. 149-150].

In world practice, the involvement of SMO into clinical trials is widespread.

It should be noted that:

1) The SMO may be involved by both the sponsor (CRO) and the hospital, and its functions (rights, responsibilities) in conducting the clinical trial are defined in the contract.

The SMO can perform auxiliary functions (choosing a hospital for a specific clinical trial and coordinating its work, finding patients, technical support, control and risk management, staff training, logistics of clinical trial procedures, organization of transportation services, etc.) that

improve trial management and administration positively influencing its holding [9, p. 160].

The SMO may perform technical work and provide other non-clinical analytical, consulting services necessary to ensure the clinical trial, in particular: interact with the ethics committee, translate, copy, prepare documents and other specialized auxiliary office activities; coordination, organization and control over the maintenance of clinical trial documentation; control over the completeness and timeliness of providing the customer with a trial of reporting information; organization (if necessary) of involvement of independent consultants on technical issues (in particular, to ensure the operation of medical equipment used during the study, if the relevant specialists are not in the hospital).

2) SMO is a different organization from CRO. If, despite its name, SMO, such an organization actually performs the functions and powers of the CRO, it will be subject to the requirements of the legislation on the CRO [17].

The nature of the services (works) ordered by the sponsor (CRO) in SMO may determine the need to conclude a contract with the hospital (researcher) or to regulate the procedure of its interaction with the hospital (researcher) in the sponsor's contract (CRO) with the hospital (researcher).

The organization of payment for the benefit of research subjects of certain funds, if it agreed in the manner prescribed by law, may be an independent subject of the contract made by the sponsor (CRO) with the vendor, which undertakes obligations to organize and conduct on behalf of and for sponsor account these payments. The subject of such agreement is services for the organization and payment of compensation in favor of the subject in connection with his participation in a clinical trial.

Implementation of such an agreement requires entering into contract with the subject of the research, which may be called a "contract for the provision of services related to the patient's participation in a clinical trial." The subject of the research does not provide services under this agreement to the specified vendor. Such a vendor acts as an agent (representative) of the sponsor based on a contract for the provision of services for the organization of the relevant payment (Fig. 3). The data obtained from the results of the research are not transferred to this vendor, it is the sponsor's property and its transfer to the latter is regulated in the sponsor's (CRO) agreements with the hospital and (or) with the researcher.

It should be noted that the agreement between the vendor and the subject does not oblige the latter to participate in the clinical trial. The reference to the fact that the subject of the trial, having given informed consent to participate in the clinical trial, has agreed to participate in it, is used in such an agreement only to indicate the condition of its conclusion and does not violate the right of this subject to terminate at any time in this trial and is not coercion to such participation.

Polar provisions are expressed regarding the payment of the research subject's participation in the clinical trial, namely:1) such payment may reduce the participant's understanding or the voluntariness of his informed consent; 2) the absence of such payment may be unethical, as participants should be rewarded for their contribution to the public good and involved in the profits of the research [18].

A study of the impact of rewards on a patient's willingness to participate in a clinical trial found that a high payment motivated him/her to participate in the study, but there was no evidence that the payment rates commonly used was unreasonable or unfair incentives [19]. During the study of the impact on the motivation of healthy volunteers, residents of European countries, it was found that: the financial motive was the main for 53.3% of them, 27.8% indicated that the motive for their participation was the desire to contribute to pharmaceutical and medical science; for 12.7% it was a social responsibility, for 6.2% it was the opportunity to get a quality free modern examination [20, p. 32].

Payment for clinical trial participation as coercion is highly rare, as it requires a certain threat of harm to life, health or loss of property. Relevant risks should be assessed during the approval of the test report, and their acceptability must be approved by the competent authorities [13, p. 185].

For example, the US Food and Drug Administration (FDA) has defined guidelines for evaluating these payments, including payment should be made during the trial and not depend on the subject's participation until it is complete; payment that encourages continued participation in the trial is acceptable but should be a small fraction of the total. In 2014, the UK Department of Health (HRA) issued a Guide to Payments and Incentives in Clinical Trials, which provided ethics committees with guidelines for assessing the acceptability of financial incentives, such as determining the proportionality of burden payments to research (in particular, the number of required hospital visits, medical procedures, keeping certain diaries, filling out questionnaires) [13, p. 187-188].

As a result of the study, two models of contractual regulation of organizational and legal relations between the subjects involved in the clinical trial were identified. The first model is more convenient for the sponsor, as he usually concludes a contract through the CRO for a clinical trial with a hospital, which itself involves co-contractors (subcontractors), concluding contracts with them, retaining responsibility for the contract with the sponsor. This model is the most common in world practice and in some countries it is the only one acceptable. The second model is common in some post-Soviet countries and is more complicated for the sponsor, as it requires the making of a contract with a hospital for a clinical trial, as well as contracts for additional work and services with other entities involved in such a trial (members of the research group, research coordinator, HMEI, SI, other medical institutions that will provide laboratory and diagnostic services). The organizational and legal relations that arise in the case of reimbursement of expenses by the sponsor and making payments to the subject of the trial are also considered. The results of the study can be used in further research of legal relations in the field of clinical trials, as well as law enforcement practice of their contractual regulation and in improving of the current legislation.

CONCLUSIONS

The proper organization of relations between different participants in clinical trials is the key to their clear and timely implementation. Such relationships will be governed by agreements between the sponsor and other subjects involved in the clinical trial. The participation of CRO and SMO in such legal relations is considered traditional.

The analysis of the regulatory framework and law enforcement practice allowed to identify models of linear and parallel organizational and legal relations between the subjects involved in the clinical trial, which affects their contractual registration.

The first is the most common model, which is that the sponsor (CRO) orders a clinical trial in a hospital, and the latter, if necessary, can involve other subjects to perform the contract.

The second model is characterized by the making of sponsorship (CRO) contracts with the hospital in which the PCT is defined, and also with the researcher, co-researchers, test coordinator, institutions involved in laboratory and (or) diagnostic tests that cannot be conducted in the hospital. In this case, the second group of agreements is concluded by the sponsor (CRO), mainly with subjects that are both employees of the hospital (or HMEI or SI involved into the trial by the sponsor) and within their working hours perform the sponsor's agreement with the hospital, and in free from work in the hospital time perform their own contracts with the sponsor.

The organization of a clinical trial in the second model may be accompanied by a set of agreements: 1) for a clinical trial: between the sponsor (CRO) and the hospital or between the sponsor (CRO), hospital and HMEI and (or) SI, if the latter are involved in the clinical trial on the basis of the hospital; 2) provision of additional services and (or) performance of work related to clinical trials between the sponsor (CRO) and the researcher and (or) other subjects involved in the clinical trial (in particular, the trial coordinator); 3) on cooperation between the hospital and HMEI or SI, if their employee is involved in the clinical trial as a researcher; 4) cooperation between the hospital and the researcher, other entities involved in the clinical trial, with which the sponsor (CRO) has entered into a contract for the provision of services and (or) work related to the trial; 5) on the provision of laboratory or diagnostic services between the sponsor (CRO) and specialized institutions (if they cannot be provided by the hospital where the PCT is defined).

The complexity of organizational and legal relations in the second model determines the need for an attentive attitude to the subject and terms of contracts, which should clearly delineate the functions of all persons involved in the clinical trial.

A sponsor (CRO) or hospital may engage SMO on a contractual basis to perform work (services) related to a clinical trial. If the sponsor (CRO) orders from the vendor services to organize the payment of the subject of the study, a contract may be concluded between this vendor and such a subject to regulate the procedure and conditions of the payment mentioned. This agreement may not restrict the latter's right to refuse to take part in the trial.

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REVIEW ARTICLE

LEGAL ENFORCEMENT OF STATE AID CONTROL IN THE FIELD OF HEALTHCARE: EXPERIENCE OF UKRAINE IN THE CONTEXT OF EUROPEAN INTEGRATION

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ABSTRACT

The aim: The purpose of this article is to concretize the directions of improving legal support of control over the state aid in the field of health care.

Materials and methods: The study analyzed the sources of the European Union law and legislative acts of Ukraine on the provision of state aid to business entities, relevant materials of the Antimonopoly Committee of Ukraine, including more than 20 decisions taken by this body based on the notification review results of the state aid provision in the field of health care. The methodological basis of the research consists of general and special methods of scientific research, in particular, dialectical, analytical-synthetic, system-structural, formal-logical, comparative legal methods.

Conclusions: Based on the results of the study directions for improving legal support for state aid control in public health sector have been proposed, in particular, legal qualification of the activities of health care providers, determining whether certain types of public health activities belong to those that constitute a common economic interest and finalizing the criteria used to assess admissibility of state aid in this area.

KEY WORDS: state aid, health care, control

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INTRODUCTION

An important task of modern democratic states is to create conditions for the preservation and strengthening of people's health, providing them with high-quality medical services. One of the means of implementing this task is the use of various forms of state support for business entities operating in the healthcare sector. The need to provide such support is due to the fact that health care activities are of great social importance and cannot always be carried out on a purely commercial (market) level since in a socially oriented country every citizen should have the opportunity to receive a necessary treatment regardless of financial capabilities. At the same time provision of state support in this area is associated with the risks of distorting economic competition, unreasonable gain by certain economic entities of competitive advantages over other entities. This, in turn, gives grounds to consider such support as "state aid to business entities", which is subject to control by specially authorized bodies.

In the European Union countries provision of state aid in the health sector with the application of the rules for monitoring such aid is a fairly common practice. So, as of September 2020, the information search system of the European Commission contains information on 120 cases on the provision of state aid (support) in this area [1]. Unlike the European Union countries, in Ukraine the system of control over state aid to business entities was introduced relatively recently. In particular, in accordance with the Association Agreement between Ukraine and the European Union (ratified by Ukraine on September 16, 2014), Ukraine has undertaken to adopt national legislation on state aid, adapting it to the relevant rules of the European Union. The Parties have agreed that they will apply the Articles of Agreement on the state aid matters using as a source of interpretation the criteria arising from the application of Articles 106, 107 and 93 of the Treaty on the Functioning of the European Union, in particular, the relevant jurisprudence of the Court of Justice of the European Union, as well as relevant secondary legislation, framework provisions, guidelines and other existing administrative acts of the Union [2]. In fulfillment of these obligations, the Law of Ukraine "On State Aid to Business Entities" [3] was adopted, the effect of which extends, among other things, to relations on exercising control over the provision of state assistance in the field of healthcare.

The primary experience accumulated in Ukraine in the application of EU rules in the state aid control in the above-mentioned area indicates the existence of problematic legal issues, the solution of which may be of interest both for this country and for other countries practicing state assistance to providers of medical and related to its services.

The above indicates the relevance of the stated topic and the expediency of its research.

THE AIM

The purpose of this study is to concretize the directions for improving the legal framework for monitoring state aid in the health sector.

MATERIALS AND METHODS

To achieve this goal relevant provisions of the Treaty on the Functioning of the European Union were analyzed, as well as the main official documents of the European Commission and the Court of Justice of the European Union, which are important for the legal qualification of certain state aid measures. Critical analysis of the relevant legislation of Ukraine was carried out. Review of the Antimonopoly Committee of Ukraine (hereinafter referred to as the Authorized Body for State Aid) status reports on the provision of state aid to business entities in Ukraine for 2017-2019 was summarized. The content of all decisions taken by the specified authorized body in the period from January 2018 to August 2020 based on the notifications review results on the provision of state aid in the health sector (23 decisions in total) was processed.

In the course of the analysis of the materials general and special methods of scientific knowledge, in particular, dialectical, analytical-synthetic, system-structural, formal-logical, comparative-legal methods were used.

REVIEW AND DISCUSSION

In accordance with the Treaty on the Functioning of the European Union in its activities the Union respects the obligations of the member countries to define their health policies and to organize and provide health care and medical services. The responsibility of the member states includes management of health services and medical care as well as the allocation of resources dedicated to them (part 7 of article 168). At the same time health sector is a subject to provisions of the same Treaty which establish general principles for the provision of state aid by member states and control over state aid (Articles 107-109) [4].

Taking into account the law of the European Union in the legal systems of the countries concerned, there has been applied an approach, according to which state support of economic entities is the object of control, which meets certain criteria, the presence of which gives grounds to qualify certain support measure as "state aid to a business entity". In particular, in Ukraine, state support is considered state aid if it simultaneously has the following features: 1) provided to a business entity; 2) carried out at the expense of the state or local resources; 3) creates advantages for the production of certain types of goods or the implementation of certain types of economic activity; 4) distorts or threatens to distort economic competition (Article 1 of the Law of Ukraine "On State Aid to Business Entities").

In case if a certain planned measure of state support of economic entities (including those carrying out activities in the field of health care) meets the above four criteria, then executive authorities or local governments intending to provide such support are obliged to submit notifications of new state aid to the Authorized Body for State Aid. Such state body reviews submitted notifications, establishes affiliation of the proposed state support measure to state aid and decides on admissibility or inadmissibility of its provision, taking into account the legislative requirements.

However, in contrast to the features of state aid enshrined in Article 107 of the Treaty on the Functioning of the European Union in some countries (including Ukraine) there is no mandatory presence of such a qualifying feature of state aid as the impact on international trade. As a result, control is exercised over state aid which does not affect international trade but concerns the state of competition only in domestic commodity markets.

Health care activities are among the economic activities that most often receive notifications of state aid from the State Aid Authority. So, according to the analysis results of the activities of such a body in Ukraine it was found that in 2018-2019 the health care sector entered the top ten spheres of economic activity in respect of which the authorized body for state aid has considered a notification on state aid [5, 6]. From January 2018 to August 2020, this regulatory body adopted:

18 decisions according to which certain measures of state support in the field of health care are recognized as non-state aid (including 5 decisions in 2018; 6 decisions in 2019; 7 decisions in 2020);

5 decisions by which measures of state support in this area are recognized as state aid, which is permissible for competition, provided that its suppliers and recipients fulfill additional obligations determined by the controlling body (including in 2019 - 1 decision; in 2020 - 4 decisions) [7].

The above shows that in most cases applicants incorrectly qualify certain measures of state support, mistakenly considering them to be state aid. At the same time the analysis of the decisions taken by the controlling body that the problematic issues stem from the payment of medical services from various sources. Thus, state and communal health care enterprises (institutions) within the scope of the state guaranteed volume provide certain medical services that are free of charge for patients and financed from the state budget, and have also the right to provide other medical services to patients on a paid basis. Accordingly, in case of providing these enterprises (institutions) with state support in any form the question arises about the legal qualification of such measures. At the same time such a qualification requires clarification of the nature of the activity of the support recipient (economic or uneconomic activity) [8; 9].

For the formation of national law enforcement practice it is important to consider the relevant sources of European Union law. From this perspective the Notification from the European Commission on the concept of state aid in accordance with Article 107 (1) of the Treaty on the Functioning of the European Union which, among other

things, contains a separate subdivision - "Health care" (subsection 2.4), is especially significant. It stipulates that the health systems of different member states of the Union differ significantly. The availability and level of competition between healthcare providers depends on these national characteristics. In some member states public hospitals are an integral part of the national health system and are entirely based on the principle of solidarity (the national health system in Spain is a prime example). These hospitals receive direct funding from social contributions, other government resources and provide their services free of charge to all categories of the population. The European Court of Justice has confirmed that, given the existence of such a system, the organizations concerned are not considered to be economic operators. If such system exists, then even an activity that is inherently economic but carried out for the purpose of providing another non-economic service is not considered an economic activity. An organization that buys goods - even in large quantities - for the purpose of providing a non-economic service is not considered a business entity because it simply acts as a buyer in the relevant market. In addition, it was stated that in many other member states hospitals and other health care providers offer their services for a fee that is paid directly by patients or through their health insurance. In such systems there is a certain level of competition between hospitals in the provision of health services. In this case the fact that the medical service is provided by a public hospital is not sufficient for the relevant activity to be considered uneconomical. According to the explanation of the EU court, medical services provided by private doctors and other specialists for a fee and at their own risk should be considered an economic activity. The same principle applies in the case of pharmacies [10]. A similar position is set out in Notification from the Commission on the application of the European Union State aid rules to compensation granted for the provision of services of general economic interest [11]. At the same time an overview of various models of financing enterprises and healthcare institutions in the EU member states (Germany, Netherlands, Spain, Poland, Czech Republic) is presented rather thoroughly in Section 4 of the Report Study on the financing models for public services in the EU and their impact on competition [12].

To find out whether certain measures to support business entities in the health care sector belong to state aid the legal positions set forth in other sources of European Union law are also important. In particular, the European Commission Resolution SA 39913 (2017 / NN) on the compensation of public hospitals indicates that the EU courts have confirmed: in those systems (in particular health care systems) where services are funded directly from social insurance fees and other public resources, and are also provided free of charge or with a small part of expenses coverage by affiliated persons for basic universal services, the respective organizations do not carry out business activities. The activities of medical institutions which are almost entirely functioning on the principles of solidarity and universality can be considered uneconomical for the purposes of assessing public assistance [13]. Paragraph 39 of General Jurisdiction FENIN Court Statement (T-319/99) determines that under the condition of the existence of a solidarity system, medical institutions are not considered subjects of economic activity [14]. Along with this the decision of Ambulanz Glöckner (C-475/99) of the EU Court of Justice noted that the services of medical organizations provided for a fee from end consumers in the market of relevant medical services are considered an economic activity [15].

At the same time legal qualification of the activities of medical institutions in national health systems, based on the principle of solidarity, is still not unambiguously resolved. Thus, in addressing this issue, Pedro Cruz Yábar focused on the legal position set out in the Judgment of the General Court in the case of the Coordination of Bruxelloise d'institutions sociales et de santé (CBI). In this case the Court agreed with the Commission's decision, which emphasized that any activity involving the supply of goods and services in a given market is an economic activity. Even if medical services were provided almost free of charge (end-users paid only a small part of the costs), it cannot be ruled out that the same services may also be provided by a private operator for a fee [16]. In its judgment the Commission referred to the judgment of the European Court of Justice in the case of Smits and Peerbooms, which applied the following position: the fact that hospital treatment is financed directly by health insurance funds on the basis of agreements and predetermined cost of services does not in any way preclude such activities from the sphere of economic activity. The concept of economic activity does not require that the service be paid for by those to whom it is provided. Payments made by health insurance funds are a reward for the medical services of the hospital that provides them, and which carries out economic activities [17]. In view of this Pedro Cruz Yábar rightly states that the indicated decisions of the Commission and the Court in the CBI case do not agree with the position set out by the Commission in the Communication on the application of the European Union State aid rules to compensation granted for the provision of services of general economic interest. As the interpretation contained in the judgment of the Court of Justice necessarily prevails over the interpretation previously set out in the Commission's Communication, it can be concluded that the interpretation available in the Communication does not currently apply. Hence, in principle, it should be borne in mind that a hospital providing medical services is an enterprise even when those services are not paid for by those who directly benefit from them and/or when the hospital operates in accordance with the principle of solidarity. However, this issue remains open, given the limited number of precedents, and current situation may change in future decisions of the Commission and the Court of Justice [18].

Thus, the above indicates the expediency of clarifying in the official documents of the European Commission its position on the qualification of the activities of health care providers to resolve the contradictions described

above. In its turn, at the national level, in the explanations of the authorized competition authorities it is advisable to specify the conditions for recognizing state aid measures of state support for healthcare enterprises (institutions), considering the possibility of simultaneous financing of their activities from different sources.

Alongside, there are problems with the qualification of state aid in relation to certain types of economic activities in the field of health care and their classification as those of general economic interest. The legal basis for raising such issues is Article 106 of the Treaty on the Functioning of the European Union, according to which business entities entrusted with the management of general economic interest services or which have features of profitable monopoly are subject to competition rules, provided that the application of such rules does not legally or actually interfere with the performance of certain tasks assigned to them. An explanation of the key concepts underlying the application of state aid rules in compensation for services constituting a common economic interest is set out in the above-mentioned Communication from the EU Commission on the Application of the EU State Aid Rules to compensation provided for the provision of services constituting a common economic interest 2012 / Since 8/02 [11]. In addition, the judgment of the European Court of Justice of 24 July 2003 № 280/00 in the case of Altmark Trans Gmbh, Regierungspräsidium Magdeburg v Nahverkehrsgesellschaft Altmark Gmbh, which sets out the criteria, according to which compensation for business entities for the costs associated with the provision of general services economic interest cannot be considered state aid [19].

As Johan W van de Gronden points out, the Altmark approach could be of great interest for health care, as universal coverage plays a major role in this sector. However, it is strongly depends on how the Community courts interpret the Altmark criteria. If they use a strict reading of the Altmark judgment many national compensation measures will be found incompatible with Article 87 (1) EC. Consequently, proper execution of many PSOs will be put at risk due to the standstill provision of Article 88 (3) EC. Conversely, a flexible interpretation of the Altmark criteria will prevent these problems from occurring [20].

However, there is currently a contradictory approach in national legal systems (particularly in Ukraine). On the one hand, at the legislative level health services are not included in the list of services of general economic interest [21]. On the other hand, in practice, the State Aid Authority recognizes that the establishment of such a list is not in line with European Union rules, according to which compensation for the provision of services, which are of general economic interest, is assessed according to the criteria for such support or is not considered State aid, or is considered State aid that is eligible for competition. Accordingly, there are cases when Authorized Body for State Aid recognizes certain activities related to the field of health care as being of general economic interest [22].

To eliminate this contradiction the initiative of the Authorized Body for State Aid in legislative amendments deserves support, taking into account the above-mentioned Judgment of the European Court in the Altmark case [23].

In the context of abovementioned, one can agree with Vassilis Hatzopoulos, who notes that the application of EU law requires the introduction of the "services of general interest" concept or "public service" in the field of health with a precise definition of its content. This is necessary both to identify which organizations can qualify as "customer organizations" and to apply the Altmark test [24].

Developing the thesis it is worth noting that according to paragraph 46 of the Communication of the EU Commission on the application of the state aid rules of the European Union to compensation provided for the provision of services constituting general economic interest 2012 / C 8/02, in the absence of specific Union rules governing the scope of the SGEI, member states have a wide margin of discretion in designating a service as SGEI and in compensating the service provider. The Commission's competence in this respect is limited to verifying whether a member state has made a manifest error in classifying the service as SGEI and to assess the state aid related to compensation [11].

Taking this into account the achievement of certainty in the application of rules for control over state aid could be facilitated by specifying in the explanations of national competition authorities and bodies implementing state policy in the field of health care, the list of activities in the health sector that can be considered as constituting common economic interest. Besides, at the level of national legislation it is possible to fix a list of special conditions for payment of compensation to healthcare enterprises (institutions) for reasonable costs for the provision of such services. It should be noted, however, that the European Commission is currently assessing the rules for public assistance for health and social services which are of general economic interest. Based on the results of such an assessment the Commission will make a decision to update the SGEI rules applicable to medical and social services [25], which in turn should be taken into account in further formation of national legislation and law enforcement practice.

Another difficult issue related to control concerns the determination of the conditions under which state assistance to business entities in health sector can be recognized as acceptable. Now legal regulation of this issue is based on general (framework) provisions of Article 107 of the Treaty on the Functioning of the European Union which, in particular, states the admissibility of state aid provided in order to promote the socio-economic development of regions in which the standard of living is low or the level of unemployment is high, and to facilitate the development of certain types of economic activities as long as such assistance does not adversely affect the terms of trade.

In the development of these provisions of the Treaty at the national level, the Criteria for assessing the admissibility of state aid to business entities to ensure the development of regions and support for medium and small businesses are approved [26]. Accordingly, the providers of state aid in the field of healthcare emphasize that such aid should

be aimed at promoting the socio-economic development of regions, and the Authorized Body for State Aid when assessing the admissibility of such aid checks it for compliance with the above criteria [9].

However, it is not always advisable to assess the admissibility of the provision of state aid in the health sector only on the basis of criteria that are calculated to ensure the development of regions. Indeed, the provision of such assistance can be aimed at achieving other goals which are referred to in Article 107 of the Treaty on the Functioning of the European Union. In this regard one of the directions for the development of national legislation on state aid should be further development of criteria for assessing the admissibility of state aid, taking into account the law of the European Union [27] and their application to assess the admissibility of state aid in health sector which aims to solve problems at the national level.

Issues of legal support for state aid include the accumulation of complete and reliable information at the national level in all existing state aid programs in terms of certain areas of economic activity (including health care). For example, in Ukraine there is still no accurate information on state aid which was provided in previous years (which should be a prerequisite for further review of such aid and assessment of its eligibility for competition). The reason for this is the insufficient level of providers awareness on the institution of state aid, improper fulfillment by some of them of the obligation to inform the supervisory authority about new and current state aid, imperfect processing of the information provided, etc.

To eliminate this problem, it is proposed to conduct a comprehensive inventory of all existing programs and measures to provide state support to business entities, the result of which should be the receipt of comprehensive information on the state of the provision of state assistance in general and in the context of individual areas of economic activity, including in the health care sector.

It can be based on an automated information retrieval system set up at the European Union level, which is designed to collect and search for information on state aid decisions, including such a criterion as the economic sector for which aid was provided. At the same time, Human health activities (Q. 86) are separately included in the list of various economic sectors which gives users the opportunity to receive and process information about state aid including this sector [1].

The implementation of these measures at the national level will be useful in exercising control by authorized bodies in the field of state aid, the creation and operation of national information systems for collecting, accumulating and processing information on state aid to business entities.

General issues related to the legal enforcement of state aid control at the level of the European Union and in individual countries were previously considered in the works of Pier Luigi Parcu, Giorgio Monti, Marco Botta [28], Vesna Tomljenović, Nada Bodiroga-Vukobrat, Vlatka Butorac Malnar, Ivana Kunda [29], Marcin Spychała [30], Marek Szydło [31], Marek Rzotkiewicz [32], A.A. Bakalinsky [33], AE Lillemäe [34] and other authors. Pedro Cruz Yábar [18], Johan W van de Gronden [20], V. Hatzopoulos [24] analyzed various aspects of the application of the European Union rules on the control of state aid in the provision of such aid in healthcare sector.

Research presented in this article made it possible to concretize provisions regarding legal support of control over state aid in this area in such aspects as: legal qualification of the activities of health care providers; determining the affiliation of certain types of activities in the field of health care to those of general economic interest; criteria used to assess the eligibility of state aid in this area; collection and processing of information on state aid programs and measures in the relevant sector of the economy.

CONCLUSIONS

The study shows that at the level of law and judicial practice of the European Union legal positions on the control of state aid have been formed regarding legal qualification of state aid in the field of health care, and which should be taken into account in the formation of national legislation and law enforcement practice in those countries, including Ukraine, where this issues exist. Wherein perspective areas for improving legal framework for monitoring state aid in the health sector can become:

clarification in the official documents of the European Commission regarding its position on the qualification of health care providers who receive funding from social contributions and other public resources and provide their services free of charge to the public;

specification in the explanations of the authorized national competition agencies of the conditions for recognition as state aid measures of state support for health care enterprises (institutions), taking into account the possibility of simultaneous financing of their activities from different sources;

implementation of the criteria determined by the Decision of the European Court in the Altmark case into national legislation, as well as the establishment of a list of special conditions for payment to health care enterprises (institutions) of compensation for reasonable costs of providing medical and other services of general economic interest;

further development by national authorities of criteria for assessing the admissibility of state aid, taking into account the law of the European Union and their application to assess the admissibility of state aid in the health care sector, which aims to solve problems at the national level;

ensuring the accumulation and publication of reliable information on the programs and measures of state assistance implemented by certain countries in various fields of economic activity, including the health care field.

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REVIEW ARTICLE

BUDGETARY TRANSFER AS A TOOL FOR FINANCING THE HEALTH SECTOR: THEORETICAL LEGAL ANALYSIS

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ABSTRACT

The aim: The purpose of the study is to: a) determine the purpose of budget transfers in the field of medicine; b) determine the characteristics that characterize budget transfers in the health sector; c) establish the significance of budget transfers in those jurisdictions in which the system of health insurance operates.

Materials and methods: The empirical basis of the study was the Report of the Minister of Health of Singapore, Information on the subvention section for 2019-2020 in Hong Kong, the Budget forecast of the US Congress for 2019, Reports of the Accounts Chamber of Ukraine for 2017, 2018 and 2019. Within the framework of this study, the following special legal methods of scientific knowledge were applied: comparative legal method, a normative-dogmatic method and a logical-legal method. The "case study" method was also widely used in this research.

Conclusions: Budget transfers in the field of medicine is a socially important institution of budget law. Budget transfers in the health care sector can be characterized by the following features: a) sectoral nature (health care sector) b) specific budgetary directions (movement of funds from the state to local budgets) c) widespread use (used both in states with medical insurance and in states where the health sector is entirely publicly funded).

KEY WORDS: budget transfers, subventions, medical subventions, financing of medicine, the health sector

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INTRODUCTION

Public finance plays an important role in ensuring the proper functioning of the health sector. Financing of medicine is one of the most socially important budget expenditures. There is an objective need to form a flexible mechanism for financing health care. One of the main instruments for establishing the appropriate flexibility is the institution of budget transfers. In countries that are focused on decentralization processes, budget transfers are a kind of instrument for "supporting" local budgets. Moreover, budget transfers are applied in all states, regardless of the administrative-territorial structure and form of government.

THE AIM

The practice of using budget transfers to ensure financing of the health sector is widely developed. At the same time, the variability of approaches to the formalization of this institution was stated. The objective of this study is to study the main aspects of the budget transfers regulation in the health sector.

MATERIALS AND METHODS

The empirical basis of the study was the Report of the Minister of Health of Singapore, Information on the subvention section for 2019-2020 in Hong Kong, the Budget forecast of the US Congress for 2019, Reports of the Accounts Chamber of Ukraine for 2017, 2018 and 2019. Within the framework of this study, the following special legal methods of scientific knowledge were applied: comparative legal method, a normative-dogmatic method and a logical-legal method. The "case study" method was also widely used in this research.

REVIEW AND DISCUSSION

Budget transfers in the health sector are widely used in various states. The main primary sources for the study of budget transfers should be the reports of the authorized bodies (long-term plans, forecasts), which analyze the procedure for using transfers to finance medicine. From the subvention distribution program for 2019-2020, it follows that the bulk of subventions in Hong Kong is directed precisely to the healthcare sector (36, 6% of the total number of subventions) [1]. At the same time, individual states, in particular, the United States, pay attention to the growth of medical expenses due to the increase in the beneficiaries of medical care. This is due, among other things, to the growing aging of the nation [2, p. 3]. From the analysis of the Report of the Minister of Health of Singapore, it follows that spending on the health sector in 2019 compared to 2018 increased, which necessitated an increase in subventions for medicine [3, p. 123].

This study also analyzed empirical materials related to budget transfers in Ukraine. We've found inconsistent approaches to the study of budgetary transfers to health care in the reports of the Accounting Chamber of Ukraine. The establishment of such an inconsistency of the Ukrainian supervisory authority raises questions. This necessitated the study of foreign approaches to the application of the institution of budget transfers in the health sector.

D. Clark notes that the task of proper regulation of public financing of medicine is: a) to minimize the inefficiency of the use of budget funds; b) to develop mechanisms for filling budgets; c) to develop efficiently functioning financial institutions; d) to ensure transparency and accountability of health financing mechanisms [4, p. 14].

Firstly, we should define such a concept as "budget transfers". Budget transfers are public funds that are transferred from one budget (federal budget, budget of a constituent entity of the federation, state budget, local budget) in favor of another budget. Accordingly, the following types of budgets can be conditionally distinguished: a) the "donor budget" (budget from which public funds are allocated) b) the "recipient budget" (budget in favor of which funds are allocated). Budgetary transfers are intended to provide efficient and flexible management of budget funds. Budget transfers can be classified according to several criteria. Depending on the purpose of the funds allocated, budget transfers can be divided into a) targeted (aimed to provide funding for a specific sphere of public life); b) aimless (allocated without indicating of their use; allows the managers of funds to independently choose the directions of their use). According to the specifics of the "direction" of funds movement, they are divided into: a) "vertical" budget transfers (funds are allocated from the budgets of the higher level in favor of the budgets of the lower level (in the case of a federal structure) from state budgets in favor of local budgets (in unitary states)) b) "horizontal" budget transfers (the movement of funds occurs between budgets of the same level). Budgetary transfers to health care are mainly targeted, "vertical" transfers. This is due to the understanding of the industry for which such funds are directed and the support of the central authorities to the local level of medical sector.

Targeted budget transfers in health financing are widely used. The following countries use such transfers: Japan, Singapore, Switzerland, Netherlands, Taiwan, USA [5], China (PRC) [6], Colombia [7, p. 41], Bulgaria [8, p. 142], Canada [9], Poland, Hungary, Czech Republic, Slovakia, Slovenia, Croatia, Estonia [10], etc.

The use of funds allocated for the medical sector in budgetary transfers depends on the model of medicine that is used by a particular country – it differs in states with medical insurance and states without medicine insurance; is excellent in economically developed countries and developing ones.

The problems associated with the use of budget transfers in the health care sector in China were studied by Liu K., Yang J. Lu S. In China, where elements of insurance medicine have been introduced, namely social and medical insurance, in order to ensure financing of medical services for the population with low-income subventions are used as part of medical and financial support programs. The aforementioned researchers note that, in fact, such budget transfers perform two tasks at once: 1) finance the participation of the poor population in China in social and health insurance; 2) ensure the purchase of medicines for such segments of the population. With the help of the program of medical and social support, 50.1% of low-income families participated in social health insurance programs, and 24.1% of such families received funds to purchase medicines [6]. In China budgetary funds in budget transfers are allocated not to ensure financing of medicine in full, but only to create conditions for participation in general health insurance programs for low-income segments of the population. In addition, funds from such programs are used to cover the costs of the drugs that such category of the population need. Colombia took a similar approach for reforming healthcare financing mechanisms in the 1990s. As D. McIntyre noted, in Colombia transfers from the state budget could only be used to ensure the participation of low-income segments of the population in medical and social insurance programs. At the same time, in the transition period, there was no complete cessation of budgetary support for hospitals [7, p. 41].

Another interesting example is the countries of Eastern Europe (Poland, Hungary, Czech Republic, Slovakia, Slovenia, Croatia, Estonia), which in 1990s carried out a reform of the national medicine financing system. The experience of the aforementioned countries has been studied by such scientists as I. Wilki and I. Mathauer. These scientists note that the countries of Eastern Europe were previously included in the sphere of political influence of the Union of Soviet Socialist Republics (USSR), which certainly could not but affect the system of financing national health systems. In the 1990s, the countries of Eastern Europe began the transition to insurance medicine, which, however, was not possible without state financial support for this area during the transition period. Moreover, even today social and medical insurance for certain vulnerable groups of the population is completely free (funded by transfers from the budget). Budget transfers were introduced simultaneously with the beginning of the reform of the healthcare financing system (except for Estonia, which started introducing social health insurance in 1992 and introduced budget transfers only in 1999). These vulnerable groups of the population mainly include: a) unemployed; b) pensioners; c) persons receiving social assistance; d) poor; d) persons under the age of 18. At the same time, in some countries (Czech Republic, Hungary, Estonia, Croatia), the number of persons whose participation in social and medical insurance is financed by budgetary transfers includes military personnel (not socially vulnerable groups) [10]. Thus, we must summarize that the financing of social and medical insurance for vulnerable groups of the population is not just an instrument of the transition period, but a completely effective mechanism for the implementation of social tasks.

Further, it is necessary to analyze the movement of such budgetary funds depending on the policy of administrative-territorial management applied by the state.

"Vertical" budget transfers are important not only for countries that have started the decentralization process, but also for countries with a traditionally strong municipal organization. For example, we can cite the United States, whose experience was studied by D. Vildasin. The scientist notes that in the United States transfers from the federal budget in favor of local budgets is a sustainable mechanism for ensuring the financial stability of such local budgets. At the same time, the healthcare sector is one of the areas that receive additional funding because of budget transfers [11 p. 47-48]. This indicates that the use of budget transfers (including subventions) as mechanisms for additional capitalization of health care is widely used not only in developing countries, but also in developed countries. Budgetary transfers for finance the health care sector are important to developing countries. Rajan D., Barrow H. and Stenberg K studied the experience of Mexico in this area. Researchers note that about 85% of all funds that are included in the federal budget for financing medicine is allocated from the federal budget of Mexico in favor of state budgets [12, p. 14]. This indicates a significant level of decentralization of management processes in Mexico in the budgetary sphere.

In Canada, budgetary transfers to health care sector have undergone a significant transformation. The Department of Finance of Canada studied historical stages of budget transfer institution for healthcare. This type of budgetary transfers received a relatively clear sectoral institutionalization in 1995 in the form of the Canadian medical and social transfer. In 2004, this unified transfer was subdivided into separate transfers - the Canadian Medical Transfer and the Canadian Social Transfer. These budget transfers are channeled from the federal budget to the budgets of the provinces and territories. These budget transfers are increasing every year (demonstrates positive financial dynamics). At the same, time in terms of accountability the main emphasis was shifted to state control over the targeted use of such funds to public control of the use of these funds at the provincial and territorial levels [9]. The Canadian experience demonstrates the need for a constant options search for the optimal institutionalization of budget transfers through which the financing of the health sector occurs. The modernization of budget transfer institutions should not be viewed as a negative factor, as the example of Canada demonstrates.

In Ukraine, the experience of public medical guarantees also exists. The National Health Service of Ukraine provides the implementation of such guarantees. Similar bodies exist in other countries: Public Health Agency in Sweden (Folkhälsomyndigheten); Federal Office of Public Health in Switzerland (Bundesamt für Gesundheit); National Public Health Organization in Greece (Εθνικός Οργανισμός Δημόσιας Υγεία здравоохраненията Канα) Public Health Agency of Canada etc.

The experience of Ukraine in the application of the budget transfers institution is also interesting. The model of budget transfers using for the purpose of financing medicine in Ukraine demonstrates an emphasized "paternalistic" approach. The Ukrainian approach contrasts significantly with the approaches of the states in which insurance medicine is established. In Ukraine today the transition to insurance medicine is only being declared. The Concept for the reform of the health care system financing (approved by the order of the Cabinet of Ministers of Ukraine from 30.11.2016 No. 1013-r) determines the need to establish an insurance medicine system [13]. First of all, it should be noted that in Ukraine there is a mechanism of full state financing of medicine, whose ineffectiveness has been repeatedly confirmed. This undoubtedly testifies the need to reform. As a "transitional elements" for the transformation of this system we could name medical subventions. Medical subvention is one of the elements of ensuring decentralization in Ukraine. However, in the future with the introduction of insurance medicine in Ukraine medical subventions can be modernized.

Medical subventions were introduced with the adoption of the Law of Ukraine "On Amendments to the Budget Code of Ukraine on the Reform of Budgetary Relations" from 28.12.2014 No. 79-VIII. This type of subvention is relatively new. First, we should define the content of such a general concept for the theory of financial law as "subvention". The term "subvention" comes from the Latin word "subvenio", which means "come to rescue" [14, p. 467]. The legislative definition of this concept has been formalized in the Budget Code of Ukraine. Subvention is a budgetary transfer for a specific purpose the use of which is determined by the body that made the decision to provide such subvention [15]. The defining characteristic of the subvention is its target nature – the subvention is assigned and used for a specific purpose.

A medical subvention is a transfer that is provided from the State Budget of Ukraine to local budgets. The importance of medical subventions is confirmed by the provisions of Appendix No. 6 "Budget transfers (educational and medical subventions, base and reverse subsidies) for 2019" to the Law of Ukraine "State Budget of Ukraine for 2019" from 23.11.2018, where the medical subvention in fact, it is the second most important budget transfer, second only to educational subvention – the size of medical subvention for 2019 is 55 billion of UAH (in EUR equivalent 1,6 billion) [16]. Despite the pandemic of coronavirus infection COVID-19 in 2020, the total amount of medical subvention is even less – 14, 5 billion of UAH (in EUR equivalent 433 million) [17]. Despite the issue of the effectiveness of the use of medical subventions, it has repeatedly become the subject of research by the Accounts Chamber of Ukraine (Reports of Accounts Chamber for 2017, 2018 and 2019). The reports for 2017 and 2018 indicate the inconsistency of the supervisory authority in their preparation (in terms of medical subvention). The situation moved in a positive direction in 2019. So, in the report of the Accounts Chamber on 2019 much more attention was paid to the issues of medical subvention. In particular, direct violations or shortcomings in the use of

the amounts of such medical subventions in the amount of 4.3 billion was found. UAH [20].

The Budget Code of Ukraine determines the legal mechanism of medical subvention. The medical subvention is used for special items of local budgets –expenditures related to the health care sector. Normative regulation of medical subventions is characterized by dualism – regulation takes place both at the level of law (the Budget Code of Ukraine [15]) and at the subordinate level (resolutions of the Cabinet of Ministers of Ukraine) [21; 22]).

Medical subventions are one of the instruments that provide public funding for the health sector. At the same time, after the transition to insurance medicine medical subventions can be reformatted into a tool for ensuring participation in the health insurance programs of persons that belong to unprotected segments of the population.

CONCLUSIONS

Budget transfers in the field of medicine is a socially important institution of budget law. Budget transfers in the health care sector can be characterized by the following features: a) sectoral nature (health care sector) b) specific budgetary directions (movement of funds from the state to local budgets) c) widespread use (used both in states with medical insurance and in states where the health sector is entirely publicly funded). The introduction of health insurance will change the purpose of the medical subvention. It will begin to play an important social function – to provide medical guarantees for vulnerable groups of the population.

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REVIEW ARTICLE

RECREATIONAL LANDS AS A COMPONENT OF HEALTH CARE: SOME ASPECTS OF LEGAL REGULATION

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ABSTRACT

The aim: The purpose of the study is to assess the impact of recreational lands on human health and determine the priority forms of their use and protection.

Materials and methods: International acts, data of international organizations and findings of scientists have been examined and used in the study. The article also summarizes information from scientific journals and monographs from a medical and legal point of view on the basis of scientific methods. This article is based on dialectical, comparative, analytic, synthetic, and comprehensive research methods.

Conclusions: Recreational lands positively influence human health through a powerful effect of natural healing resources in combination with health-improving and therapeutic procedures on the body, which is becoming increasingly popular, and in some cases, it is the most effective treatment of all.

Recreational lands are an independent category of land with a special legal regime of use, characterized by a developed or undeveloped natural area containing natural resources for treatment, recovery, rehabilitation, and prevention of diseases, which are under the special protection of the state and territorial communities. Special protection of the state in today's conditions is extremely important because there has been a negative trend in Ukraine regarding raider attacks. The objects of such attacks are exclusively those companies that are competitive in the market, have achieved significant profits, and continue to develop their activities by creating new branches and introducing new technologies. In particular, attacks on the property of agricultural enterprises and business entities that carry out activities in the field of IT services have become frequent in recent years [1, p. 172]. The main target of attacks by raiders on agricultural enterprises is their land. Similarly, without state support and protection, recreational land can be the object of raider attacks.

The priority form of using recreational land is the placement of resorts and sanatoriums that provide recreational services. Recreational lands can also be used for health improvement in the "wellness" form or within the framework of health tourism.

KEY WORDS: human health, recovery, land

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INTRODUCTION

The regulatory documents of the World Health Organization and the decisions of the European Court of Human Rights recognize the right to health to be a fundamental right. Ensuring the right to health and preserving the health of the population is carried out, inter alia, by using the beneficial and recreational properties of the land. The value of health improvement and treatment on recreational lands is determined by staying in natural conditions and the positive impact of various natural healing factors. Therefore, visiting ecologically clean places, recreational places, and carrying out medical procedures with the help of natural healing resources of the earth is a guarantee of good health.

The essence of the concept of recovery is reduced to the possibility of restoring the body's resources, improving working capacity, and productivity. British scientists from the University of East Anglia conducted more than 140 studies, which involved about 290 million people from 20 countries. It was found that outdoor recreation helped to reduce the risks of developing type II diabetes mellitus, cardiovascular disease, high blood pressure and helps to avoid premature death [2]. That is why the health improvement on recreational lands using the natural healing properties of the earth requires research.

A number of international instruments recognize the need for the rational use of available natural resources to improve and maintain human health, in particular, the first principle of the 1992 Rio Declaration on Environment and Development notes that "caring for people is central to efforts to achieve sustainable development. They have the right to a healthy and fruitful life in harmony with nature" [3]. In turn, the World Health Organization defines that global health is being influenced by three trends: population aging, rapid unplanned urbanization, and globalization, all of which results in unhealthy environments and behaviors [4]. According to a report published by the World Health Organization, the polluted environment is a leading cause of death in the world [5]. WHO also identifies several other environmental causes and their relation to mortality, name-

ly: land pollution, exposure to chemicals, climate change and ultraviolet radiation, etc. [6]. It follows that the issue of proper use, protection and enhancement of the healing, medicinal and health-improving properties of the earth is relevant and important for the preservation of human health.

A modern and developed state is called upon to take care of the life, health, safety and development of the population as the fundamental intrinsic value of any society, and one of the important areas of modern state regulation is precisely the measures aimed at restoring and preserving the natural healing resources of the earth and creating conditions for maintaining and improving health.

THE AIM

To study the impact of recreational lands on human health, as well as to determine the priority forms of their use and protection.

MATERIALS AND METHODS

International acts, data of international organizations and findings of scientists have been examined and used in the study. The article also summarizes information from scientific journals and monographs from a medical and legal point of view with scientific methods. This article is based on dialectical, comparative, analytic, synthetic, and comprehensive research methods.

REVIEW AND DISCUSSION

The WHO charter proclaims the principle that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human [7]. If we refer to the European Court of Human Rights, the right to health is defined in a comprehensive manner and includes, inter alia, the right to a favorable ecological environment, which affects the state of health. A number of ECHR decisions are devoted specifically to the violation of the right to life and health in connection with negative environmental factors, in particular the following decisions: the Case of Guerra and Others v. Italy, 19 February 1998, Hatton and Others v. the United Kingdom, 8 July 2003, Dubetska and Others v. Ukraine, 10 February 2011, Hrymkovska v. Ukraine, 21 July 2011, and Dzemyuk v. Ukraine, 4 September 2014, etc. The main problem of protecting the rights to a favorable ecological environment, which affects the state of health, is that the 1950 Convention for the Protection of Human Rights and Fundamental Freedoms does not contain an article that would directly protect the rights of everyone to an environment safe for life and health. Therefore, the analysis of the ECHR practice is carried out in a comprehensive manner in accordance with the provisions enshrined in various articles of the Convention. In fact, the ECHR recognizes the existence of a violation of environmental human rights only in the context of Article 8 of the Convention, which guarantees the right to respect for his private life.

Various factors can have a significant impact on human health [8, 9, 10, 11], among which a special place is occupied by the state of the environment in general and the state of lands in particular. It is customary to refer to recreational lands as lands that have natural recreational properties that are used or can be used for the prevention of diseases and the treatment of people. The definition shows that the impact of recreational land on human health is significant.

Characterizing the recreational lands as a component of health care, their main characteristics can be distinguished as follows:

1. Recreational lands have natural healing properties. Natural healing properties are the natural healing resources on the territory of this category of lands, such as mineral and thermal waters, medicinal mud and ozokerite, brine of estuaries and lakes, seawater, natural objects and complexes with climatic conditions favorable for treatment, suitable for use for the purpose of treatment, medical rehabilitation and disease prevention (Article 6 of the Law of Ukraine On Resorts dated October 05, 2000). According to Chapter 1 of the Law of Georgia on Tourism and Resorts No. 599 dated 6 March 1997 natural curative (health resort) resources are mineral waters, therapeutic mud, carst caves suitable for treatment, the sea, forests, healing climate and other natural resources, which are used for treatment, preventive care and rehabilitation [12].

Thus, water, balneological, agroclimatic resources, or even several resources, are located on recreational lands. It is important to emphasize that usually it is not the lands themselves that have healing properties, but other natural healing resources located on them. There are enough potential natural resources in the world to allow extensive use of such resources for health and wellness purposes. Therapeutic and recreational methods are traditionally subdivided into the following main ones: climatotherapy (treatment with the help of a favorable climate), balneotherapy (mineral waters); peloidotherapy (mud), and additional: thalassotherapy (sea water), aerotherapy (mountain air), speleotherapy (cave microclimate), phytotherapy (phytobath, phytocenoses microclimate, i.e. a combination of a certain set of plants) [13, p.138].

2. The healing and recreational properties of recreational lands are of natural origin and usually cannot be created (reproduced) artificially. Therefore, according to Principle 2 Report of the United Nations conference on the human environment (Stockholm, 5-16 June 1972), the natural resources of the earth, including the air, water, land, flora and fauna and especially representative samples of natural ecosystems, must be safeguarded for the benefit of present and future generations through careful planning or management, as appropriate [14]. According to the 1982 World Charter for Nature, man can alter nature and exhaust natural resources by his action or its consequences and, therefore, must fully recognize the urgency of maintaining the stability and quality of nature and of preserving natural resources [15]. The 1992 UN Convention on Biological Diversity establishes that parties to the convention should take appropriate measures to preserve biological diversity [16]. The European Commission also pays great attention to preserving natural resources and limiting the negative impact of their use for healing and recreational purposes [17]. In other words, it is necessary to talk about the

special value and need for increased protection of natural healing resources located on recreational lands by states, considering their nature of origin and in many cases non-reproducibility.

3. The natural healing resources of recreational lands are used in accordance with the characteristics and condition of each organism because each person has his or her own unique and inimitable organism and therefore all the features must be taken into account. For example, mud baths cannot be used by everyone, since its properties can in some cases, on the contrary, worsen the state of human health because of some diseases, pathologies, which, as a result of using mud baths, can be aggravated.

Because the temperature of the mud can reach about 100 degrees Fahrenheit, water will be drained from the body and can cause dehydration. If you have sensitive skin, the warm mud may cause skin irritation. It is important to be monitored by a spa professional while taking a mud bath because staying in the bath too long can cause heatstroke, nausea and fainting [18].

Therefore, according to the European Social Charter, everyone has the right to benefit from any measures enabling him to enjoy the highest possible standard of health attainable [19].

4. In fact, the impact of recreational lands on human health is carried out first through their official recognition as resorts of state or local importance. After receiving a special legal status, such lands are specially protected by the state and one can count on the proper quality of the received health services offered by the resorts. For example, pursuant to the Law of Ukraine No. 2637-VIII dated December 05, 2018 "On declaring the natural territories of the Kuyalnik estuary of the Odesa region as a resort of state importance", the above territories and the unique natural healing resources of this area have acquired special protection from the state.

5. Recreational lands, after the official assignment them the corresponding legal status, receive priority over lands with similar legal regimes, since recreational lands have valuable health-improving properties. For example, the valuable natural resources of the Kuyalnik estuary of the Odesa region make it possible to treat and prevent a wide range of diseases, from injuries of the musculoskeletal system to diseases of the gastrointestinal tract [20]. There are also different types of excellent mineral and thermal waters in Hungary, each suitable for treating different health problems: containing alkaline, bromine, radon, sulphates and iron, or in some cases they can be muddy-calcareous, sulphuric or carbonated. Mineral and thermal waters are most commonly used to treat musculoskeletal disorders, but they are also hugely beneficial in curing dermatological conditions, gynaecological problems, sports injuries [21], which of course must be taken into account in the protection and use of these lands.

6. Legislation of different countries defines a different, in comparison with other categories of land, legal regime for granting, withdrawing, using, protecting and changing the designated purpose of recreational lands. For example, the relevant provisions of the Law of Georgia On Tourism and Resorts No. 599 dated March 6, 1997, the Land Code of the Republic of Tajikistan, the Land Code of Ukraine, and the Law of Ukraine "On Resorts" dated October 05, 2000, are devoted to the peculiarities of the legal regime of this category of land. In addition, the aforementioned regulatory legal acts establish separate restrictions on the use of land for recreational purposes as objects of civil turnover. Thus, Articles 83 and 84 of the Land Code of Ukraine indicate that land under recreational facilities that have special ecological, health-improving, scientific, aesthetic, and historical-cultural value cannot be transferred from state and communal property to private property unless otherwise provided by law. Article 89 of the Land Code of the Republic of Tajikistan establishes the legal regime of recreational lands, referring land plots with natural healing factors (mineral springs, healing mud deposits, climatic and other conditions) favorable for the organization of prevention and treatment to this category. The lands of resorts are subject to special protection. In order to protect natural healing factors, sanitary protection districts are established at all resorts. Within these districts, it is prohibited to provide land plots for use by those enterprises, institutions, organizations, which activities are incompatible with the protection of natural healing properties and favorable conditions for recreation of the population [22].

7. Facilities associated with the use of natural healing properties of recreational lands should be located on these lands. As indicated in the Appendix to the General Assembly Resolution of the World Charter of Nature No. 37/7, humanity is a part of nature and life depends on the continuous functioning of natural systems that are a source of energy and nutrients [15]. Therefore, the emphasis should be placed on the healing and recreational properties of the land and the best option for using such lands is to place resorts, sanatoriums, and health centers. For example, given the existence of 1,500 thermal wells and more than 270 types of certified mineral and thermal water, Hungary has 98 certified resorts [21]. Thus, the use of recreational land as a means of production or an economic spatial basis should be of a secondary nature.

The Law of Ukraine "On Resorts" No. 2026-III dated October 05, 2000 determines that a resort is a developed natural territory on recreational land, has natural healing resources necessary for their operation, buildings and structures with infrastructure facilities, is used for the purpose of treatment, medical rehabilitation, disease prevention, and recreation. The above law identifies a category that is new for land legislation as a healing and recreational area – a natural area that has mineral and thermal waters, therapeutic mud, ozokerite, brine of estuaries and lakes, climatic and other natural conditions favorable for treatment, medical rehabilitation, and prevention of diseases. The concept of a resort in the legislation of Georgia is excellent, namely, the Law of Georgia On Tourism and Resorts reduces the concept of a resort only to a resort area where treatment and rehabilitation buildings or other infrastructure are located, without taking into account the presence or absence of natural healing resources of the

land. The resort is a resort site where treatment or recovery buildings or other infrastructure are located. In the legislation of Georgia, the need for the availability of natural healing resources in the territories of resorts is defined through the concept of resort activities, where natural healing resources are already allocated as an integral part of resort activities [12].

Thus, sanatoriums are located in the resorts, provide treatment, prevention and rehabilitation services using natural healing resources, which makes it possible to argue about the location of such health facilities on recreational lands.

8. A separate form of use of recreational lands is tourism. There is no generally accepted and unambiguous concept of understanding the type of tourism, the purpose of which will be to use the healing properties of the earth's natural resources to improve human health. Different authors call it differently: health tourism [23], medical tourism [24], recreational tourism [25], [26], "wellness" tourism [27 p.50], etc. Thus, Atul D. Garud notes that relatively modern definitions "medical tourism", "wellness tourism" and "health tourism" refer to treatments that have been planned in advance to take place outside a patient's usual place of residence [28, p.318].

According to the Directorate-general for internal policies policy department for structural and cohesion policies transport and tourism research for the TRAN committee, medical tourism is a component of tourism activities and includes directly medical, health, and resort services. Herewith, medical tourism includes people who travel for the purpose of receiving treatment. Health tourism serves to maintain or improve personal health and well-being. Resort tourism focuses on healing, relaxing, or improving the body, which is preventive and/or curative in nature [29]. In turn, the Global Wellness Institute (GWI) defines wellness tourism as travel associated with the desire to support or increase personal well-being and believes that wellness tourism is not medical tourism, since the purpose of medical tourism is to travel to receive treatment for a diagnosed disease, malaise or a pathological condition. Within the framework of health tourism, a person is motivated by the desire for a healthy lifestyle, disease prevention, stress reduction, and bad lifestyle habits [30, pp. 9, 11]. Travel to receive treatment for a diagnosed disease, ailment, or condition, or to seek enhancement. Travel to maintain, manage, or improve health and wellbeing. Motivated by desire for lower cost of care, higher quality care, better access to care, and/or care not available at home. Motivated by desire for healthy living, disease prevention, stress reduction, management of poor lifestyle habits, and/or authentic experiences. Activities are reactive to illnesses, medically necessary, invasive, and/or overseen by a doctor.

Recently, such a form of using the healing and health properties of lands as "wellness" has been developing all over the world. Wellness refers to the overall process of maintaining a healthy balance of the mind, body and spirit, which promotes good health and wellbeing. Multidimensional and holistic, wellness is a never-ending process of people becoming aware of and making lifestyle choices in order to enjoy a healthy and fulfilled life [31].

In our opinion, it is recreational tourism that better matches the essence and purpose of recreational lands since the emphasis is not on the possibility of obtaining certain medical services using specialized medical workers, but on the alternative procedures carried out in interaction with natural healing resources (sea coast, hot, warm and cold mineral springs, estuary mud deposits, forests, etc.), which are located on recreational land, for the sake of implementing a set of preventive measures to prevent the development of the disease or maintain the patient's condition. Along with the above forms, namely: the placement of sanatorium-resort institutions and the implementation of health tourism, we single out a separate form of land use for health purposes – "wellness".

CONCLUSION

Wellness is the key to good health. One of the main factors of healing and treatment is the use of the natural healing properties of the earth, it is becoming increasingly popular and, in some cases, something more effective simply does not exist. Recreational lands have a positive impact on human health through a combination of the effects of recreational and medical procedures with a powerful impact of the full range of natural healing resources on the human body.

Recreational lands are an independent category of lands with a special legal regime of use, characterized by a developed or undeveloped natural area containing natural resources for treatment, recovery, rehabilitation, and prevention of diseases, which are under the special protection of the state and territorial communities.

Recreational facilities (resorts and sanatoriums) that provide recreational services are located on recreational lands. Recreational lands can be used for health improvement within the framework of recreational tourism or in the form of "wellness".

The preservation of such lands should be ensured by increasing the efficiency of environmental policy, by identifying specific ways of their effective use.

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REVIEW ARTICLE

TOWARDS CREATION OF UNIFIED REGULATION ON SURROGACY IN EUROPE: RECENT TRENDS AND FUTURE PERSPECTIVES

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ABSTRACT

The aim of this paper is to study the existing international legal framework, regulating international surrogacy agreements and to analyse the possibility of adoption of respective unified European legal instrument.

Materials and methods: The article is based on international legal acts, jurisprudence of the European Court of Human Rights, reports and scientific articles. The research is grounded on dialectical, formal logical methods, methods of synthesis and analysis, comparative legal method and the method of modelling.

Conclusions: The authors came to conclusion about the necessity of introducing of unified legal instrument dealing with international surrogacy cases. The article illustrates that the work towards harmonization of surrogacy in Europe started at the beginning of 21st century and the experts group of the Hague Conference on Private International Law is currently working on drafting a respective protocol. The authors provide a list of questions that were not noticed by the mentioned experts but should be included in the protocol.

KEY WORDS: international surrogacy, harmonization of surrogacy regulation, European Court of Human Rights, Hague Conference on Private International Law, best interests of the child

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INTRODUCTION

Surrogacy, as defined by the Oxford dictionary, is the practice of giving birth to a baby for another person or couple, usually because they are unable to have babies themselves [1]. Legal doctrine defines between *traditional* and *gestational* surrogacy, where in *traditional surrogacy* the surrogate mother is also the biological mother of a child she carries, while in *gestational surrogacy* the surrogate mother does not have any genetic link with the future baby. Normally, traditional surrogacy is strictly prohibited by the national legislators and if they choose to allow surrogacy – only gestational type is allowed.

Surrogacy can be further divided into *commercial* and *altruistic*. In accordance with commercial surrogacy model, the surrogate mother receives remuneration for carrying and giving birth to the baby. Altruistic surrogacy envisages that the surrogate mother does not receive any remuneration, however some jurisdictions allow the intending parents to compensate her expenses. The countries in Europe, that allow surrogacy, tend to opt for altruistic surrogacy.

There is no consensus in Europe on how to regulate surrogacy. A broad study shows that the approach of the national legislators in Europe may fall within following four categories:

- no regulation for surrogacy is provided, however in practice surrogacy contracts are signed and enforced (e.g., Belgium);
- surrogacy is not allowed, however the discussions on allowing it in the future are held (e.g., Spain);
- surrogacy is allowed, and the legislator provides for the regulation on surrogacy (e.g., Ukraine, Russia, Greece);
- surrogacy is strictly forbidden by the law (e.g., Germany, France) [2].

Global statistics show that a number of surrogacy cases, especially a number of concluded international surrogacy contracts was increasing each year until the beginning of 2020. Global COVID-19 pandemic has slowed down continuing growth of surrogacy due to travel restrictions and restriction for the foreigners to cross the borders of the countries, implemented by most of legislators in Europe. This tendency is believed to continue until the end of global pandemic and is supposed to end with the removal of travel restrictions. Before the coronavirus restrictions, surrogacy was recognized to be an emerging global market, estimated "to cross $27.5 billion by 2025" in accordance with the data of Global Market Insights [3].

Couples where one or both of partners were infertile were seeking a possibility to enter into surrogacy contract either in their jurisdiction or were opting for *reproductive tourism*. The reasons for such tourism may be different: trying to avoid legal restrictions for surrogacy provided by the national legislation of the intending parents (e.g., access to surrogacy only to heterosexual married couples, necessity of genetic link with a future baby of at least of one intending parents, impossibility to use ova or sperm donors, outlawing of surrogacy etc.) or trying to save finances (as in certain Eastern-European jurisdictions, like Ukraine or Russia the price for surrogacy may be much

less than in the other European countries where surrogacy is allowed). In these cases, international surrogacy takes place, when the intending parents are the nationals of one (or two) country (ies), while the surrogacy itself is happening in another country, where, usually, surrogate mother resides. The risks that the stakeholders may face were broadly studied in the jurisprudence. For instance, R. Deonandan has defined the following legal risks:

- *to the country of origin of the intended parents* (when the country calls the tourists for liability for the acts that are legal in the country of destination but are illegal in the home country of the intended parents);
- *to the destination country* (if needs of emerging surrogacy industry will influence the laws of the destination country);
- *to the surrogate mothers* (doubts whether surrogate mothers are participating in surrogacy programs because of their low economic income or because they really decide so);
- *to the clinics;*
- *to brokering parties;*
- *to the children born as a result of surrogacy* [4].

As it was stated in the report, prepared by the Permanent Bureau of the Hague Conference of Private International Law, international surrogacy cases can result in the problems concerning "the establishment and / or recognition of the child's legal parentage and the legal consequences which flow from such a determination (e.g., the child's nationality, immigration status, who has parental responsibility for the child, who is under a duty to maintain the child, etc.)" [5].

Notwithstanding a significant number of risks and problems, arising out of international surrogacy, there is no unified international legal instrument dealing with these problems.

THE AIM

The aim of this paper is to study the existing international legal framework regulating international surrogacy agreements and to analyse the possibility of respective unified European legal instrument adoption.

MATERIALS AND METHODS

The article is based on international universal and regional European legal instruments, the jurisprudence of the European Court of Human Rights, reports of the European Parliament, International Commission of the Civil Status, Hague Conference on Private International Law and the UN Special Rapporteur on the sale and sexual exploitation of children, including child prostitution, child pornography and other child sexual abuse material and scientific articles. The research is grounded on dialectical, formal logical methods, methods of synthesis and analysis, comparative legal method and the method of modelling.

REVIEW AND DISCUSSION

As it was stated above, there is currently **no unified legal instrument dealing specifically with the international surrogacy. Fragmentary regulation is provided by both universal and regional international instruments.**

Among *universal legal acts* one may name *Universal Declaration of Human Rights (1948)* [6], Art. 15 of which lays down that "everyone has the right to a nationality. No one shall be arbitrarily deprived of his nationality nor denied the right to change his nationality". This article is supposed to provide a minimum standard for a child, born as a result of international surrogacy, however in practice this article does not help to combat the cases of stateless children, because it does not answer the question, which state should grant such nationality and what the relevant mechanism should be [7]. Pursuant to Parts 2,3 of Art. 24 of the *International Covenant on Civil and Political Rights (1966)* [8], "every child shall be registered immediately after birth and shall have a name. Every child has the right to acquire a nationality". As B. Ni Ghrainne and A. McMahon have observed, as in the case with the Universal Declaration of Human Rights, it is unclear, which state should grant a nationality to the child and upon which conditions. Moreover, it is stated in Point 8 of the General Comment 17 of the Human Rights Committee, that the States are not obliged to give their nationality to every child born in their territory [7]. However, the General Comment provides for requirement of the States to "adopt every appropriate measure, both internally and in cooperation with other States, to ensure that every child has a nationality when he is born" [9]. Drafting and adoption of Convention on International Surrogacy, containing the norms ensuring that the children are not stateless, can be an appropriate measure in the light of the mentioned General Comment. Principle 3 of the *Universal Declaration of the Rights of the Child* (1959) [10] stipulates that the child shall be entitled from his birth to a name and nationality. Under Principle 6 of the same Declaration, "the child, for the full and harmonious development of his personality, needs love and understanding. He shall, wherever possible, grow up in the care and under the responsibility of his parents, and, in any case, in an atmosphere of affection and of moral and material security; a child of tender years shall not, save in exceptional circumstances, be separated from his mother...". The mentioned principles of the Universal Declaration are declarative and do not identify the responsible states and the mechanism of ensuring that the child is provided with the nationality and is growing up in the care and under the responsibility of his parents. *The Convention of the Rights of the Child* (1989) [11] operates with the term "best interests of the child", which shall be a primary consideration in all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities, administrative authorities or legislative bodies (Art. 3). In our opinion, the concept of the best interests of the child should be a basis when drafting the Convention on International Surrogacy. The Convention of the Rights of the Child repeats a number of guarantees, provided by the mentioned international legal acts, such as: registration immediately after birth, having the right from birth to a name and the right to acquire a

nationality (Art. 7) and ensuring "that a child shall not be separated from his or her parents against their will except when competent authorities subject to judicial review determine, in accordance with applicable law and procedures, that such separation is necessary for the best interests of the child (Art. 8). *Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography* (2000) [12] lays down a holistic approach to the trafficking in children. In accordance with the Point a) of Art. 2, for the purposes of the present Protocol: a) sale of children means any act or transaction whereby a child is transferred by any person or group of persons to another for remuneration or any other consideration. While surrogacy is a form of assisted human reproduction, that allows infertile couples to exercise their reproductive right, and is not a sale of children, however in the circumstances when it is not properly regulated, in opinion of Ms. Maud de Boer-Buquicchio, Special Rapporteur on the sale and sexual exploitation of children, including child prostitution, child pornography and other child sexual abuse material, "surrogacy arrangements risk compromising the fundamental rights of the child to human dignity, the right to identify, including nationality, access to origins and the enjoyment of family life" [13].

There is a number of *European regional legal instruments* that also provide some rules, applicable in cross-national surrogacy. *The Convention for the Protection of Human Rights and Fundamental Freedoms* (1950) (hereinafter – Convention) [14] protects the right to respect for private and family life (Art. 8), stipulating that "everyone has the right to respect for his private and family life, his home and his correspondence". Several cases involving international surrogacy was decided by the *European Court of Human Rights* (hereinafter – the ECHR), where the ECHR has interpreted Art. 8 of the Convention. For example, in the case of *Menneson v. France* (2014) [15] the ECHR has been guided by the best interests of the child and has decided that non-recognition of French authorities of the legal parent-child relationship between children born by a surrogate mother in the United States of America and the intended parents as violation of the children's right provided by Art. 8 of the Convention, despite the fact that surrogacy agreements in France contradict the public order and thus are null and void. One should notice that children were almost 14 years old when the decision of the ECHR became final. The ECHR came to the same conclusion in another well-known case - *Labassee v. France (2014)* [16]. It is interesting that the ECHR came with another conclusion in the case *Paradiso and Campanelli v. Italy (2017)* [17], where the Italian couple challenged the refusal of the authorized Italian authorities to recognise a parent-child relationship arisen as a result of surrogacy carried in Russia. In this case the child was not genetically related with the Italian spouses as a result of mistake (different gametes were used by the clinic) and the ECHR thus ruled that there was no family life between the child and the intended parents. As M. Ni, Shuilleabhain notes, in this case the ECHR "does not ascribe the same precedence to the "best interests" of the individual child. Instead, the interests of the affected child appear to rank in pari passu alongside the interests of the children more generally and the interest in curbing illegal conduct" [18]. As the ECHR decided in this case, "agreeing to let the child stay with the applicants, possibly with a view to becoming his adoptive parents, would have been tantamount to legalising the situation created by them in breach of important rules of Italian law". In 2019 the ECHR has issued the *Advisory opinion* concerning the recognition in domestic law of a legal parent-child relationship between a child born through a gestational surrogacy arrangement abroad and the intended mother, requested by the French Court of Cassation [19]. Being guided by the "best interests of the child", the ECHR has decided that despite the fact that surrogacy contradicts the public order under French law, there is a legal way to recognize a child-parent relationship with the intended mother that does not have genetic link with the child – adoption, that should be quick and effective. The Advisory opinion was used in the following cases, heard by the ECHR – *C and E v. France* (2019) *and D v. France* (2020) [20]. It is also important to note that ECHR has supported a reproductive tourism in a number of its decisions – e.g., *S.H.. and others v. Austria* (2011) [21].

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 (ETS No 164) (1997) [22] is another European instrument, providing a number of bioethical rules that can be of use in the international surrogacy cases – equitable access to health care (Art. 3), professional standards (Art. 4), requirements for informed consent (Art. 5), respect for private life in relation to information about his or her health (Art. 10), non-selection of child's sex except when serious hereditary sex-related disease is to be avoided etc.

The European Union has not adopted any harmonized rules on surrogacy. However, some applicable rules may be found in the *Charter of Fundamental Rights of the European Union* (2012) [23]. Under Part 3 of Art. 24 of the mentioned Charter, "every child shall have the right to maintain on a regular basis a personal relationship and direct contact with both his or her parents, unless that is contrary to his or her interests". *Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells* [24] lays down the standards that can be used in cases where donor gametes are needed for surrogacy fulfilment in the EU.

There is no specialized legal instrument regulating surrogacy in Europe, which is of great concern of all the stakeholders involved and there's no surprise that several studies on harmonization of surrogacy in Europe have been carried up to date.

One of the first research towards surrogacy and maternal filiation was conducted in 2003 by *the International Commission on Civil Status (ICCS)*, an international organization, aiming to facilitate collaboration between the states

in the matters of civil status. The questions in the status of the maternal filiation were summarized in concept note "L'établissement de la filiation maternelle et les maternités de substitution dans les États de la CIEC". In 2014 another study was carried by the ICCS, dedicated to the surrogacy and child marital status [25].

"A comparative study on the regime of surrogacy in EU Member States" was issued by the European Parliament in 2013. The study considers different approaches EU can choose towards surrogacy regulation and studies, in particular, the possibility of framing surrogacy by either substantial harmonization, harmonization of conflict-of-law rules or joining an international convention is studied. As a conclusion, the authors have noticed that it is necessary "to access the relationship between the EU, the Hague Conference on Private International Law and the ICCS in the field of surrogacy. Their work is progressing, and the EU should remain a key-actor in the negotiations and research" [26].

In 2010 a project on parentage and surrogacy was started by the Hague Conference on Private International Law. Following a profound research and studies, in March 2019 the experts' group decided to draft the convention "on the recognition of foreign judicial decisions on legal parentage", and "a separate protocol on the recognition of foreign judicial decisions on legal parentage rendered as a result of an international surrogacy arrangement (hereinafter – the Protocol)" [27]. Summing up the offers of the experts, the following views were expressed:

- a lot of experts offered that the Protocol should cover the legal parentage in the international surrogacy agreements only;
- the judgments concerning legal parentage of the child born by a surrogate should be delivered shortly after birth, possible criteria for the recognition of judgements on legal parentage were discussed;
- the possibility of certification to verify that surrogacy agreement was conducted in accordance with the Protocol was offered;
- the necessity to ensure free and informed consent of the surrogate;
- keeping the information on the child's origin to safeguard the right of the child to information about its genetic origin;
- role of intermediaries in the international surrogacy cases;
- possible "minimum standards concerning the eligibility and suitability of the surrogate mother, and the eligibility and suitability of the intending parent" and other questions" [27].

The experts outlined that the convention and the Protocol will be drafted and presented in the final report, which is planned on March 2022. If this ambitious and important project is completed as planned, we will have the draft of the instrument, having the potential to eliminate the problems of the stateless children and minimizing other risks listed in this article. Some of the scholars are sceptical about the success of any new convention on surrogacy, because there is little probability that the countries where surrogacy is banned would sign it, moreover, negotiations on such instrument would take years [7].

The study of legal literature shows that the desirable contents of such convention is much wider than was offered by the Hague Conference on Private International Law. For example, R. Pol offered draft provision of the proposed international instrument, including, among others, necessity of establishing the "Competent Authority" at the federal level of every state, which will be communicating between the contracting parties' establishing the "Governing Committee", being in charge of applications of intending parents and interested surrogate mothers to enter into international surrogacy agreement; establishing the authority for resolution of disputes [28]. M. Flatscher-Thoni, C. Voithofer have proposed adoption of ART Convention, containing pre-treatment measures (ensuring providing the patients with the necessary information); treatment measures (minimal legal standards of the relevant contracts should be met), post-treatment measures (installing of an arbitrary board) [29].

There is no doubt that the project conducted by the Hague Conference on Private International Law has the biggest potential to succeed among all the recent endeavours, however in our opinion, the list of questions it regulates should be extended. For example, the final report, available on the website of the project, does not contain the information on the authority which will have discretion to control fulfilment of the Protocol and the authority, which will decide the disputes between the parties to international surrogacy.

CONCLUSIONS

Parties to an international surrogacy contract and a baby (babies) born after the contract is fulfilled are facing several risks, the most dangerous of which entails leaving the children stateless and resulting in the situations when the child-parent relations are not recognized by the country of the intended parents' origin. There is no unified legal approach to avoid and resolve such issues provided at the international or regional (European) level.

Existing international, European and European Unions' legal instruments regulate some separate issues of international surrogacy cases, which do not provide practical solutions to existing problems. The ECHR has developed a few cases, dealing with international surrogacy, supporting, for example, a reproductive tourism or advising on ways of recognition of child-parent relations in the surrogacy cases with the intended parent who is not the biological parent of the child, however these rules do not substitute the international binding legal instrument. Sometimes from the moment of child birth to the moment when the decision of the ECHR is issued more than 10 years can pass and there is a need of the instrument that can deal with such cases on a rapid way.

The necessity of introducing of unified legal instrument dealing with international surrogacy cases is discussed during almost last two decades and the Hague Conference on Private International Law is currently drafting such protocol, the

work is expected to be finished by March 2022. However, some questions that should be regulated by the Protocol, in our opinion, were not included in the Report of the Expert group as of March 2019. It is believed that the protocol shall also provide for authority which will have discretion to control fulfilment of the Protocol and the authority, which will decide the disputes between the parties to international surrogacy.

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REVIEW ARTICLE

CURRENT ISSUES OF LEGAL REGULATION OF SURROGATE MATERNITY AND ENFORCEMENT OF RIGHTS OF SURROGATE MOTHERS

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ABSTRACT

The aim: To propose effective jurisdictional methods in the field of legal regulation of surrogacy and ensuring the rights of surrogate mothers in the EU.

Materials and methods: The research is based on international documents in the field of surrogacy, Ukrainian legislation, decisions of the European Court of Human Rights, scientists' works in the field of legal regulation of surrogacy, etc. General scientific methods (synthesis, induction, system method) and specific scientific methods (comparative legal and special legal methods) are used.

Conclusions: The study found that today some issues related to the surrogacy legal nature, conditions and procedure for its implementation remain out of the EU's attention. It is established that the adoption of a separate regional (within the EU) legal act will fully solve the existing problems, ensuring the effectiveness and transparency of surrogacy, will unify the medical tourism's mechanisms in the field of surrogacy. The authors have developed and proposed to enshrine the main provisions on surrogacy in the EU Regulation / Directive.

KEY WORDS: assisted reproductive technologies, human rights, surrogacy, surrogate mothers' rights

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INTRODUCTION

Today both altruistic and commercial surrogacy are allowed in a few European countries. The countries in which it is permitted are extremely attractive to: 1) foreigners who, avoiding the relevant prohibitions at the level of their national legislation, come to these countries for the purpose of applying the surrogacy procedure; 2) foreign corporations that carry out professional activities in this area and resort to cross-border reproductive services. Citizens of Ukraine also actively use the opportunities of surrogacy. However, a quantity of important issues related to the using of surrogacy in the European Union remain unresolved; regulatory support of the rights of surrogate mothers seems to be avowedly imperfect and is not accompanied by sufficient legal guarantees. It creates a need to study relevant international documents in this area in order to develop and implement certain legal innovations for states that use surrogacy.

THE AIM

The aim of this article is to review current issues in the field of legal regulation of surrogacy and ensuring the rights of surrogate mothers in the EU, as well as to identify optimal ways to solve existing problems.

MATERIALS AND METHODS

As an empirical basis, the research is based on international documents in the field of surrogacy, Ukrainian legislation, decisions of the European Court of Human Rights, the work of scientists in the field of legal regulation of surrogacy, and so on. General scientific methods (synthesis, induction, system method) and specific scientific methods (comparative legal and special legal methods) are used.

REVIEW AND DISCUSSION

The possibilities of modern medicine have created a qualitatively new legal paradigm - human reproductive law. As can be seen from the report of the Committee on Social Affairs, Health and Sustainable Development of the Parliamentary Assembly of the Council of Europe (rapporteur - Petra De Sutter) "Anonymous donation of sperm and oocytes: balancing the rights of parents, donors and children" of 20 February 2019, as a result of the use of assisted reproductive technologies, more than eight million children have been born worldwide today [1] and this number is growing steadily.

One of the types of assisted reproductive technologies is surrogacy, which is used in Ukraine according to a special procedure approved by the Order of the Ministry of Health

of Ukraine № 787 of September 9, 2013 [2] and in some foreign countries. At the same time, there are significant differences in legal regulation in the current legislation of many European countries, which gives rise to a number of discussions among scholars, legal practitioners, physicians and other social groups. Therefore, the legal nature of this phenomenon, its essence and purpose remain unclear, and legal regulation at the supranational regional level within the European Union needs to be detailed.

Thus, according to Baiborosha N.S., there are only a few legal documents in this area in the European Union: the Principles of 1989, the Explanatory Report to the Principles of 1989, the Convention for the Protection of Human Rights and Dignity in connection with the application of biology and medicine: 1997 Convention on Human Rights and Biomedicine and 1997 Explanatory Report to the Convention on Human Rights and Biomedicine. All the above documents, with the exception of the Convention, are of a recommendatory nature [3].

Some scientists suggest treating surrogacy as the fertilization of a genetically foreign woman (without using of her biological material) by implanting or transplanting an embryo using the genetic material of a male and a female who are married for the purpose of bearing and giving birth from the spouses, on the basis of relevant agreement between the spouses and the surrogate mother [4, p. 43; 5, p. 72]. However, this approach is quite debatable. There is currently no consensus among scholars on this issue. It is worth noting that we also do not share the above definition and consider it somewhat outdated, narrow. We believe that all methods of assisted reproductive technologies, including surrogacy, are methods of treatment, and therefore the possibility of their use can in no way depend on a person's social status, in particular, gender self-identification, marriage or same-sex partnership.

According to Lawrence Lvoff, there is a definition of surrogacy in 9 countries of the European Union. The law regulates pregnancy with the help of a third party, intention to give a child, agreement before the pregnancy, refusal of adoption, reference to the genetic link, reference to "agreement" / agreement [6] Of course, there are gaps in legal regulation that create a number of barriers for homosexuals, single people who for one reason or another are not married, people living in the same family without marriage registration, and violations of the rights of women who intend to become surrogate mothers (significantly limiting them) in the specified opportunity).

In this context, it should be emphasized that throughout the world, regardless of nationality and citizenship, the right to paternity has two dimensions - social and physiological. In the social dimension, it is possible to exercise the right to parenthood through appropriate social institutions. At the same time, in physiological dimension, this right follows from the very nature of man - the right to have a child arises from birth, and a person can exercise this right by reaching the appropriate level of physical maturity and emotional development. It is worth noting that the right to parenthood, even in the physiological dimension, is much broader than the physiological readiness and ability to conceive a child.

Both social and physiological components are markers of human health. Thus, the inability to conceive naturally due to physical or psychological characteristics should be considered as a health disorder with the obligation of the state to provide appropriate medical care and ensure the right to reproduce with all available resources of modern medical science. It is noteworthy that in 1987 the World Medical Association (WMA) adopted a Regulation on in vitro fertilization and embryo transplantation, which defines in vitro fertilization and embryo transplantation as a medical method of infertility treatment available in many parts of the world [7]. Note that the MMA clearly defines surrogacy as a method of treatment

Given this, we hold the position that access to treatment including surrogacy, should not be limited under any circumstances other than medical contraindications (for example, the presence of socially dangerous mental illness or hereditary diseases). In addition, homosexuality is recognized as the norm and is absent in the latest editions of the International Classification of Diseases [8] (in terms of the right to treatment by surrogacy by same-sex partners).

Moreover, the term "health" covers not only the physical but also mental and social well-being of a person, which is directly consistent with the position of the World Health Organization (hereinafter - WHO) [9]. At the same time, social well-being, among other determinants, presupposes the ability of people to conceive and give birth to children. In turn, the WHO Statute (Constitution) states that everyone has the right to the highest attainable standard of health, regardless of their social status. [9]. It follows that surrogacy, as a treatment method, should be available to everyone, without exception, who for some physiological or psychological reason can not have children, and not only to those who are married.

Consequently, depriving unmarried persons of the right to use the surrogacy procedure is not in line with generally accepted international standards and poses a serious threat to all countries where surrogacy is permitted. This also creates significant obstacles for people who come to other countries, including continental Europe, through medical tourism, in order to use the surrogacy procedure.

This state of affairs is also explained by the fact that modern democratic society has only recently taken on obligation to tolerate a person's infertility or other grounds that make it impossible to have genetically related children, as well as to refrain from stigmatizing such a person. At the same time, historically, the topic of infertility has always been taboo, and infertile people, especially women, have often been stigmatized [10, p. 163]. It is difficult to believe that such a stigma still exists in certain societies and is strangely superimposed on stigmatization of a surrogate mother, assisted gestation as a treatment method, and on a child [11, p. 48].

However, this state of affairs is unacceptable. In our view, all countries where surrogacy is permitted should create regulations that would allow every person (including a foreigner), regardless of their marriage, including same-sex

partnerships, to use surrogacy as a treatment method. For example, from January 1, 2019, this practice is successfully used in Washington State (United States) [12].

In addition, it should be noted that surrogacy and its integral component - assisted gestation - are always used in combination with other methods of assisted reproductive technologies. However, surrogacy is burdened by legal uncertainty and imperfection of its other necessary components (taking donor material, instrumental fertilization, etc.) that precede auxiliary gestation.

Summarizing, we must state that currently in Ukraine and in many countries around the world the following issues are unresolved: the number of oocytes from one donor that can be used by a medical institution; amount of sperm from one donor (from one dose) that can be used by a medical institution to one recipient; state monitoring of gamete donations' amount (especially important for female donation); control of the amount of donor material during women's donation; mandatory selection of blood group of donor and recipient; sexual selection of embryos to select the child sex.

However, the most systemic and conceptual shortcomings that significantly affect medical tourism and the person's rights to motherhood and fatherhood are the following: lack of regulation of surrogacy at the level of separate (special) international legal act that would prevent conflicts of private international law regarding surrogacy; lack of a clear unified form of contract for the provision of surrogacy services; uncertainty of the list of the rights of the surrogate mother's child during participation in the program of assisted reproductive technologies (in this case the experience of Great Britain is positive); violation of the woman's rights (future genetic mother) in the absence of registered marriage or homosexual sexuality with the use of assisted reproductive technologies; problems of relationship between medical secrecy, the right to secrecy about the state of parents' health and the child's right to information about their origin (non-medical aspect); stigmatization of surrogate mothers and committing criminal offenses against them in some cases; insufficient number and / or ineffectiveness of supranational legal remedies for the rights of surrogate mothers within the framework of criminal proceedings.

Thus, surrogacy is a separate set of medical, ethical and legal issues that are inextricably linked to other methods of assisted reproductive technologies and are a transnational problem of lack of legal regulation. To confirm this thesis, we note the following.

Along with this, as rightly noted by I.V. Chekhov, there is currently no regulation of the commercial program of surrogacy, which can lead to the transformation of the child and the surrogate mother into a "commodity" [13, p. 59]. Indeed, in the modern world there is an active demedecalization of surrogacy, a vision of a market service, which involves the use of appropriate manipulations to attract a third person - a surrogate mother (gestational courier). This is a significant problem for the development of medicine, as well as public order in many countries. Ferraretti A.P., Pennings G., Gianaroli L. and other scientists rightly point out that in some cases, due to the relevant legal prohibitions in their countries of residence, but wanting to take advantage of surrogacy, always resort to cross-border reproductive services [14, p. 262]. Having the necessary amount of money, they migrate to other countries, where the use of assisted reproductive services, including commercial surrogacy, is allowed at the legislative level, primarily to Ukraine. Thus, in the Resolution of the European Parliament (hereinafter - the Parliament) of December 17, 2015 "On the Annual Report on Human Rights and Democracy in the World 2014 and the European Union's policy on the matter" Parliament condemned the practice (ed. - commercial) surrogacy, which undermines a woman's human dignity because her body and its reproductive functions are used as a commodity; pointed out that the practice of gestational surrogacy, which involves the reproductive exploitation and use of the human body for financial or other gain, particularly in cases of vulnerability of women in developing countries, should be banned and immediately addressed in human rights instruments [15]. A similar position is reflected in the report of the Committee on Social Affairs, Health and Sustainable Development of the Parliamentary Assembly of the Council of Europe (rapporteur: Petra De Sutter) "Children's rights related to surrogacy" of 23 September 2016 [16].

However, according to L. van Zyl and R. Walker, it is impractical to prohibit all forms of commercial surrogacy. Researchers are proposing to introduce a model that would motivate surrogate mothers to provide their services for appropriate compensation. At the same time, there should be a professional regulatory body that would oversee the selection of surrogate mothers, their training and compliance with ethical standards. This body would ensure fair payment, information of the parties about their rights and obligations, voluntary consent and legality of contractual restrictions concerning the surrogate mother. L. van Zyl and R. Walker believe that in this way the exploitation and unreasonable demands of future parents would be eliminated, minimizing the risk of harm [17]. We share this approach and believe that commercial surrogacy deserves to exist but should be regulated by an appropriate program that would clearly define the procedure, conditions and grounds for its implementation.

Undoubtedly, the realities of legal regulation in the field of surrogacy are far from ideal, as they are based on numerous anachronisms (are outdated) and do not correspond to the current level of society development. At the same time, for example, Ukrainian legislation in the field of reproductive medicine is considered the most liberal in Europe. This attracts foreigners to Ukraine (who are the main consumers of surrogacy services) and specialized foreign corporations. However, liberalism should not mean uncontrolled use of assisted reproductive technologies, including surrogacy. In view of this, we consistently defend the position on need to regulate these relations at the level of a special (separate) legal act - the Law of Ukraine "On Surrogacy", which would be based on a "model" international and designed to solve all

or at least most existing problems in the specified plane. A similar novel could be useful for Greece (where surrogacy is used quite actively) and other countries.

In addition, we are convinced that States in which surrogacy is prohibited (France, Germany, Norway, Sweden, etc.) should review this issue at the level of national legislation, taking into account its medical aspect and the provisions of Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms which enshrines the right of everyone to respect for their private and family life [18]. Of course, on the one hand, the European Court of Human Rights (for example, in Labassee v. France, application № 65941/11, judgment of 26 June 2014 [19] and in Mennesson v. France, application [65192/11, decision of 26 June 2014 [20]) states that each state can decide on its own whether to allow or prohibit surrogacy within its territory. However, on the other hand, in the case of "S.H. and others v. Austria" (application no. 57813/00, judgment of 3 November 2011) the Court held that the couple's right to conceive a child and use artificial insemination for that purpose is protected by Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms, as the decision is one of aspects of private and family life [21]. In turn, in the case of "Dickson v. the United Kingdom" (application № 44362/04, judgment of 04 December 2007) The European Court of Human Rights explicitly stated that the denial of access to artificial insemination to applicants in prison affected the applicants' right to privacy and family life, including the right to respect for their right to become genetic parents [22]. We believe that the unconditional recognition of surrogacy as an accessible method of treatment should become a universally recognized world practice.

In contrast, some international feminist organizations (such as The International Coalition for the Abolition of Surrogate Motherhood) oppose the legalization of surrogacy, [23] considering auxiliary gestation humiliating for the surrogate mother for some reason. However, as long as the world community's perception of surrogacy is in the grip of such speculation, existing problems will remain unresolved and hundreds of thousands of people will be deprived of the opportunity to make proper use of the institution of surrogacy.

The next problem is that quite often surrogate mothers, despite their high social mission, are stigmatized, "branded" (we have already mentioned above). This is primarily due to negative attitude of certain social groups to artificial insemination and assisted reproductive technologies in general. Moreover, in some cases, surrogate mothers are harassed or even victims of criminal offenses. Often surrogate mothers are left with their problems, not being able to effectively protect and / or restore their rights. All this indicates the imperfection of legislative mechanism for ensuring their rights, and especially the unified international mechanism, with elements of imperative to prohibit such harassment. It should be noted that in legislative world practice of any country today there is no criminal liability for bullying (harassment) of a surrogate mother, i.e. intentional systematic commission of physical, psychological or economic violence against her, which leads to physical or psychological suffering, health disorders, loss of ability to work or deterioration of the quality of victim's life.

In addition, as stated in paragraph 4 of the Declaration of Fundamental Principles of Justice for Victims of Crime and Abuse of Power, adopted by General Assembly resolution 40/34 of 29 November 1985, victims should be treated with compassion and dignity. They have the right to access justice mechanisms and compensation for damages as soon as possible in accordance with national law [24]. All this indicates the need to establish appropriate legislation regulating the participation of surrogate mothers who have suffered from criminal offenses in criminal proceedings.

Therefore, we believe that in criminal proceedings where the victims are surrogate mothers, the participation of a representative (professional lawyer) should be recognized as mandatory, because only then will they be able to exercise their rights properly, effectively and freely. In turn, we also emphasize the need to establish a proper procedure for persons who are surrogate mothers of free legal aid.

CONCLUSIONS

1. The study shows that today a number of issues related to legal nature of surrogacy, conditions and procedure for its implementation remain out of the EU's attention. Nevertheless, a perfect mechanism should be created for people who want to take advantage of this medical and legal institute. In our opinion, the adoption of a separate regional (within the EU) legal act will fully solve the existing problems, ensuring the effectiveness and transparency of surrogacy, will unify the mechanisms of medical tourism in the field of surrogacy.
2. We see a close position on the need to eliminate any discrimination in access to treatments such as in vitro fertilization and assisted gestation. Exceptions are only relevant medical contraindications (for example, the presence of socially dangerous mental illness or hereditary diseases).
3. Based on the provisions of Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms, which enshrines the right of everyone to respect for their private and family life, the EU Regulation / Directive should lay down the basic provisions on surrogacy:

1) all methods of assisted reproductive technologies, including surrogacy, are methods of treatment;
2) possibility of applying such methods can in no way depend on a person's social status, in particular, gender self-identification, the fact of being married or having a same-sex partnership;
3) access to treatment: states are obliged to provide appropriate medical care and ensure the possibility of exercising the right to reproduction with all available resources of modern medical science;
4) restriction of access to treatment based on medical contraindications;
5) unification of the agreement form on provision of surrogacy services;
6) list of rights of all participants during participation in the program of assisted reproductive technologies;

7) measures to prevent stigmatization of surrogate mothers and commission of criminal offenses against them in some cases;
8) creation of national professional regulatory bodies that would oversee the selection of surrogate mothers, their training and compliance with ethical standards with the development of standards for their activities;
9) ensuring the right of a representative (professional lawyer) to participate in criminal proceedings where the victims are surrogate mothers on a gratuitous basis.

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REVIEW ARTICLE

LEGAL REGULATION OF SURROGACY AT THE INTERNATIONAL AND NATIONAL LEVELS: OPTIMIZATION OF PERMISSIONS, PROHIBITIONS AND LIABILITY

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ABSTRACT

The aim: To identify the issues that arise in states that consolidate different approaches to the use of surrogacy technologies and formulate the main trends towards unification of legislation in this area.

Materials and methods: The study used a complex of general scientific and special methods of cognition, in particular, dialectical, generalizing, comparative legal and others. The research is based on the national and international legislation of different countries, the jurisprudence of national courts and the practice of the ECHR, doctrinal research by scientists from different countries.

Conclusions: The development of an international legal document which aim is to protect the rights of children born with the use of surrogacy technology is substantiated on the basis of the main principle enshrined in paragraph 1 of Art. 3 of the Convention on the Rights of the Child - the principle of the best interests of the child.

KEY WORDS: surrogacy, assisted reproductive technologies, the origin of the child, contractual regulation of family relations, cross-border criminal liability

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INTRODUCTION

The first child using surrogacy technology was born 40 years ago by fertilizing the surrogate's egg with the customer's sperm (traditional surrogacy). Since then, the use of surrogacy technology in the world has become quite popular in solving the problems of childlessness. Traditional surrogate motherhood, in which a surrogate mother is genetically related to a child, is now almost never resorted to, although it is still allowed in the laws of some states. In modern medicine, usually gestational surrogacy is used, in which the surrogate mother is not biologically related to the child. That is why it is believed that gestational surrogacy is more benign for a surrogate mother. The presence of a biological connection between a child and one (or both) potential parents favorably distinguishes surrogate motherhood from adoption, in which usually a biologically alien child is adopted, and makes this way of solving the problems of combating childlessness for prospective parents a higher priority.

And despite the fact that a lot of time has passed since the first experience of using surrogacy, the attitude towards this technology in society is not unambiguous. This is due to the fact that surrogate motherhood is not a purely medical problem, but affects the moral, ethical, religious aspects, in connection with which states have different attitudes towards its legal regulation.

In some countries, surrogacy is prohibited, in others it is allowed, in some states it is not regulated at all. It should be noted that no matter what approach to the legal regulation of surrogacy one or another country chooses, everyone has problems with its application and the consequences of its application. It is safe to say that surrogacy has become a common problem for all states and requires the development of a common concept for its regulation.

THE AIM

The purpose of this article is to study the national legislations of different states to identify problems associated with the use of surrogacy and to find ways to develop a general concept of its legal regulation at the international level.

MATERIALS AND METHODS

The research is based, firstly, on the study of the national legislation of a number of European states (Belarus, France, Germany, India, Russia, Ukraine, Switzerland, etc.), which provide various regimes of legal regulation of surrogacy as a reproductive technology. By means of a comparative analysis of their prescriptions, general and different provisions in such legal regulation have been identified, and the problems associated with cross-border recourse to

surrogacy are shown. In addition, some decisions of the ECHR, which resolved the issue of the balance of human rights when using surrogacy technology, were studied. Finally, the materials of the judicial practice of individual states are also analyzed in terms of establishing the legal consequences of resorting to the technology under study.

REVIEW AND DISCUSSION

ISSUES OF COUNTRIES WHICH LEGISLATION PROHIBITS SURROGATE MATERNITY.

Many European countries prohibit the use of surrogacy technologies. The methods of prohibitions in such states differ: in some countries, such a prohibition is either directly contained in the Constitution or established by the courts, based on the interpretation of its more general provisions; in others, it is contained in civil law or established by special laws; thirdly, it is also supported by sanctions in the criminal law.

For example, in Germany courts, based on Part 1 of Art. 1 of the Constitution, which declares that "Human dignity shall be inviolable. To respect and protect it shall be the duty of all state authority" [1] and section 1591 of the German Civil Code [2], according to which "The mother of a child is the woman who gave birth to it", come to an unequivocal conclusion that surrogacy is prohibited [3].

At the same time, a special law was adopted in Switzerland: Federal Act on Medically Assisted Reproduction [4], which established that "Ovum and embryo donation and surrogate motherhood are prohibited" (art. 4). The principle of the monism of the criminal law is unknown to the Swiss criminal law. Therefore, it is not surprising that criminal liability for violation of this prohibition was established not in the Swiss Criminal Code, but in the same Federal Act on Medically Assisted Reproduction. Article 31 (as amended by Federal Act of 12.12.2014 [5]) provides that "Any person who uses an assisted reproductive technique in a surrogate mother shall be liable to a custodial sentence not exceeding three years or to a monetary penalty. The same penalty shall apply to any person who acts as an intermediary for surrogate motherhood".

However, despite the existing bans, residents of these states sometimes deliberately violate national legislation in order to solve the problem of childlessness. To do this, they apply for the use of surrogacy technology in those countries in which this technology is allowed at the legislative level. As a result, such parents in their country, and sometimes in the country to which they come to apply this procedure, have difficulties with legalizing their parental relations, and sometimes – problems associated with bringing them to justice, including criminal one [6]. As you know, the criminal legislation of many European countries proceeds in such cases from the so-called principle of "double wrongfulness", which consists in the fact that the possibility of criminal prosecution under the legislation of a particular country for a crime committed outside its borders is conditioned by the recognition of the act as criminal under the law of the place of its commission. For example, according to clause "a" part 1 of Art. 7 of the Criminal Code of Switzerland "Any person who commits a felony or misdemeanor abroad ... is subject to this Code if the offence is also liable to prosecution at the place of commission or the place of commission is not subject to criminal law jurisdiction" [7] Thus, referring to the technology of surrogacy, for example, on the territory of Ukraine (according to the legislation of which these actions are not criminal), a Swiss citizen or resident, even after returning to the jurisdiction of his state, cannot be held criminally liable.

In the EU countries many judges have come up with legal arrangements that grant a child born from a commercial gestational surrogacy legal parentage with its "intended parents" [8]. In particular, "In a number of States ad hoc, 'ex post facto' remedies have been found with a view to reducing the harmful impact of this legal limbo for children. These remedies are ways of trying to cope with situations which are, in effect, a fait accompli: the child is already born and usually the surrogate mother does not wish to care for the child and the intending parents do» [9].

An analysis of the practice of the ECHR allows us to name some of the response measures that such states apply in relation to their citizens who have violated the prohibition of national legislation on surrogacy. Such measures should, for example, include:

- refusal to guarantee legal recognition of a father-child relationship that was legally established in the state in which the surrogate mother gave birth to a child (*Mennesson v. France* [10] and *Labassee v. France* [11]);
- the authorities' refusal to grant permission to enter the territory of the state of a child who was born in another country from a surrogate mother until the intended parents provide sufficient evidence to confirm their family relationship with the child (*D. and Others v. Belgium* [12]);
- taking away the child and transferring it for adoption (*Paradisoi Campanelli v. Italy* [13]);
- refusal of the authorities to register all information from the birth certificate of children born abroad in accordance with the agreement on gestational surrogacy (*C and E v. France* [14])

There have also been attempts in Italy to prosecute alleged parents for violating the ban on surrogacy. However, since Italian criminal law also recognizes the already mentioned so-called principle of "double wrongfulness", the court in this case dropped the charge on the grounds that the parents were not criminally responsible for the actions that are lawful in the territory of the state where they were committed [15, p. 6-7].

The application of such negative consequences to citizens who are forced to turn to medical institutions in other countries to fulfil their natural need for parenting naturally causes their discontent. They reasonably believe that by such actions states violate their right to respect for private and family life guaranteed by Art. 8 EConvHR, States, on the other hand, justify the possibility of applying negative consequences to alleged parents by actions in the public

interest in order to protect health or morality, protect the rights and freedoms of others. Thus, for example, in *Mennesson v. France* and *Labassee v. France* The Court noted that the State intervention had two legitimate aims, as defined in Art. 8, namely "health protection" and "protection of the rights and freedoms of others". The court also found that the refusal of the French authorities to recognize the legal relationship between children born as a result of surrogacy technology stems from the desire to prevent French citizens from seeking help outside of France for reproductive technology, which is prohibited in that country in order to protect children and a surrogate mother.

Thus, in regulating relations on the use of surrogacy technologies and their consequences, it is necessary to try to maintain a fair balance between private and public interests, in which the ECHR plays an important role. It should be noted that when resolving disputes related to the use of surrogacy technologies, the ECHR most often makes decisions in favor of the intended parents. Thus, in *Mennesson v. France* The Court stressed that states should be left with wide boundaries in the choice of decision-making related to surrogacy, given the complex ethical issues and lack of consensus on these issues in Europe. However, these choices are narrow when it comes to parenthood, in which a key aspect of individuals' identity has been involved. The Court had to find out whether a fair balance had been struck between the interests of the State and the immediate interests of persons, with particular emphasis on the fundamental principle that, whenever children are affected, their interests should prevail.

However, in *Paradiso and Campanelli v. Italy* The ECtHR dismissed the applicants' complaint and recognized the actions of the Italian authorities as legitimate, pursuing legitimate aims to counteract violations and aimed at protecting the rights and freedoms of others. The main argument in this case was the lack of a biological connection between potential parents and a child born to a surrogate mother. And despite the fact that the reason for this was the mistake of the medical institution, whose services the potential parents turned to, the court considered that the implementation of the exclusive powers of the state to recognize the legal parent-child relationship is possible only in the case of biological connection or adoption. Thus, the removal of the child and the transfer of him for adoption was recognized as legal.

All of the above allows us to conclude that in countries where surrogate motherhood is prohibited, there is a need to think about the possible reform of legislation and regulatory regulation of the registration process of potential parents' parental rights in relation to a child born by a surrogate mother in another state.

ISSUES OF COUNTRIES WHICH LEGISLATION ALLOWS SURROGATE MOTHERHOOD.

Surrogacy is allowed in Belarus, Great Britain, Georgia, Russia, USA, Ukraine and other countries. The laws of these states regulate the use of this technology in different ways. In some countries, only altruistic surrogacy is allowed, in which the surrogate mother does not receive remuneration for bearing and giving birth to a child, but is only entitled to compensation for losses and costs associated with surrogacy. In other countries, commercial surrogacy is allowed. It is the latter that become a refuge for childless people who come there for the purpose of bearing and giving birth to a child for them by a surrogate mother. It is worth noting that the services of surrogate mothers from such countries are used not only by childless couples from states where surrogacy is prohibited, but also by citizens of those countries where the use of this technology is permitted, but associated with significant organizational and financial difficulties. So, statistically about half of all U.K. surrogacy contracts involve overseas surrogates — many of them in locations (like California) where commercial surrogacy contracts are enforceable [16, p. 7].

It should be noted that many of the countries that allow commercial surrogacy are emerging economies. The incomes of citizens of such countries are quite low, and women are forced to accept the role of a surrogate mother in order to earn money. Many researchers note that commercial surrogacy in economically underdeveloped countries is a form of exploitation of women [17, p. 12].

The governments of some countries, which have become the center of reproductive tourism, are forced to respond to abuses in this area in the most radical way. So, in 2012, about 10,000 foreign clients visited India to provide reproductive services; almost 30% of them were either single or homosexual. After ten years of commercial surrogacy, India has finally banned commercial surrogacy for foreigners [18]. The ban was based on Ms Jayarshi Wad's lawsuit in the New Delhi Supreme Court, in which she argued that surrogacy was a violation of women's rights to life and liberty. Commercial surrogacy for foreign citizens was also prohibited in other countries, that used to be the "surrogacy havens", due to all the ethical and moral questions arising from commercial surrogacy and the inherent risk of human rights violations» [19, p. 17]).

After the introduction of a ban on commercial surrogacy in India, as well as in Thailand, Nepal and Cambodia, the center of transnational reproductive tourism shifted to the countries of Eastern Europe, the leaders of which in this area are Russia, Ukraine, Belarus, Georgia. The lack of state control over the conclusion of agreements on surrogacy and the use of this technology is the reason for the lack of statistics on the number of children born to surrogate mothers. The scope of this procedure, for example, in Ukraine and Russia, was revealed only when journalists discovered dozens of babies born to surrogate mothers, whom their biological parents could not pick up due to the closure of state borders during the quarantine period caused by the coronavirus pandemic (COVID-19) [20; 21].

The next problem faced by countries that allow surrogacy is to find an answer to the question: whose rights are in priority – a surrogate mother or potential parents? And related questions: how is parental rights transferred from a surrogate mother to potential parents (in the event that parental rights

initially arise for the surrogate mother and her spouse)? Is it possible to enforce a surrogacy agreement if the surrogate mother refuses to voluntarily transfer the child or rights to it? Countries that allow surrogacy deal with these issues in different ways in their national legislation.

So, for example, in accordance with Part 4 of Art. 51 of the RF FC, persons who are married and have given their written consent to implantation of an embryo to another woman for the purpose of carrying it, can be registered by the child's parents only with the consent of the surrogate mother. In the judicial practice of the Russian Federation, there are several high-profile cases related to the refusal of a surrogate mother to give consent to the transfer of a child to biological parents [22]. The priority of the rights of a surrogate mother in relation to the rights of potential parents is also sharply criticized by judge of the Constitutional Court of Russian Federation S.D. Knyazev: "The purpose of surrogacy as a method of treating infertility is to provide a married man and woman, who are unable to independently realize their reproductive rights, the ability to become parents of their genetic child. In this regard, the question inevitably arises of whether the option of legal regulation chosen by the legislator, which removes, according to many experts, in the interests of children even the potential for disputes over the rights to a child between a surrogate mother and genetic parents, corresponds to the purpose of the institution of surrogate motherhood" [23].

The opposite approach is laid down in the family legislation of Ukraine and Belarus which enshrines the presumption according to which the parents of a child born by a surrogate mother are the customers (Art. 123 of the FK of Ukraine [24], Art. 52 of the Code of the Republic of Belarus on Marriage and Family [25]). This approach makes these countries very attractive for transnational reproductive tourism, since the priority of the rights of potential parents is enshrined in the legislation of these countries.

It should be noted that art. 21 of the Law of the Republic of Belarus "On Assisted Reproductive Technologies" [26] regulates in sufficient detail the issues related to the use of surrogacy. Particularly noteworthy is the fact that the legislator fixes the essential terms of the contract and the rights and obligations of a surrogate mother.

Allowing only altruistic motherhood significantly limits the use of this technology. Usually, in this case a relative or a good acquaintance of the family becomes a surrogate mother for the intended parents, who, out of the kindness of her heart, agreed to bear a child for a childless couple. And despite the fact that with altruistic surrogate motherhood, it is difficult to reproach the exploitation of a surrogate mother who is forced to agree to bear someone else's child in order to earn money, many issues still arise.

GENERAL ISSUES THAT ARISE IN THE LEGAL REGULATION OF THE APPLICATION OF TECHNOLOGIES OF SURROGATE MATERNITY AND THE TRENDS OF THEIR SOLUTION.

The issues that were faced by national governments and the ECHR in the field of surrogacy technologies have caused concern at the highest international level. As a result, these issues are being actively discussed at various international platforms in order to develop common guidelines and approaches in the legal regulation of surrogacy. For example, since 2011, the Permanent Bureau of the Hague Convention on Private International Law has been studying issues of private international law, including issues arising in the context of international agreements on surrogacy. In 2018, several UN agencies organized an inter-agency meeting on surrogacy and human rights in Bangkok. In June 2019, during the 74th session of the UN General Assembly, the Special Rapporteur on the sale and sexual exploitation of children, including child prostitution, child pornography and other child sexual abuse material, presented a report on the protection of the rights of children born from surrogacy arrangements.

Based on a study of the practice of surrogate motherhood using, national legislative regulation, and judicial practice, she identified issues and provided recommendations for improving national legislation in order to comply with the minimum guarantees of the rights of children born to surrogate mothers. It also proposed to consider the possibility of developing a model law based on the available scientific evidence and good practice on the application of the principle of the child's best interests by states in the context of domestic law and public international law governing international and transnational surrogacy procedures [27]

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CONCLUSIONS

It seems that the development of an international document aimed at protecting the rights of children born with the use of surrogate motherhood technology is the only possible way to solve the issues that arise in this area. Unification of legal regulation in the field of application of surrogacy technologies should be carried out on the basis of the main principle enshrined in paragraph 1 of Art. 3 of the Convention on the Rights of the Child - the principle of the best interests of the child. In this paradigm, national legislation should also develop, regardless of whether the use of surrogacy technology is allowed or prohibited in the state. Particular attention in acts dedicated to the regulation of surrogacy should be paid to finding the optimal balance between the interests of the surrogate mother and potential parents. It is also necessary to develop a system for monitoring the use of surrogacy technology at the international and national levels. This will minimize violations and abuses in this area.

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REVIEW ARTICLE

EAST SLAVIC SURROGATE MOTHERHOOD: STATE OF LEGAL REGULATION AND RISK OF HUMAN RIGHTS VIOLATION

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ABSTRACT

The aim: The aim of the study is to determine the state of legal regulation of surrogacy in Ukraine, Russian Federation and Belarus, to identify risks of human rights violations, to identify legal and medical mechanisms to combat the exploitation of women, and to outline a portrait of a surrogate mother.

Materials and methods: The empirical basis is the legislation of Ukraine, Russian Federation and Belarus, which regulates the service of surrogacy, information from the websites of agencies and clinics in this area, as well as personal stories of 41 surrogate mothers, set out in open sources. The following methods were used: dialectical, comparative, statistical, induction and deduction, questionnaire, analysis and synthesis, content analysis.

Conclusions: The results of the study clarify both the common features of the legal regulation of surrogacy in the East Slavic countries, and the specifics of each of them; the main problems in the field of its application are outlined; the risks of violation of the rights of genetic parents, children and surrogate mothers are characterized. Legal and medical mechanisms for counteracting the exploitation of surrogate mothers have been identified.

KEY WORDS: surrogacy, gestational courier, genetic parents, child, embryo

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INTRODUCTION

Surrogacy service is one of the most controversial. On the one hand, it is a unique opportunity to have your own child for people who are not able to conceive (bear, give birth) on their own. On the other hand, this phenomenon is criticized for: the possibility of use only by wealthy people; degradation of women; negative impact on a child [1]; unethical nature of such a procedure; exploitation of vulnerable position of women; risks of violation of the rights of genetic parents, surrogate mother and child.

The policy of different states on this issue is diverse and provides for three main regimes of its legislative regulation: prohibitive, altruistic and permissive [2]. In surrogate countries, any surrogacy is prohibited (Austria, Iceland, Italy, Moldova, Germany, Norway, Pakistan, Romania, Saudi Arabia, Serbia, some US states, France, Switzerland). In countries with altruistic regimes, there is a ban on commercial surrogacy, while it is allowed free of charge (Australia, Belgium, Great Britain, most provinces of Canada, the Netherlands, some US states). In countries with a permit regime, surrogacy is allowed (Ukraine, Belarus, Georgia, Kazakhstan, Kyrgyzstan, the Russian Federation, some US states, the Canadian province of Quebec), but has certain conditions and restrictions. The regime of zero legal regulation should be added to these groups, which, in turn, can be divided into positive-zero (when the lack of legal regulation is not an obstacle to the provision of services: Azerbaijan, Ireland, Japan) and negative-zero (countries where the service of surrogacy is insignificant (ex lege null), for example, in Poland [3]).

One of the most favorable conditions for obtaining the service of surrogacy exists in the East Slavic countries (Ukraine, Russian Federation and Belarus). Attractive for people who want to become parents, especially from abroad, in their markets is the relatively high quality of medical services and lower prices than in other countries. The study of these states' legislation has shown that the key common features for them are: 1) relations are regulated through the conclusion of the contract for the provision of services; 2) both non-commercial and commercial surrogacy and exclusively gestational (for which there is no genetic link between the surrogate mother and the embryo) are allowed; 3) potential parents (or at least one of them) must have a genetic link with a child; 4) the service is not provided to homosexual couples; 5) persons may use the service only on medical grounds; 6) there are no restrictions on the service price. At the same time, the practice of these services has a few legal, medical, economic, social and ethical issues.

THE AIM

The aim of the study is to determine the state of legal regulation of surrogacy in Ukraine, the Russian Federation and Belarus, to identify risks of human rights violations, to identify legal and medical mechanisms to combat the exploitation of women, and to outline a portrait of a surrogate mother.

MATERIALS AND METHODS

The empirical basis is the legislation of Ukraine, Russian Federation and Belarus, which regulates the service of surrogacy, information from the websites of agencies and clinics in this area, as well as personal stories of 41 surrogate mothers, set out in open sources. The following methods were used: dialectical, comparative law, statistical, induction and deduction, questionnaire, analysis and synthesis, content analysis.

REVIEW AND DISCUSSION

There are no official statistics on the number of surrogacy services provided in Russia, Ukraine and Belarus. According to unofficial sources, several thousand children are born to surrogate mothers in Ukraine every year [4, 5]. According to the European Surrogacy Center, at least 22,000 children are born to surrogate mothers in Russia each year, with an annual increase of at least 20% [6]. Given the social importance and problems that exist in the field of surrogacy, it is seen that this phenomenon needs official registration.

Analysis of the legal regulation of the use of surrogacy shows that in Ukraine and Russia it is carried out by general acts: The Family Code[1], health care legislation[2] and civil status acts[3]. Special acts regulating the application of surrogacy procedures in these states are adopted by the Ministry of Health and operate at the secondary level[4]. These issues are regulated in more detail in Belarus. In addition to the general act of Family law[5], a special Law "On Assisted Reproductive Technologies", 07.01.2012 № 341-3, as well as bylaws[6] of the Government and the Ministry of Health[7] are dedicated to them. The conclusion of an agreement between a parent and a surrogate mother in Ukraine and Russian Federation is based on the general clauses of the Civil Code regarding the agreement on the provision of services[8]. Unlike in Russia and Ukraine, in Belarus, the surrogacy agreement is named and has mandatory conditions[9].

There is no definition of surrogacy in the legislation of Ukraine. In Russia, it is defined as the delivery and birth of a child (including premature birth) under a contract between a surrogate mother (a woman who bears a fetus after the transfer of a donor embryo) and potential parents whose gametes were used for fertilization, or a single woman for whom childbearing and childbirth is not possible on medical basis (paragraph 9 of Article 55 of the Law "On Fundamentals of Public Health in the Russian Federation", paragraph 77 of the order № 107n). In Belarus, surrogacy is defined as a type of assisted reproductive technology, which is a combination of sperm and egg removed from the body of the genetic mother, or a donor egg outside the woman, the development of resulting embryo, subsequent transfer of this embryo to the uterus, carrying and giving birth to a child (Article 1 of the Law "On Assisted Reproductive Technologies").

At the same time, the regulations of the parties to this agreement differ in three countries. In Russia, the agreement is signed between the spouses-potential parents and the surrogate mother or between a single woman-genetic mother and surrogate mother (Article 55 of the Law "On the Fundamentals of Public Health in the Russian Federation"). At the same time, in practice the issue of the possibility of using the service of surrogacy and registering a child as one's own by persons who are not in a registered marriage, as well as by single persons (both women and men) resolved differently. Russian legislation in this regard, as well as the practice of its application, are quite contradictory [7, 8].

In Ukraine the issue is not fully resolved. On the one hand, paragraph 6.11 of the Procedure for the use of assisted reproductive technologies in Ukraine defines the list of documents required for surrogacy from a spouse in whose interests surrogacy is carried out, including a copy of marriage certificate (which, according to Article 21 of the Family Code of Ukraine, is a family union of a female

[1] In Ukraine - Art. 123 of the Family Code of Ukraine, January 10, 2002 № 2947-III; in the Russian Federation - articles 51, 52 of the Family Code, 29.12.1995 N 223- ФЗ .

[2] Law of Ukraine "Fundamentals of the Legislation of Ukraine on Health Care", November 19, 1992 № 2801-XII (Article 48); Federal Law "On the Fundamentals of Public Health in the Russian Federation", 21.11.2011 N 323- ФЗ (Article 55).

[3] Order of the Ministry of Justice of Ukraine "On approval of the rules of state registration of civil status acts of Ukraine", 18.10.2000 № 52/5 (p. 11); Federal Law of the Russian Federation "On Civil Status Acts", 15.11.1997 № 143 (Article 16).

[4] Order of the Ministry of Health of Ukraine "On approval of the Procedure for the use of assisted reproductive technologies in Ukraine", 09.09.2013 № 787 (Section VI); Order of the Ministry of Health of the Russian Federation "On the Procedure for using of assisted reproductive technologies, contraindications and restrictions on their use", 30.08.2012 № 107н.

[5] Code of the Republic of Belarus "On Marriage and Family", 09.07.1999 № 278/3 (Article 52).

[6] Resolution of the Council of Ministers of the Republic of Belarus "On the essential terms of the surrogacy agreement", 04.11.2006 № 1470.

[7] Resolution of the Ministry of Health of the Republic of Belarus "On approval of the list of medical indications and contraindications to surrogacy, procedure and scope of medical examination of surrogate mothers, genetic mothers and their spouses",14.09.2006 №71.

[8] Civil Code of Ukraine, January 16, 2003 № 435-IV; Civil Code of the Russian Federation of 30.11.1994 N 51- ФЗ.

[9] According to Art. 21 of the Law "On Assisted Reproductive Technologies" essential conditions of surrogacy agreement are, in particular: the provision by one woman (surrogate mother) to another woman (genetic mother or woman who used a donor egg) services of carrying of a pregnancy and childbirth, conceived with the participation of an ovum (ova) removed from the genetic mother' body, or a donor egg (ova); quantity of embryos that will be transferred to the uterus of surrogate mother; an indication of healthcare organization (s) in which the connection of the sperm (s) and ovum will take place, removed from the body of the genetic mother, or donor egg (eggs), transfer of the embryo (embryos) in the uterus of surrogate mother, monitoring the course of her pregnancy and childbirth; the surrogate mother's duty to follow all the doctor's instructions and to provide the genetic mother or the woman who used the donor egg and her husband with information about her health and the health of child (ren), etc.

and a male). On the other hand, one of such documents is a notarized copy of a written joint agreement between a surrogate mother and a woman (husband) or spouses, which means that one of the spouses may be a party to the agreement. Despite the lack of a direct ban, the possibility to use the service of surrogacy for persons who are not in a registered marriage and single persons is not provided.

In Belarus, the parties to the agreement are a potential mother (a woman who used a donor egg) and a surrogate mother. Married females enter into a contract with the written permission of their husbands. However, if the potential mother is a genetic mother, she is not allowed to have a husband. At the same time, if a potential mother has used a donor egg, she must have a husband, as only his sperm are used to fertilize the donor egg (Articles 20, 21 of the Law on Assisted Reproductive Technologies). It follows that the service of surrogacy in Belarus can be used by a married woman who is in an actual marital relationship or a single woman, but a single man cannot.

In addition to the surrogate mother and genetic parents, the subject of the legal relationship is the clinic and may be an agency and intermediaries. In all three countries, the nature of the relationship between the medical institution and the parents, as well as between the medical institution and the surrogate mother, remains unclear; the status of agencies and intermediaries is unregulated. In this regard, the UN stressed the need to regulate all intermediaries involved in surrogacy arrangements, use of contractual arrangements, and ethical standards) [9].

Analysis of information from the websites of agencies and reproductive centers of the three countries showed that today the surrogacy market is filled with offers that vary significantly in price and scope of services (differentiated service packages such as standard, elite, premium). Thus, the elite offer a number of additional services, such as patronage and control of the program, additional legal services, city tour, babysitting services[10]. One of the clinics operating in Ukraine offers at least 20 packages of services that differ not only in price (the cheapest differs from the most expensive seven times), but also in a number of positions, including accessibility for single couples and single people, the country, in which the birth will take place, providing legal support, etc.[11]

Moreover, it is even possible to choose the child's sex. This option requires special attention, because in Russia and Belarus, usually, it is not available, except in cases of inheritance of diseases related to sex (Part 4 of Article 55 of the Russian Federation Law "On Fundamentals of Public Health in the Russian Federation" and Article 15 of the Law of the Republic of Belarus "On Assisted Reproductive Technologies"). Thus, the choice of sex is allowed only on medical grounds, not social. There is no such prohibition in the legislation of Ukraine, although it is contained in Art. 14 of the Convention for the Protection of Human Rights and Dignity of the World concerning the Application of Biology and Medicine, which Ukraine signed on March 22, 2002, but has not yet ratified. This provision is aimed at preventing gender discrimination, degrading human dignity and violating the natural relationship between women and men. Thus, Ukraine, leaving this issue out of regulation, does not adhere to international standards, but at the same time receives additional benefits from people who want a child of a certain sex.

In all three countries the legal nature of the surrogacy agreement, understanding of such key concepts as surrogacy, agreement on it, surrogate mother, genetic parents, remain debatable; rights and responsibilities of surrogate mothers and genetic parents; legal relations between genetic parents, surrogate mother and clinic, agency, intermediaries [10; 11; 12; 13]. The issues of unilateral refusal to perform the contract, refusal of parents from the born child, the fate of the child in case of death of parents or one of them, their divorce are not regulated by law. Therefore, the quality of the contract is an important aspect of using this method of reproductive medicine.

Incomplete legislation and the temptation to make big profits create high risks of violations of the genetic parents' rights, surrogate mothers and children, determine the favorable environment for the development of crime, attractiveness of the market for fraudsters.

One of the important issues involving the risks of violating the rights of prospective parents is the *recognition of their paternity*. This problem is especially acute in Russia, where the transfer of a child to parents is carried out with the consent of the surrogate mother[12]. The Constitutional Court of the Russian Federation in its decision of 15.05.2012 № 880-O pointed to the surrogate mother's ability to register herself as the child's mother in birth certificate, which is recorded in the birth certificate, thus stipulating for the woman who gave birth, rights and responsibilities of the mother. As a result, parents have no guarantee that the child will be handed over to them. This problem, in experts view, hinders the development of the service in Russia [14].

Instead in Ukraine (Article 123 of the Family Code) and Belarus (Article 52 of the Marriage and Family Code) the presumption of the child's origin from the parents-donors

[10] According to Part 2 of Art. 123 of the Family Code of Ukraine in case of transfer to another woman's embryo of a person conceived by a spouse (husband and wife) as a result of the use of assistive technologies, the child's parents are the spouses. <?> The information is taken from the sites of such agencies and clinics as Center Semya. https://xn----7sbbjlcv3aghvajcuff5m.xn--p1ai/surrogatnoye-materinstvo-2020/surrogatnoe-materinstvo-pakety-uslug-centra-semja.html; Agency «babyforyou». https://babyforyou.org/dlya-surrogatnyh-mam/; Feskov human reproduction group. https://surrogate-mother.ru/surrogatnoe-materinstvo

[11] Feskov human reproduction group. https://surrogate-mother.ru/surrogatnoe-materinstvo;

[12] According to Part 4 of Art. 52 of the Family Code of the Russian Federation, persons who are married to each other and gave their written consent to the implantation of embryo to another woman for the purpose of childbirth, may be recorded by the child's parents only with the woman's consent who gave birth (surrogate mother); for item 5 of Art. 16 of the Law "On Civil Status" in the state registration of the child birth on application of the spouse who agreed to implant the embryo in another woman for the purpose of childbirth, along with a document confirming the birth of a child, must be presented a document issued by a medical organization certifies the fact of obtaining the consent of woman who gave birth to child (surrogate mother) to the record of the specified spouses by the child's parents.

of genetic material which is an important guarantee of the rights of the latter. However, it should be noted that in Ukraine the settlement of this issue is controversial. If the Family Code recognizes the parents of the child as a spouse, the Rules of State Registration of Civil Status establish an additional requirement for surrogate mother's consent to the registration of spouses' parents[13], which allows the surrogate mother to refuse to give such consent and register the child in her name. As a result, there are additional risks for the couple when registering a child, because the surrogate mother can blackmail the couple, demanding, for example, additional fees. For comparison in Belarus, when registering the birth of a child from a surrogate mother, the applicant provides only a surrogacy agreement (paragraph 19 of the Regulation of the Council of Ministers "On the procedure for registration of civil status and issuance of documents and (or) certificates by civil registration authorities").

It has already been noted that in all three countries a surrogate mother cannot act as an egg donor. Lack of direct family ties (however, surrogate mothers are related to genetic parents and the child) reduces the risk of surrogate mothers wanting to keep the child. An analysis of the stories of surrogate mothers revealed that in half of the cases, women did not have attachment to the child - they perceived the need to give the baby as due. At the same time, in 5 cases, this attachment was such that it was difficult to transfer the child to genetic parents. In addition, there is the problem of determining the origin of child from the parents, when the embryo was conceived using donor material [16], when the donor egg and male reproductive cells are used for conception, as well as when donor zygotes and embryos are transferred to the surrogate mother [17].

The surrogacy market is attractive to black brokers, pseudo-agencies and those involved in fraud or blackmail. In particular, genetic parents suffer from surrogate mothers demanding additional services for the threat of having an abortion. Some women, due to childless couples, undergo a complete medical examination of their body, and sometimes treatment, after which they disappear [18]. In order to counter such manifestations, a number of agencies compile and publish blacklists of surrogate mothers, i.e. women who have committed fraud or other unfair acts[14].

In practice, there are such manifestations of illegal activities of agencies and clinics as masking the purchase of children under a surrogacy agreement. This can happen through the fictitious marriages of surrogate mothers with foreigners, artificial insemination of these women and the sale of children born to foreigners; giving visibility to the procedure of surrogacy, when the prospective parents do not provide any biological material at all and as a result the newborn child is not genetically related to them [18, 19, 20]. In such cases, the alleged parents may be complicit in illegal actions, as well as become victims of crime, or, being in the arms of a desired child with an uncertain legal status, may be forced to violate the law.

Foreign couples from countries where surrogacy is not recognized or prohibited face the problem of recognizing and admitting their children, which sometimes leads to criminal prosecution of those who try to take such children out of the country where surrogacy is allowed, in those countries where it is prohibited [16]. Thus, in 2016, the Embassy of the Republic of Poland appealed to the law enforcement agencies of Ukraine with information about citizens of their country who tried to obtain passports for two children who were allegedly born to this couple in Ukraine. The Polish side was suspicious of the date of birth of children, which coincided with the date of their mother's entry into Ukraine. Based on the information contained in the letter of the embassy, law enforcement agencies undertake legal proceedings under Part 3 of Art. 149 of the Criminal Code of Ukraine [21].

Applications for recognition of children have been repeatedly submitted to the European Court of Human Rights. Regarding these issues, the Court in "Mennesson v. France and Labassee v. France" stressed that a wide margin of appreciation had to be left to States in making decisions relating to surrogacy, in view of the difficult ethical issues involved and the lack of consensus on these matters in Europe [22].

At the same time, at the request of the French Court of Cassation, the ECHR issued an advisory opinion dated 10.04.2019 with recognition in domestic law of a legal parent-child relationship between a child born abroad through a gestational surrogacy arrangement and the intended mother, designated in the birth certificate legally established abroad as the "legal mother", in a situation where the child was conceived using the eggs of a third-party donor and where the legal parent-child relationship with the intended father has been recognized in domestic law) [22].

Also, every case of surrogacy always carries the risk of abandoning children. According to the Commissioner for Children's Rights in Ukraine, at least 10 children are known to have been abandoned by their parents from abroad [23]. In Ukraine, more than 80% of children are taken from surrogate mothers by foreigners [4, 24], and the state accompanies these children only before departure. The risks of potential orphanhood are also significant in situations where the genetic parents abandon the child because of his/her illness or if they divorce and the child

[13] In accordance with paragraph 11 of Section 3 of the Rules of state registration of civil status in the case of childbirth by a woman who was transferred to the body of such an embryo, state registration of birth is carried out at the request of the spouse who agreed to such transfer, to which simultaneously with the document the fact of child birth by this woman, an application for her consent to registration of the spouses by the child's parents, as well as a certificate of genetic kinship of the parents (mother or father) with the fetus.

[14] In particular, blacklists of surrogate mothers are published on the following sites: : https://surmama-donor.ru/chernyy-spisok-surrogatnykh-mam/;http://www.surconsult.by/%d0%b4%d0%bb%d1%8f-%d0%b3%d0%b5%d0%bd%d0%b5%d1%82%d0%b8%d1%87%d0%b5%d1%81%d0%ba%d0%b8%d1%85-%d1%80%d0%be%d0%b4%d0%b8%d1%82%d0%b5%d0%bb%d0%b5%d0%b9/%d1%87%d1%91%d1%80%d0%bd%d1%8b%d0%b9-%d1%81%d0%bf%d0%b8%d1%81%d0%be%d0%ba/; https://surmoms.com/blacklist/.

is no longer needed. From the personal stories of surrogate mothers, three cases of child abandonment were identified. On the other hand, the interests of children always suffer in disputes between genetic parents and surrogate mothers. Judicial proceedings in such cases can take a long time, which negatively affects the child, who gets used to one family, and then by court decision moves to another.

Therefore, children's rights are the least protected in surrogacy. All three countries do not monitor their fate after crossing the border, in particular, the legal regime prohibiting surrogacy, the state of which the genetic parents have citizenship, is not an obstacle to concluding an agreement. It should be noted that some clinics and agencies have made it a rule not to provide services to those persons in whose countries surrogacy is prohibited [25]. However, this practice is not common. Given the high risk of violations of children's rights, UN experts consider it necessary: to adopt clear and comprehensive legislation that prohibits the sale of children, in the context of surrogacy; to ensure that in all parentage and parental responsibility decisions involving a surrogacy arrangement, a court or competent authority makes a post-birth best interests of the child determination, which should be the paramount consideration; to protect the rights of all surrogate-born children, regardless of the legal status of surrogacy arrangement under national or international law) [9].

There are also high risks of exploitation of surrogate mothers, including their use as incubators who agree to become a gestational courier. Due to the widespread provision of services by women in India and Thailand, commercial surrogacy for foreigners has been banned in these countries since 2016. Such risks are exacerbated by the lack of regulatory restrictions on totaling of providing surrogacy services of single woman and encourages them to engage in these activities regularly[15], poor living conditions in the last months of pregnancy and low maintenance [26; 27; 28].

At the same time, some mechanisms can be identified to counteract the exploitation of surrogate mothers. *Legal mechanisms* include: 1) permission to enter into an agreement on a gratuitous basis only on the basis of kinship of the parties[16]; 2) only the marital status of a surrogate mother under commercial surrogacy[17]; 3) the requirement for the surrogate mother's husband to give written consent (in case of her marriage)[18]; 4) notarization of the contract[19]. *Medical mechanisms* include: 1) age restrictions and lack of medical contraindications. Age thresholds are set in all countries. Thus, in Ukraine (paragraph 6.4 of the order "On approval of the Procedure for the use of assisted reproductive technologies in Ukraine") a surrogate mother may be an adult woman, the upper age limit is not set (although clinics, of course, set upper age barriers). In Belarus (Article 22 of the Law "On Assisted Reproductive Technologies") and Russia (paragraph 78 of Order № 107n), the age of a surrogate mother ranges from 20 to 35 years; 2) restriction of surrogate mothers to participate in the program more than a certain number of times. It is usually set by agencies that have an unspoken rule regarding a woman's participation in the program no more than three times[20], which does not preclude her from once again applying to another agency. There is also a rule of a break between pregnancies at 12 months[21]; 3) limiting the number of embryos that can be transferred to the uterus of a surrogate mother. Thus, in Russia there is no more than 2 embryos, as an exception – 3 ones provided that the surrogate mother gives voluntary informed consent after giving her a doctor full information about the high risks of miscarriage, low survival and high risk of disability among premature babies (pp. "e", paragraph 83 of the order № 107n). In Belarus there are no more than 2 embryos, and for a patient who has reached 35 years, as well as a patient regardless of age, for which the use of assisted reproductive technologies three or more times did not lead to pregnancy - no more than 3 embryos (Article 7 of the Law "On reproductive technologies"). In Ukraine (paragraph 3.8 of the order) there is a recommendation to transfer to uterine cavity no more than 1-2 embryos, and with the predicted reduced probability of implantation - 3 embryos (with clinical justification and with the patient's consent).

A separate problem is the stigmatization of surrogate mothers. Despite the fact that the market of surrogacy in Russia, Ukraine and Belarus is developing, and more and more participants uphold positive image of this activity, in society there is still condemnation and harassment of surrogate mothers. There is a stereotype of a surrogate mother as a woman from a small town or low-income village, which makes her vulnerable and forces her to

[15] Thus, according to information taken from the websites of surrogacy centers, women who already have surrogacy experience receive a higher financial reward. See, for example, the Mother to All Surrogacy Center. https://surmama.in.ua/ru/vse-o-surrogatnom-materynstve/

[16] Provided in Belarus in accordance with Art. 21 of the Law "On Assisted Reproductive Technologies", which stipulates that the surrogacy agreement may be concluded free of charge in cases where the surrogate mother is a relative of genetic mother or woman who used the donor egg, or a relative of the husband of genetic mother or woman who used donor egg

[17] Provided in Belarus, in accordance with Art. 22 of the Law "On Assisted Reproductive Technologies", only a married woman can act as a surrogate mother on a commercial basis.

[18] This requirement is available in the legislation of all three countries: paragraph 6.10 of the order "On approval of Procedure for the use of assisted reproductive technologies in Ukraine", Art. 21 of the Law of Belarus "On Assisted Reproductive Technologies", paragraph 78 of the order "On the use of assisted reproductive technologies, contraindications and restrictions on their use" in Russia.

[19] In Belarus, according to Art. 21 of the Law "On Assisted Reproductive Technologies", in Ukraine - according to item 6.11 of the order "About the statement of the Order of application of auxiliary reproductive technologies in Ukraine" the notary has to be convinced of free will of parties. Instead, in the Russian Federation there is no such requirement for the agreement.

[20] Family Medicine Center. https://www.cfm.ru/poleznaja-informacija/stati/kak-stat-surrogatnoi-mamoi.

[21] Surrogacy Center «Artemida». https://artemida.ua/ru/info-surrogacy/; Family Medicine Center. https://www.cfm.ru/poleznaja-informacija/stati/kak-stat-surrogatnoi-mamoi.

accept another's child in order to improve her financial situation.

One of the definitions of surrogacy is formulated in the scientific literature, which reflects public opinion, it is the commercial surrogacy – that is similar to existing forms of care work/services but is stigmatized in the public imagination, among other reasons, because of its parallels with sex work) [29]. Negative attitudes towards surrogate mothers are observed not only among the general public, but also among acquaintances, relatives, neighbors and medical staff. This necessitates the anonymity of this procedure, including secrecy in clinics where the child is born, the surrogate mother's move in the last months of pregnancy to other cities under the legend of "earnings" in order to hide their condition.

An analysis of 41 personal stories of surrogate mothers published in open sources[22] revealed a certain portrait of them, according to which the vast majority of women (88%) experienced financial difficulties and provided services on a commercial basis, half of them seeking to buy new housing. Thus, these indicators confirmed the social stereotype according to which women agree to bear another's child mainly in order to improve their financial situation. It was also found that at least 40% gave birth to foreigners (in a quarter of cases - for compatriots, and in a third of cases there was no information). In a situation where there is a decline in birth rates in these countries, such indicators indicate a distraction of some women of reproductive age from replenishing the gene pool of their populations. This is due to the initiatives taking place in Russia and Ukraine to ban the provision of surrogacy to foreign citizens.

CONCLUSIONS

Common features of the legal regulation of surrogacy in the East Slavic countries are: 1) the relationship is determined by the contract for the provision of services; 2) both non-commercial and commercial surrogacy and exclusively gestational (for which there is no genetic link between the surrogate mother and the embryo) are allowed; 3) potential parents (or at least one of them) must have a genetic link with the child; 4) the service is not provided to homosexual couples; 5) persons may use the service only on medical grounds; 6) there are no restrictions on the price of the service. In all countries, the protection of the rights of parents, surrogate mothers and children needs additional regulation.

Settlement of surrogacy relations in Ukraine and Russia is insufficient due to the lack of special regulation, the predominance of bylaws and the application to specific legal relations of the general provisions of the contract for the provision of services. As these states interfere less in these legal relationships, their members - clinics, agencies, genetic parents and surrogate mothers - gain more freedom, but also carry increased risks. In Belarus, the legal regulation of surrogacy is more detailed, although not without drawbacks.

There are restrictions on the ability to use surrogacy for unmarried people (Russia, Ukraine), single women (in Ukraine - a gap in regulation, in Russia it is allowed, but there are difficulties in registering a child) and single men (all three countries). The risks of violations of children's rights are high in all states, in particular, due to unregulated interaction with foreign states of prohibitive or negative-zero type of regulation. The problem of recognition of paternity is most observed in Russia, although in some respects it affects Ukraine and Belarus. A distinctive feature of surrogacy services in Ukraine is the option of genetic parents to choose the sex of the child, which raises several ethical objections.

The study of the personal stories of surrogate mothers confirmed the social stereotype that women agree to bear another's child mainly in order to improve their financial situation. Therefore, in the considered states various legal and medical mechanisms of counteraction to exploitation of surrogate mothers are developed. The legal ones include permission to conclude a contract on a gratuitous basis only on the ground of kinship of the parties; only the marital status of a surrogate mother in commercial surrogacy; the requirement for the surrogate mother's husband to give written consent; notarization of the contract. Common to all countries medical mechanisms are age restrictions and lack of medical contraindications; restriction of surrogate mothers to participate in the program more than a certain number of times; limiting the number of embryos that can be transferred to the uterus of a surrogate mother.

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[22] The cases of surrogate mothers were taken from: https://svoi.city/read/monologi/82241/istoriya-surrogatnoj-mami-iz-doneckoj-oblasti; https://www.6262.com.ua/list/205078; http://www.avicenna-nsk.ru/about/news/395; https://www.bbc.com/ukrainian/features-42995390; https://life.pravda.com.ua/society/2020/05/29/241146; https://pink.ua/news/8966; https://news.tut.by/society/519111.html

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REVIEW ARTICLE

MEDICAL-LEGAL PROBLEMS OF INTERFERENCE IN THE RIGHT TO HUMAN AUTONOMY IN POSTMORTEM REPRODUCTION

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ABSTRACT

The aim is a theoretical and methodological substantiation of revealing the possibility of interfering in the autonomy of a person during posthumous reproduction and establishing the existing protection of the rights and interests of postmortem children.

Materials and methods: The legislation of the European Union, the USA, Great Britain, New Zealand, Spain, Germany, Ukraine, the statistical data published by the international organizations are analyzed. In the course of the research a systemic, axiological approach and methods of analysis, synthesis, generalization were used.

Conclusions: It is proved that reproductive interference in the autonomy of the deceased in order to have a child is possible only on law basis, and in its absence - by a joint decision of the council of doctors, family lawyers, relatives of the deceased, taking into account the moral principles of society, public interests, rights and interests and other constituents (other heirs). It is emphasized that the origin of a postmortem child can be established based on a court decision. It is emphasized that post-mortem children should not have any discrimination; they are equal with other children. It was found that the system of rights of postmortem children includes personal non-property rights of a child (right to life, health, name, surname of biological parents); property rights (right to inheritance, right to social security). The primary is the system of non-property rights that ensure the physical and social life of the postmortem child.

KEY WORDS: autonomy, interference, life, postmortem children, reproduction

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INTRODUCTION

Due to modern medical technology, posthumous reproduction becomes available to anyone. This possibility was first announced in the late 1970s by Cappie Rothman – urologist from the Los Angeles, according to which Gabi Vernoff gave birth to a baby girl, Brendalin, through sperm obtained by Rothman 30 hours after her husband died. According to the US Sperm Bank, only three such procedures were performed in the 1980s, and fifteen in the 1990s, and from 2000 till 2014, its number increased to 130 averaging eight each year. Despite the obvious medical progress in posthumous reproduction, several medical and legal problems still arise in this area. In particular, it is the legitimacy of interfering in the right to human autonomy after death, possibility of protecting the rights of a postmortem child (from the Latin *post mortem* - posthumous). In modern European legislation, the issue of reproduction of human tissues is regulated by Commission Directives 2004/23/EU, 2006/17/EU (8, February 2006), 2012/39/EU (26, November 2012) of the European Parliament and of the Council on certain technical requirements for donation, obtaining and testing of human tissues and cells [2]. Despite the regulation of technical issues of reproduction, posthumous reproduction before doctors, lawyers, relatives of the deceased there are some complex problems about the feasibility of its implementation, possibility of interfering in posthumous human autonomy, prospects for a healthy child, full protection of their rights.

THE AIM

The aim of the paper is theoretical and methodological substantiation of identifying the possibility of interfering in the autonomy of a person during posthumous reproduction and establishing the existing protection of the rights and interests of postmortem children.

MATERIALS AND METHODS

This study was conducted during June-August 2020. The main materials of the study are the provisions of Commission Directives 2004/23/EU, 2006/17/EU (8, February 2006), 2012/39/EU (26, November 2012) of the European Parliament and of the Council, legislation of the European Union, the United States, the United Kingdom, New Zealand, Spain, Germany, Ukraine on reproductive technologies and statistics published by international organizations. The basic research methods are analysis, synthesis, formal-legal method. Exactly these methods have made it possible to establish the actual and legal capacity for post-mortem reproduction and related legal issues regarding the protection of the rights of a postmortem child. A systematic approach was used to identify a set of medical and legal issues in the field of posthumous reproduction: the possibility of interfering in a person's autonomy after his/her death and protecting the rights of a newborn child after the death of one parent. The ap-

plication of the axiological method revealed the values of posthumous reproduction.

REVIEW AND DISCUSSION

I.V. Venediktova drew attention to the urgency of protection of the rights and interests of postmortem children in the study of reproductive relations [3]. The need to establish a balance of interests of the postmortem child, one of the parents, other heirs is determined in the work of M.L. Shelyutto [4]. The work of S. Simanna is devoted to the question of whether posthumous reproduction should be allowed in the absence of the prior consent of the deceased [5]. E. Harbinya addresses the issue of human rights after death [6]. Finally, the ethical component of postmortem birth was the subject of J. Greenfield's research [7].

Analyzing various scientific sources, it should be noted that in science and practice there is no common understanding of ethical and legal issues in the field of interference in the autonomy of the deceased, as well as the rights and interests of postmortem children. The problem of this issue is sometimes exacerbated by opposing approaches in the legal regulation of these relations, which is established by different states, which is reflected in diametrically opposed scientific positions. Therefore, the topic of protection of interference in the autonomy of a person during the posthumous reproduction, as well as ensuring the rights and interests of postmortem children is relevant for research.

The appearance of a postmortem child is the result of medical intervention in a person's autonomy, his/her physical genetic integrity and lifelong intentions. Such interference in scientific sources has not received a single conceptual position, as it is a complex ethical and legal issue. It also needs medical research and observation, including post-mortem reproduction, post-mortem fertilization, family and community development. In medical practice, there is still insufficient data on the psycho-emotional, physiological state of such children. Therefore, the legal regulation of the relevant relations is still in the process of formation. However, it should not be premature than medical conclusions about the safety of such a child.

At the same time, legal scholars insist that in order to ensure the realization of the rights and interests of the testator's postmortem children, in particular, in the field of inheritance, such persons should be legally defined as heirs. It is fundamental that every child, regardless of procedure of origin, should have equal rights with other children, because a born postmortem child can not have an idea of their origin and intentionally influence their appearance.

Legal regulation of posthumous reproduction and the status of a postmortem child, as noted above, are established differently in foreign legal systems. For example, New Zealand has developed Guidelines for the use of surviving ovum after the death of a woman, using of surviving embryos after the death of one or both gamete donors, collection of sperm from a deceased man, removal and using of dead woman's ovum, removal and use of reproductive tissues of a deceased man or woman [8].

Judicial practice regarding the rights and interests of postmortem children has developed in the United States, however, not always in positions of protection of the rights and interests of such children. For example, the decision of the Supreme Court of the United States in the case "Astrue v. Capato ex rel. B.N.C., 566 US 541 (2012)" regarding the rights of twins conceived as a result of in vitro fertilization 18 months after the death of their father, the right to social security was denied. The court relied on section 416 (h) (2) (A) of the Social Security Act, holding that twins may receive social security benefits "only if they are entitled to inherit from the deceased under state will law" Astrue, 566 USA, 559. Because the deceased was living in Florida at the time of death, Florida's will law applied, and children were not entitled to an inheritance, depriving them of the right to social security benefits. The Massachusetts Supreme Court has ruled that there are limited circumstances in which posthumously conceived children may exercise the right to inherit under a will, including: (1) they have a surviving father or legal representative who must prove genetic relatedness; (2) the deceased father gave his unambiguous consent to the posthumous reproduction; (3) the submission of an application for acceptance of the inheritance corresponds to the statute of limitations [9].

It follows from the above that the protection of the rights of postmortem children still remains uncertain. This is partly due to the fact that the birth of a child after the death of one of the parents is interference in certain autonomy of a person after his/her death. Autonomy of human rights is based on the fourth generation of human rights, which provides independence and alternativeness of the person in the choice of lawful behavior within the norms of morality and law [10, p. 106]. Accordingly, a person should have the right to choose the possibility of genetically inheriting their lineage and no one can interfere with this right. Autonomy should, in principle, transcend death, allowing people to control their confidentiality / identity / personal data after death, similar to their posthumous control over property through the concept of freedom of will [7]. Along with this, scientific sources put forward two different concepts of respect for autonomy: 1) the model of "non-interference", according to which it is inadmissible to interfere in the human body without his/her prior consent; 2) the model of "respect for desire", according to which we should treat a person as he/she most likely would like to be treated [6].

A two-pronged approach to this complex ethical and legal issue needs to be addressed at the regulatory level. In the case of proper legal regulation, the problem of interfering in the autonomy of a person after his/her death is transferred to the state, which must develop mechanisms for permissible and inadmissible, such interference. For example, a written refusal to donate reproductive material for the life of a deceased person may be considered as a person's reluctance to continue genetically. At the same time, public interests and the interests of other persons must be considered [4, p. 49]. Thus, interference in the autonomy of the deceased is possible only on the law basis, and in its absence - by a joint decision of the council of doctors,

family lawyers, relatives of the deceased, considering the moral principles of society, public interests, rights and interests of relatives and other constituents**,** heirs). It is always a coercive interference with the integrity of the deceased and is therefore a coercive act. An exception to this rule is when a person freezes their gametes for artificial insemination with the gametes of a particular person, i.e. enters into a contract, as evidenced by civil contracts or other documents (applications, approvals, treatment programs in the health care facility, etc.) [11, p. 36].

The medical possibility of postpartum children raises several important legal issues: the establishment of identity between the deceased and the child born, legal establishment of the child's origin and legal status. Establishing the origin of the child from the deceased has two aspects: physiological (direct use of biomaterials of the deceased for the birth of a child); legal (interference in human autonomy regarding the desire to have children). Physiological origin should be traceable. This sign is established by item g, Art. 1 of Commission Directive 2006/17 / EU (8, February 2006): "traceability" means the ability to locate and identify a tissue / cell at any stage from procurement, processing, testing and storage to disposal to a recipient or disposal; traceability also includes the ability to identify a donor, tissue establishment, or manufacturing facility that receives, processes, or stores tissues / cells, and ability to identify recipients in medical facilities where tissues/ cells are applied to recipients; traceability also includes the ability to locate and identify all relevant data relating to products and materials in contact with such tissues/cells" [12]. Therefore, when conducting genetic identification of a postmortem child, it is necessary to identify a sign of traceability between the cells of the child and the donor.

Let's pay attention to the fact that in vivo cryopreservation of genetic material (gametes, embryos) in itself does not necessarily indicate a person's intention to resort to posthumous reproduction: in some cases, delivery of genetic material and the creation of embryos is planned only their lifetime use in purposes of childbirth, in others - both variants of reproduction are used (lifelong, posthumous) or the task of posthumous conception is directly set taking into account the expected or probable death of a person seeking to have a child [5, p. 92]. Due to the existence of different behaviors of a person in donation, the question of establishing the origin of the child is open, which is to some extent due to the state of regulation of relevant legal relations in the laws of foreign countries.

For example, on 18 September 2003, the British Parliament passed amendments to the law requiring any man wishing to be the father of a child born as a result of using of reproductive technology after his death to give his prior written consent to such record [13, p. 34]. In some countries to determine the origin of the child it is necessary to conduct a paternity test and posthumous consent to conception [6, p. 285]. Similarly, Article 9.2 of the Spanish Law on Assisted Reproductive Methods of 26 May 2006 allows the use of reproductive material for twelve months after the death of a husband to inseminate his wife with legal consequences arising from family origin. The use of reproductive material after death is possible subject to the husband's consent in a special document, will or instruction. This right is also granted to unmarried men. To regulate the legal status of future embryos, they are considered as nastiturus [14].

According to Articles 128 and 132 of the Family Code of Ukraine, the basis for recognition of paternity is any information certifying the origin of the child from a certain person; in the event of the death of a woman who considered herself the mother of the child, the fact of her motherhood may be established by a court decision [15]. Thus, in Ukraine, the origin of a postmortem child can be established on the basis of a court decision.

In addition to the origin of the postmortem child, the question of the legal status of such a person is acute. In our opinion, in this aspect the fairest is the application of the preamble of the Universal Declaration of Human Rights on Equality of Human Rights [16]. That is, postmortem children should not be discriminated against in any way; they are equal to other children in all legal relationships, including hereditary ones.

Moreover, it is in the field of inheritance that the problem of determining the legal status of postmortem children remains unresolved. Under Ukrainian law, such a person is deprived of the legal opportunity to be called upon to inherit both by law and by will. Although the legal doctrine has formed two opposing positions on the possibility of recognizing inheritance rights for a child, not only born but also conceived after the discovery of the inheritance. Proponents of the former generally deny inheritance by postmortem children, arguing that legal uncertainty that exists between the day of the opening of the inheritance and the possible birth of a child, which, in turn, can lead to the destruction of the structure of all inheritance law [17].

Other scholars, on the other hand, believe that the testator's child belongs to the first priority heirs, regardless of the method of conception and delivery, as well as regardless of the birth date after the testator's death, if the testator left genetic material for subsequent birth of a child [18, p. 260].

The issue of recognition as an heir of a person born as a result of posthumous reproduction is regulated differently in foreign legislation. Yes, in some countries the inheritance rights of such children are denied. Other states refer to the circle of heirs of the testator's postmortem children. In particular, according to § 2101 of the German Civil Code, in the case of the appointment of the person's heir not conceived at the time of commencement of succession, it should be considered an additional heir, unless proven otherwise. If the will of the testator does not meet the need for additional heirs, then such an appointment is invalid. Prior to the birth of a child conceived after the death of the testator, the main heirs are the legal heirs (§ 2105 of the German Civil Code) [19].

It should be noted that the inheritance of post-mortem children must ensure both the stability of property turnover and the interests of other participants in the relevant legal relations – heirs, recipients, creditors of the testator. That

is why the recognition of postmortem children as heirs should be carried out subject to certain conditions. This is primarily a period during which artificial insemination can be performed using assisted reproductive technologies. In our opinion, such a period should be six months from the date of commencement of succession, as it corresponds to the period established for its acceptance. Also, the condition of inheritance by postmortem children is proposed to recognize the relevant order of the testator expressed in the will. That is, recognition of such persons as heirs, taking into account their conception after the commencement of succession, should be carried out only at the will of the testator. Otherwise, the proposed proposal may be a fertile ground for numerous abuses by other parties to the relationship. Thus, it seems more appropriate to limit inheritance by postmortem children to inheritance by will, without changing the range of heirs at law, which are imperatively defined by law.

We believe that the general system of rights of postmortem children should be regulated. This system should be built taking into account the principle of equality of rights with other subjects of legal relations. Such a system should include: 1) personal intangible rights of the child (right to life, health, name, and surname of biological parents); 2) property rights (right to inheritance, right to social security). At the same time, primary system is the non-property rights that ensure physical and social life of the postmortem child.

CONCLUSIONS

1. Reproductive interference in the autonomy of the deceased in order to have a child is possible only on the basis of law, and in its absence – by a joint decision of the council of doctors, family lawyers, deceased's relatives, taking into account the moral principles of society, public interests, rights and interests of relatives and other interested persons (other heirs).
2. In case of disputes, the origin of the postmortem child may be established on the court decision basis. These children should not have any discrimination; they are equal to other children.
3. Post-mortem children shall not be discriminated against in any way or on an equal footing with other children on the basis of origin or other characteristics.
4. The system of rights of postmortem children includes: 1) personal intangible rights of the child (right to life, health, name, and surname of biological parents); 2) property rights (right to inheritance, right to social security). The primary is the system of non-property rights that ensure physical and social life of the postmortem child.
5. Promising direction of research is to identify and address problems that arise due to inadequate protection of the rights and interests of postmortem children.

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REVIEW ARTICLE

SOCIAL DANGER OF DOMESTIC VIOLENCE AND THE NEED FOR REHABILITATION OF ITS VICTIMS

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ABSTRACT

The aim: To investigate the social danger of domestic violence, find out its principal manifestations, consequences, and impact on women and minors' health. Based on the acquired knowledge, to suggest ways to overcome this problem, which will minimize the consequences of domestic violence.

Materials and methods: The authors studied and analyzed international legal acts, Ukraine's legislation, and scientific publications on domestic violence. The method of statistical processing of analytical data of the World Health Organization (hereinafter - WHO), the Institute of Demography and Social Research at the request of the UN Population Fund, the Ministry of Social Policy of Ukraine, the Ministry of Internal Affairs and the Prosecutor General's Office of Ukraine (for 2017 - first half of 2020) were used. A comparative method of research was useful in comparing the number of cases of domestic violence in Ukraine and Europe during the COVID-19 pandemic.

Conclusion: It is concluded that domestic violence is a socially dangerous act that negatively affects all family members, as it causes significant damage to health and life. The most dangerous are the consequences of domestic violence on the physical and mental health of women and minors, who are particularly vulnerable to this negative manifestation. Rehabilitation is said to help minimize the effects of domestic violence, restore the physical and mental health of victims, and return them to normal social life.

KEY WORDS: family, criminal offense, victim, physical and mental health

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INTRODUCTION

During the Second World War, there were mass and serious human rights violations, so the question arose about their protection after its end. Therefore, the world community has adopted several international acts to protect human rights and freedoms. In particular, the adoption of the UN Universal Declaration of Human Rights (1948) and enshrining in Art. 1 principle, according to which "all people are born free and equal in dignity and rights." Of course, the protection of fundamental human rights and freedoms and the adoption of international instruments in this area is an important step, but the efforts of all states must be directed not only to guarantee but also to protect and defend them.

An integral part of the Institute for International Protection of Human Rights is the principle of equality between women and men, the prohibition of any discrimination on the grounds of sex. The fight against women's discrimination takes place in such areas as politics, economics, education, and family. To this end, many international instruments have been adopted to respect equality between women and men, including: the UN Declaration on the Elimination of Violence against Women (1993); Optional Protocol to the United Nations Convention on the Elimination of All Forms of Discrimination against Women (1999); Council of Europe Convention on Preventing and Combating Violence against Women and Domestic Violence (Istanbul Convention) (2011). A number of UN Security Council Resolutions have also been adopted: № 1325 on women, peace, and security, reaffirming the idea of protecting women and enhancing their role in conflict prevention and resolution (2000); № 1960 on combating sexual violence in the context of women's issues, peace, and security (2010); № 2106 on the central role of gender equality and the empowerment of women in political, social and economic rights and opportunities in efforts to prevent sexual violence in armed conflict (2013); № 2242 on the need to protect women in conflict situations and give them a more critical role in their prevention and resolution (2015) and others. Nevertheless, in many countries worldwide, the international legal principle of equality of men and women is still violated, one of the manifestations of which is violence against women, in particular, domestic violence. The situation has become especially acute and more frequent during the COVID-19 pandemic in both Europe and Ukraine. Thus, in April 2020, emergency services in Europe received 60% more complaints from women suffering from domestic violence than a year earlier, according to the World Health Organization [13].

In Poland, domestic violence causes more injuries than car accidents, assaults, or rapes together [11, p. 25]. According to the WHO, 38% of murders of women in the world are committed by their husbands. However, in some countries, this figure is as high as 70% of cases [10]. The death toll from domestic violence in France is also alarming. Thus, in 2019, 146 women became its victims (compared to 2018, there were 25 more murders - by 21%), and accordingly, 27 men were killed by their partners. Thus, the total number

of murders by partners in France is 173 people. In general, in 84% of violent death cases in a couple, the victims are women, mostly of French origin, aged 30 to 49 or older than 70 years. And most often, the crime is committed with a knife or firearm, in 17% of cases, death occurs as a result of suffocation [28].

However, domestic violence is perpetrated not only against women but also against minors, with more severe consequences than for adults. Back in 1985, at a WHO meeting in Switzerland, it was stated that any intentional or unintentional act against a child by an adult, community, or state is considered child abuse, which further adversely affects the health, physical and psychosocial development of the child [14, p. 44]. According to the WHO, more than one billion children have been affected by various forms of violence worldwide over the past year. Thus, in 75% of cases, they faced domestic violence: in every third case, they experienced psychological violence, in every fourth - physical [7]. Martha Everard, the head of the WHO office in Ukraine, also pointed out the "adverse childhood events" manifested in domestic violence against minors. For example, in the European region, due to minors' domestic violence or abuse, the death rate among children under the age of 15 is 850 per year, with the highest mortality rates in the post-Soviet countries. Therefore, domestic violence is a very serious problem worldwide, one in four children suffers from physical violence and its consequences and one in ten suffers from sexual violence; one in three children suffered emotional abuse at an early age. That indicates that as a result of domestic violence, family members' physical and mental health suffers negative consequences and always needs rehabilitation. In this regard, the representative of the Department of Violence and Injury Prevention of the WHO Regional Office for Europe Dinesh Sethi said that based on WHO data on the effects of domestic violence, each country should develop a strategy to prevent violence and injury, which should be supported by law [7].

Social projects help reduce the number of cases of domestic violence. Positive in this sense is the example of Poland in the implementation of social campaigns such as "I love. I don't hit", "I love. I react", "I love. I don't shout", and "I love. I have time". Social communication itself is an extremely valuable and essential tool in the fight against violence regarding women and children and helps to show that the family is an exceptional value in human life. These programs help to combat violence; support the strengthening of interpersonal relationships; learn to respect order and be tolerant, appreciate kindness and inform about the negative consequences of violence, which can be eliminated with the help of appropriate specialists.

THE AIM

To investigate the social dangers of domestic violence, to find out its consequences and impact on women and minors' health. Based on the acquired knowledge, suggest ways to overcome this problem, which will minimize the consequences of domestic violence.

MATERIALS AND METHODS

The authors studied and analyzed international legal acts, Ukraine's legislation, and scientific publications on domestic violence. The method of statistical processing of analytical data of the World Health Organization (hereinafter - WHO), the Institute of Demography and Social Research at the request of the UN Population Fund, the Ministry of Social Policy of Ukraine, the Ministry of Internal Affairs and the Prosecutor General's Office of Ukraine. In particular, empirical materials on domestic violence complaints in Ukraine for 2017 - the first half of 2020 and data on the number and types of criminal offenses related to domestic violence in Ukraine in 2013, 2017, and 2018 were studied and processed. A survey of 1,800 respondents in Ukraine aged 18 and older was analyzed according to a nationally representative sample conducted by experts from the United Nations Population Fund on the forms, types, and ages from which respondents faced domestic violence. A comparative research method was also useful in comparing the number of cases of violence in Ukraine and Europe during the COVID-19 pandemic, including the number of victims of domestic violence in France in 2018-2019.

REVIEW AND DISCUSSION

According to Articles 33-40 of the Convention on preventing and combating violence against women and domestic violence (hereinafter referred to as the Istanbul Convention), there are nine domestic violence forms. But eight of them have been identified as criminalized, including "psychological violence"; "persecution"; "Physical violence"; "Sexual violence, including rape"; "Forced marriage"; "Female genital mutilation"; "Forced abortion and sterilization" and "sexual harassment". Domestic violence is characterized by increased social danger, as it causes significant damage not only to the life and health of family members but also to social relations in the field of family and child-rearing. In November 2011, Ukraine acceded to the Istanbul Convention of the Council of Europe, but only on December 6, 2017, the Verkhovna Rada of Ukraine adopted the law "On Amendments to Certain Laws of Ukraine following Ratification of the Council of Europe Convention on Preventing Violence against Women and Domestic Violence and combating these phenomena" [4].

According to this Law, the Criminal Code of Ukraine was supplemented with a new article number 126[1] "Domestic Violence" as follows: *"intentional, systematic commission of physical, psychological or economic violence against a spouse or former spouse or another person with whom the perpetrator is (was) in the close family relationship, which leads to physical or psychological suffering, health disorders, disability, emotional dependence or deterioration of the quality of life of the victim."* Of course, this is a favorable decision because domestic violence cases were silenced or ignored by society and the state. They were considered an internal problem for a long time and, therefore, turned into latent offenses. Recently some attention to this socio-legal severe

Fig. 1. Number of domestic violence complaints in Ukraine

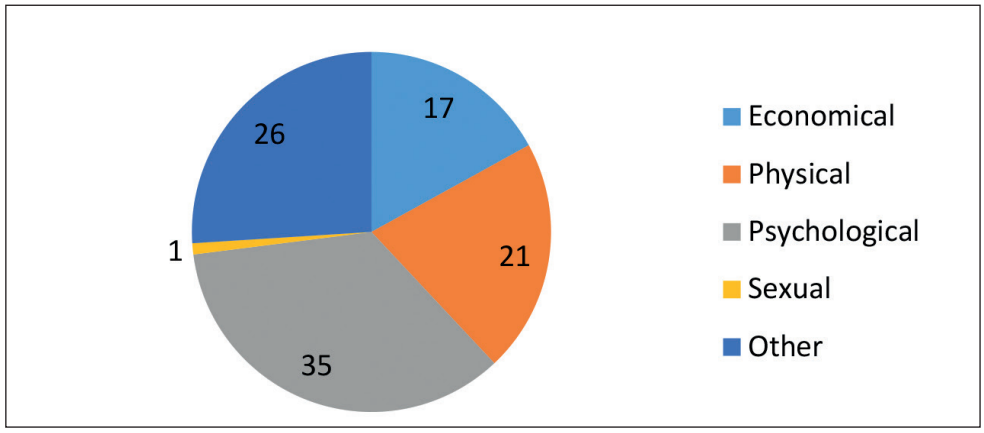

Fig. 2. Forms and amount of domestic violence in Ukraine

problem has been drawn because these actions committed by members of their own families cause more severe psychological and physical harm than actions by third parties.

The family is an important social and legal institution of the state and society, determined by a set of social norms and patterns of behavior that constitute the socio-legal cell of society and the state. Sociologists argue that the family is a kind of microsocial community of people that performs extremely important functions that any other social and legal structures are unable to perform [1, p. 52] and is therefore recognized as an invaluable treasure that builds our identity from an early age and gives us a sense of security and care [20, p. 175]. Depending on the spheres of life, the following main functions of the modern family are distinguished: socializing, reproductive (demographic), educational, economic, primary social control, spiritual communication, and others. [2, p. 14-16]. Therefore, it is fair to say that when a family is strong, a state is strong too. The moral and psychological state of society depends on the moral and psychological "health" of the family. In particular, domestic violence is the most socially dangerous and deviant behavior of its members, as it violates the basic principle of family life - the safe and comfortable existence of each member [3].

According to statistics, more than 3 million children in Ukraine witness domestic violence every year, and almost 70% of women experience various forms of abuse and humiliation from men. Every year, about 1,500 women die from violence by their own husbands, and this trend has been increasing for the past three years. In general, according to statistics, every second person in our country has experienced domestic violence, and the number of appeals to law enforcement agencies over the past five years has increased by almost 34% (from 110 to 165 thousand) [5, p. 4].

In particular, the Minister of Social Policy at the UNFPA International Forum "Ukraine on the Way to Overcoming Domestic and Gender-Based Violence" pointed out that one in five women in Ukraine faces various domestic violence forms. Men are not an exception, but 90% of victims of violence are women. During 2019, more than 130 thousand domestic violence complaints were registered, of which - 88% from women, 10% - from men, 2% (1,055 complaints) from children, which is 15% more than in the same period last year [21]. Accordingly, in 2017, these figures were 92.1 thousand, and in 2018 - 115, 5 thousand [22] (Fig.1).

According to the Prosecutor General's Office of Ukraine, at the end of December 2019, 2,554 criminal offenses related to domestic violence were registered, and in May 2020, their number increased by 69% compared to the same

Table 1. Number and types of criminal offenses related to domestic violence in Ukraine in 2013

Intentional homicide	**55**
Intentional homicide, in excess of the limits of necessary defense	4
Negligent manslaughter	2
Incitement to suicide	2
Intentional grievous bodily harm	120
Intentional moderate bodily injury	83
Intentional minor bodily injury	1019
Beatings and cruel treatment	97
Torture	3
Threat of murder	28
Unlawful deprivation of liberty	3
Rape	3
Negligent severe or moderate bodily injury	19

Table 2. Number and types of criminal offenses related to domestic violence in Ukraine in 2017

Grave and especially grave crimes	**172**
Intentional minor bodily injury	592
Intentional grievous bodily harm	92

Table 3. Number and types of criminal offenses related to domestic violence in Ukraine in 2018

Grave and especially grave crimes	**179**
Intentional minor bodily injury	699
Intentional grievous bodily harm	88

period last year [23], and the number of deaths in Ukraine as a result of domestic violence last year - 777 people, 305 of whom - children [24]. During the six months of 2020 in Ukraine, more than 101 thousand applicants have already applied to the police for domestic violence, which is 40% more than last year [25].

Experts from the United Nations Population Fund surveyed 1,800 respondents in Ukraine aged 18 and older, which showed that 44% of Ukraine's population had experienced domestic violence during their lifetime, with 30% of them suffering from domestic violence during childhood. About half of those who have been victims of childhood violence have encountered it in adulthood. Besides, experts from the United Nations Population Fund noted that women were more likely to experience domestic violence in adulthood (33% vs. 23% of men) and men in childhood (34% vs. 27% of women); 35% of Ukrainians have experienced psychological violence (most often constant humiliation and controlling behavior), 21% with physical (beating, as well as locking, tying, forcing to stand still), 17% - with economic (forcing to report for every penny, misappropriation or destruction of property), 1% - with sexual violence (forced sexual intercourse) [26] (Fig. 2).

According to research, domestic violence not only destroys harmony in the family and causes family unhappiness, leads to resentment and hatred of family members, but also often is one of the prerequisites for the spread of crime in society, and can become even a constant criminogenic factor. Thus, 23% of serious violent crimes are committed directly in families [6, p. 273 - 280] (Table 1,2,3).

Calculations made by the Institute of Demography and Social Research for the United Nations Population Fund show that 1.1 million Ukrainian women face physical and sexual aggression in the family each year, but most of them conceal such facts [10]. Domestic violence in Ukraine is the cause of 100,000 days of hospitalization, 30,000 calls to trauma departments, and 40,000 calls to doctors. Simultaneously, only 10% of domestic violence victims seek professional help [9]. After all, many people still consider such relations to be "normal". In fact, various spheres of human existence are filled with violence. Unfortunately, it has become the norm of people's lives.

As Polish experts rightly point out, the manifestations of domestic violence in the family environment do not actually depend on culture, religion, environment, education, intellectual level of a person or belonging to a social group. But without a doubt, domestic violence, they believe, is a degrading form of behavior, always breaking the law, and often causing physical injury. Moreover, mainly domestic violence is not manifested in one-time actions, but is committed over a long period of time and tends to increase [11, p. 24].

Therefore, according to Polish scholars, domestic violence is a deliberate act based on a significant predomi-

nance of forces and directed against family members, which not only violates personal rights but also causes suffering and injury and is usually directed against women, children, older people, as well as sick family members [12, p. 14]. Besides, domestic violence, as Polish scholars rightly recognize, also harms the dignity and fundamental rights and freedoms of family members [11, p. 23].

The consequences of domestic violence for women are often severe and tragic, as they lead not only to physical damage to health but also to irreversible emotional disorders. They often develop a complex post-traumatic stress syndrome, which manifests itself in states of excessive arousal [11, p. 33]. Such a woman may also suffer from insomnia and experience constant fatigue or anxiety, which makes her emotionally unstable, panic attacks, or becomes irritable and nervous. Also, domestic violence victims are characterized by depressive states, which are accompanied by passivity, feelings of helplessness, problems with concentration and memory, and others. In fact, such women lose faith in themselves, and in the future, they cannot make their own decisions and feel helpless. Women victims of domestic violence do not believe in their own strength and believe that it is impossible to stop violence from a partner. Therefore, among the victims of domestic violence, there may be a tendency to the self-destruction of the individual, the manifestations of which are: alcohol, drugs, suicide attempts. In particular, about 10% of women victims of domestic violence try to commit suicide [11, p. 36-37].

No less alarming is the number of children affected by domestic violence in Ukraine, almost 60% of children aged 2 to 14 suffer from psychological or physical violence in the family. Such preliminary results of the study were announced by the Head of the UNICEF Office in Ukraine Yukie Mokuo at the international conference "Assistance to Victims of Violence" [27]. The medical literature indicates that most patients treated for post-traumatic stress disorder (PTSD) are victims of domestic violence, especially if it is experienced in childhood, have psychological problems such as affective lability, impulsivity, aggressive behavior towards themselves and other people, dissociative symptoms, constant feelings of guilt or shame [12, p. 39].

According to researches, if a child has experienced domestic violence at least four times, the risk of suicide increases to 49 times [7]. Besides, such children are six times more likely to commit suicide, and about 50% start using drugs. Almost 100% of mothers who have experienced domestic violence have given birth to sick children - mostly with neurosis, stuttering, enuresis, cerebral palsy, mental disorders [8]. Therefore, the consequences of domestic violence for children, regardless of whether it has been applied to them or if they have only witnessed it, according to Polish experts, harm their health and development. In particular, this can manifest itself in negative consequences for the emotional state, which without the intervention of specialists can lead to low self-esteem; fear; stress; a state of excessive arousal or apathy; self-destruction of the individual; criminal and anti-social activities; poor learning outcomes; bad relationships with peers; isolation from society; distrust; aggression. Domestic violence also harms a minor's health, which can lead to several psychosomatic symptoms; complex disorders after traumatic stress disorder (C-PTSD) [15, p. 42].

In addition, such children become aggressive in the future and use violence in their own families to their children and family members because they copy their parents' patterns of behavior [16, p. 51]. Children who grow up in a family where there was violence constantly live with a sense of danger, they hide and suppress their feelings, try to cope with despair and helplessness, feel lonely both in the family and outside it [17, p. 148].

Minors who have witnessed or been victims of domestic violence may have difficulty understanding love and normal family relationships in the future. Researchers of this problem claim that domestic violence can manifest itself in the transgenerational inheritance of images that they received in their childhood [17, p. 149]. Therefore, children who are domestic violence victims may develop psychophysical disorders, such as disability, emotional and mental disorders. In the future, such individuals will not always be able to adapt to the environment, they seek to isolate themselves in interpersonal relationships, and may even commit suicide, because the neurohormonal system undergoes irreversible changes that significantly reduce the child's resistance in affective situations [18, p. 48].

It is not for nothing that doctors and psychologists recognize domestic violence as a particularly traumatic experience that causes irreversible and long-lasting consequences in the victim's mental life. It can even change a person completely [19, p. 40] and can manifest itself in: low self-esteem, deep distrust of people, especially men, difficulties in domestic relations, leading a satisfactory sex life [19, p. 43-44]. However, doctors note that most often, domestic violence facts are silenced and hidden by both parties [5, p. 9-10]. Therefore, to recognize one of its forms in the form of physical violence against family members, including minors, despite the symptoms, it is difficult even for an experienced doctor, pediatric surgeon because victims of such violence usually do not provide reliable data, about the mechanism of injury or call false data about their receipt [14, p. 45].

Another dangerous type of domestic violence, along with physical, is psychological. According to research by doctors and psychologists, in such cases, its victims are very likely to identify himself/herself with the offender, which is a reaction to the situation and was called the Stockholm syndrome because the victims are willing to act in offenders' interests. However, in such cases, the aggressor may require the woman not only to submit but also to make her like such submission. According to experts, "the primary goal of the perpetrator of violence is to enslave the victim. He achieves his goal by exercising despotic control over every aspect of the victim's life. "However, submission in itself rarely satisfies him; most of the perpetrators have a psychological need to justify their behavior, and for that, they need the full consent of the victim [11, p. 37-38]. Humiliation, unfair, cruel treatment, which is one of the

manifestations of domestic violence, can leave their mark on the emotional structure of the individual and, under certain conditions, generate appropriate, deviant behaviors [29, p. 51]. According to doctors, even mentally healthy people often develop mental disorders after the violence, which is an acute reaction to domestic violence, such as post-traumatic stress disorder, adaptation disorders, depressive disorders, behavioral disorders, etc., which are also considered harmful to health - his mental function [29, p. 44]. Therefore, most of the research on domestic violence is consistent with the statement that aggression and cruelty in the future can be mastered in the parental family [29, p. 52]. Thus, assistance to domestic violence victims always requires rehabilitation from its negative consequences and should be addressed in conjunction with representatives of many fields: medicine, psychology, pedagogy, sociology, ethics, law, economics, and others. [14, p. 47].

CONCLUSIONS

Domestic violence is a socially dangerous act that negatively affects family members because it causes significant damage to health and life. The consequences of domestic violence are the most dangerous for both the physical and mental health of women and minors, as they are particularly vulnerable to it.

In order to protect victims of domestic violence, the Criminal Code of Ukraine was amended by Art. 126^1 of the Criminal Code and Section XIII-1 "Restrictive measures" and considered as positive by us. However, it is extremely important to address the harmful effects of violence against family members.

Based on this, we believe that rehabilitation is one of the ways to solve this problem, which minimizes the consequences of domestic violence. Doctors are often among the first to be approached by a victim of violence. Of course, in this case, it depends on them will they be able to provide not only the necessary medical care but also to support the victim morally and psychologically, to evoke and strengthen victims' self-confidence, and to direct them for further social and legal assistance. In particular, the medical and social rehabilitation center is called upon to overcome domestic violence's consequences. Its activity is aimed at restoring and preserving psychophysiological functions, optimal working capacity, and the level of social functioning of violence victims.

Therefore, the rehabilitation of domestic violence victims is a necessary and vital measure, as it helps restore the health of the victim, save lives and resocialize a person as much as possible. Only then will we be able to achieve the idea of sustainable development of the family, its quality and balanced life as members of the family, society, and the state.

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REVIEW ARTICLE

COERCED STERILIZATION AS A REPRODUCTIVE RIGHTS VIOLATION

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ABSTRACT

The aim: To outline and systematize the issues related to violations and restrictions on the realization of the right to reproduction. To develop propositions and recommendations on improving the prevention and combating various manifestations of coerced sterilization.

Materials and methods: Theoretical basis for studying this issue includes scientific publications, research of the legislative systems of different countries, the conclusions of international non-governmental organizations. The authors of the paper have also taken into account international regulations, including UN Conventions and Directives, decisions of the European Court of Human Rights (ECHR), as well as analytical data provided by international organizations. Determinants in the study of this problem are the analysis, synthesis and generalization of the experience and legislative base of foreign countries, which are closely related to formal and comparative methods. Systematic, structural, dialectical and statistical methods have been also used in this paper to substantiate the problem of sterilization.

Conclusions: The most radical decision to refuse from reproduction is surgical sterilization (defertilization). It can be classified as voluntary, forced and coerced. The problems of preventing and combating coerced sterilization are among the most difficult ones. Bribery and mental coercion of persons in order to obtain consent for sterilization are either not regulated by law and do not entail any liability, including criminal, or even are part of the state government policy to regulate the number of citizens in overpopulated countries, HIV-infected people, including prisoners or transgender people.

KEY WORDS: reproductive rights, coerced surgical sterilization, coerced sterilization of convicts, coerced sterilization of transgender people

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INTRODUCTION

A person has reproductive rights from the moment of birth, they are part of the private life sphere and belong to the category of natural and inalienable, so their protection must be ensured both at national and international levels. However, there is a problem of coerced sterilization in trerms of the right of not interfering human reproductive activities existence.

The right to reproduce one's kind is inherent in many other human rights. The case law and experience of human rights organizations illustrate that reproductive rights are often a context, where such inalienable human rights as the right to life and health, the right to dignity, the right to liberty and security of person, and the right to non-interference in family and private life, as well as the prohibition of torture, inhuman or degrading treatment are violated. The emergence of regressive tendencies in some states and the attempts of some governments to exercise control over the realization of the right to reproduction of certain socially vulnerable groups is of concern. The free exercise of a person's right to reproduction, especially in the medical, social and legal aspects remains an urgent problem for the whole world community. Coerced sterilization is the violation of the natural human right to reproduce one's kind. This type of sterilization occurs under the pressure of psychological, political, material circumstances. Many states either contribute financially to this phenomenon or establish discriminatory rules against those who do not wish to undergo this medical procedure. Convicted persons, transgender people, HIV-infected persons and representatives of the poorest layers of the population in overpopulated regions, such as India, Peru and others, are subject to coerced sterilization.

The existence of this problem is also due to insufficient legal regulation, gaps in solving the problem of the responsibility for bribery or mental coercion to sterilization, which leads to profanity, so we can overcome obstacles to human reproductive rights only by eliminating or reducing the negative impact of these factors.

THE AIM

The aim of this article is to define the concept of coerced sterilization and structuring of its varieties; to research the problems and the status of protecting the realization of reproductive rights both at national and international levels; to suggest the ways on improving the prevention and punishment of cases of forcing individuals to renounce the right to reproduce one's kind.

MATERIALS AND METHODS

This research is based on the analysis of the experience and legislation of such countries as Ukraine, Great Britain,

Central America and Africa countries, USA, Germany, China, Uzbekistan, Tunisia, Singapore, India, Czech Republic, Japan, Sweden, illustrating the coercion of persons to surgical sterilization. The empirical basis of the research also consists of the UN, WHO and other international and governmental organizations' international legal acts, laws, decisions of the European Court of Human Rights (ECHR). In addition, the authors have used statistics from international organizations, expert opinions, doctrinal ideas and views on this issue.

The analysis of scientific sources demonstrates that the issues for the realization of reproductive human rights are covered in the studies of Pashkov V., Gutorova N., Horodovenko V., Lyfar A., Biletska E. and others [1; 2; 3; 4]. However, the concepts of coerced sterilization, the allocation of its types, grounds and problematic issues of its legal regulation were not the subject of a separate thorough study. The methodological basis of the study consists of general scientific and special methods. The authors of the paper use dialectical, statistical, formal, comparative methods and method of generalization. Historical and logical methods are also used to study the essence of the problematic issues and to develop sound recommendations for their solution.

REVIEW AND DISCUSSION

The idea of reproductive rights as human rights is new and comprehensive. If we recognize that every person can freely enjoy and use their fundamental rights guaranteed by the Constitution, the Convention for the Protection of Human Rights and Fundamental Freedoms, the Universal Declaration of Human Rights, then we recognize that everyone has the right to freely exercise and control their reproductive life.

The realization of person's reproductive rights means that everyone has the right to reproduce and the freedom to decide when and how often to do so or not to do it at all. It also means that everyone has the right to decide on reproduction without discrimination, coercion and violence [5, § 7.2-7.3].

When a person is coerced to renounce his or her reproductive rights, he or she is restricted from disposing his or her private life, protecting own health, and exercising his or her rights as a person and as a citizen.

The right to reproduction is important for the realization of a wide range of fundamental human rights, in particular the human right to life and health, respect for dignity, freedom and personal integrity, non-interference in family and private life, and the prohibition of torture and inhuman or degrading treatment. These rights cannot be effectively protected without guaranteeing that everyone can independently determine when, how and whether to have children, to control own reproductive function, to obtain access to important information and services on reproductive health and be free from violence and coercion in this area.

Natural and inalienable human rights cannot be fully realized without guaranteeing the freedom of reproductive choice. In turn, reproductive rights derive their meaning and strength from long-recognized human rights [6].

The most radical decision to refuse from reproduction is surgical sterilization (defertilization), which is a medical manipulation aimed at depriving fertility. As a result of surgery a person usually permanently loses reproductive function.

In general, sterilization can be divided into types depending on the will of the person to whom it is applied:

forced sterilization is a medical manipulation that is carried out against the will (with disregard of the will) of a person using deception or physical violence;

voluntary sterilization is a medical manipulation that is carried out on the voluntary, conscious and aware initiative or consent of a person [7];

coerced sterilization is a medical manipulation performed to a person who although agrees to perform it, but his or her will is significantly affected under the pressure of circumstances. Methods of involuntary sterilization are bribery and mental coercion. Involuntary sterilization, its types and methods are the subject of this research.

Many countries in the modern world encourage sterilization by financial means or force to it by establishing discriminatory rules for a fertile people.

Involuntary sterilization can be divided into types **according to the range of persons** to whom it is applied (HIV-infected, drug addicts, transgender people, prisoners, sterilization of the poorest layers of the population in overpopulated countries).

Involuntary sterilization of HIV-infected people and drug addicts is a marginalizing practice used wordwide, especially in countries with a high incidence of HIV.

Thus, the non-profit American organization Project Prevention pays women who use drugs for their sterilization. More than 1,300 women had been sterilized up to 2010. The project expanded its activities to the United Kingdom and Kenya in 2010. Project founder Barbara Harris is offering women living with HIV USD $ 40 for the IUD installation and USD $ 300 for sterilization [8, 9, 10].

The practice of involuntary sterilization of this category of persons has been recorded in a number of countries such as the Dominican Republic, Venezuela, Chile, El Salvador, Honduras, Mexico and Nicaragua. A survey of 285 women living with HIV from four Central American countries (El Salvador, Honduras, Mexico and Nicaragua) in 2015 found that about 25% of them were under pressure from health care professionals [11]. Health care professionals informed women in order to sterilize them that their HIV status revoked their right to choose another method of contraception and refused to provide them medical services needed to prevent vertical transmission of HIV in the event of denial.

But the most widespread cases of coerced sterilization of HIV-infected people occur in Africa. In Namibia, health care professionals threatened to ban an infected person to communicate with children or refused to perform an abortion if a person did not agree to sterilization [12]. In South Africa women are threatened with discontinuation of giving essential antiretroviral drugs if they do not sign a sterilization consent form [13].

Governmental and non-governmental organizations often encourage patients' consent to sterilization in this way. They justify involuntary sterilization on medical grounds, saying that HIV-positive or drug-addicted persons should be sterilized to reduce the transmission of HIV from mother or father to children and to prevent the birth of children with physical or mental disabilities of drug-addicted parents. However, it seems that this procedure violates not only the principle of medical ethics, but also usefulness, because the treatment should be useful for the patient. Sterilization is not required for this. Back in the 1990s, inexpensive drugs were developed for antiretroviral treatment that reduced the risk of mother-to-child transmission of HIV to less than 2 percent. Those drugs are available even to the poorest layers of the population and to countries with underdeveloped health care systems [13]. In addition to sterilization, there is currently a large number of alternative contraceptives. That is the reason that bribing or mental coercion of patients in order to obtain their consent to sterilization is a gross violation of natural human rights and cannot be justified.

Involuntary sterilization of criminals is a medical manipulation offered to criminals in exchange for shortening the sentence or mitigating the conditions of serving it. This research deals with sterilization, which is an irreversible procedure and does not involve the restoration of the reproductive functions of criminals. Quite a large number of countries apply drugs that suppress sexual function for some period of time to criminals (pedophiles, rapists), but such procedures are not the subject matter of this research because these functions are restorable.

A person receives an offer to perform sterilization operation in exchange for release from punishment or mitigation of punishment, it should be considered an influence on his will. This procedure deprives a person of the ability to reproduce and causes serious physical and psychological disorders. That is why the surgical castration of criminals, for all its external voluntariness, must be recognized as involuntary and identified as a violation of human reproductive rights.

Involuntary sterilization of transgender people is a medical manipulation that is mandatory for legal gender reassignment of transgender people.

The most pressing issue of involuntary sterilization in the modern world is the existence of laws on mandatory sterilization of transgender people in many countries. They require that transgender people must be sterilized before they can legally change their sex.

The Committee of Ministers of the Council of Europe Recommendation, adopted in 2010, calls for "appropriate measures to ensure full legal recognition by any person's change of gender in all spheres of life, in particular, by enabling them to change gender and name in official document in a prompt, transparent and accessible manner" [14]. The Yogyakarta Principles for the Application of International Human Rights Law on Sexual Orientation and Gender Identity also emphasize: "No one may be coerced to undergo gender reassignment, sterilization, or hormone therapy as a prerequisite for the legal recognition of gender identity" [15].

Nowadays, there are countries in the world which do not require surgery for legal gender reassignment; there are countries, where such a procedure is mandatory. For example, the Art. 51 of the Fundamentals of the legislation of Ukraine on health care notes that the issue of relevant changes in the legal status of a transgender person is resolved on the basis of a medical certificate of gender reassignment [16]. The Art. 257 of the Marriage and Family Code of Kazakhstan stipulates that transgender people can change their name, last name and middle name according to the chosen gender only after surgical correction of sex [17]. The Order of the Minister of Health Care and Social Development of the Republic of Kazakhstan No. 187 on approval of the Rules of medical examination and gender reassignment for persons with sexual identification disorders in 2015 also confirmed the mandatory nature of surgical correction of sex [18].

The bill on Transgender People Rights Protection of 2019 in India also provides that a person may apply to change his or her legal gender to male or female, but it requires prompt intervention as evidenced by medical records [19].

The high-profile case of Takakito Usui, a 43-year-old transgender man (that is, one who was born a woman, but identifies himself as a man), who wants to be recognized as a man in the Japanese population and marital registry, is currently widely covered in Japan. However, he must remove his ovaries and uterus according to the law, as well as to make surgery that his genitals look like male ones, to be over 20 years old, single, having no minor children and be diagnosed with a "gender identity disorder". Takakito Usui wanted to obtain a new documents proving his masculine identity without sterilization, but he was refused. The man filed a lawsuit on family cases and the court rejected his application. The court concluded that the preservation of the reproductive function of an individual of the appropriate sex, obtained by him or her at birth, is impractical after gender correction [20]. More than 7,800 Japanese have been forcibly sterilized to obtain legal recognition of their desired sex since the adoption of the law in 2004.

Activists and opponents of this approach call these laws aggressive and contrary to the human right to self-identification. The European Court of Human Rights stated in 2017 that 22 countries, which are under its jurisdiction, still require sterilization as part of a legal gender reassignment.

In 2017 judgment in *A.P., Garçon and Nicot v. France*, the European Court of Human Rights held that the French law provision requirement that transgender persons undergo a sterilization procedure or other medical treatment before changing the gender identity on their birth certificates violated their rights to respect for private life [21]. The European Committee of Social Rights found a similar requirement in the Czech Republic to violate the European Social Charter [22].

Laws on the coerced sterilization of transgender people are unconstitutional because they violate human rights and guarantees of respect for one's identity. Many transgender people do not have the opportunity to undergo sterilization and surgical correction due to the lack of health,

financial resources or unwillingness to lose reproductive function. Besides, the use of invasive surgery is a serious interference in the body and can cause serious physical harm. Therefore, the decision on such a surgery should be completely voluntary without any pressure from the state. Progressive European countries that abandoned the practice of compulsory surgical sex reassignment have acknowledged that they violated the reproductive rights of their citizens in the past. Thus, the Swedish Parliament on March 21, 2018 decided to pay compensation to those people who were coerced to undergo sterilization for legal gender reassignment. This is approximately 600-700 people who are entitled to compensation in the amount of 22,500 euros [23]. Sweden became the first country that compensated transgender people for serious violations of their natural reproductive rights.

Involuntary sterilization in overpopulated countries and members of national minorities is a medical manipulation offered to individuals in exchange for material rewards or by imposing discriminatory restrictions on those who do not wish to lose fertility. This type of involuntary sterilization is very often a part of some countries' government policy.

For example, involuntary sterilization in China was used until 2017 as a part of the "one child policy". The motives were to provide financial incentives and employment opportunities for those who adhered to them, and to impose sanctions (economic or others) on those who violated this policy. A similar situation exists today in Uzbekistan, where some women are reported to be required to present a "sterilization certificate" while being employed [24]. Governmental financial assistance in Tunisia covered only the first four children. Income tax benefits, maternity leave, the allocation of public apartments and school places were applied only to the first three children in Singapore, [25].

The United States Congressional-Executive Commission on China (CECC) found out that the Chinese authorities used the revocation of state benefits and permits, as well as the abolition of registration for unsterilized women and their children as a coercion to be sterilized [26]. The family planning authorities in Puning launched on April 7, 2010 a 20-day campaign to conduct 9,599 sterilizations. Punitative authorities detained 1,377 people who are parents or relatives of the targets who were subjected to sterilization for obvious pressure. The Amnesty International Foundation accused the Puning City authorities in 2010 for forcing people to be sterilized by imprisoning their elderly relatives [26]. Since their adult children refused to be sterilized, they were kept until the children agreed to be sterilized. Many of the detainees were in appalling conditions, in cramped rooms with high humidity, where there was no room even to sit down [26].

Public sterilization clinics were officially active in India until 2017, where various financial incentives and compensations were offered to those who would undergo sterilization. The government raffled off various prizes, starting from the Tata Nano (one of the cheapest vehicles in the world) up to motorcycles, mixers and TVs among those who were sterilized. About 4 million sterilizations were performed only in 2013-2014 in India. Less than 100,000 of those surgeries were performed on men [27].

Does the government have the right to restrict the freedom and rights of a person to have the desired number of children? Is it justified to use its socio-economic mechanisms of influence to achieve the goals of population control? Are there any restrictions on this type of "influence"? Proponents of population control argue that population control is necessary to combat global poverty and the continuing deterioration of the environment.

If the government forces its citizens to be sterilized by imposing discriminatory restrictions on fertile persons, this can undoubtedly be considered as the violation of the inalienable human right to reproduction. At the same time, the use of material incentives such as money, food, clothing and other material benefits to motivate the population to sterilization also raises serious ethical issues. Studies have shown that those incentives work best for the very poor and uneducated layers of the population. Such individuals are economically vulnerable due to poverty and often do not understand the full essence and consequences of this manipulation due to the lack of education.

Control of the population through bribery and blackmail restricts human freedoms and is contrary to the natural rights to reproductive health enshrined in the UN Declaration of Human Rights.

New studies demonstrate that population growth is often accompanied by an increase in resources. Moreover, economic development leads to lower birth rates without the need for severe population control measures. It is now well documented that as countries become richer, citizens of such countries tend to choose fewer children in the family on their own. This phenomenon is called the birth transition [28].

Governments should invest in family planning and population control programs that establish ethical guidelines for improving public education on these issues, as well as contain information on alternative contraceptives. Such measures will avoid unnecessary ethical dilemmas and conflicts.

Another form of pressure on the poorest layers of population and national minorities is forcing them to sign a sterilization agreement, at the moment when it was not expected that individuals would be able to make an informed and balanced decision. Thus, women during childbirth are asked to immediately decide on sterilization and asked to sign a consent form, sometimes written by hand, in difficult to understand language, or using unfamiliar terms, or terms in Latin [29]. In Indian sterilization camps in Uttar Pradesh state, poor illiterate women undergo a consent procedure in a hurry. Women were only informed about sterilization, without mentioning any other possible long-term method of family planning. They were asked to leave a fingerprint without reading the content of the suggested form or without fully explaining the essence of the procedure. The Indian government reportedly paid private physicians for every done sterilization. For example, the Santushti Foundation offered to pay Rs 15,000 per surgery, and hospitals and clinics an additional Rs 500 per case,

when 30 surgeries are performed in one day in an inpatient facility. This practice created a powerful incentive for physicians to force sterilization [30].

Government family planning programs in Uzbekistan have also led to the situation, when physicians force wemen to agree to sterilization in order to receive bonuses [31]. In response to such incidents, the International Federation of Obstetricians and Gynecologists (FIGO), the world's only professional organization for obstetricians and gynecologists, has adopted an ethical guidelines that emphasize that sterilization is a voluntary procedure; that patients should be informed that sterilization is irreversible; that sterilization can never be justified by emergency medical care; that consent to sterilization should never be a condition of receiving other medical care or any benefits [32]. Thus, respect for the autonomy of sterilization decisions requires that any counseling, advice, or information provided by health care providers or any other support to health care professionals or family members should be impartial. Practitioners and the public should be aware that only clear, accessible and understandable instructions will ensure a person's full, free and informed consent to sterilization [33]. This will allow the person to make the best decision for him or her, realizing that the final sterilization is an irreversible procedure.

The European Court of Human Rights also emphasizes the need for free and informed consent while deciding on sterilization. Thus, the ECHR in the case of N.B. v. Slovakia (No. 29518/10) dated June 12, 2012 found a violation of the applicant's rights, who although voluntarily signed sterilization agreement, but that agreement was not complete and final [34].

Analyzing the different types of involuntary sterilization in relation to the range of persons to whom it is applied (recipients), it should be noted that involuntary sterilization can also be differentiated by other criteria that contain its essential features, such as subjects (agents) of application, methods, goals, degree of compulsion. Thus, **agents of application** (those who initiate the interference with a person's reproductive rights) are, first of all, *the state*, when involuntary sterilization is to some extent enshrined in state programs, regulatory acts, supported by government payments, etc. For example, the above-mentioned India with the legal requirement of legal gender reassignment only in the presence of surgical intervention and China with its "one child policy". In addition, the agent of applying involuntary sterilization is *society, community* in situations of "veiled" state intervention and the absence of the relevant regulations or concepts of "purity of the nation", "eugenic experiment", etc. Sterilization is implemented through the activities of certain non-governmental organizations or charitable foundations, such as in Kenya, the Dominican Republic and other countries, where the promotion of sterilization of HIV-infected people, as mentioned above, is widespread.

Involuntary sterilization, according to the **methods** of application, can be carried out by the assistance of both *direct* methods of the state (in the presence of the state-declared policy of population reduction) and *indirect* methods (when the policy of population reduction or application of involuntary sterilization to certain segments of the population is not directly declared, but is implemented in the way of incentives, bonuses or payments, for example, to physicians who make such sterilizations). Thus, genetic experiments on a national scale are in the past in conditions of the rise of worldwide public awareness and the adoption of the concept of state compliance with the minimum standard of human rights. However, some states use "indirect" methods to encourage people related to reproduction (physicians, obstetricians, social workers) to "gently" induce certain layers of the population to be sterilized. This also may include cases of material incentives for the recipients of involuntary sterilization, such as payment of monetary compensation or participation in the lottery, like in India until 2017.

According to the **goals** that society / state puts before involuntary sterilization, one can distinguish them as clearly *"socially useful"*, such as:

– the health of the nation (with involuntary sterilization of HIV-infected people);

– security of society (with involuntary sterilization of vulnerable groups, including high crime rate, homeless people, prone to alcohol or drug addiction, etc.);

– special prevention (for criminals who committed sexual crimes);

– legal certainty (regarding the gender status of transgender people),

and clearly *doubtful* goals (genetic, eugenic "purity of the nation" programs or current genetic "biohacking" – concepts that promote sterilization as a preventive measure against certain hereditary and genetic diseases, such as cervical cancer, ovarian cancer, as well as a mean of prolonging youth, etc.).

It seems that coerced sterilization, in contrast to both voluntary and forced, can have certain **degrees of compulsion**, and can be divided into:

– *absolutely coerced* (for example, sterilization of transgender people);

– *relatively coerced* (HIV-infected, sterilization for benefits, etc.).

Thus, all the above-mentioned types of sterilization, which we refer to coerced, have common features – they are carried out to a person who, although gives consent to their implementation, but the will is limited, is significantly affected by the pressure of circumstances, bribery, mental coercion, bureaucratic or legal rules, procedures and regulations, policies of the state and society, and therefore can not be considered fully voluntary, and is not forced, because it is carried out with the formal, but the consent of the person.

CONCLUSIONS

Thus, coerced sterilization does not clearly meet the requirements and standards for human rights and fundamental freedoms and is often a measure of the state that significantly

restricts or deprives a person of the right, including reproductive rights, and does not clearly comply with the principle of proportionality that is used, in particular, in the practice of the ECHR, and despite being used for a legitimate purpose and lawful means of intervention (which is often not observed in coerced sterilization) also violates the requirements of propriety, reasonableness and balance, which constitute the proportionality in its narrow sense.

The right to reproduce, in the current democratic society, as an inalienable natural right of every human being should not be subject to any restrictions. The decision not to reproduce must be entirely voluntary, and a person receiving it must not be bribed or pressured by either the state or other persons. Besides, the irreversibility of the surgical sterilization procedure imposes on the state the obligation to ensure that the person's consent to this procedure is complete, informed and uncoerced.

Human rights can give states a powerful incentive, legal commitment, and a wide range of strategies that allow implementing changes – to identify violations, to rethink public perceptions, and to overcome economic and social barriers to reproductive health protection. Governments must begin to search ways to improve their legal and regulatory frameworks to ensure unresisted realization of everyone's own reproductive rights. The use of human rights as a tool to identify the necessary changes will ensure effective protection of the right to reproduction. It is quite difficult to prosecute coerced sterilization from the legal point of view, because the person outwardly seems to voluntarily agree to such a procedure, although under the pressure of certain circumstances – financial incentives or the threat of certain oppression of the rights. In addition, the legislation of many countries does not consider the promotion of sterilization as a crime. The governments of such states may subsequently apologize and offer financial compensation to victims of coerced sterilization policies. But there are exceptions – for example, Part 4 of the Art. 134 of the Criminal Code of Ukraine provides criminal liability for coercion to sterilization and it is the latest decision, but hardly successful, since the term "coercion" is not revealed and can be interpreted very broadly, hardening the separation of coerced sterilization from forced one, etc.

It seems that states in order to prevent cases of coerced sterilization can take the following measures:

1) purposeful active policy of the states' governments in regard to unimpeded realization of the right to reproduction;
2) reduction of regulatory differences and unregulations in the field of reproductive health protection through legislative amendments;
3) establishment of criminal and other types of liability for the violation of patients' reproductive rights and, in particular, for coerced sterilization;
4) protection of the patient-physician relationship. The relationships between patients and their physicians are focused on trust and confidentiality. Probably, these principles are more important in the field of reproductive health than in any other field. It often involves intimate, difficult conversations and decisions, when patients are highly dependent on the opinion of the physician;
5) strengthening comprehensive sex education. Ensuring that adolescents and young people have the resources and knowledge to have sexually healthy lives and reproduction, which is an important component of their educational and social development;
6) support and funding for family planning centers that offer medically accurate information and quality care. Such centers help women to take decisions about birth and the number of children through awareness of contraceptives, pregnancy testing, counseling for sexually transmitted diseases, etc.;
7) encouragement of the states to protect and expand their medical programs in the field of protecting the realization of reproductive rights by human beings.

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REVIEW ARTICLE

LEGAL RESTRICTIONS ON MEDICAL INTERVENTION DURING OPERATION ON FEMALE GENITALIA FOR NON-MEDICAL PURPOSES

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ABSTRACT

The aim: To identify problems associated with non-medical genital surgery and establish the limits of acceptable medical intervention in such operations.

Materials and methods: The study is based on a theoretical basis, which includes reviews of legislation, reports from non-governmental organizations, and is based on empirical data: decisions of the European Court of Human Rights, international regulations, statistics of the World Health Organization. Systemic and structural, comparative legal and functional methods, systematization, analysis and synthesis were decisive in the research process.

Conclusions: "Female genital mutilation" or "female circumcision" is essentially a separate type of bodily injury that is caused intentionally in accordance with various social domestic and religious traditions and beliefs of certain emigrant ethnical religious communities. Such actions are a form of discrimination and violation of women's rights on the basis of gender, as well as a form of child abuse, as the vast majority of such operations are carried out on girls under 12 years of age. Medical intervention in case of operations on female genitalia, including for non-therapeutic purposes, can be considered legitimate only with the informed consent of the patient and on conditions that the level of danger to human health from such intervention corresponds to the concept of personal autonomy, that is, it does not require direct state intervention for the reasons of urgent social necessity.

KEY WORDS: consent to harm, female genital mutilation, female circumcision, bodily injury, gender discrimination

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INTRODUCTION

Despite the fact that most female circumcision operations are performed in Africa and the Middle East countries, female circumcision has reached the level of an international problem that exists in over 30 countries. Female circumcision is also performed in Latin America, Asia, as well as in Australia and New Zealand. Although this practice is not common in Europe, migrants living in Western Europe often carry out these operations. The causes of female genital mutilation depend on the level of development of society, region, family, their culture and traditions. The most common reason for such a phenomenon is the social norm in the corresponding environment, where women are simply afraid of being rejected by society, because there such an operation is considered a commonplace.

Thus, this problem does not really go to the distant past, but it exists in the present, because any modern country can face it. That is why the World Health Organization is currently actively fighting against the practice of female circumcision.

One of the indisputable facts of recognizing the existence of the problem of female circumcision in the world was the adoption on 11 May 2011 of the Council of Europe Convention on Preventing and Combating Violence against Women and Domestic Violence (hereinafter referred to as the Istanbul Convention).

According to Art. 38 of the Istanbul Convention, the Parties shall take the necessary legislative or other measures to ensure the criminalization of such forms of intentional conduct as: a) removal, infibulation or making any other injury in whole or in a part of the labia majora, labia minora or clitoris; b) forcing or inducement of a woman to be subjected to the acts listed in subparagraph (a); c) incitement, forcing a girl to be subjected to the acts listed in subparagraph (a), or inclining her to do so [1].

THE AIM

The aim of this article is: a) to determine the state of legal regulation of the operations on the female genitalia for non-medical purposes; b) establishing the limits of permissible medical intervention in the case of such operations.

MATERIALS AND METHODS

The theoretical and empirical basis of the study includes the reviews of national and foreign legislation, doctrinal positions, decisions of the European Court of Human Rights, regulations of Italy, Sweden and other Parties to the Istanbul Convention, statistics of the World Health Organization. International legal acts of the United Nations and the World Health Organization are also used in the work.

In particular, regarding the legality of female circumcision and permissible medical intervention, the provisions

of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine were studied as well as the Convention on Human Rights and Biomedicine; Declaration of Lisbon on the Rights of the Patient; Council of Europe Convention on "Preventing and Combating Violence against Women and Domestic Violence"; Convention for the Protection of Human Rights and Fundamental Freedoms; the case of the European Court of Human Rights LASKEY AND OTHERS v. THE UNITED KINGDOM; 20 cases in which a reasonable suspicion was raised of mutilation of female genitalia (female circumcision) under the Criminal law of the EU (cases were registered in the countries of the European Union, in particular in Germany, France (most cases), Italy, Spain, Sweden, Norway). The statistics of the countries where the pernicious practice of female genital mutilation is traditionally the most common - Egypt (95.8%), Djibouti (93.1%), Guinea (95.6%), Mali (91.6%), Somalia (97, 9%), Sierra Leone (94%) and Sudan (North Sudan - 80% of respondents).

The methodological basis of the work is based on general scientific and special research methods. The dialectical method is used to define the terms "removal", "infibulation", "any other injury", "female genital mutilation", the statistical method is used in the analysis of statistical data, the comparative - in the study of the experience of countries such as Ukraine, Italy, Sweden and other countries, Parties to the Istanbul Convention. Comparative method and generalization method are used in the study of the legislation of some countries and the decisions of the European Court of Human Rights. Through the use of logical and historical methods, a deeper understanding of the essence of the problem is achieved, and it is possible to provide sound suggestions and recommendations for their solution.

REVIEW AND DISCUSSION

According to Art. 2 of the Convention for the Protection of Human Rights and Fundamental Freedoms, human life, health are the highest social values and are under special protection of the state. The current Criminal Code of Ukraine (hereinafter the Criminal Code) prohibits causing harm to the life and health of another person under a threat of criminal liability. Such a prohibition is established by a number of norms provided by Articles 115-128 of the Criminal Code. In addition, the current criminal legislation of Ukraine contains provisions for the protection of human life and health from improper medical practice (medical activity), for which criminal liability is established in Articles 131, 132, 134, 138-144 of the Criminal Code.

The criminal acts provided by these norms are within the general concept "crimes in the field of medical activity". A common feature of these norms (both "general" and "special" in the field of medical activity) is that they provide for the liability for unlawful (intentional or negligent) harm to life and health of *another* person. Accordingly, harmful acts against oneself or others, with the informed consent of the latter or their legal representatives, may in certain circumstances, be considered non-criminal or even lawful interference in the life and health of a person.

A separate problem is the commission of certain acts by medical workers in the absence of medical necessity. In the latter case, a clear example is the practice of female circumcision. In accordance with the judicial practice of the European Court of Human Rights (hereinafter ECHR) on the protection of patients from unwarranted medical intervention (examination and treatment) [10] under Articles 2, 8 and 14 of the Convention for the Protection of Human Rights and Fundamental Freedoms (hereinafter the Convention for the Protection of Human Rights) and a number of international documents on bioethics [2; 3], medical staff is prohibited from performing medical intervention without the informed consent of the patient, as well as from conducting such operations for non-medical purposes, if they cause harm to the patient's health. However, except for the situations where there is a more or less clear regulation of the legality (or illegality) of their conduct (in particular, abortion, euthanasia, etc.), a systematic approach to determining the admissibility of medical intervention in the European practice is still missing.

The Istanbul Convention [1], which aims to prevent and eliminate this phenomenon, also provides an international mechanism for monitoring the implementation of its provisions at the national level. In accordance with this Convention, amendments were made to the Criminal Code of Ukraine, in particular to Art. 121 of the Criminal Code of Ukraine. The concept of grievous bodily harm was expanded by supplementing it with such a feature as genital mutilation. According to Art. 38 of the Istanbul Convention, States - Parties shall take the necessary legislative and other measures to ensure that the above forms of intentional female genital mutilation are criminalized [1; 16].

These operations are performed without medical and / or cosmetic indications for their conducting, which differs from the permitted forms of medical intervention and plastic (cosmetic) operations on the genitals [6, p. 2].

It should also be noted that there is no single comprehensive approach to defining the concept of consent to such an operation, which leads to the fact that, according to the World Health Organization (hereinafter WHO), medical workers actually perform about 18% of operations of female genitalia mutilation [11].

One of the reasons for this situation is the lack in the legislation of the States - Parties to the Istanbul Convention, of a clear prohibition to conduct such operations, regardless of the consent of an informed adult person. The analysis of the criminal law of 28 European countries, 21 of which have already ratified the Istanbul Convention [12], showed that: 13 countries (Austria, Belgium, Croatia, Denmark, Estonia, Germany, Italy, Norway, Portugal, Great Britain, Romania, Sweden, Switzerland) have provided in their national legislation a separate (special) rule on liability for female genital mutilation. Moreover, 10 of these countries have established such responsibility regardless of the woman's consent to such an operation. At the same time, 15 countries did not provide for a separate rule on female

genital mutilation and did not amend their domestic (national) legislation, and therefore female genital mutilation is punishable by their laws in general as bodily injuries of some severity [13].

The Criminal Code of Ukraine provides for a gender-neutral norm, which establishes the liability for mutilation of both female and male genitalia. But despite the fact that the Criminal Code of Ukraine contains such a feature as genital mutilation, it remains unclear what exactly should be understood by such acts and how to be in a situation when this female circumcision is performed by a medical worker in relation to an adult with her informed consent for such an intervention. Can such acts be considered as a circumstance that excludes the criminality of the act, and the consent of the victim to conduct such an operation can be recognized as lawful?

This issue is particularly relevant against the background of the fact that a number of local regulations of other countries, Parties to the Istanbul Convention, clearly state that these operations are conducted for non-medical (non-therapeutic) purposes and are aimed at depriving the organs of proper sexual function (Article 538bis of the Italian Criminal Code). [7, p. 20].

In accordance with the features given in the above international acts and the WHO guidelines, the term "female genital mutilation" can be defined as all procedures involving partial or complete removal of the external genitalia for *non-medical* purposes [9, p. 4]. Thus, the above four types of female genital mutilation in their content are carried out for non-medical purposes. The indication of the non-medical purpose of this operation is also because the fact that for a long time (from the mid-nineteenth century to the 50s of the twentieth century) female circumcision (including clitoridectomy) was used as a method of "treating female weaknesses", including nymphomania, depression, hysteria, etc. [14].

International law recognizes female genital mutilation as a gross form of discrimination and a significant violation of women's rights. This tradition is typical (99%) for the western, eastern and north-eastern regions of the African continent, as well as for some countries in Asia, the Middle East and among the closed communities of North American immigrants and Europe.

The issue of banning this practice in Europe has arisen due to a significant increase in the number of representatives of certain communities in the European Union, especially in Germany and France. Such actions are a consequence of religious or ethnical and religious traditions and beliefs and are carried out as a part of the rite of coming of age, preparation for marriage, adult life, preservation of female virginity.

In order to implement the above-mentioned international agreements, the countries of the European Union have adopted a number of local regulations on the prevention and counteraction to the facts of female genital mutilation (female circumcision). In particular, the Law on Combating Female Circumcision was adopted in Sweden in 1982 (Law № 1982: 316). At the same time, as of 2009, according to the police, about twenty cases of reasonable suspicion were identified, two of which were the subject of court proceedings. But, as researchers note, cases in this category are characterized by a fairly high degree of latency [6, p. 5–6].

Cases of female genital mutilation in accordance with the court practice of these countries can be divided into two groups, namely:

a) cases of female circumcision in its pure form (so-called "typical" cases of female circumcision [15, p. 102], in which the intent and mainly a special purpose - religious or traditional, including marriage practices) are taken as the criteria;

b) cases of female genital mutilation, which can be attributed to this group only conditionally, as they can be recognized as such only in terms of consequences (so-called "atypical" cases of female circumcision) [15, p. 99].

The fact is that the Istanbul Convention does not differentiate between the acts committed in connection with religious or traditional practices and others, including negligent acts, which are the result from, for example, medical error, negligence, etc.

The analysis of the content of Art. 121 of the Criminal Code of Ukraine also allows us to conclude that, firstly, there is no clear definition of what exactly should be meant by genital mutilation and, secondly, how exactly this feature corresponds to other signs of serious injuries, the types of which are listed in Art. 121 of the Criminal Code.

I. Mytrofanov, I. Lysenko, K. Hryn, M. Ryabushko [16] reasonably paid attention to these problems. Researchers in other countries also pay attention to this issue. For example, Inger-Lise Lien analyzed over 50 cases in the last 10 years in Norway (2017 study), none of which had been charged [8]. Among the main reasons for this situation, the author points (i) lack of medical proof; (ii) determining the timing of the scar; (iii) the parents' denial of knowing about the procedure; (iv) lack of witnesses in Norway that can connect parents to the crime; (v) children who cannot remember or know if they were cut or not as the procedure was done when they were babies; (vi) lack of competence by those who report cases, generating many false alarms such as labia adhesion, and (vii) the principle of 'in dubio pro reo' (when in doubt, find for the accused) [8].

It should be noted that the legislation of some countries also does not establish a legal difference (distinction) between these acts. Thus, in accordance with Part 1 of Art. 538biz of the Criminal Code of Italy, criminally punishable are any actions that led to the removal of certain parts of female genitalia and resulted in a physical or mental disorder (without specifying the degree of such disorder). Similar provisions are contained in the criminal law of other EU countries that are the Parties to the Istanbul Convention. That is, under the laws of these countries, the consequences, which actually are in a specific form of grievous bodily harm, make a separate rule, and liability for their infliction arises regardless of the specific purpose or intention, i.e. without taking into account the nature of this operation as such. It should also be noted that criminally punishable under the Criminal Code of the States - Parties to the Istanbul

Convention are any actions that have led to female genital mutilation in accordance with the above four types. Such actions are criminally punishable regardless of the age of a person in respect of whom the operation was performed, i.e. actions committed at the request (with the consent) of an able-bodied adult are punishable if they correspond to the four types of genital mutilation. As for such actions committed by the victim against herself, they do not entail criminal liability, but may be the grounds for proceedings under this rule of criminal law, if it is established the fact of aiding, abetting, inciting or otherwise instigating this girl for the procedure of female genital mutilation.

The stated above gives grounds to draw the following conclusions: - cases (criminal proceedings) concerning female genital mutilation are characterized by a high degree of latency; - the number of cases (criminal proceedings) brought to a conviction is a relatively small percentage of the total number of cases (criminal proceedings) involving female genital mutilation; - persons found guilty of committing these acts, in the vast majority of cases belong to the ethnic groups in which the commission of such acts is a traditional practice; - the legislation of the EU Member States generally does not contain a clear distinction between female genital mutilation and other actions that result in injury to female genitalia (in particular, due to improper medical practice).

In view of the above, it can be argued that in the vast majority of cases, the legislation of the States - Parties to the Istanbul Convention, recognizes such operations as criminal, regardless of the consent of a victim. That is, the fact of a victim's consent to such an operation is not considered as creating a circumstance that excludes the criminality of the act. However, none of the normative acts that have been analyzed contain a clear indication that a victim's consent to conduct such an operation against her does not exclude the criminal liability of a person who carried it out.

In view of the above, a question arises that is relevant for the current criminal legislation of Ukraine - is voluntary and informed consent of an adult important for making an operation of female circumcision and what is the solution to the issue of liability for the operation of female circumcision? This issue is of particular importance because, unlike the legislation of other States - Parties of the Istanbul Convention, the criminal legislation of Ukraine does not contain a separate (special) rule that would establish responsibility for these actions. It is also not taken into account that such operations can be carried out for any purpose, including those which are the result of improper medical intervention, medical error, etc., which somewhat offsets the tasks set before the States - Parties of the Istanbul Convention.

The issue of consent to medical intervention in the general sense is also urgent. In other words, it is important to find the limits according to which medical intervention, which, although not life-threatening (with life-threatening intervention, including actions such as euthanasia, it is more or less clear), but is unacceptable from a moral and ethical point of view, culture, traditions, customs, etc. Does such intervention require a ban, including through the means of criminal influence by the state?

In this regard, it is important to refer to the analysis of Art. 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms, in particular, the right to respect for private and family life. According to the content of this article, everyone has the right to respect for his/her private and family life, his/her home and correspondence. Public authorities may not interfere in the exercise of this right, except for the cases where such interference is carried out in accordance with the law and is necessary in a democratic society in the interests of national and public security or economic well-being of the country, to prevent riots or crimes, to protect health or morality or to protect the rights and freedoms of others [4]. Despite the numerous cases of the ECHR, including in the field of bioethics, there is no clear answer to the above question. It is also unclear what mechanism is involved in the exercise of this right to medical intervention.

To resolve this issue, we should refer to the case of *LASKEY AND OTHERS v. THE UNITED KINGDOM* [5]. The applicants in the present case considered that their accusation of violence and bodily harm in the course of concerted sadomasochistic activities between adults was the State interference in their private lives and a violation of Art. 8 of the Convention. In particular, it was about the admissibility of state intervention in the voluntary infliction of harm to each other and the extent to which the consent of the victim is illegal and does not exclude the liability of the person who caused the injury.

According to the decision in this case, several clear theses were formulated. Thus, the court found that the injuries which had been or could have been caused by the applicants' activities were substantial in nature and that the conduct in question was extreme in all respects. Therefore, public authorities acted within their competence to protect their citizens from the real risk of serious physical harm or serious injury. Considering this, the following was stated:

1) the notion of the need for intervention implies that it corresponds to an urgent social need and, in particular, is proportional to the legitimate aim;

2) determining the level of harm to be allowed by law in the situations where the victim agrees to inflict it is a matter for the State concerned, as it relates, on the one hand, to public health considerations and the general deterrent effect of criminal law, and on the other hand, it relates to the autonomy of the individual [5].

According to Art. 121 of the Criminal Code of Ukraine mutilation of genitals is a serious injury. Thus, in terms of the severity of the damage, the infliction of such consequences corresponds to the notions "serious damage to health" and "serious injuries, mutilation" specified in the ECHR's decision.

In view of the above, we should agree with the solution of this problem proposed by V.I. Antipov, who considers the voluntary consent of the adult victim to inflict bodily harm on him/her necessary to recognize a circumstance that does not exclude liability, but only mitigates punishment (Part 2 Article 66 of the Criminal Code of Ukraine), so that such punishment is recognized as necessary, appropriate,

sufficient and permissible state interference in private life in a democratic society. On conditions of proportionality of the sentence imposed, this will significantly reduce the possibility of the ECHR's satisfaction of the complaints of violations of paragraph 2 of Art. 8 of the Convention [17, p. 295].

Thus, according to the judicial practice of the ECHR, consent to harm is not unlimited, even in cases where the latter is not explicitly prohibited in its content and corresponds to understandable and established in society (or in some part of it) moral and ethical, religious beliefs and so on.

CONCLUSIONS

The stated above allows us to conclude that medical intervention, including that one conducted for non-therapeutic purposes, can be considered legitimate only if the level of danger to health from such intervention corresponds to the concept of autonomy of the individual, therefore, does not require direct state intervention for the reasons of urgent social necessity. Female circumcision clearly does not correspond to the concept of autonomy of an individual as such actions have serious consequences. That is why, the conduct of this operation by a medical worker, even in a medical institution and with the informed consent of the injured adult, cannot be considered as a circumstance that excludes the criminality of the act.

Taking into account the above, the following conclusions can be formulated: 1) the term "female genital mutilation" or "female circumcision" is well established in international practice, and the commission of such acts is mandatory for criminalization in accordance with the Istanbul Convention; 2) these criminal acts are essentially a separate type of bodily injury, which are caused intentionally in accordance with different social domestic and religious traditions and beliefs of certain emigrants' ethnical and religious communities and which are represented in different percentages in the European Union; 3) such acts are one of the forms of discrimination and violation of women's rights on the basis of gender and abuse of children, as the vast majority of operations are conducted against the girls under 12 years of age; 4) international instruments oblige to criminalize these acts separately, regardless of whether they are provided for in the relevant provisions of national law as a certain type of bodily injury; 5) in accordance with the current legislation of the States - Parties of the Istanbul Convention, all acts that have led to the consequences of four types and / or certain mental or physical harm are recognized as criminally punishable; 6) the current criminal legislation of Ukraine in Art. 121 of the Criminal Code enshrines such a feature as genital mutilation, with no indication of its non-medical (non-therapeutic) purpose, and the legislative wording allows to recognize a person of both female and male sex as a victim of this crime; 7) according to the practice of the ECHR, consent to harm is not unlimited even in cases where the latter is not explicitly prohibited in its content and corresponds to understandable and established in society (or in any part of it) moral and ethical, religious beliefs, etc.; 8) medical intervention, including that one conducted for non-medical (non-therapeutic) purposes, may be recognized as lawful only if the level of health risk from such intervention corresponds to the concept of autonomy of an individual and therefore does not require direct state intervention for the reasons of urgent social necessity.

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REVIEW ARTICLE

INVOLUNTARY ADMISSION OF A MENTALLY ILL PERSON AS RESTRICTIONS OF THE RIGHT TO LIBERTY

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ABSTRACT

The aim: To determine the grounds of involuntary admission of a mentally ill person in the context of the possibility to restrict his or her right to liberty.

Materials and methods: The authors have studied and analyzed international legal acts, legislation of certain countries, judgments of the European Court of Human Rights, case law on involuntary admission of a mentally ill person by using philosophical, general and special scientific research methods.

Conclusions: The imperfection of the legal regulation of relations concerning the involuntary admission of a mentally ill person leads to illegal restriction of the personal right to liberty. It has been proven that involuntary admission and restriction of the freedom of a mentally ill person can be justified, if we take into account the requirement of "therapeutic necessity" for a mentally ill person, the requirement of protecting the rights of others and guaranteeing their safety, the requirement of ensuring the best interests of a mentally ill person.

KEY WORDS: a mentally ill person, involuntary admission, human rights, the right to liberty, restriction of the right

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INTRODUCTION

Issues of social isolation of a mentally ill person through his involuntary admission are relevant to the legal and medical sciences of any country in the world. Every fourth person in the world experiences mental or neurological disorders at some period of his life. About 450 million people suffer from such diseases, which puts mental disorders among the leading causes of deteriorating health and disability worldwide [1]. However, a mental disorder does not mean that a person with a mental illness is deprived of basic human and civil rights. It is important to ensure respect for human rights among such a vulnerable category of population as the mentally ill persons. At the same time, people with mental disorders may in some cases manifest the acts of aggression rather than endangering other people. There are frequent reports in the mass media that a mentally ill person has taken hostage either family members or outsiders, etc. There is a need for involuntary admission of a person with mental disorders. This problem is "supranational", it has international nature. Therefore, the task of law in general and civil law in particular, is to determine the criteria for the admissibility of involuntary admission of a mentally ill person, which is essentially a restriction of the human right to liberty.

It should be noted that a widespread violation of the fundamental rights and freedoms of a person with a mental disorder is his or her unjustified admission into such long-term psychiatric facilities as psychiatric hospitals, social boarding schools and shelters, where fundamental human rights are not guaranteed. Conditions in such facilities are generally unacceptable, and patients are at risk of abuse or neglect or lack of appropriate care [2]. Ombudsmen also pay attention to this fact, pointing out that there is still the practice of applying physical restraint and / or isolation without documentary evidence of this fact in health care facilities, where people with mental disorders are kept [3, p. 140]. This indicates a violation of the human right to liberty.

There are many problematic issues regarding the involuntary admission of mentally ill persons, which attract the attention of both physicians and lawyers. The issues of involuntary admission in terms of admissibility of restriction of personal right to liberty have been studied on a piecemeal basis and are still relevant despite the significant scientific interest in the legal and ethical aspects of mental health [4-5], the problematic issues of involuntary treatment of mentally ill people [6; 7, p. 516-545], protection of mental health of persons deprived of liberty [8, p. 1204], observance of human rights while applying coercive measures of a medical nature in criminal proceedings [9].

THE AIM

The purpose of this research is to determine the grounds for involuntary admission of a mentally ill person in the context of possible restriction of his or her right to liberty, as well as to analyze the law-enforcement practice in this area.

MATERIALS AND METHODS

To achieve the purpose of the research, the authors have studied and analyzed international and legal acts, regulatory acts of certain countries on involuntary admission of a mentally ill person, the decision of the European Court of Human Rights, case law on involuntary admission of a mentally ill person. Conclusions and propositions based on the results of the research have been made on the basis of the analysis of scientific works of well-known specialists in the field of medicine and medical law, statistical data.

In the course of the research the authors have used a set of philosophical, general and special scientific research methods. In particular, the method of analysis and synthesis made it possible to clarify the grounds for involuntary admission of a mentally ill person and the factors stated in the case law of the European Court of Human Rights and national courts to establish the fact that such involuntary admission was lawful and necessary under certain circumstances. The comparative and legal method provided an opportunity to compare the experience of different foreign countries in the field of legal regulation of relations on involuntary admission of a mentally ill person.

REVIEW AND DISCUSSION

According to the World Health Organization (WHO), mental health is a state of well-being, when everyone can realize their own potential, cope with life stresses, productively and efficiently work, and contribute to the life of own community. Impaired mental health indicates the presence of a mental disorder. The American Psychiatric Association reports that one out of five adults in the United States has a mental disorder in any given year. Every 24th American adult suffers from a serious mental illness, and every 12th suffers from a substance abuse disorder [10]. However, not only the countries with the highest standard of living have such sad statistics. Thus, as of January 1, 2017, 1,673,328 people in Ukraine were registered due to mental and behavioral disorders, including 69,492 – due to disorders related to alcohol and drug addiction (or 3.9 percent of the population) [11].

One of the personal non-property rights of a mentally ill person is the right to liberty. The Universal Declaration of Human Rights (1948) proclaims in the Art. 3 that everyone has the right to life, liberty and security of person [12]. This provision of the Universal Declaration of Human Rights has been further embodied in other international legal acts. The right to liberty is provided by p. 1 of the Art. 9 of the International Covenant on Civil and Political Rights (1966) [13], subparagraph (e) of paragraph 1 of the Art. 5 of the Convention for the Protection of Human Rights and Fundamental Freedoms (1950), which provides that everyone has the right to liberty and security of person; no one shall be deprived of his liberty exept in the following cases and in accordance with a procedure prescribed by law: the lawful retention of persons for the prevention of the spreading of infectious diseases, of persons of unsound mind, alcoholics or drug addicts or vagrants.

Many mentally ill people are persons with disabilities, so the protection of their fundamental rights, including the right to liberty, is carried out through additional legal mechanisms. Thus, the Article 14 of the Convention on the Rights of Persons with Disabilities (2006) declares that States Parties shall ensure that persons with disabilities, on an equal basis with others: (a) Enjoy the right to liberty and security of person; b) are not deprived of their liberty unlawfully or arbitrarily, and that any deprivation of liberty is in conformity with the law, and that the existence of a disability shall in no case justify a deprivation of liberty [15]. These provisions of the Convention on the Rights of Persons with Disabilities stem from decades of UN work to change attitudes and approaches towards people with disabilities, including those with mental disorders. This international document raises the movement from the consideration of persons with disabilities as "objects" of charity, medical treatment and social protection to a new level up to the view of persons with disabilities as "subjects" endowed with the rights and capable of realizing these rights, and making decisions for their lives based on their free and informed consent, and treats them as active members of society [16]. Thus, the social isolation of mentally ill persons with disabilities through their involuntary admission should not lead to deprivation of their liberty, although restriction of their right to liberty in order to protect the rights and freedoms of others is possible.

Principle 15 of the UN General Assembly Resolution 46/119 "Protection of persons with mental illness and improvement of psychiatric care" (1992) also provides an approach that every effort should be made to avoid a person being treated in a mental health facility in order to avoid involuntary hospitalization. Principle 16 of this Resolution defines the specifics of involuntary admission of a person in a mental health facility as a patient in two cases: 1) if a person has been already voluntarily admitted as a patient, he may be involuntary detained in a mental health facility as a patient; 2) if a qualified mental health practitioner authorized by law for that purpose determines that the person has a mental illness and considers: a) That, because of that mental illness there is a serious likelihood of immediate or imminent harm to that person or other persons; or b) That, in the case of a person whose mental illness is severe and whose judgment is impaired, failure to admit or retain that person is likely to lead to a serious deterioration in his or her condition or will prevent the giving of appropriate treatment that can only be given by admission to a mental health facility in accordance with the principle of the least restrictive alternative. In the second case, if possible, you should seek the advice of another similar mental health practitioner, independent of the first. In case of disagreement of the second mental health practitioner with the first the involuntary admission or retention may not take place. Involuntary admission or retention shall initially be for a short period as specified by domestic law, for observation and preliminary treatment pending review of the admission or retention by the review body. The grounds of the admission shall be communicated

to the patient without delay and the fact of the admission and the grounds for it shall also be communicated promptly and in detail to the review body, to the patient's personal representative, if any, and unless the patient objects, to the patient's family. A mental health facility may receive involuntarily admitted patients only if the facility has been designated to do so by a competent authority prescribed by domestic law [17].

Characterizing the Regulations and views of the World Psychiatric Association on the rights and legal protection of the mentally ill persons, adopted by the General Assembly of the World Psychiatric Association at the VIII World Congress of Psychiatry (1989), Iryna Seniuta notes that this document contains a number of guarantees, as: 1) voluntary treatment should be encouraged and access to voluntary treatment should be regulated in the same way as the treatment of somatic diseases; 2) patients of mental health facilities or those who seek help voluntarily must be protected by the same legal and ethical rules as the patients with any other diseases; 3) the final decision on the admission or placement of a patient in a mental health facility may be taken only by a court or a competent independent body specified in the law, and only after appropriate and proper hearings; 4) the need for deprivation of liberty shall be reviewed at regular and fixed intervals in accordance with the provisions of national law; 5) imprisoned patients should have the right to a qualified guardian or lawyer to protect their interests [7, p. 531].

The above indicates that the priority is the voluntary treatment of a mentally ill person, free informed consent of such a person is the basis for the treatment of a mentally ill person. At the same time, when there is a danger both for the mentally ill person and for others, there is a need for his social isolation through involuntary admission. Determining the degree of such danger, its criteria, it is equally difficult for both a physician and a lawyer of the law enforcement agency that should decide on the involuntary admission of a mentally ill person.

Regarding the legal regulation of relations on involuntary admission of a mentally ill person, various countries have developed different approaches. Thus, the Law on Mental Health (1994), in the Republic of Poland, establishes two regimes of involuntary admission of a mentally ill person: emergency and non-emergency. A mentally ill patient in the first case may be admitted if he / she poses a direct threat to his or her life, life or health of others (the decision on the admission is taken by a psychiatrist, after which the decision is subject to judicial review). In the second case, a mentally ill patient can be admitted only on the basis of a court decision at the suit of a family member or social protection institution [18]. Subsequently, this Law was amended, in particular in 2008, in order to create a legal mechanism for providing persons with mental disorders with various forms of assistance that make life possible in the family and social environment.

Involuntary treatment of the mentally ill persons, under Swedish law, is generally considered as an undesirable exception to standard care. However, the law stipulates separate judgments while deciding on involuntary treatment. In particular, there is ambiguity on the issue of suicide, since it is argued that the risk of suicide may not be sufficient for justified compulsory care. Besides, organizational factors sometimes lead to involuntary treatment decisions that could be avoided given a more patient-oriented health care organization [5].

The Mental Health Act 1983 of the United Kingdom, as amended in 2007, contains restrictions on involuntary mental health treatment of detained patients, but there are few of them. There are restrictions on psychosurgery and electroconvulsive therapy, and treatment that lasts more than three months and requires the second conclusion under the statutory scheme that it is "appropriate", but any other mental health treatment of detained patients may be mandatory provided at the discretion of the responsible clinician [6].

The Mental Health Act (2017) of India explicitly provides the rights of patients with mental illness and establishes the ethical and legal responsibilities of mental health professionals and the government. The rights of patients with mental illness are fundamental human rights and should be clearly stated, since they belong to a vulnerable group in terms of assessment, treatment and research. Such rights are respected considering the ethics of providing mental health care, which refers to respect for autonomy, the principle of non-abuse, charity and justice, confidentiality, informed consent to involuntary treatment, etc. [4].

Under Ukrainian Law on Mental Health Care, a person suffering from a mental disorder may be admitted to a mental health facility without his or her informed written consent or without the written consent of his or her legal representative, if his or her examination or treatment is possible only on inpatient basis and while establishing a severe mental disorder of a person, as a result of which he or she: commits or shows real intentions to commit actions that pose an immediate danger to him or her or others, or unable to meet their basic needs independently at a level that ensures his or her viability [19].

Under the national legislation of the respective country, mentally ill persons are often recognized as incapable persons depending on the degree of mental disorder. There is no single approach to the placement of incapable persons into specialized institutions in Europe, especially regarding the agency empowered to decide on the placement, and the guarantees provided to the persons concerned. In some countries (Austria, Estonia, Finland, France, Germany, Greece, Poland, Portugal and Turkey), the decision on involuntary admission of a person to the institution for a long term is taken directly or approved by a judge. Other legal systems (Belgium, Denmark, Hungary, Ireland, Latvia, Luxembourg, Monaco and the United Kingdom) allow a guardian, close relatives or administrative authorities to decide on the placement in a specialized institution without the authorization of a judge. A few essential requirements, which in particular relate to the health of a person, hazards or risks, and / or the provision of medical certificates, is applied in regard to the admission in all of

the above countries. In addition, the guarantees of several national legal systems include the obligation to interview the person concerned or to ascertain his or her views on his or her placement; the establishment of a time limit for termination or review of the placement by law or court; and the possibility of providing legal aid. The person concerned in some countries (Denmark, Estonia, Germany, Greece, Hungary, Ireland, Latvia, Poland, Slovakia, Switzerland and Turkey) has the opportunity to appeal against the initial placement decision without the consent of his / her guardian. Finally, some states (Denmark, Estonia, Finland, Germany, Greece, Ireland, Latvia, Poland, Switzerland and Turkey) directly allow the person concerned to apply periodically to the court for a review of the legality of long-term placement [20].

The movement to expand the boundaries of involuntary admission of the mentally ill has been actively developing in the United States in the early XX-th century, but since the 1960s Americans have been trying to achieve restrictions on involuntary admission of the mentally ill persons. The trial in Wisconsin in October 1972 in the case of Lessard v. Schmidt became heinous.

Alberta Lessard, who suffered from schizophrenia, filed a lawsuit alleging that the state law, under which she was subjected to involuntary civil commitment violated her constitutional rights, because it allowed involuntary civil commitment in a mental health facility for the period of l45 days without benefit of hearing on the necessity of detention; required no informing the patient about the right to such a jury trial; failed to give the right to counsel or appointment of counsel at a meaningful time; failed to permit counsel to be present at psychiatric interviews; failed to provide access to an independent psychiatric examination by a physician of the allegedly mentally ill person's choice; permitted commitment of a person without a determination that the person is in need of commitment "beyond a reasonable doubt" (the most strict standard of evidence, which was used only in criminal law at that time to prove the guilt of the accused) and failed to describe the standard for commitment so that persons may be able to ascertain the standard of conduct under which they may be detained with reasonable certainty. The court declared the existing involuntary psychiatric commitment procedure in Wisconsin to be unconstitutional, and required state authorities to make a mandatory court hearing with a patient's counsel on the validity of an immediate involuntary commitment of a mentally ill patient, to hold such a hearing no later than 48 hours after patient's involuntary commitment to a mental health facility, at the request of the patient to hold a full hearing to resolve the issue of the need for further involuntary stay of the patient in a mental health facility by a jury, etc. In addition, the court noted that the right of the country to deprive a person of fundamental liberty to freely go about own business should be based on the understanding that society was extremely interested in such deprivation [21].

As one can observe, society takes on the role of a "caring" family member while involuntary admission of a mentally ill person. The direct decision on such "care" and the need for social isolation of a mentally ill person is made by a physician or a lawyer on behalf of society. If the decision for involuntary admission of a mentally ill person is made by a physician, he positively decides that a mentally ill person becomes dangerous primarily to himself, he can harm his health, then there is a "therapeutic need" for his involuntary admission. Besides, a physician establishes that a mentally ill person poses a threat to other members of society, manifests the acts of aggression, makes damage to property or health of others, commits sexual abuse, etc.

A rather difficult issue in the law-enforcement practice is to determine whether a mentally ill person actually commits actions that pose an immediate danger to him or others, which may be one of the conditions for involuntary admission of a mentally ill person and the basis for restricting his right to liberty. The legislator uses evaluative concepts to determine the grounds for involuntary admission of a mentally ill person, the interpretation of which will be carried out directly by the law enforcement agency, and its decision is the basis for the restriction of liberty of a mentally ill person.

Disputes over the involuntary admission of mentally ill persons are the subject of consideration by the European Court of Human Rights (ECHR) in the context of protecting the right to liberty and security of person, proclaimed in the Art. 5 of the Convention for the Protection of Human Rights and Fundamental Freedoms (1950).

Thus, the applicant of the ECHR judgment in case of "Stanev v. Bulgaria" (2012) (application No. 36760/06) complained about his placement in a social care home for people with mental disorders and about his inability to obtain permission to leave the home (Article 5 of the Convention). Referring to the relevant national law, the ECHR notes that Bulgarian law provides the placement in a social care institution as a protective measure taken at the request of the person concerned, and not as a coercive measure. However, given the specific circumstances of the case, this measure led to significant restrictions on personal liberty, led to deprivation of liberty without considering the applicant's opinion or wishes. With regard to the compliance of the procedure with established law, the ECHR notes that, first, the trustee of a person with limited incapacity is not authorized to take legal decisions on his behalf under national law. Any agreements entered into force in such cases are valid only if they are signed jointly by the trustee and the ward. The court concludes that the decision of the applicant's trustee to place him in a social care home for people with mental disorders without his prior consent is invalid under Bulgarian law. This conclusion is sufficient itself for the ECHR to find that the applicant's deprivation of liberty was contrary to the Article 5. In any case, the ECHR considered that the measure was not lawful within the meaning of the Article 5 § 1 of the Convention, because it was not based on any subparagraphs from (a) to (e). The ECHR notes that the applicant was entitled to social assistance because he had no housing and could not work as a result of his illness. It believes that the well-being of a person with mental disorders in certain circumstances

may be another factor that should be taken into account in addition to the medical examination while assessing the need to place a person in an institution. However, the objective need for housing and social assistance should not automatically lead to the application of measures related to deprivation of liberty. It is obvious to the ECHR that if the applicant had not been deprived of legal capacity due to his mental disorder, he would not have been deprived of his liberty [20].

The judgment of the European Court of Human Rights in the case of "I. N. v. Ukraine" (2016) (application No. 28472/08) is of interest regarding determining the criteria for involuntary admission of a mentally ill person and the expediency of restricting his right to liberty. This judgment states that the applicant had alleged that his placement in a mental health facility had been unlawful, that his examination by a psychiatrist had been carried out on the instructions of the prosecutor's office, because he had addressed the prosecutor's office with complaints on the actions of certain public authorities set out in an offensive form. According to the applicant, this fact could not be an excuse for placing him in a medical facility. The ECHR recalls that deprivation of liberty is such a serious measure that its application is justified only when other, less severe measures have been considered and found to be insufficient to safeguard the interests of the individual or society. This means that the compliance of deprivation of liberty with national legislation is not a sufficient condition; it must also be necessary in particular circumstances. With regard to the deprivation of liberty of persons with mental disorders, then a person cannot be deprived of liberty as "mentally ill", if the following three minimum conditions are not met: first, it must be reliably proved that the person is mentally ill; secondly, the mental disorder must be of a type or degree that gives rise to involuntary confinement in a mental health facility; and thirdly, the validity of long-term detention in a mental health facility depends on the persistence of such a disease [22].

CONCLUSIONS

International legal norms and legislation of certain countries are aimed at ensuring the protection of human right to liberty in case of involuntary admission of a mentally ill person. The use of such a measure as involuntary admission of a mentally ill person is a restriction on the freedom of persons with mental disorders. A person cannot be deprived of liberty as "mentally ill", if three conditions are not met: first, it must be reliably proved that the person is mentally ill; secondly, the mental disorder must be of a type or degree that gives rise to involuntary confinement in a psychiatric hospital; and thirdly, the validity of long-term stay in a psychiatric hospital depends on the persistence of such a disease. The national authority under specific circumstances taking a decision on the involuntary admission of a mentally ill person, which is a restriction on his or her right to liberty, may also consider additional factors as defined by national law.

Compulsory psychiatric treatment and restriction of the right to liberty of a mentally ill person may be justified, if we simultaneously take into account the requirement of "therapeutic necessity" for a mentally ill person, the requirement of protecting the rights and freedoms of others and guaranteeing their safety, the requirement of ensuring the best interests of a mentally ill person.

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REVIEW ARTICLE

EUROPEAN STANDARDS FOR ASSESSING THE HEALTH OF A PERSON WHO PROBABLY SUSTAINED MISTREATMENT DURING DETENTION OR CUSTODY

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ABSTRACT

The aim: The purpose of this paper is to identify and characterize the standards for assessing the health status of a person who is likely to have been mistreated during detention or custody.

Materials and methods: The provisions of international regulations, as well as the case law of the European Court of Human Rights (hereinafter - ECHR, Court) were studied in the preparation of the paper. A set of general scientific and special methods of cognition was used, in particular, the comparative-legal method, the system-structural method, the generalization method, the method of analysis and synthesis, and others.

Conclusions: Medical examinations and forensic examinations of persons detained or incarcerated and alleging torture or mistreatment are appropriate provided that they comply with European standards set out in the case law of the ECHR and the recommendations of international organizations, which whereas will ensure the effectiveness of formal investigations of such facts.

KEY WORDS: detainee's state of health, assessment of the detainee's state of health, medical examination, forensic examination, torture, mistreatment of a detainee

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INTRODUCTION

Article 3 of the Convention for the Protection of Human Rights and Fundamental Freedoms ("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, if there are appropriate grounds, are subject to significant restrictions. Thus, the right of a person alleging mistreatment to a proper medical examination, together with the right of access to a lawyer and the right to notify a third party about detention, are fundamental precautionary measures against mistreatment of detainees, and non-compliance indicates a violation of Art. 3 of the Convention. In order to ensure it, the following issues are relevant: conducting a full expert assessment of allegations of misconduct within the framework of a formal investigation by the competent authorities; proper doctor's qualification who conducts the medical examination of a person and examination to identify the torture signs; quality of the questions asked to the expert; promptness of the medical examination of a person claiming torture; elimination of contradictions in medical documentation, etc. Separate aspect of the problem of compliance with the requirements of Art. 3 of the Convention constitute such national models of investigation, as stated by the ECHR in many cases, in which the failure of authorities to promptly and thoroughly investigate allegations of mistreatment filed by persons suspected of committing crimes becomes systemic within the meaning of Art. 46 of the Convention [1].

THE AIM

The aim of this paper is to identify and characterize the standards for assessing the health status of a person who is likely to have been mistreated during detention or incarceration.

MATERIALS AND METHODS

In preparing the paper, the provisions of international regulations governing the medical examination and forensic examination of persons detained or incarcerated and alleging torture or mistreatment, the case law of the ECHR on these issues (for this purpose, ECHR's 21 relevant decisions were analyzed). It was used a set of general scientific and special methods of cognition, in particular, the comparative legal method, system-structural method, the method of generalization, the method of analysis and synthesis, and others to achieve the goal of the research.

REVIEW AND DISCUSSION

Article 3 of the Convention stipulates that no one shall be subjected to torture or to inhuman or degrading treatment or punishment.

According to the established practice of the ECHR, when a person raises a well-founded complaint of a violation of Article 3 of the Convention, treatment by State agents, it is the duty of the authorities to conduct an "effective formal investigation" capable of establishing the facts and complaints will be true, until the culprits are identified and punished.

The minimum standards for the effectiveness of investigation, as established by the Court's case-law, require that it be independent, impartial and open to the public, and that the competent authorities act with exemplary diligence and efficiency [2].

During the investigation of torture or mistreatment of persons detained or incarcerated, the medical examination and forensic examination of the person alleging such treatment shall be of particular importance. Thus, in the cases of "Danilov v. Ukraine" and "Rudyak v. Ukraine" the ECHR noted that a medical examination, together with the right of access to a lawyer and the right to notify a third party of detention, are fundamental precautionary measures against mistreatment of detainees and should be applied from the outset of imprisonment. Such measures will not only guarantee the applicant's rights but will also enable the respondent Government to relieve themselves of the burden of providing a plausible explanation for these injuries [1; 3].

A study of international human rights law and the administration of justice allow us to identify standards for assessing the health of a person who is likely to have been mistreated during detention or incarceration. In particular, such standards include: 1) conducting a full peer review of allegations of torture or mistreatment as part of an effective formal investigation; 2) compliance with the proper medical examination procedure of a person who has reported torture or mistreatment; 3) proper doctor's qualification who conducts the medical examination of a person who declared torture or improper treatment and the right to freely choose a doctor; 4) compliance with the requirements for the form and completeness of the medical opinion; 5) promptness of medical examination of a person who claims torture or misconduct; 6) providing evidence by a doctor regarding his/her conclusion. We will try to analyze the relevant decisions of the ECHR and the recommendations of international organizations and on this basis to draw some conclusions.

The peculiarity of the first standard (conducting a full expert assessment of allegations of torture or mistreatment in the framework of an effective formal investigation) is that on the one hand any allegation of torture or mistreatment by the competent authorities must be formally investigated and on the other - it is within the framework of such an investigation that a full expert assessment of the applicant's allegations must be carried out, as the ECHR has repeatedly emphasized in its decisions.

Thus, in the case of "Grigoryan and Sergeyeva v. Ukraine" ECHR, finding a violation of Art. 3 of the Convention, noted that the prosecutor's office had considered the applicant's complaint of mistreatment in the context of repeated investigations, and that no criminal proceedings had been instituted, which did not comply with the principles of effectiveness. Such a procedure significantly narrows the investigation, as it allows only a limited number of investigative actions. In particular, the Court pointed out that without initiating a criminal case, the authorities could not conduct a full expert assessment in order to eliminate inconsistencies in medical evidence [4].

Similar shortcomings of the investigation were found by the ECHR in the case "Strogan v. Ukraine", in which the Court found that the investigation had been limited to a medical examination of the applicant and the interrogation of police officers and other persons involved, and that no steps had been taken to resolve the discrepancies between the police and the applicant's testimony.

In other cases, there were the violations of these aspects of Art. 3 of the Convention, the ECHR stated that: the investigating authorities had not eliminated the inconsistency in the medical evidence from the case file [6], in particular, the inconsistency of the various expert opinions on the origin of the applicant's injuries had not been remedied [7]; according to the applicant's complaints of mistreatment, which was partially confirmed by the forensic examination report, no criminal proceedings had been instituted for more than two years [8]; this case investigation, which lasted more than seven years, did not go further than the trial by the Court of first instance, and the completeness and reliability of forensic examinations were questioned by investigators who repeatedly questioned experts and appointed additional examinations, etc. [9]. In the case of "Dolganin v. Ukraine" the ECHR noted a selective approach to the examination of the evidence, given that during the inspections the prosecutor's office had never mentioned that the results of the applicant's medical examination at the hospital indicated that he might have suffered an abdominal injury. The testimonies of the police officers, who allegedly took part in the alleged mistreatment, were accepted by the prosecutor's office, and the applicant's arguments were not verified.

Special attention should be paid to the importance of comprehensively recording (photographing) bodily injuries inflicted on the victim, as well as recording and storing evidence in the room where torture was reportedly used, as noted in paragraph 106 of the Istanbul Protocol (The Manual on Effective Investigation and Documentation of Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (hereinafter - Istanbul Protocol).

Otherwise, improper preservation of evidence of torture may lead to the ECHR recognizing a violation of the Convention. Thus, in the case of "Sizarev v. Ukraine" the Court found the investigation ineffective due to the fact that detention center administration did not take any measures to preserve the evidence, as immediately after the incident the traces of blood were washed away without prior inspection of the scene and drawing up a report [11].

The second standard concerns the proper medical examination of a person who has reported torture or mistreatment. The general requirements for this standard are

contained in paragraph 124 of the Istanbul Protocol. Thus, in accordance with these provisions, the examination is carried out in the most suitable place in the opinion of the doctor and the victim, behind closed doors (outsiders remain outside the room); access to a lawyer must be provided.

The third standard (appropriate qualification of the doctor conducting the medical examination of a person who has reported torture or mistreatment and the right to freely choose a doctor) follows from the documents of the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment. According to these provisions, among the main guarantees of prevention of mistreatment of persons detained on suspicion of committing a crime is the right of a detainee to be examined by a doctor, which also includes the right to be examined by a doctor of his/her choice and receive adequate medical care [12].

In addition, to ensure proper medical examination of a person alleging torture or mistreatment, both the appropriate qualifications of the examiner, his/her specialization (ability to detect and record torture-related injuries) and initial examination are important. the applicant to detect signs of torture or mistreatment. Compliance with these requirements will facilitate the proper recording of injuries, which is essential given the inadmissibility of inspection delays.

In its practice, the ECHR draws attention to the above issues, emphasizing the importance of compliance with these standards. In particular, in the case of "Gerashchenko v. Ukraine" the Court noted that the Government had referred, in particular, to a medical certificate issued by a neurosurgeon stating that the applicant had not suffered any injuries which fell within his area of competence. The Court saw no reason to question this finding but noted that the scope of the examination was rather limited, as the doctor was not invited to assess the applicant's general health or to establish the presence or absence of injuries other than those of neurological origin. The grounds for this particular medical examination the day after the applicant's actual, but apparently undocumented, detention remained unknown [13].

In another case "Serikov v. Ukraine" the ECHR noted that an hour after the applicant's release from the police, he had suffered a number of injuries. The ECHR rejected the Government's argument that the ambulance paramedic had not recorded any injuries to him immediately before his release. Thus, the Court pointed out that the limits of paramedic's examination were limited and that its purpose was primarily to provide the applicant with emergency medical care and not to record his injuries [14].

The ECHR drew similar conclusions in the case of "Lunev v. Ukraine" with the only difference that the initial medical examination, which later led to numerous findings that applicant had not suffered any injuries, was superficial, as it appeared to be intended to establish whether the applicant had any health problems and whether he could have been in custody instead of being found to have been injured.

The next standard concerns compliance with the requirements for the form and completeness of a medical opinion. The main requirements for medical examination and medical opinion Istanbul Protocol (paragraph 162) include, in particular, objectivity and impartiality; proper professional doctors' experience and their special knowledge in documenting torture; clarity and comprehensibility of formulations and medical terminology, as well as indication of only the facts and all examination significant circumstances

Special requirements should be made to the content of the expert's report. Thus, Annex 1 to the Istanbul Protocol formulates the main issues to be reflected in the relevant expert document, which include, in particular: a) the survey circumstances (in particular, personal data of the subject and his/her condition; date and place of the survey, etc.); b) background (detailed description of the history reported by the respondent; methods of torture and complaints of symptoms, etc.); c) physical and psychological examination (report on all identified symptoms); d) conclusion (opinion on the possible connection of symptoms with probable torture); e) authorship of the report.

Paragraph 105 of the same document highlights the six most important questions to ask when drawing up a medical report in order to gather physical and psychological evidence of torture. Thus, such questions include the Istanbul Protocol's question of relationship between the established data and the report of probable torture; factors of physical condition of the subject and stress that affect the clinical picture; the ratio of obtained data with the expected or typical reactions to corresponding stress; stages of recovery of the subject; possibility of erroneous allegations of torture, etc.

The ECHR also emphasizes the importance of asking the right questions to experts in its decisions. Thus, in the case of "Chmil v. Ukraine" the Court has noted a violation of Art. 3 of the Convention, the Court stated that various investigative actions had been carried out during the investigation, including four forensic examinations. However, all these actions seem to have been rather superficial. In particular, with regard to forensic examinations, the Court noted that the experts had never been asked whether the applicant could have been injured in the circumstances described by him or in the circumstances described by the police officers [16].

In addition, it is important to pay attention to the recommendations on the specificity of the wording in examination conclusions, which the doctor sets out in the relevant document. Thus, according to § 187 of the Istanbul Protocol, the following terms are commonly used: a) does not correspond: the injury could not have been caused by the trauma described by the patient; b) answers: the injury could have been caused by the described injury, but it is not specific and could have been caused by a large number of other causes; c) high degree of conformity: the damage could have been caused by the described injury and the number of other possible causes was small; d) typically appearance of the injury is usually observed in this type of injury, but other causes are possible; e) makes a diagnosis: this appearance of the injury indicates that it could not

have been caused by anything other than that described.

Finally, attention should be paid to another important issue, which concerns the possibility of taking into account both the conclusions of forensic medical examinations of public institutions and the conclusions of forensic medical examinations conducted by a private institution, in which the ECHR commented in "Nechiporuk and Yonkalo v. Ukraine". Thus, in the present case the ECHR stated that, on the one hand, the applicant had set out a detailed and consistent version, supported by a forensic examination carried out by a private institution, according to which he had been subjected to electric shock during his stay in the police station. On the other hand, the authorities' version, supported by official forensic findings, was that these injuries "could have been caused by blunt objects", without any further details and no comment on the forensic report of private institution, although it was attached to the materials of the criminal case against the applicant.

In the present case, the Court was strucked by the fact that the trial court ignored, as is apparent from its judgment, alternative medical report contained in the case file and confirmed what the applicant had complained about.

Another standard concerns the promptness of medical examination of a person who alleges torture or mistreatment. As a general rule, it is important to conduct a medical examination of the alleged victim of torture in a timely manner. At the same time, such an examination must be carried out regardless of how much time has elapsed since the use of torture until the traces of it have disappeared.

The ECHR emphasizes in the case "Bocharov v. Ukraine" on the importance of the very first medical examination of a person who alleges torture or mistreatment, noting that the initial results, in addition to those obtained after a direct examination of the applicant, in contrast to a later examination based on documents, were confirmed by the applicant's allegations of mistreatment and suspicious circumstances of his detention and custody [18].

In another case, "Pomilyayko v. Ukraine", the ECHR stated that due to the delay before the first forensic examination it had been impossible to draw precise conclusions as to the extent and nature of the applicant's injuries [19]. The ECHR reached essentially similar conclusions in the case of "A.N. v. Ukraine" [20].

Some cases of non-compliance with the promptness of medical examination of a person who alleges torture or mistreatment have been noted by the ECHR, in particular in the cases of "Ilhan v. Turkey" (medical examination of the applicant was conducted 36 hours after the event) [21]; "Kucheruk v. Ukraine" (forensic medical examination of the applicant's injuries was carried out 37 days after the incident) [22]. In these cases, these facts, together with other circumstances, allowed the ECHR to state a violation of Art. 3 of the Convention, in connection with the failure of the public authorities to provide a comprehensive and thorough examination of the applicants' injuries immediately after the relevant complaints, caused irreparable damage to the ability to establish the relevant facts.

In the studied context, the case "Danilov v. Ukraine", in which the ECHR noted the delays in gathering evidence, in particular because the fact that the applicant had broken seven ribs was established only four months after his detention, although he had complained of rib pain during the first medical examination, which took place within twenty-four hours after detention [1].

Finally, the last standard concerns the provision of evidence by a physician regarding his or her opinion. The purpose of the doctor's written or oral testimony, in addition to providing an expert opinion on the degree of compliance of the medical examination results with the patient's allegation of mistreatment, is also to report these results and relevant conclusions to the competent authorities or court (paragraph 122 of the Istanbul Protocol).

The ECHR also emphasizes the importance of interrogating an expert who conducted a medical examination and forensic examination. Thus, in the case of "Bocharov v. Ukraine" the Court, assessing the appropriateness of questioning the medical staff to clarify the case circumstances as fully as possible, noted that, despite the accuracy of the applicant's diagnoses, which were to play a key role in investigation, the case file did not show that any of the medical workers who examined the applicant shortly after his dismissal were questioned [18].

Referring to scientific sources, it should be noted that the issue of compliance with standards for medical examinations of detainees during the investigation of allegations of violence and torture against them in various contexts has already been raised in the literature [23; 24; 25; 26; 27; 28; 29; 30]. At the same time, foreign researchers consider this problem in two aspects: 1) in the context of ensuring the quality of medical examination of detainees and 2) in the context of the very fact of conducting a medical examination of detainees. In the first plane, British researchers, for example, draw attention to the problem of doctors' lack of necessary knowledge and criteria for identifying the facts of violence against detainees [31]. Similar issues are raised by Basoglu, M. [32], who provide guidance on the assessment and documentation of torture and the provision of medical care to victims of torture. Mostad K., Moati E. conclude that one of the main reasons for poor medical examination is the phenomenon of so-called doctors' "passive participation" in torture, which, in particular, is manifested in the provision of knowingly false medical opinions and failure to report torture. [33]. A similar position is covered by Modvig J, Rytter T. [34]. However, as noted by Silove D., Rees S. one of the factors that can lead to medical complicity in torture is double loyalty, through which doctors put the perceived interests of their organization or state before their absolute duty to care for their patient [35].

Regarding another aspect of medical examination of detainees, Spanish researchers, in particular, draw attention to the frequent cases of lack of information of detainees about their right to medical examination and deliberate violation of national and international norms on mandatory examination of detainees [36].

CONCLUSIONS

An analysis of the issue of assessing the health status of a person who is likely to have been mistreated during detention or incarceration in accordance with European standards allows us to draw the following conclusions.

First, models for investigating allegations of mistreatment of detainees or in custody in some European countries, including Ukraine, have been assessed negatively by the ECHR. The reluctance of the authorities to ensure a prompt and thorough investigation of allegations of mistreatment by persons suspected of committing crimes constitutes a systemic problem for these States within the meaning of Art. 46 of the Convention.

Secondly, in accordance with the case law of the ECHR and the recommendations of international organizations, the standards to be met by assessing the state of person's health likely to have been ill-treated during detention or custody include: 1) a full peer review of allegations of torture; misconduct within the framework of an effective formal investigation; 2) compliance with the proper procedure of medical examination of a person who has reported torture or mistreatment; 3) the appropriate qualifications of the physician conducting the medical examination of a person who reported the torture or mistreatment, and the right to freely choose the doctor; 4) compliance with the requirements for the form and completeness of medical opinion; 5) promptness of the medical examination of a person who claims torture or misconduct; 6) providing evidence by a physician regarding his/her conclusion.

Third, for the first time in 2012, the standard for conducting a full expert assessment of allegations of torture or mistreatment within the framework of an effective formal investigation was reflected in the national legislation of Ukraine. Thus, in accordance with Part 6 of Art. 206 of the Criminal Procedure Code of Ukraine if during any court hearing a person claims violence against him during detention or detention in an authorized public authority, public institution (public authority, public institution, which by law has the right to detain persons), the investigating judge is obliged to record such a statement or accept a written statement from the person and 1) ensure the immediate conduct of a forensic examination of the person; 2) instruct the relevant body of pre-trial investigation to conduct an investigation of the facts set forth in the person's application; 3) take the necessary measures to ensure the safety of the person in accordance with the law.

The interpretation of this normative provision allows concluding that it is imperative for the pre-trial investigation body to enter information into the Unified Register of Pre-trial Investigations upon application and to conduct a formal effective investigation.

Fourth, at the national level, the problem of compliance with the standards to be met by assessing the state of health of a person who is likely to have been mistreated during detention or custody is largely in law enforcement, as recent high-profile examples show that the existence of a law that meets European standards, the legal awareness of law enforcement officers is quite low, which, in fact, is the cause of a flagrant violation of the law and their excess of official authority.

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REVIEW ARTICLE

THE RIGHT TO MEDICAL ASSISTANCE FOR DRUG ADDICTS: EXAMINATION OF THE PROBLEM

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ABSTRACT

The aim: The purpose of this article is to conduct a thorough review and assessment of the exercise of the right to medical care for drug addicts, in particular in custody, through the analysis of international acts and strategies in the fight against drug addiction, as well as drug policies of individual States.

Materials and methods: The study is based on the analysis of international documents, the drug control strategies, the case law of the European Court of Human Rights and analytical researches in this area. The article is based on dialectical, system and structural, comparative and legal methods, the method of analysis and synthesis.

Conclusions: Ensuring human rights without any discrimination should be a priority in the politics of modern States. The implementation of prevention and rehabilitation programs based on scientific evidence is also important. The current situation, in which persons who use drugs experience significant restrictions of their rights and freedoms, is unacceptable.

KEY WORDS: drug abuse, drug addicts, drug policy, treatment of drug addicts, custody

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INTRODUCTION

The UN General Assembly decided in the year 1987 to celebrate June 26 as the International Day against Drug Abuse annually to mark the determination to create a drug-free society. Despite the long-term efforts of the international community and the policies of individual States in the fight against drugs, the world continues to witness an alarming trend of growing number of drug addicts. Based on multi-year studies UN have concluded that a country with more than 7% of the population using drugs is doomed. Such a State has no future. 35 million people worldwide suffer from drug-related disorders and need treatment according to the 2019 World Drug Report. 17.4 million people inject drugs. Almost every eighth injecting drug addict has HIV [1]. The number of people in the European region who use drugs at least once a year is about 275 million, or about 5.6% of the world's population aged 15 – 64. Every 4th person in the European Union has used drugs at least once in his (her) life according to the European Monitoring Center for Drugs and Drug Addiction. Citizens of the European Union spend about 24 billion euro on illicit drugs annually [2]. Such data show the global drug problem and should encourage the need for greater international cooperation to ensure integrated action in the area of health and criminal justice.

The United Nations Office on Drugs and Crime (UNODC), in particular the Commission on Narcotic Drugs, as the decision-making body of the UN system responsible for drug control, adopted in 2019 in Vienna Ministerial declaration on strengthening concerted actions at the national, regional and international levels to accelerate the implementation of joint commitments to address and counter the world drug problem. The declaration, among the commitments to address health problems arising from drug abuse, emphasizes the new challenges associated with the global drug problem in the world: expansion and diversification of the range and market of drugs, illegal demand for chemicals, growth of organized crime, in particular trafficking in human beings, illicit trafficking in firearms, cybercrime, in some cases terrorism, money laundering obtained from illicit drug trafficking. It is also a large set of health-related problems: drug services and health care system do **not meet the necessary requirements**; drug-related mortality rates are increasing; many countries have high rates of HIV, hepatitis C and other blood-borne infections; the harmful effects and health risks associated with the use of new psychoactive substances have reached alarming levels; synthetic opioids and the use of medicinal substances for non-medical purposes are a real threat to health and safety of the population, as well as the cause of complex tasks of scientific and regulatory content, in particular in determination of the status of substances list. And the legal supply of substances for medical and scientific use, including pain relief and palliative care, remains low or not existing in many parts of the world.

THE AIM

The purpose of this article is to conduct a thorough review and assessment of the exercise of the right to medical care

for drug addicts, in particular in custody, through the analysis of international acts and strategies in the fight against drug addiction, as well as drug policies of individual States.

MATERIALS AND METHODS

European Convention on Human Rights; Maltese Declaration of the World Medical Association; international documents of the United Nations and the World Health Organization, in particular the UN Convention on Narcotic Drugs, UNODC Regional Programme for South Eastern Europe (2020 – 2023); European penitentiary rules; data from the European Monitoring Center for Drugs and Drug Addiction and the International Drug Policy Consortium for 2018; World Drug Report 2019; the EU Drug Strategy for the period 2013 – 2020; decisions of the European Court of Human Rights.

The methodology of research and achievement of results is based on a set of general and special methods of cognition: dialectical, system-structural, comparative-legal, methods of analysis and synthesis.

REVIEW AND DISCUSSION

Drug abuse is a socially dangerous phenomenon and a particularly serious disease that negatively affects a person's relationship with the outside world. Drug abuse is considered a disease that requires appropriate treatment. For the most part, drug addicts belong to so-called "vulnerable groups" in terms of health and lifestyle. Vulnerable individuals and groups are categories of persons who for various reasons are restricted on the capacity to independently perform fundamental human and civil rights and freedoms and therefore need assistance to meet their basic physiological and social needs, as well as the rights and interests of both property and personal non-property character [4].

According to the Single Conventions on Narcotic Drugs of 1961 and **UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of** 1988, other documents in this area, the main task of the drug control system is to ensure health and well-being of mankind. Human rights and freedoms follow from the recognition of dignity and value of the individual. They are universal and integral, and a person cannot be deprived of them on the ground that he or she is using drugs or is HIV-positive. At the time, UN High Commissioner for Human Rights Navanethem Pillay noted that "drug users should not be deprived of any rights".

Instead, drug addicts are usually subject to harassment, violations of their rights, and often by law enforcement agencies. The most typical situations are: violation of the right to freedom from torture, ill-treatment and inhuman treatment in connection with **arbitrary detention** of drug users and abuse in compulsory drug treatment centers [6;7;8]; violation of the right to health due to restriction of access to essential medicines, prevention, treatment, care and support **for people living with HIV/AIDS;** violation of the right to life **in the application of death penalty** or extrajudicial execution for drug-related crimes (more than 30 countries apply death penalty for drug-related crimes) [9]; violation of the right to freedom from slavery, as some compulsory drug treatment centres use forced labor, etc. The most ill-treated are drug addicts who end up in custody – in places of temporary detention, restriction or imprisonment. Most people who are in custody **can be categorized as very poor** because they use psychotropic substances and have physical and mental disorders, i.e. need treatment. Instead, the conditions of their custody do not meet the established standards; their right to adequate medical care and health care is not respected and is a dominant factor in the relationship between prisoners and staff, which in turn leads to violence and abuse with regard to these people. It should be agreed that such persons often find themselves in conditions that further pose a threat to their rights, including in the granting of proper medical care [10].

A. Kamarunzaman and J.L. McBreyer and a number of international organizations point out that drug addicts face high levels of stigmatization and discrimination when accessing medical facilities for assistance. They are denied medical care while in detention, where they become victims of humiliation, physical and psychological violence [11]. In turn, the members of the International Drug Policy Consortium conclude that in 2018 in most countries people who use drugs become victims of institutional violence, stigmatization and discrimination [12].

Any person, regardless of his (her) specific characteristics, has equal rights and freedoms, as well as equal opportunities for their implementation in accordance with generally accepted principles and norms of international law. Any forms of discrimination on the part of State bodies, their officials, legal entities under public and private law, as well as individuals are prohibited. The standard of proper conduct is enshrined in Art. 3 of the European Convention on Human Rights, according to which: "No one shall be subjected to torture or to inhuman or degrading treatment or punishment". One of the fundamental decisions of the ECtHR states that Art. 3 of the Convention is the embodiment of the fundamental values of democratic societies that are part of the Council of Europe and is considered one of the most important fundamental provisions of the Convention, **from** which no derogation is permitted (Selmuni v. France [13]). According to the Court, the conduct was "degrading" if it was intended to provoke feelings of fear, torment and inferiority on the victims and thus to humiliate and insult them (Kudla v. Poland [14]). So the failure to provide adequate medical care to drug addicts in **temporary detention facilities, places of deprivation and** restriction **of liberty** during the withdrawal syndrome is nothing more than torture and violation of the provisions of the Convention.

The European Union has adopted a single approach in the fight against drug addiction, which is reflected in the Drug Strategy for the period 2013 – 2020. The main emphasis in this document is placed on the measures of medical and social response to this problem. Such measures should, first of all, ensure the person's right to the highest

level of physical and mental health, as well as appropriate treatment; secondly, provide equal access to such treatment [15]. In turn, the World Health Organization has adopted European health policy framework "Health – 2020" to improve health and reduce inequalities among people in need of health care. It states that social values and human rights are crucial in the area of health care, which can be achieved, first of all, by increasing the level of well-being of the population and reducing inequalities in the issue of receiving adequate medical care. These provisions should operate and apply to persons in places of temporary detention, restriction or imprisonment. [16].

The main problem now is that many countries do not ensure proper discharge of their responsibilities for health care, assistance, and creation of proper conditions for treatment of persons, including drug addicts, in correctional institutions. **The expert group advising the Regional Office on the organization of prison health** once drew attention to this problem and determined that the responsibility for ensuring the health of persons in such institutions should be assigned to State authorities; the ministries of health and their structural units should provide medical services and appropriate care; protection and human rights, including to health care, must be respected; standards of care should be based on those provided to persons, who are not under detention.

International organizations have adopted a number of regulations, rules, conventions and recommendations, practical manuals, which focus on the fight against drug abuse, health care and treatment of drug abuse and the responsibilities of penitentiary services, medical services operating in such institutions, medical facilities for the provision of appropriate medical care and rehabilitation. For example, the World Health Organization along with the United Nations Office, has developed a "Good governance for prison health in the 21st century: A policy brief on the organization of prison health", which enshrines the basic rights of detainees and convicts, as well as the responsibilities of medical services: the right to health care; provision of preventive, ethical and technical standards by medical services; such services should only provide medical care and not be involved in the enforcement of sentences; medical services should be integrated into national health systems and policies, including active participation in training, professional development, especially in the context of working with prisoners [17]. However, it should be emphasized that assigning responsibilities exclusively to healthcare professionals in penitentiary institutions in matters of health care is not quite right, as other employees of such institutions have to be able to provide first aid, and therefore must undergo appropriate training. The European Prison Rules describe the specifics of providing medical care to persons in need, including drug addicts. Thus, these rules recommend each penitentiary institution to have at least one qualified general practitioner and other medical staff who obtained an appropriate level of medical training (par. 41.4); a doctor or a qualified nurse should examine each prisoner as soon as possible (par. 42.1); every prisoner should be able to receive treatment in case of withdrawal syndrome because of the abuse of drugs, psychotropic substances or alcohol (par. 42.3.d); it is recommended to transfer prisoners in need of special treatment and prisoners with mental disorders (par. 47) to specialized institutions or civilian hospitals, if such treatment is not possible within penitentiary institutions (par. 46.1) [18].

The Maltese Declaration of the World Medical Association determines the main responsibilities of doctors and other health professionals working in penitentiary institutions, the main of which are: such entities must act in accordance with the rules of medical ethics; make efforts to prevent involuntary and inappropriate treatment; conduct an examination of the patient's mental characteristics; do a full examination [19]. That is, the activities of health professionals should be primarily focused on the fact that they work according to the principle "doctor – patient". The persons in **places of deprivation and** restriction **of liberty** should be able to exercise their right of access to health care at any time and receive appropriate treatment at the same level as individuals, who are not under detention. All health professionals in correctional facilities should understand that their primary responsibility to those in such facilities is to provide adequate and qualified medical assistance. This duty is also enshrined in the United Nations Principles of Medical Ethics, which stipulate that persons obliged to provide medical care to detainees and convicts should protect the latter against torture and other cruel, inhuman or degrading treatment or punishment. States parties are encouraged to oblige health personnel, particularly physicians, charged with the medical care of prisoners and detainees have a duty to provide them with protection of their physical and mental health [20, p.438].

Attention should be paid to the publication of the European Monitoring Center for Drugs and Drug Addiction "Health and social responses to drug problems" to address the issue of receiving proper medical care for drug addicts in correctional facilities. The paper places the emphasis on the fact that persons falling into criminal justice system demonstrate higher rates of drug use and therefore there is a necessity to meet their complex medical needs. That is, it is necessary to provide all relevant services for prevention and treatment of drug abuse. We are talking about opioid replacement therapy and detoxification [21, p.130]. The researchers on opioid substitution therapy concluded that drug addiction is a serious disease and every professional should play his (her) part in ensuring that prisoners are properly treated and the drug-related harm is minimized. However, in turn, they stress that this form of treatment is insufficient in correctional facilities [22].

The joint position of the World Health Organization and the United Nations Office on Drugs and Crime is that substitution therapy is an effective, safe and cost-effective treatment for opioid dependence [23]. The patient is regularly prescribed heavy drug substitutes under the supervision of doctors as part of substitution therapy. Typically, these drugs contain active substances such as methadone or, more often, buprenorphine. The prescription of substitution therapy and distribution of opioid agonists to opioid

addicts for the use in officially recognized medical practice, approved by the competent authorities do not contradict the provisions of Single Conventions on Narcotic Drugs of 1961 and the **Convention on Psychotropic Substances of 1971**. Substitution therapy has successfully been introduced in the United States since the 1970s; it has widely been used in Europe since the 1990s. In Germany alone, the government spends to ten billion euro a year on drug prevention and treatment. Nowadays, more than 600,000 clients are involved in substitution therapy programs worldwide. The largest number of them are in the United States (about 200 000), and in the European countries (up to 400 000). Substitution therapy is used in Lithuania, Latvia, Estonia and Kyrgyzstan, Kazakhstan, Georgia, and Belarus. Supportive care is also successfully carried out in Asian countries: Iran, China, and Thailand. By the way, Iran, an Islamic country, in which even the use of narcotic drugs is subject to the death penalty, has demonstrated full support for such programs [24].

However, the 2019 World Drug Report states that 46 countries have claimed that there is no such treatment option in their penitentiaries. Effective treatment in accordance with international human rights obligations is not sufficiently available [1]. For example, methadone is included in the list of drugs banned from circulation in Russia. This substance is also banned in the Republic of Crimea after the occupation of the peninsula. A year after the ban on the use of methadone in Crimea, UN special envoy for HIV / AIDS in Eastern Europe and Central Asia Michel Kazachkin noted that dozens of patients, who had previously been in substitution therapy, died. Over 100 of 805 patients died. Most of them returned to drug use and were prosecuted. Those, who illegally kept methadone at home in attempt to escape punishment, were imprisoned. Besides, 200 patients of the 805 were HIV-positive [25]. In 2019, the European Court of Human Rights refused to satisfy the complaint of Russians I. Abdyusheva, I. Anoshkin and O. Kurmanaievskyi, which they filed against the Russian Federation on the ground that Russian hospitals, where they were treated for drug addiction, refused to prescribe methadone and buprenorphine, which are used as substitution therapy in some States (Abdyusheva and Others v. Russia). In taking the decision, the Court was guided by the argument that the use of methadone and buprenorphine was not a treatment for drug abuse but **the replacement of one addiction with another one, as the effects of these drugs is incompatible with those of heroin. Although substitution therapy is widely used in some countries** falling within the scope **of** the ECtHR, its effectiveness is considered controversial [26]. Thus, today there is no single approach to the use of substitution therapy in the treatment of drug addicts despite scientifically proven facts and tested positive results of its application. Sometimes it leads to gross human rights violations and irreversible consequences.

It should be noted that most places of detention and imprisonment cannot provide adequate medical care and treatment. Besides, this form of therapy in the above places is simply not available. As for detoxification, it can be in the form of both individual and group consultation. Detoxification should be provided with appropriate control over this procedure. If the **patient is undergoing** a severe **crisis**, symptomatic treatment of withdrawal syndrome can be included, including for monitoring the relevant symptoms [21, p. 133].

Health and Social Response to Drug Addiction emphasizes that there is often partnership between health services operating in **places of deprivation and restriction of liberty** and drug care organizations that allow provide continuous treatment in most European countries [21, p. 130].

Besides, the experts found various alternatives to punishment that can be used at different stages of criminal proceedings in the abovementioned publication of the European Monitoring Center for Drug Abuse – from arrest to sentencing for drug addicts, namely: prevention and inaction; distraction; creation and active work of committees to combat drug abuse; suspension of investigation or prosecution with elements of treatment; **a stay of execution of the sentence** with the elements of treatment; creation of a separate judicial body to hear cases related only to drugs; drug treatment; conditions for convicts with the elements of treatment; restriction of liberty with the elements of treatment; alternating imprisonment and release with the elements of treatment; conditional release with the elements of treatment [21, pp.131 – 132]. The above alternatives are relevant in determining the treatment of drug addicts in correctional facilities, but in our opinion it is unlikely that penitentiary services, courts and health care facilities will take responsibility for the use of such alternatives. But in the future the relations regarding the provision of appropriate medical care to persons who use drugs, psychotropic substances and their precursors, and, where necessary, the replacement of detention and deprivation of liberty with the possibility of receiving medical care and treatment in special medical institutions, should be established between ministries of health, their units and penitentiaries of all countries. Unfortunately, nowadays, people in penitentiary institutions do not exercise their right to health care at the appropriate level, because there is an insufficient level of medical care in most countries of the world, especially in relation to drug addicts, although proper health care plays an important role in **alleviating** suffering of such persons.

Thus, international organizations, non-governmental organizations and movements, which try to overcome the problem of drug abuse, are actively working on providing relevant assistance to combat drug addiction. However, the key role in resolving this issue belongs to the State, which can officially determine the direction of drug policy. The State should not violate, but protect human rights, including the rights of drug addicts. The commentary to the 1961 UN Convention on Narcotic Drugs notes that it is up to each State to determine the extent, to which it wishes to impose penalties for non-medical drug use or to give preference to drug prevention only through administrative and legal measures against cultivation, production and dis-

tribution of drugs [27]. The analysis of foreign legislation and measures to combat drug trafficking in the European Union and the United States shows a gradual transition of these countries from the policy of "war on drugs" while disseminating the following concepts of harm reduction from non-medical drug use: introduction of substitution maintenance therapy; decriminalization of certain types of acts for minor misdemeanors; replacement of imprisonment for drug addicts by more **lenient punishments**, etc. [28, p. 7].

The main tasks of the drug policy of modern States should be health care, which includes expanding access to medicine, development of harm reduction programs and programs of prevention, treatment, care and support; providing support in the area of alternative development, as well as poverty reduction, education opportunities, employment issues, social security, etc.; human security, as the efforts of law enforcement agencies should be aimed primarily at identifying those who cause the most serious problems related to drugs, and not only those who are small-time dealers [28, p. 8].

The United Nations Office on Drugs and Crime (UNODC) is proposing to build on its current strategic multi-sectoral approach in South Eastern Europe in the four-year period 2020 – 2023. This document outlines the principles, on which the Regional Programme for South Eastern Europe rests and the planned activities during the 2020 – 2023 programming cycle. The current document also analyzes the linkages between the UNODC work and the Sustainable Development Goals and the 2030 Agenda for Sustainable Development, to which all United Nations bodies and agencies aim to contribute, as well as sets these important parameters against the background of the current situation in the region in areas relevant to UNODC's mandate ad-dressing the interconnected challenges to security, rule of law and health). South Eastern Europe lies on the most direct route between some of the world's leading producer and consumer regions of opiates, and likewise serves as a transit corridor for migrants and refugees from Asia and the Middle East to Western Europe; it saw one of the world's largest population movements in 2015 – 2016, as well as an influx of foreign terrorist fighters. These features highlight the challenges faced by the governments of the region in controlling their borders and fighting the smuggling of migrants as well as that of drugs, weapons, and other illicit goods [29, p.8].

Among the important steps envisaged by this plan are: enable relevant national counterparts and line Ministries to develop and implement evidence-based interventions and policies in family settings as well as in school and community settings (including workplace; support evaluation of the effectiveness of interventions and policies, including related data collection, research and reporting, by relevant counterparts and mainstream it in strategic documents. Besides, to promote, develop and utilize evidence-based treatment modalities and interventions to en-hance national capacities and assure greater quality of services; support national professionals and policy-makers in developing strategic documents and technical tools and in conducting relevant assessments of treatment of drug use disorders, including monitoring and evaluation, to adequately track trends and identify corrective measures; support evaluation of the effectiveness of intervention sand policies, including related data collection, research and reporting, by relevant counterparts and mainstream in strategic documents [29, p. 82].

According to the new agenda for sustainable development for the period of 2016 – 2030 – Sustainable Development Goals, humanity has committed itself to ending epidemics of AIDS, tuberculosis, malaria and tropical diseases that are not given due attention, and to ensure the fight against hepatitis, water-borne diseases and other infectious diseases (par. 3.3), as well as to improve the prevention and treatment of substance abuse, including drug and alcohol abuse (par. 3.5). Such commitments must be a priority in the policies of modern nations to end the world's drug pandemic, and thus to improve health, safety and quality of life of the population.

CONCLUSIONS

Based on the above-stated, we can conclude that guaranteeing and ensuring human rights without any discrimination should be a priority in the politics of modern States. The drug policy of States to support drug addicts is the basis for finding the solution to the problem of drug abuse. The implementation of prevention and rehabilitation programs based on scientific evidence is also important. Besides, the current situation, in which persons who use drugs experience significant restrictions of their rights and freedoms, is unacceptable.

Drug addicts who are in places of detention have a guaranteed right to an adequate level of medical care and treatment without any discrimination; quality medical assistance regardless of the detention regime; receiving medicine, rehabilitation, prevention; due attention and professional doctors' attitude in accordance with international legal standards. All health professionals must be independent in providing care and making professional decisions in relation to prisoners. After all, all persons in need of care, regardless of their location, mental and health state of, are first and foremost patients who have the right to proper medical assistance.

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REVIEW ARTICLE

ALCOHOLISM AS A PROFESSIONAL DISEASE OF THE REPRESENTATIVES OF JUSTICE

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ABSTRACT

The aim: The purpose of the research is to summarize the leading experience of European countries on the protection and prevention of the alcoholism problem among judges, attorneys and prosecutors as representatives of justice.

Materials and methods: The subject under discussion has been considered based on sources on this issue (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: Analysis of existing statistics as well as decisions of the disciplinary bodies of justice indicates the predisposition of justice representatives to alcohol dependency, which is caused by a number of reasons. Based on medical research, it is substantiated that stress is the determining factor in prompting a justice officer to use alcohol as a means capable of exerting an antidepressant effect. But in addition to quickly de-stress, alcohol is attractive for its availability. We refer such availability as: financial, social and psychological, corporate, territorial, legislative one. It is argued that among the representatives of justice alcoholism has a harmful effect not only on their health. It has a negative impact on professional discipline and is fraught with de-ethicalization of representatives' of justice behavior. The alcohol dependence of justice officials can cause doubts on their competence, hold them accountable and undermine public confidence in the credibility of justice.

KEY WORDS: alcoholism, litigation stress, justice, alcohol addiction

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INTRODUCTION

According to the World Health Organization, alcohol consumption and its level is one of the most important public health problems worldwide. The latest data indicates that alcohol abuse is the reason for 1 in 20 deaths [1], and is one of the most common mental disorders, with a prevalence of 8 to 14 percent [2], not to mention other negative effects on human health and behavior, as well as the productivity and effectiveness of various spheres of activity.

Alcoholism has no social, gender or financial barriers, covering different segments of population. Nevertheless, large-scale studies show that the level of alcohol consumption directly depends on the profession and industry of employment [3]. Activities related to the administration of justice are one of the indicative ones in this sense. There is some evidence that people involved in this work environment experience alcohol problems that are dangerous, harmful, or otherwise correlate with alcohol consumption disorders at a higher rate than other professional groups. As it turned out, 21% of attorneys have problems with alcohol, 28% of them suffer from depression of some degree, and 19% have signs of anxiety disorder [4]. Research from Australia has shown that 30.6% of court officials and 32% of attorneys are at risk for problem of alcohol drinking [5].

Alcohol abuse, whether in or outside the workplace, has a negative impact on work, leading to consequences such as health problems, long-term disability, decreased productivity and presentability, team conflicts and an unstable work environment, accidents at workplace, reputational damage [6]. It has significant economic and social impact in justice sphere. The inability to fulfill professional duties causes a redistribution of colleagues' workload, which reduces the productivity of their work, and as a result - ineffective time and human resources usage. The public interest is the ability of a judge, an attorney, a prosecutor to adequately assess the circumstances of the case entrusted to one and to make objective decisions, as well as the adequate behavior of these persons in a trial and outside it. The public opinion on the latter directly affects the credibility of justice among the population [7].

Alcohol is the cause in many cases of disciplinary proceedings initiated for violation of legal and ethical norms by representatives of justice system, damage to the client and harm to profession's credibility.

Due to the potentially serious medical, social, and economic consequences of alcoholism in the sphere of justice, its assessment needs to be detailed.

THE AIM

Our study is aimed at providing readers with an overview of the reasons that are highly likely to contribute to the development of alcoholism of justice's representatives,

as well as to demonstrate the consequences of its impact on the profession. We will also offer a system of methods aimed at preventing and combating alcoholism in this professional environment.

MATERIALS AND METHODS

We use statistics of the World Health Organization, the Legal Profession Assistance Conference, as well as information and decisions by professional bodies in the justice sphere in the United States and Ukraine (ABA, the Highest Council of Justice). We also use data from medical and other researches, analytical materials and scientific publications by the USA, Canada and Australia with open access, reflecting the results of studying the problems of litigation stress and, as a result, alcoholization of judges, attorneys, and prosecutors. The article is based on the dialectical method, which made it possible to study the essence of litigation stress and alcohol dependence, the risks of which it develops. Statistical, structural-logical and analytical methods were used to study the causal connections between the work conditions of justice officials, litigation stress and alcohol.

REVIEW AND DISCUSSION

Causes and risks of alcoholism development in justice. There are several theories regarding the reasons for the development of representatives' of justice alcohol addiction.

According to one version, alcohol is part of the corporate culture of lawyers. Maintaining formal and informal corporate ties is accompanied by events where alcohol is always present, giving an atmosphere of complacency and relaxation.

Alternatively, it is also assumed that alcohol problems accompany lawyers from their student days. After entering law school (having high level of life satisfaction and stable mental health at that time), law students experience significant increases in anxiety and depression during their first year of student's life. According to ABA, law students are ones of the most demoralized and depressed among all students, a quarter of them fall into the category of risk of developing alcoholism [8]. There are many reasons for it: heavy load, high competition level, lack of social connection feeling, the initially pessimistic and adversarial nature of law, the Socratic methods of teaching it, external motivation to study it, in which the emphasis is on future dividends associated with the profession, and which depend on academic performance and rating [9;10]. Trying to cope with stressful situations on their own, law students resort to alcohol, transferring this practice to their future professional activities.

Nevertheless, most studies associate high rates of alcohol addiction among representatives of justice with the stress they experience due to the specifics of the professional environment (litigation stress).

Features of the profession and professional stress. The medical literature considers litigation stress as a process and result of exposure by a set of stressors, the nature of which is diverse. They can be of objective and subjective origin, depending on physical or psychosocial factors. Their influence can negatively affect human health and lead to serious psychological and behavioral problems. Although in many respects the appearance and level of stress depends on a person's internal attitudes and his/her reaction to stressors, in the justice system a huge role is played not only by work conditions, but by the specifics of the professional environment – the litigation itself. It acts as an objective condition, the readiness for the perception of which must be established at the stage of preparation for the profession.

The adversarial nature of the trial, in which a judge, an attorney and a prosecutor are involved by the nature of their activities, is based on a conflict, which emotionally responds with a feeling of irritation, anger, fear, and being worried. The conflict potential of judicial sphere is complemented by the need to constantly search for atypical solutions in a limited time. It entails constant mental stress. In addition, each of the representatives of justice is responsible for the decision he/she makes, for the chosen defense tactics or line of prosecution, often at the risk of feeling dissatisfaction, resentment, grief or accusations against one from the disgruntled participants of the trial.

They must control their feelings of empath, hatred, irritation, anger and be restrained in their reflection. Constant emotional control is fraught with stress. Scientists have proven that, for example, controlled empathy is the most dangerous and stressful type of it. It itself includes neurological activity. When a person engages in automatic empathy, tension is easily released. Both brains' hemispheres work to achieve homeostasis. This process is interrupted while controlled empathy [11].

In addition, the litigation is aimed at solving the problems of people whose life stories can be traumatic. This is especially true for criminal, family, juvenile cases. Constant involvement in the traumatic events of someone else's life is fraught with vicarious trauma for the representatives of justice (the terms “compassion fatigue”, “burnout”, secondary trauma could also be used) [12]. Professionals who consistently work with traumatized people and traumatic situations, experience the same trauma symptoms, including worrying, avoidance, numbness, and constant excitement. They can also experience extreme vigilance, hopelessness, anger and cynicism, insomnia, fear, guilt, chronic exhaustion and physical ailments [13]. The majority of judges and lawyers ascertained the presence of these feelings in various combinations [14;15].

Social factors. All representatives of justice are bound by the requirements of ethical codes, which establish behavioral rules not only at work, but also outside it. The high social status of their profession entails increased public attention to their personality, demeanor and lifestyle. It causes social distance and puts a lot of pressure making them to maintain an ideal image.

In countries with a low level of trust to judiciary system, such as Ukraine, the lack of social support is a powerful stressor for representatives of justice. It also affects their social isolation and generates a decrease in self-esteem, negatively affects confidence and work efficiency [16].

It is still the totality of the features of the trial and the professional roles of its key players (which require a high level of responsibility and emotional self-control, self-restraint and tension) is the factor which initially create favorable conditions for the onset and development of stress and depression. The natural desire to relax leads a person to find effective remedies. One of them is alcohol, which blocks inhibitory brain cells, making the consumer feel relaxed and relieving anxiety [17].

Why it is still alcohol (more than drugs or, for example, physical activity, which can also positively influence stress) is becoming the choice of the representatives of justice? There are several reasons for this.

Alcohol as a stress reliever and its availability. Among the possible means of relieving stress and feelings of anxiety, alcohol compares favorably with its varied "availability."

Several studies have shown that alcohol in small doses can improve the performance of complex cognitive tasks aimed at solving problems in a stressful situation [18]. Although the interconnection between alcohol and stress is determined by many factors (genetic, individual, situational, gender, age ones), recent experiments have shown that alcohol has a similar effect to mild antidepressants. It was found that a single intake of alcohol affects in the way of the same biochemical mechanism as the "rapid antidepressants" from the group of NMDA glutamate receptor antagonists. Alcohol promotes long-term neuroadaptive changes that can alleviate the symptoms of depression, often mentioned in the self-medication hypothesis. Acute ethanol exposure produced long-term antidepressant and anxiolytic behavior [19].

During the period of the stressor's action, endogenous opioid peptides (endorphins) are produced in the brain, which help to minimize adverse psychoemotional effects. However, in the subsequent period, there is a deficiency of endorphins due to their excessive release during the action of the stressor, i.e. the syndrome of "recoil" develops. Endorphin deficiency is accompanied by anxiety and depression symptoms. According to the endorphin compensation hypothesis, people consume alcohol after experiencing a traumatic experience in order to increase the level of endorphins in the brain and their mood in that way. As maintaining high levels of endorphins requires more and more alcohol, a vicious circle gradually forms, which could lead to the development of being alcohol addicted. The endorphin compensation hypothesis explains why, in most cases, alcohol is consumed sometime after a stressor's impact, and not during it itself [20].

Thus, alcohol creates the illusion of a quick stress relief, which is in line with the expectation of quick stress relief. Although in the medical literature there is enough information on the existence of feedback, when alcohol abuse causes stress, depression, addiction, forming a vicious circle. However, alcohol is attractive because, unlike antidepressants, it does not require a doctor's appointment, diagnosis or prescription. Alcohol, unlike drugs or medicines, is available for sale with certain age restrictions. A person does not need to go far or contact specialized institutions or certain people in order to buy it. Among the possible psychoactive substances, it is financially affordable, diverse and could also satisfy a person's taste preferences. The state, regulating the alcohol market does not ban its sale and consumption. The fact of drinking alcohol doesn't violate any legal norms.

The culture of drinking alcohol is woven into the system of social relations. It is not condemned, unlike drug addiction. Alcohol abuse in society is characterized by a condescending attitude. Moreover, in some countries, such as Russia, the alcoholization of society is connected with historically strong traditions and lifestyle. The existence of a large number of customs that serve as a reason for drinking alcohol, which are not easy to eradicate, since traditions are an element of social reality, leads to population's loyalty to alcohol. That is, alcohol is psychologically and socially available. This factor is reinforced by the corporate culture of alcohol consumption among lawyers, which we have already mentioned.

Another argument in favor of alcohol, which in most cases is preferred by representatives of justice, is the difficulty of diagnosing alcoholism. Even in a medical conditions, the screening rate for alcohol consumption remains below 50 percent [2]. Among the representatives of justice, it is aggravated by the fact that it is not customary to talk about the problem of alcohol addiction. It is primarily connected with reputational risks for professional activity. Representatives of aid programs to lawyers note that the reluctance to admit their alcohol addiction is associated not only with perfectionism, but also with the fear of damaging their reputation, losing the trust of colleagues and clients, and losing their license and work [21]. And these fears are absolutely justified.

Impact on work and possible consequences. Alcoholism, as well as other addictions to psychoactive substances, cause doubt on their compatibility with the professional status of the representatives of justice. And it's not only about its clinical reflections (disorders of thinking, hypochondria, persecution mania, low self-esteem, anxiety, depression, impulsiveness, alcoholic degradation of personality) [22], which negatively affect the productivity and efficiency of any activity. Any addiction distorts the normal flexibility of a person's behavior towards dehumanized compulsive behavior and decontrolling [23]. Addiction weakens the neural mechanisms responsible for making reasonable decisions, and a person moves from independent behavior to automatic sensory-controlled behavior [24]. A person loses the ability to perceive reality adequately, self-regulation of his behavior, there is a tendency to an asocial way of life. Ethical norms are losing their regulatory effect. And it is unacceptable for the professional environment in the administration of justice.

Alcohol addiction, affecting the emotional, mental, and physical state of the representatives of justice, could rise a question on their competence. It is directly mentioned in corporate ethics acts that regulate professional activity of lawyers. The commentary on the Bangalore Principles of Judicial Conduct states that "the competence of a judge can

narrow, or cause doubts by the effects of drugs or alcohol use ..." [25].

Practice shows that attorneys suffering from addiction are most often prosecuted for wasting and embezzlement of client funds. According to ABA, in 2013, 936 attorneys were convicted of substantiated claims [26]. The link between alcoholism and professional negligence and misconduct is confirmed by a report prepared by the Legal Profession Assistance Conference [27]. Studies in Canada and in the United States estimate that approximately 60% of discipline prosecutions involve alcoholism. Similarly, something over 60% of all malpractice claims involve alcohol abuse. More significantly, a recent study has suggested that 90% of serious disciplinary matters involve alcohol abuse. It is confirmed by the results of previous studies, according to which "50 to 70 percent of disciplinary cases are related to alcoholism." Its authors concluded that the true rates are significantly higher, given the mystery that shrouds such abuse [28].

Moreover, in US disciplinary practice alcoholism is a factor that determines one of three approaches to bring judges to liability: the punitive approach, the rehabilitative approach, or the mitigating factor approach [29].

It should be admitted that there are no such studies in Ukraine. However, disciplinary practice in this direction is extensive, although not generalized. An illustrative example of the connection between alcohol abuse and violation of ethical professional standards and responsibility is the case of a judge of the Supreme Court. This case is very interesting for its circumstances.

In March 2019, a judge, who at that time had not yet entered office, was detained and brought to administrative responsibility for driving while intoxicated. While hearing the administrative case in court, he only denied the fact of driving a car. These words were refuted by various evidence, including the testimony of several witnesses. Thus, he lied, which was established by the courts of various instances, in order to avoid responsibility. He had already fully acquired the status of a judge at the time of the trial. It was still the lie, that the Supreme Court judge resorted to, that triggered the disciplinary proceedings. As a result, the judge's dismissal was initiated. At the same time, the disciplinary body emphasized that the status of a judge imposes on a person an additional burden of responsibility for behavior, including behavior in the past. "Maintaining high standards of behavior requires a judge to avoid creating the impression of inappropriate behavior both in office and in private life. A judge must be aware that he/she represents the judicial power of the state and must not allow behavior on his/her part that could harm the authority of justice." Without assessing the judge's behavior before his appointment as a Supreme Court judge, the disciplinary body concluded that "the provision by a judge of the Supreme Court of false information in court that did not correspond to the factual circumstances of the case in order to avoid responsibility for his actions indicates a violation of high standards of ethical behavior of a judge and cannot be justified by a person's right to defense. ... being a judge of the Supreme Court, which is the highest court of the court system, he couldn't not to realize that his behavior significantly undermines the authority of justice and public confidence in court, as it affects the main elements of the judge's ability to perform the work entrusted to him as a judge on administration of justice... "[30].

This example shows that the primary reason for the de-ethicalization of the judge's behavior was his alcohol abuse. We can draw two conclusions from it. Firstly, the ethics of justice officials can be retroactive. Secondly, alcohol can have a prospective effect on the discipline and responsibility of these persons.

It is still the social side that makes the alcoholization of justice representatives to be dangerous at the state level, in contrast to other professions, where it is only about human health. Therefore, it is very important to develop and to implement a set of measures aimed at preventing and combating alcoholism in the administration of justice sphere.

Methods of combating alcoholism in the justice sphere. Considering the specifics of the status and professional sphere of justice, which we mentioned, its representatives need support that can prevent alcoholization and minimize its negative consequences for both the individual and society. The methods should be of a comprehensive nature (psychological, organizational, rehabilitation, social security) and be implemented at different levels.

State approach. First, the state, which exercises its power through the means of justice, should be interested in ensuring that the health of representatives of justice sphere couldn't be undermined by alcohol addiction. To do this, it should, in its own way - through legislative regulation, provide for measures that are able, first, to reduce the influence of stressors, as a result of which stress arises, which induces alcohol drinking. For example, there should be a regulated workload on judges, which can be ensured not only by mathematical calculations, but also by appropriate organizational measures: timely filling of vacancies, introduction of clear procedural rules, and ensuring appropriate work conditions. For the purpose of timely diagnosis of the disease, it is advisable at the legislative level to provide for the obligation of representatives of justice to undergo a medical examination by a narcologist annually [7]. In matters of discipline and responsibility, priority should be given to the rehabilitation approach [29]. It is based on the possibility of providing a lawyer with a probationary period with the obligatory condition of treatment and a sober lifestyle. It is most beneficial both for the professional facing the problem of alcohol, and for the society, which will continue to benefit from his/her experience and knowledge, and for the state, which will incur less rehabilitation costs than training a new lawyer. As a measure of social protection of justice officials who have suffered from alcohol addiction, it is permissible to provide for the possibility of dismissal from office due to illness, and not within the framework of disciplinary action.

An important component of state policy should be the initiatives aimed at increasing the credibility level of representatives of justice in society, creating a high level of

trust in them, which will contribute to the social support of these persons.

Corporate approach. Professional sphere offers just as many opportunities. Corporate level is more flexible, since the system of possible means of alcohol prevention and rehabilitation depends directly on the bodies of professional community.

It is imperative that each of the corporate communities (judges, attorneys, prosecutors) develop, implement and popularize assistance programs aimed at combating litigation stress and alcohol addiction. They should provide for psychological support, access to counseling and assistance. Such programs should be documented. They need to clearly outline the corporate policy on alcohol and other substance abuse, a statement of support for the mental and physical health of members of the professional community, resources and methods of such support. For example, a "hot line" can help to talk about the problem faced by a representative of justice, to get a consultation by a psychologist or an addiction specialist by phone. Particular attention should be paid to privacy issues. Its full provision is necessary in order to induce alcohol-addicted justice officials to ask for help. Part of such assistance programs should be cooperation with medical centers aiding in alcoholism treatment.

Special attention should be paid to educational activities among lawyers. Explanatory work should be carried out from the student's bench and strengthened during special training. To this end, the centers responsible for training judges, lawyers, prosecutors should include in their professional training programs such training, which is aimed at developing stress resistance, training in stress management skills and avoiding vicarious trauma. They should also ensure cooperation with specialists in this direction.

A local approach provides for a focus on the personality and workplace of justice representatives. It includes paying the attention by a lawyer to himself and by his/her colleagues. Taking care of one's own health should be among the first human needs. Realizing a problem, finding resources to solve it, seeking help are a sign of strength, not weakness. In the workplace, it is possible to create conditions for shifting attention from alcohol to sports, which helps to overcome stress, having a positive effect on the emotional and physical condition of the individual. In court buildings, law firms and prosecutors' offices, it is advisable to provide areas for relaxation and active physical exercise. If possible, psychologist's offices should also operate for free psychological support and assistance. Special attention should be paid to the organization of working hours and the daily routine in which there should be a place for having a rest.

Of course, the mentioned measures are not exhaustive. After all, the mechanisms of combating alcoholism, including in the justice system, are very diverse. We can continue to talk about, for example, additional vacations, the institution of supervision or relaxation practices. But even the measures we have mentioned in this article are enough to assess the current situation in the field of counteracting alcoholism in such an important sphere for society. For example, in Ukraine, there is no comprehensive research of this problem, no legislative or corporate initiatives aimed at supporting and helping justice officers in counteracting the challenges of the profession.

CONCLUSIONS

Justice officials are one of the professional communities most vulnerable to stress, depression and alcohol addiction. Among the reasons contributing to alcoholism there are the corporate culture of lawyers, traditions formed during their education, litigation stress. It is still precisely in the desire to quickly relieve stress that representatives of justice resort to alcohol, which could have an antidepressant effect. Therefore, alcohol addiction appears as a result of self-treatment, which they resort to, considering the variety of alcohol availability: financial, socio-psychological, corporate, territorial, legislative. The causes of litigation stress are manifold and of subjective and objective nature. The latter includes the professional environment. The stressful nature of a conflict-based litigation creates conditions for the development of stress, vicarious trauma among the representatives of justice, which increases the risks of their alcohol addiction. Statistics and literature sources show a causal relationship of professional environment of justice → stress → alcohol. This makes it possible to further study alcoholism as an occupational disease of justice officers.

Alcohol dependence of representatives of justice is not only the result of the negative work conditions in the justice environment impact, but also has an effect, including a prospective one, on the discipline and responsibility of its representatives. Alcoholization of the justice sphere is dangerous not only for the health of its representatives. It is also fraught with de-ethicalization of the lawyer's behavior, causing doubts on one's competence, as well as undermining the credibility of justice in society and devaluation of moral principles. Overcoming the problem of alcoholization of representatives of justice requires an integrated approach and the adoption of measures of a psychological, organizational, rehabilitation, social security nature at different levels: state, corporate and local.

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REVIEW ARTICLE

LEGAL REGULATION ISSUES OF OBTAINING ORGANS AND TISSUES FOR TRANSPLANTATION

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ABSTRACT

The aim: To analyze the views of scientists and practitioners on the legal regulation of organ and tissue transplantation, as well as analyze the factors that affect the activity of clinical transplantation.

Materials and methods: The materials for this study were scientific publications and statistics. Methods of analysis, synthesis, observation and generalization were used in the process of this research.

Conclusions: Legal professionals generally adhere to the principle of the priority of human rights over expediency, while health professionals allow the removal of the transplant from the body of the deceased without her lifetime consent. The activity of clinical transplantation is influenced by the following factors.by many different factors: detailed legal regulations; availability of a well-organized system of transplantology, specially trained teams; the existence of a presumption of consent to the removal of organs and tissues after death; the attitude of society to transplantology.

KEY WORDS: Transplantation, deceased donation, living donation, presumed consent

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INTRODUCTION

Although most countries in the world are continually trying to increase the number of transplant operations, only a few are able to achieve the desired results. The growing list of patients waiting for the necessary transplant and the constant lack of donor organs prompt politicians, scientists, and practitioners to seek new approaches to address this issue.

THE AIM

To analyze the views of scientists and practitioners on the legal regulation of organ and tissue transplantation, as well as analyze the factors that affect the activity of clinical transplantation.

MATERIALS AND METHODS

The materials for this study were scientific publications and statistics. Methods of analysis, synthesis, observation and generalization were used in the process of this research.

REVIEW AND DISCUSSION

The active development of science has stimulated the emergence of new activities that pose a challenging task for society. One of such new directions of medical activity is transplantology. "With its development (V.P. Salnikov, S.G. Stetsenko. Transplantation of human organs and tissues: problems of legal regulation. 2000) clinical transplantology raised a few moral, ethical and legal issues. The resolution of the first two is connected with the purposeful activity of representatives of various spheres of social life. Lawyers' task is to develop effective, based on the real needs of practical transplantology, mechanisms for the legal regulation of organ and tissue transplantation. World experience shows that in countries where the legal regulation of transplantation is of great importance, the success of transplants is more obvious "[1].

The existence of transplantation at the current stage, when therapeutic cloning and artificial cultivation of necessary organs and tissues are still underdeveloped, is possible only based on the necessary donor material obtained from living or dead persons. Today, this is the core of all transplantology, and the development of transplantology in a country largely depends on proper legal regulation of the procedure for obtaining donor material.

Transplantation using living donors, usually, is quite clearly regulated in the legislation of the countries and has no fundamental issues. A surgical intervention aimed at removing the graft for subsequent transplantation is, of course, possible if the following conditions are met: genetic affinity with the recipient or the existence of close social ties; voluntary informed, competent consent of the donor; the age of the donor; the absence of disease transmitted by transplantation of donor material.

From a legal perspective, the issue that needs to be most carefully regulated in transplantation using living donors is the issue of obtaining their informed consent to remove the necessary transplants. Of course, the principle of priority of the interests of a living donor applies here. The donor's consent is based, first, on the receipt of complete, objective and comprehensive information about future intervention and its possible complications, the degree of risk. Moreover, the information should be provided in an accessible and understandable manner, considering the fact that a potential donor may not have sufficient knowledge in the field of medicine.

Another necessary component of a living donor's consent is its voluntariness, i.e. decision-making in the absence of psychological, physical influence, and any other external factors that would indicate the involuntary nature of such consent. The word "voluntary" (H.Ya. Lopatenkov. Patient's rights. 2005) emphasizes that this decision cannot be the result of external coercion or the result of the active persuasion of anyone (even a doctor) in need for a specific course of action. It should not be the result of the active influence of another person's will but should only result from personal choice based on complete information on the issue [2].

According to the Global Observatory on Donation and Transplantation (GODT), which works with the WHO, most transplants are made from organs and tissues obtained from the dead persons. For example, in 2018, of the 95,479 kidney transplants performed worldwide, only 36.2% were from living donors; of 34074 liver transplants - 19.2% were from living donors [3]. Besides, most organs can only be obtained from a deceased person. Therefore, the most pressing issue is the legal regulation of transplantation using donor material from a deceased person.

Among the critical aspects of post-mortem donation is obtaining a person's lifetime consent to a graft removal after death. The most serious (Grishchenko V. Ethical issues of cell and tissue transplantation. 2002) of its aspect is associated with the receipt of organs and tissues for transplantation, which requires compliance with all principles of medical ethics and legal regulation [4]. It is essential to determine the role of the deceased's will regarding the possibility of removing organs and tissues that he/she expressed during life. And here the countries do not have a common opinion. There are three modern systems of posthumous organ donation:

1. Presumption of consent.

That means that organ donation is automatically considered possible for patients diagnosed with brain death unless they have specifically registered their lifelong refusal to sacrifice themselves for transplantation. However, in some countries, despite legal permission, doctors still ask permission from relatives.

2. Informed consent.

It is a voluntary system of organ donation, according to which relatives give permission at the time of a potential donor's death, usually knowing that the potential donor has expressed a desire to become a donor.

3. Required request.

In the United States, physicians responsible for potential donors should ensure that someone communicate with their family about organ donation.

In the scientific literature, the presumed consent, i.e. the presumption of consent to the removal of organs or tissues from a corpse for transplantation, is defined (S.H. Stetsenko, O.H. Pelagesha Medical Law of Ukraine (legal principles of transplantation of human organs and tissues). 2014) as a legal order, according to which representatives of a medical institution are allowed to remove organs or tissues from a deceased person for further transplantation if during their lifetime the person or his relatives after death did not declare in a certain way their consent to the removal of organs or tissues. In other words, if during the life of the person or after his death, relatives have not stated that they are disagree - then their consent is presumed (presumption of the consent) to remove the grafts for further transplantation [6].

While informed consent, i.e. the presumption of disagreement with the removal of organs or tissues from a corpse for transplantation, is a legal order (S.H. Stetsenko, O.H. Pelagesha Medical law of Ukraine (legal principles of transplantation of human organs and tissues). 2014), according to which representatives of a medical institution are prohibited from removing organs or tissues from a deceased person for further transplantation if there is no evidence of written consent to become a donor of anatomical materials for transplantation or no evidence of such consent from relatives of the deceased. In other words, in order to be able to remove organs or tissues, medical staff must have the written consent of the deceased, which she gave during life, or the consent of the relatives of the deceased [6].

There is also no consensus among scientists and experts dealing with transplantation regarding the need to introduce a particular system of posthumous donation. In the legal literature (I.A. Ivannikov. Medical law. 2008), there is no consensus on the legal validity of the presumption of consent. Its supporters refer to the priority of a living person's interests over the deceased, and opponents of the presumption point to its inconsistency with the advantages of choice, expression of will [7].

For example, D.Yu. Karkavina (D.Yu. Karkavina. The patient's table book, or How to protect your rights when seeking medical care. 2007) considers the presumption of consent as a means that is fully justified in order to save human life, the treatment of which is already found in medicine (unlike man - a potential source of donor organs, which cannot be cured at the current level of medical development) [8]. According to A.A. Zhalinskaiia (A.A. Zhalinskaiia Discussions on the legislation on transplantation in Germany. 1998.), one who wants to protect their right to inviolability after a death must act by active expression of will [9].

Opponents of the presumption of consent believe that this is a violation of a number of human rights, the lack of due respect for the individual's rights after death. N.V. Putilo (N.V. Putilo. Commentary on the Fundamentals of the legislation of the Russian Federation on public health. 2003.) indicates that the presumption of disagreement would more logically and consistently protect the interests of relatives of the deceased, the inviolability of the body of the deceased [10]. H.N. Krasnovskii (Krasnovskii H.N. Bioethical and criminal problems in the Law of the Russian Federation "On transplantation of organs and (or) human tissues." 1993) indicates that, above

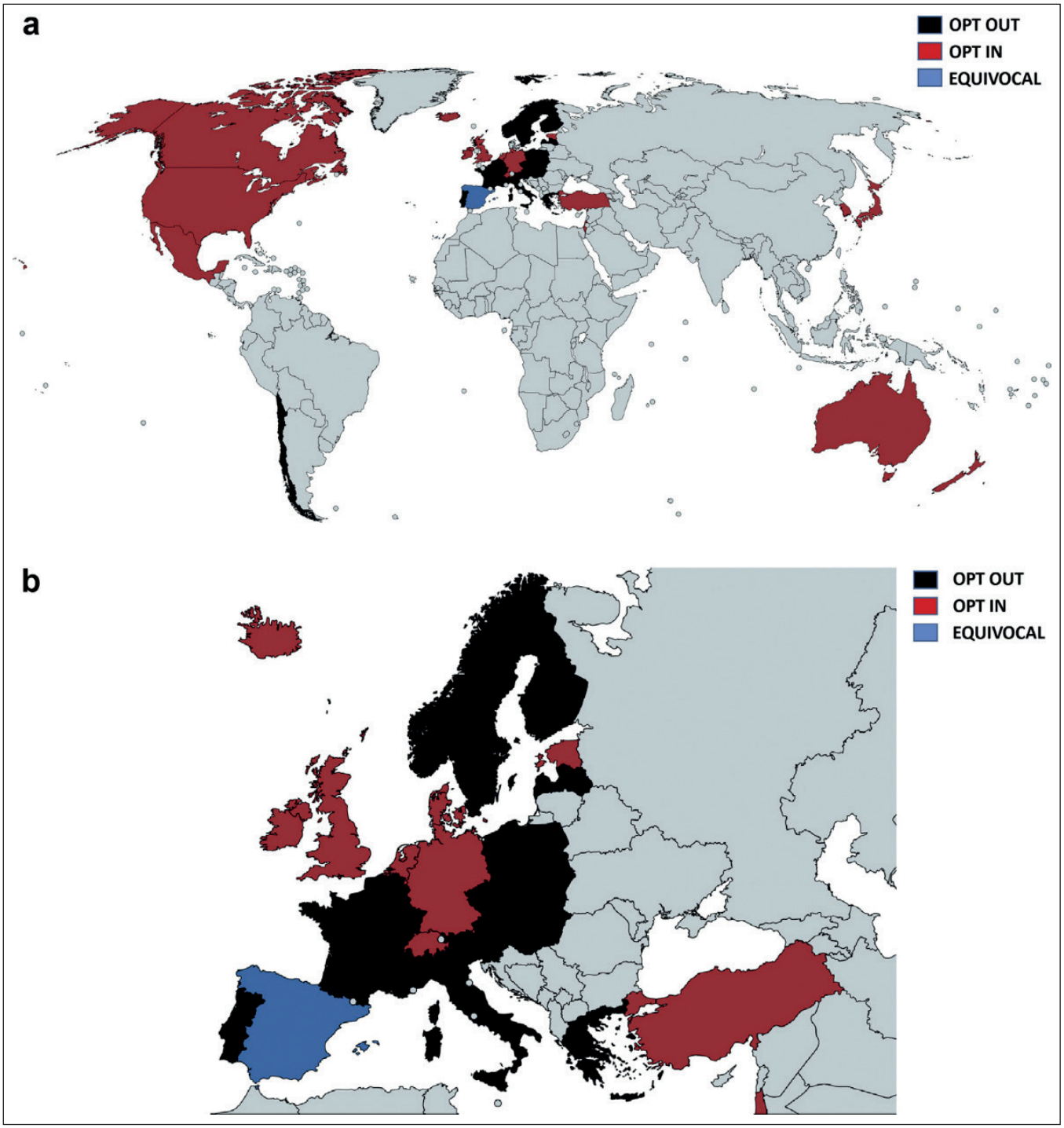

Fig. 1. Distribution of countries of the Organisation for Economic Co-operation and Development by presence / absence of presumed consent
Source: Adam Arshad, Benjamin Anderson and Adnan Sharif. Comparison of organ donation and transplantation rates between opt-out and opt-in systems. Clinical Investigation. 2019; vol. 95, issue 6: 1453. doi:https://doi.org/10.1016/j.kint.2019.01.036

all, human rights are ignored, in particular, the donor's one, who certainly during his/her life must adequately address the issue of the possibility of using his/her organs or tissues for transplantation after death, i.e. the legislator does not recognize the priority of donor rights [11].

Specialists in medicine are more categorical about the legality of removing organs and tissues from the dead. Thus, the famous cardiac surgeon Yu. L. Shevchenko notes: "Have you ever thought about how many human organs, including hearts, are thrown into the morgue every day? After all, healthy organs could save someone"[12]. Ukrainian specialist V. Saenko claims that "50-60 people die in an ambulance in a year alone. That means that at least 35-40 hearts and 100-120 kidneys can be transplanted. And we get just a few units "[13]. "If to be guided by the presumption of disagreement, there will be no transplantology," - says N.A. Tomilina, nephrologist [14].

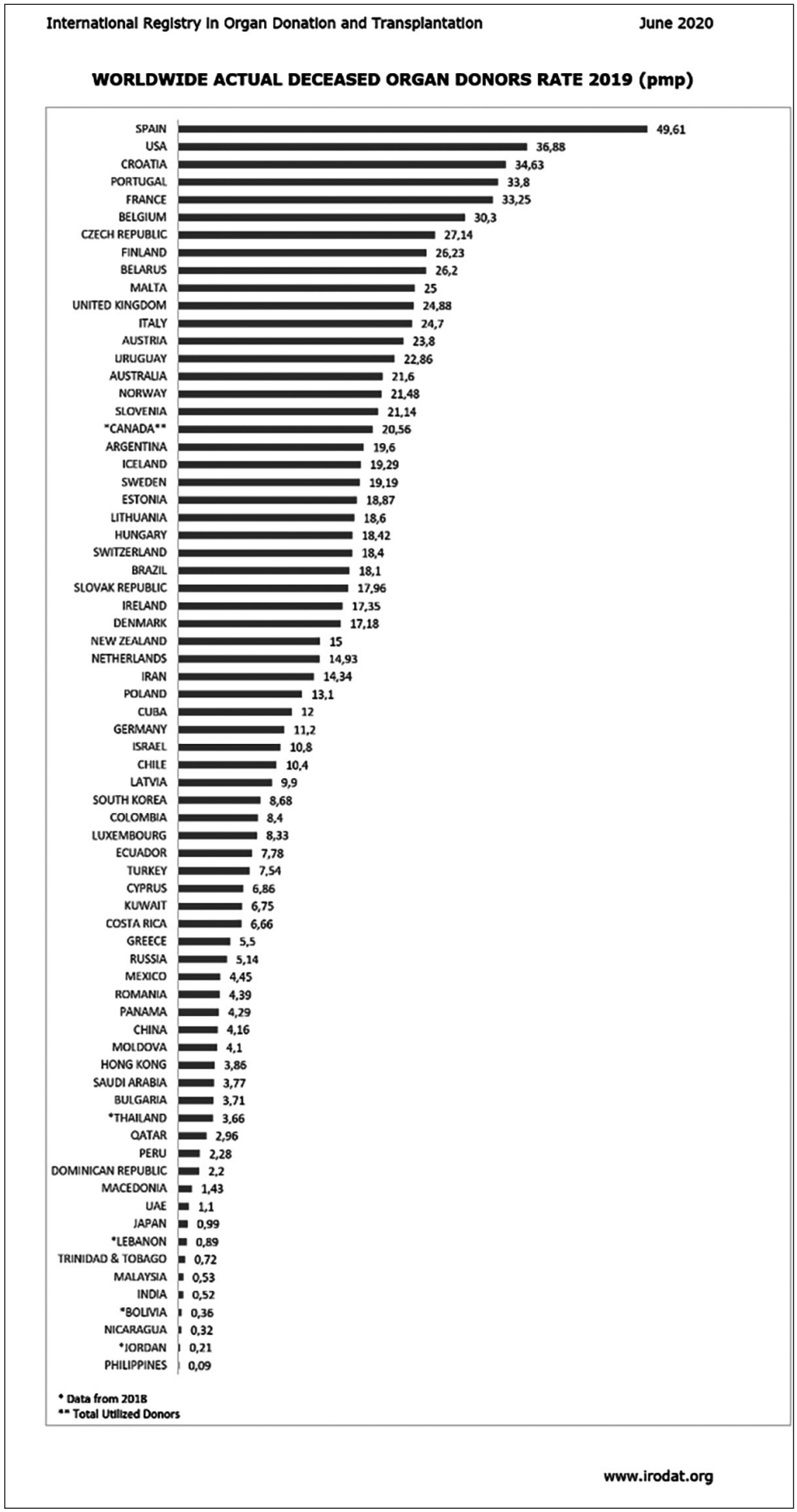

Fig. II. Statistical International Registry in Organ Donation and Transplantation (IRODaT) 2019.

The supporters of the presumption of consent's main argument is that otherwise, the development of clinical transplantation is significantly inhibited. But this seems to be a very ambiguous question.

Thus, researchers Adam Arshad, Benjamin Anderson and Adnan Sharif in 2019 analyzed 35 countries registered in the Organization for Economic Cooperation and Development. Among these countries, 17 have a statutory presumption of opt-out and 18 have a presumption of opt-in. Indicators of organ donation and transplantation were obtained for 2016 from the Global Observatory for Donation and Transplantation. The distribution of the countries analyzed by the authors is given in Figure 1. Spain is listed separately, as in the presence of a legally defined presumption of consent, relatives are still asked for consent to remove organs and tissues from the deceased.

The study (Adam Arshad, Benjamin Anderson and Adnan Sharif. Comparison of organ donation and transplantation rates between opt-out and opt-in systems. 2019.) found that there is no significant benefit for countries that currently have a presumption of disagreement and which are considering the possibility of moving to the presumption of consent. Although historically in some of the countries analyzed, there has been a significant increase since the introduction of the presumption of consent, such as Belgium. Other countries showed worse results, i.e., there was no difference, or there was an actual drop in organ donation level, including Singapore, Brazil, Chile, Sweden, and later Wales [15].

These findings are indirectly supported by data provided by the International Registry in Organ Donation and Transplantation (IRODaT). See Tab. II. As you can see, the number of operations in 2019 (for some countries in 2018) for transplantation using organs and tissues of the deceased per million was in the US, Portugal, where there is a presumption of disagreement, 36.88 and 33.8, respectively. While in Sweden, Norway, where the presumption of consent applies, this rate is 19.19 and 21.48, respectively [16].

Spain, the country with the highest rate of post-mortem donation - 49.61 in 2019, which is much more than in any other country, recognizes the presumption of consent, but relatives are still asked every time there is a question of removing anatomical material from a deceased person. Although the presumption of consent was actually introduced in Spain in 1979, only with the introduction of the National Transplant Organization (ONT) – ten years after that – the donor donations level began to improve. Within a few years of ONT's work, Spain became the country with the highest number of organ donors per million. Spain has invested in training more than 16,000 health workers in organ donation and transplantation since the founding of ONT. And since 1992, Spain's position as a world leader has remained continuous [17].

The second illustrative example is Germany. Despite the fact that in this country (Mark Hallam, Astrid Prange. German parliament: Explicit consent is still necessary from organ donors. 2020), the level of organ donation is 11.5 donors per million people, which is almost three times lower than in the United States, and more than four times worse than that of the world leader Spain, the German Parliament on January 16, 2020, rejected the proposal of the Ministry of Health for a new system of organ donation. Due to the low number of donors, the Minister of Health wanted to have a system of presumption of consent, relying on people who refuse to make donations. Thus, the rules of organ donation in Germany will remain mostly unchanged. The country will adhere to a system of informed consent, according to which only people who voluntarily register as organ donors have the right to participate in posthumous donation. However, in an attempt to reduce German waiting lists for transplants, when renewing national cards, people will be asked if they want to donate organs [18].

The low level of transplants with the use of deceased donors in Germany is justified, among other things, by the lack, in contrast to Spain, a well-organized system in this area. In Germany (Fabian Becker, Keith J. Roberts, [...], and Harald H. Schrem. Optimizing Organ Donation: Expert Opinion from Austria, Germany, Spain and the UK 2020) "donor evaluation is almost exclusively organized and coordinated by intensive care therapy physicians, while DSO transplant coordinators are rarely consulted. In recent years, the assessment of potential organ donors has been seen as an increasing workload of intensive care physicians from all four countries and all German experts ... All experts from Germany reported in this study an overload of resuscitation doctors, a lack of qualified staff, and a lack of experienced consultants who take responsibility and help doctors identify and evaluate potential organ donors. This may, at least in part, explain the decline in organ donation due to shortcomings in the recognition and accounting of potential organ donors." [19].

Eric Johnson and Dan Goldstein conducted an interesting online experiment in 2003, asking people if they wanted to be donors. Some people were told that they were not organ donor by default and were given the opportunity to confirm or change their default status. Others were told that they should be donors to the body by default and were again given the opportunity to confirm or change this status. When participants had to choose to become an organ donor (i.e. agree to a potential donation), only 42% did so. However, when they had to abandon, 82% agreed to be donors.

How many of you have changed your default mobile phone settings? This force can be used to change behavior. Setting default options can significantly impact results, from increasing donor organs to increasing personal savings to better investment. Never underestimate the force of inertia [20].

Thus, we fully agree with the researchers, who believe that "the most critical issue that is not expected to be resolved is the apathetic attitude and behavior of the public regarding organ donation. The gap between the desire for organ transplantation (if ever needed) and the simultaneous reluctance to donate organs (if possible) simply will not change with the transition to the presumption of consent… Changing attitudes is a crucial factor, and new strategies to change this need to be considered. For example, Israel has introduced a system of organ allocation priorities for registered donors, and initial results have shown a significant increase in both the level of consent and actual organ donation [19]. Although some scientists believe that therapeutic organ and tissue cloning based on genetic technology is the best way out and solving ethical transplantation problems [21].

CONCLUSIONS

The views of scientists and practitioners on the legal regulation of organ and tissue transplantation are differing widely. Legal professionals generally adhere to the principle of the priority of human rights over expediency, while health professionals who are directly involved in clinical transplantation have a more categorical view, especially regarding posthumous donation, and concede the removal of the transplant from the body of the deceased without her lifetime consent.

The activity of clinical transplantation is influenced by many different factors. It is not possible to single out certain factors as the main ones. However, it seems that an important role is played by: detailed legal regulations; availability of a well-organized system of transplantology, specially trained teams; the existence of a presumption of consent to the removal of organs and tissues after death; the attitude of society to transplantology.

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REVIEW ARTICLE

SIDE EFFECTS OF DIETHYLSTILBESTROL (DES) FROM THE PERSPECTIVE OF TORT LAW

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ABSTRACT

The aim of the article is to analyze the reasoning of the Supreme Court of California in *Sindell v. Abbott Laboratories*.

Materials and methods: Materials of the study encompass US case law as well as case law of other countries concerning compensation of damage caused by defective drugs and other cases of uncertain causation. The survey is conducted within the framework of comparative law studies. In addition, elements of law and economics approach are also employed in the paper.

Conclusions: Case of *Sindell v. Abbott Laboratories* has launched a new direction in discourse on causation in tort law and product liability. The mathematical elegance of the Court's theory is that net burden of liability borne by a particular drug manufacturer is equal to the amount of damage actually caused by its drug.

KEY WORDS: diethylstilbestrol (DES), alternative liability, toxic tort, causation, market share liability

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INTRODUCTION

Tort law is based on the principle of personal liability: the damage must be reimbursed by the person who caused it. The obligation to compensate cannot be imposed on a person until it has been proven that the actions of that person were the legal cause of the damage. During the trial the burden of proving that it was the defendant who caused the damage rests with the plaintiff [1, p. 1602; 2, p. 324]. Therefore, if the plaintiff fails to discharge his burden of proof, court rules in favor of the defendant.

However, there are some cases where discharging the said burden of proof appears to be impossible due to the factors for which the plaintiff cannot be blamed. These cases are commonly referred to as cases of "uncertain causation" (See: [3–9]) or "toxic torts" (See: [10–12])[1]. Among them there are cases where a person sustains injuries as a result of ingesting dangerous defective drug manufactured according to one and the same formula by a number of pharmaceutical companies. Due to the passage of time evidence (pertaining the brand of the drug taken) may become unavailable or unreliable and therefore the person may be unable to identify the pharmaceutical company that produced the pills and thus caused the damage which is sought to be compensated. Under these circumstances the courts encounter the dilemma either to follow the established rules on causation and leave the injured person uncompensated or to fashion a new approach that would satisfy the intuitive sense of justice and allow for compensation in the perplexed cases of uncertain causation.

THE AIM

The aim of the article is to analyze the decision of the Supreme Court of California in a prominent case relating to the injuries caused by a defective drug which manufacturer cannot be identified.

MATERIALS AND METHODS

Materials of the study encompass US case law as well as case law of other countries concerning compensation of damage caused by defective drugs and other cases of uncertain causation. The survey is conducted within the framework of comparative law studies. In addition, elements of law and economics approach are also employed in the paper.

REVIEW AND DISCUSSION

From 1941 to 1971, the drug diethylstilbestrol (DES) was sold on the American market. It is a synthetic substitute for the female hormone estrogen. Doctors prescribed it to pregnant women to prevent miscarriage [14]. However, it was later found that DES is a carcinogen and can cause malignant tumors (including adenocarcinoma) of the genitals in female children whose mothers took the drug during pregnancy [15, p. 964-965]. The cancer provoked in this way has a latent period no less than 10-12 years [14].

In total, during the said period, 1.5 to 3 million women were administred the drug [14]. So probably hundreds, or

[1] Pesticides are also among the dangerous toxic substances that can cause actionable damage. On the international legislation see: [13].

even thousands, of their daughters have developed malignant tumours. One of the victims was Judith Sindell. As a result of her mother's taking DES while being pregnant, Ms. Sindel developed a malignant bladder tumor. On this basis she applied to court claiming damages.

Decision of the Supreme Court of California in the case of *Sindell v. Abbott Laboratories,* not to exaggerate, became a new milestone in the evolution of modern tort law [16–22].

Since the case concerned damage caused by a defective product, the plaintiff had to prove not only that the damage was caused by the defective drug, but also that the drug was manufactured by no other than the defendant. In this regard, Judith Sindell encountered an insurmountable obstacle: DES is a generic formula and more than two hundred pharmaceutical companies used it to produce the drug.

When prescribing the drug, physicians did not specify a particular brand, because drugs from different manufacturers were therapeutically equivalent and interchangeable. In addition, it has been more than twenty years since Ms. Sindell's mother took DES, so it was no longer possible to identify the exact brand of the pills her mother took.

Therefore, Ms. Sindell filed a lawsuit against eleven pharmaceutical companies, which at the time of her mother's pregnancy produced a total of 90% of the DES on the market. Three concepts were invoked to substantiate the claim: alternative liability, concert of action and industry-wide liability.

The concept of alternative liability is represented by the case of *Summers v. Tice* [23] the facts of which are also known as two hunters dilemma[2]. In this case, two hunters acting negligently fired in the same direction. As it turned out, the shot hit the third hunter. But it was impossible to identify whose pellets hit the victim, since the hunters used the same rifles and the same pellets. The court held that in such circumstances both hunters should be jointly and severally liable for the damage caused. To be precise, the Court ruled that the burden of proof should be reversed - and it is not the plaintiff who has to identify the defendant whose pellet caused damage, but instead it is each of the defendants who has to prove that it was not his pellet that caused the damage. And since the defendants in *Summers* were not able to identify the origin of the pellet, the court found them jointly and severally liable for the damage [23].

In *Sindell* the applicability of the said concept was denied[3]. The Court pointed out that in order to apply alternative liability, everyone who could be the culprit of the damage has to appear before the court. In other words, a guarantee is needed that the person who actually caused the damage is among the defendants brought to trial. This was the case in *Summers*, where both hunters were brought to court. Ms. Sindell, on the other hand, filed a lawsuit against only a small portion (eleven of the more than two hundred) of the pharmaceutical companies that manufactured DES. Thus, it is possible that the company, whose pills were actually taken by the plaintiffs' mother, was not present at all among the cohort brought to trial. In such circumstances, to impose joint and several liability (as the *Summers* case provides) on defendants in respect of whom there is no guarantee that any of them has actually caused harm seems to be an unfairly broad interpretation of alternative liability doctrine.

Secondly, the plaintiff asserted that the damage was caused by the defendants acting in concert[4] (since, if the damage was caused by the joint actions of several persons, they are jointly and severally liable for it and thus there is no need to identify which of the defendants produced the exact pills Ms. Sindell's mother took and which was involved in some other way, e.g. by promoting or advertising DES). According to the plaintiff, the concert of actions consisted in all the defendants relying on each other's clinical trials (on drug safety) and benefiting from each other's marketing strategies to promote the drug on the market.

This argument was based, in particular, on the special rules governing the production and marketing of the drugs in the United States. Thus, according to the legislation in force at the time, as long as a certain drug is not "generally recognized as safe", every company that intends to produce it must apply to the Food and Drug Administration (FDA). Accordingly, production can be started only if the application is approved by the FDA. But as soon as the FDA assigns a drug the status of "generally recognized as safe", it can be manufactured by anyone without the need for prior application. Until 1952, when DES was granted the status of "generally recognized as safe", applications for its production were submitted 123 times [14].

In this context, the plaintiff 's argument probably should be interpreted as follows. All companies that applied to FDA to approve DES's safety and efficacy thereby contributed to the drug being given the status of "generally recognized as safe", which resulted in its further spreading on the market and increasing the number of its manufacturers.

All the DES-manufacturers did act in a similar way to some extent. But is this similarity enough to prove they acted in concert? The court answered this question in the negative. For a court to find concert of action, there must be an express agreement or tacit understanding between the actors, and everyone has to realize the wrongfulness of the other's actions. In the Court's view, the plaintiff had not proved it.

That there is a certain pattern traced in all the defendants' course of actions – it is due to the fact that the market of drugs is thoroughly regulated and pharm companies just followed the established procedures. Manufacturers should not be accused of conspiracy on the sole ground that they all operate under the same regulatory standards. Otherwise, it would mean that within some industry, each

[2] Comments on the case see: [24; 25].

[3] Comments on the applicability of alternative liability in Sindell see: [15, p. 985-995; 26, p. 788-791; 27, p. 156-158].

[4] Comments on the argument see: [15, p. 978-985; 26, p. 792; 27, p. 150-151].

manufacturer can be held liable for damage caused by a defective product of another manufacturer solely on the ground that it operates on the same market and thus takes part in the promotion of the similar product.

Finally, to substantiate her claim, the plaintiff resorted to so called industry-wide liability. In particular, she referred to the case of *Hall v. E. I. Du Pont de Nemours & Co., Inc.* [28]. In this case, there were 12 incidents where children were injured by explosions of blasting caps, and it was impossible to determine which company produced the particular cap. The Court ruled that all six companies that constituted the entire blasting cap industry should be held liable. The decision was grounded on the fact that the companies did pursue a coordinated safety and labeling policy. Moreover, significant part of the safety functions was delegated by all industry members to an association called the Institute of Makers of Explosives.

In *Sindell* the Court rejected this argument as well[5], stating that the application of industry-wide liability requires that all industry participants exercise joint control over the risks. That is, the product safety standards must be set by the agreement of all manufacturers compounding the industry. And so it was with *Hall*, because the requirements for labeling and design were set by an association voluntarily formed by the manufacturers. Thus, each of the manufacturers was involved in fashioning product safety standards. In contrast, in the pharmaceutical industry, safety standards are set by a government body, namely the FDA. Therefore, the risks are controlled more by the FDA, rather than by each manufacturer individually or by all manufacturers together.

In addition, while industry-wide liability is appropriate for centralized industries with a small number of manufacturers, its application is hard to justify in a case of a decentralized industry with several hundred manufacturers, as was the case in *Sindell*.

Having concluded that neither of three doctrines pleaded by the defendant solve the problem, the Supreme Court of California developed a new doctrine named market share liability (hereinafter – MSL).

The Court held that, provided the plaintiff brings to court manufacturers whose aggregate market share in the product is considered substantial, each of those manufacturers should compensate for the damage caused by the product in proportion to its own market share in that product. Thus, if damages amount to 1 million USD and the defendant's market share is 30%, that defendant has to pay the plaintiff 300,000 USD (unlike in *Summers*, where the hunters' liability was joint and several). That is so because the manufacture's market share indicates the probability of this manufacture's product being the actual cause of the damage [26, p. 798; 27, p. 158].

The mathematical elegance of MSL doctrine is that ultimately the net burden of liability that falls on a particular pharm company is equal to the net amount of damage caused by that particular company. Therefore, application of MSL in long run results in the same allocative effects that would have been achieved provided the full knowledge (as to the identity of the manufacturer in each particular case) and application of the regular requirements for proof of causation: plaintiffs receive exactly the same compensation, and defendants bear exactly the same burden of liability.

According to *Sindell*, the plaintiff does not have to sue all the drug manufacturers – it is enough to sue manufacturers whose aggregate market share is substantial. There are two ways to treat *Sindell* decision with regard to the allocation of liability between the defendants [27, p. 162-163; 29, p. 941; 30, p. 89, 105].

First, the companies brought to court reimburse the plaintiff only the portion of damages corresponding to their aggregate market share. Second, the companies brought to court reimburse the plaintiff's damages in full, thus covering also the portion that must have been borne by the companies not sued by the plaintiff.

Judge Richardson, in his dissenting opinion, interprets the majority's conclusion in the letter way, noting that "those defendants who are brought to trial in this state will bear effective joint responsibility for 100 percent of plaintiffs' injuries despite the fact that their "substantial" aggregate market share may be considerably less" [14].

In addition, the decision of the majority inter alia states that the defendants against whom the lawsuit is filed have the right to involve other co-defendants (cross-complain). However, such a right is of value to the defendant only if he is able to reduce his own liability by involving another defendant. If the amount of liability depends only on the defendant's market share and does not depend on the number of defendants before the court – it does not make sense for the defendants brought to court to possess such a right [27, p. 162-163].

This interpretation effectively means that the risk of insolvency, liquidation or other events that render a company unreachable for a lawsuit – rests with the companies that hold up well at the time the plaintiff learns about the injury. Of course, for the plaintiffs this interpretation has an obvious advantage, as they avoid undercompensation. However, the overall allocative effect of such an interpretation cannot be considered optimal, as the net burden of liability borne by each manufacturer exceeds the amount of damage it actually caused. From a legal point of view, this seems unfair, since manufactures appear to be treated unequally. From an economic point of view, this will negatively affect the manufactures' interest in carrying out the relevant activities and may result in underproduction. This second, economic argument is particularly important because much of the *Sindell*'s criticism is based on the assertion that MSL places an excessive burden of responsibility on pharmaceutical manufacturers, and this burden will discourage them from investing in the development, research, and production of new drugs (which, of course, would entail large-scale public losses).

[5] Comments on this argument see: [26, p. 792-793; 27, p. 152-155].

In particular, this point was made by Justice Richardson. In his dissenting opinion he stated:

"It seems to me that liability in the manner created by the majority must inevitably inhibit, if not the research or development, at least the dissemination of new pharmaceutical drugs. <…> I also suggest that imposition of so sweeping a liability may well prove to be extremely shortsighted from the standpoint of broad social policy. <…> It is counterproductive to inflict civil damages upon all manufacturers for the side effects and medical complications which surface in the children of the users a generation after ingestion of the drugs, particularly when, at the time of their use, the drugs met every fair test and medical standard then available and applicable. Such a result requires of the pharmaceutical industry a foresight, prescience and anticipation far beyond the most exacting standards of the relevant scientific disciplines. In effect, the majority requires the pharmaceutical research laboratory to install a piece of new equipment – the psychic's crystal ball" [14].

In this context, Robert A. Kors believes that *Sindell* decision has another flaw, that potentially may lead to the net burden of manufacturer's liability being larger than the amount of damage actually caused by it [29, p. 938-939, 942]. While *Sindell* sets forth MSL, the victim, who can accurately identify the manufacturer (if prescriptions, receipts, checks, etc. miraculously survived), still has the right to claim damages in full from this particular manufacturer on the basis of general rules for proving causation. It means that any given manufacturer may be sued both on the ground of general rules and on the ground of MSL doctrine.

However, the equation between the net burden of liability and the net amount of damage caused by a manufacturer will not be distorted given that the ratio between individualized claims (to each of the manufacturers) replicates the ratio between market shares of the respective manufacturers. And since it seems plausible, the availability of individualized claims will not make a significant difference regarding the correspondence of net liability to net damage caused by each manufacturer.

However, the same cannot be said of the *Sindell*'s interpretation, according to which the companies brought to court have to distribute among themselves the share of damages that would have fell on the companies that did not appear in court. Such an interpretation will always result in a disproportion between the burden of liability and the amount of damage caused.

Lastly, it should be mentioned that after *Sindell* there were a number of attempts to apply the MSL doctrine to substances other than DES. In particular, to asbestos, silicone implants, lead paints, donor blood, latex gloves, tobacco products, pesticides and methyl tert-butyl ether (MTBE) which polluted groundwater (see: [31-37]). And though not all the attempts have been successful, there is no denying that the *Sindell* case paved the way for a brand new perspective on the issue of uncertain causation and inspired scholars and judges around the world to further elaborate on the issue.

CONCLUSIONS

Case of *Sindell v. Abbott Laboratories* has launched a new direction in discourse on causation in tort law and product liability. The California Supreme Court has ruled that the inability to identify a defendant should not be an insurmountable barrier that prevents a victim of a dangerous drug from obtaining compensation. The mathematical elegance of the Court's theory is that net burden of liability borne by a particular drug manufacturer is equal to the amount of damage actually caused by its drug. This means that, theoretically in long run the distributive effects of market share liability are the same as they would have been had the complete knowledge been available and each victim been able to identify the brand of the drug her mother ingested.

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REVIEW ARTICLE

MENTAL DERANGEMENT AS A MANDATORY ELEMENT OF LIMITED SANITY

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ABSTRACT

The aim: Complex analysis of theoretical and practical aspects of study of mental derangement as a mandatory element of limited sanity and development of new approaches to such state's assessment.

Materials and methods: An analysis of criminal legislation and researches made by scientists from Brazil, Denmark, Great Britain, Portugal and the USA concerning mental derangements of persons who committed crimes and were considered as having limited sanity, publications in mass media, analytical materials, judicial practice (with the purpose to define certain types of crimes and types of mental derangements of such group of people) has been made. For comparison analysis within the framework of study of problems of mental derangement as a mandatory element of limited sanity 1422 court verdicts were selected from Unified Register of Court Rulings of Ukraine (as of August 2020) concerning persons who committed criminal offences under circumstances which allow to consider such persons as having limited sanity. The methods of statistical analysis, system structural method, method of legal phenomenon system analysis and comparative method were applied during the research.

Conclusions: Due to significant increase of quantity of people with mental derangements it is necessary to envisage legally types of mental derangements qualified as limited sanity. This will allow to oblige bodies of criminal justice to conduct mandatory psychiatric examinations after all kinds of crimes when there are grounds to assume that the person during criminal offence commitment was not able to fully understand his (her) actions and (or) control. Consequently, every person having mental derangement and considered as having limited sanity should be subject of compulsory measures of medical care during sentencing, and duration of such care should be legally stipulated with regard to the type of mental derangement.

To prevent commitment another crimes by persons with mental derangement and considered as having limited sanity it is necessary to develop correlation programs with certain schemes of treatment, separate categories of people in need of psychiatric help, relevant financing and coordination mechanisms for interaction between the law enforcement bodies and local governance.

KEY WORDS: criminal offence, limited sanity, mental derangement, compulsory measures of medical care

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INTRODUCTION

Study of the person committed criminal offence always was a metter of interest not only to researchers in the field of criminal law and criminology, but to psychologists and psychiatrists. This is due to the theories of criminal behavior explanation because the issue of causes of crime commitment is still not properly clarified.

Sanity is mandatory feature to be established for bringing person to criminal responsibility. This characteristic of person who committed criminal offence allows defining such person's mental condition, ability to perceive certain deed's unlawfulness and to control own actions during its commitment.

It is undeniable fact that person's criminal behavior is influenced by different factors (social-economic, political, historical, cultural etc.) that taken together cause stress situations, deterioration of emotional state and emergence of mental derangements. For example, economical instability in the world due to SARS COVID-2019 pandemic, tense political situation and other factors predetermined the increase of crimes committed quantity both in the world and in Europe. According to Numbeo data, as of July 2020 Venezuela is the country with the highest crime rate (84,36) in the world, and Ukraine – in Europe (48,84) [1].

Criminal responsibility and the insanity defense are topical issues confronting the criminal justice system. To ensure due process, uphold judicial integrity and maintain the integrity of criminal proceedings, courts must determine when a defendant is responsible for alleged criminal acts, and when the insanity defense is applicable. For every criminal offence, two requirements must be established: the *actus reus* and the *mens rea* [2, p. 685]. While the *actus reus* denotes an overt or proscribed act, *mens rea* on the contrary is concerned with the criminal intent to perform the *actus reus* [3].

That's why defining of mental condition of the person committed criminal offence has crucial importance for criminal proceedings (namely in case of establishing mental derangement – for application of necessary compulsory measures of medical care). Mental derangement

and criminal offence committed is a double-egged sword which ignited a lot of discussion between psychiatrists and lawyers. If sensible middle is found, it is possible to develop special rules of behavior with people who committed criminal offences having mental derangements.

THE AIM

The aim of this article is to present a complex analysis of theoretical and practical aspects of mental derangement study as a mandatory element of limited sanity and formulation of new approaches to such state's assessment.

MATERIALS AND METHODS

An analysis of criminal legislation and researches made by scientists from Brazil, Denmark, Great Britain, Portugal and the USA concerning mental derangements of persons who committed crimes and were considered as having limited sanity, publications in mass media, analytical materials, judicial practice (with the purpose to define certain types of crimes and types of mental derangements of such group of people) has been made.

For comparison analysis within the framework of study of problems of mental derangement as a mandatory element of limited sanity 1422 court verdicts were selected from Unified Register of Court Rulings of Ukraine as at August 2020 concerning persons who committed criminal offences under circumstances which allow to consider such persons as having limited sanity.

The method of statistical analysis, system structural method, method of legal phenomenon system analysis and comparative method were applied during the research.

REVIEW AND DISCUSSION

The concept of responsibility is in focus when we consider the human rights of people with mental health problems. It is a general principle of law "that the person liable to be punished should at the time of his crime have had the capacity to understand what he is required by law to do, and to control his conduct in the light of such decisions. Normal adults are generally assumed to have these capacities, but they may be lacking where there is mental disorder or immaturity, and the possession of these normal capacities is very often signified by the expression 'responsible for his action' " [4]. If someone is not responsible for his/her actions then it is argued they should not be punished for them and instead diverted to the appropriate services [5].

It should be stressed that in some foreign countries people with mental illness are over-represented in the criminal justice system. The 2011-2012 Annual Report of the Correctional Investigator found that 36 % of federal offenders were identified at admission as requiring psychiatric or psychological follow-up, and 45 % of male inmates and 69 % of female inmates received institutional mental health care services [6]. The over-representation of people with mental illness in the corrections system may be increasing over time. Between 1997 and 2010, symptoms of serious mental illness reported by federal offenders at admission increased by 61 % for males and 71 % for females [7]. Notably the partial excuse of diminished responsibility due to intoxication – in 2013 in Germany, out of 935,788 accused, 749 (0,08 %) were found totally irresponsible and 17,968 (1,9 %) partially irresponsible [8].

However, only some states are keeping records of mentally ill persons who committed criminal offences and are treated during their sentence. For example, there is no record of persons having limited sanity in Ukraine. Instead Department of Criminal Punishments of Ministry of Justice of Ukraine is registering data on restraint measures commutation, custodial sentences, non-custodial sentences, judgments of acquittal, quantity of convicted men, women, juveniles, persons sentenced for life imprisonment. Meanwhile, according to statistics 1,2 mln of Ukrainians (e.g. more than 3 % of the population) suffer from mental derangements, and this number is growing every year. Ukraine is ranked first in Europe on quantity of mental derangements among population – almost 2 mln of our fellow countryman become patients of mental health clinics every year [9, p. 105].

Study of mental derangement as a mandatory element of limited sanity, requires two aspects to be considered. The first one (psychiatric) means that person to whom state condemnation (in the form of criminal responsibility) is applied may have mental derangement that does not deprive him (or her) of the ability to understand meaning of his (or her) actions and control them. Whereas such derangements belong to mentality, consciousness and are of critical importance for defining the matter of sanity, they should be taken into account by court in a certain way. The second (legal) consists of constant tendency to measure of punishment individualization and – due to this – increased attention to the subjects of crime. That's why combination of these circumstances define the main goal to be achieved by introducing the institute of limited sanity – establishing legal grounds and mechanisms that enable understanding by court (via forensic psychiatric examination of the defendant) the meaning of the latter's mental disorder (which does not excluded his (or her) sanity) for resolve the issue of his (or her) guilt and responsibility.

When defining limited sanity, it is of utmost importance to answer properly the question of the ability of a subject to realize the actual nature and public danger of the actions (inaction) or to direct them, psychiatrists based on medical and legal (psychological) criterion of sanity / insanity rely on data obtained from a pathopsychological examination [10, p. 44].

World Health Organization specialists point out that mental health should be seen as a valued source of human capital or well-being in society. It contributes to individual and population health, happiness and welfare, enables social interaction, cohesion and security, and feeds national output and labor force productivity. We need good mental health to succeed in all areas of life [11]. In this way person's mental health is a complex phenomenon

mainly consist of his (or her) social and communication skills; consequently, mental health status does not defined exclusively by presence or absence of mental derangement. Regarding this, mental disorders represent disturbances to a person's mental health that are often characterized by some combination of troubled thoughts, emotions, behavior and relationships with others. Examples of mental disorders include depression, anxiety disorder, conduct disorder, bipolar disorder and psychosis [12]. In addition to this, there are three basic approaches to deal with mental disorders as grounds for excluding criminal responsibility:

(1) The overwhelming majority of legal orders accept mental disorder as separate ground – mostly labeled "excuse" or "defense" – for excluding criminal responsibility. Although the criteria look very similar, the resulting practical differences range from very restrictive application, notably in the English-speaking world, to fairly frequent use in some civil law countries.

(2) A small group of legal orders – a couple of American states – admits mental disorders only insofar as they constitute mistake or involuntariness, i.e. negate the requirement of intent or, rather in theory than in practice, of a voluntary act.

(3) Another small group – mainly Sweden which, however, is gradually returning to the mainstream – adopted a unified system of social control in which mental disorders are only relevant to determine the suitable kind of treatment of the offender [13, p. 51; 14, p. 168-181; 15; 16, p. 26].

It all proves that main argument in favor of limited sanity concept means the absence of clear boundaries between different in severity mental derangements. On the contrary, there are gradual transitions that cause confusion – to consider such person sane, or having limited sanity, or insane. This is also stressed by M. Rahmdel, who notes that the problem is that certain people suffer from less severe mental illnesses that, while still debilitating, are neither medically nor psychologically categorized as insanity. That is, although these illnesses influence both their faculty of decision-making and their behavior, the law recognizes these people as being fully criminally liable. Thus, apparently the former law held more conformity with scientific rules. In practice, courts regard such cases as instances of mitigating circumstance [17, p. 202].

It should be stressed that the International Statistical Classification of Diseases and Related Health Problems (ICD-10), approved by the World Health Organization in 2007, stipulates mental and behavioral disorders in chapters F00-F99. These include, among others, F00-F09. Organic, including symptomatic, mental disorders (F00. Dementia in Alzheimer's disease, F01. Vascular dementia, F02. Dementia in other diseases classified elsewhere, F06. Other mental disorders due to brain damage and dysfunction and to physical disease), F10-F19. Mental and behavioral disorders due to psychoactive substance use (F10. Mental and behavioral disorders due to use of alcohol, F11. Mental and behavioral disorders due to use of opioids, F12. Mental and behavioral disorders due to use of cannabinoids, F13. Mental and behavioral disorders due to use of sedatives or hypnotics), F20-F29. Schizophrenia, schizotypal and delusional disorders etc. [18].

Most researchers, defining medical criterion of limited sanity, examine all mental derangements that does not exclude sanity (in other words – does not reach the psychotic level) at the moment of certain person's crime commitment. This is about endogenous, exogenous mental diseases, vascular disorders, infectious lesions, psychoactive substances dependence, statuses conditioned by developmental pathology. But despite of nosological belonging of mental derangement the main thing is to determine, firstly, whether the person had mental derangement at the moment of crime commitment, and secondly, what was such derangement's level of influence upon the decision to commit crime.

Research on the topic: "Crime, psychiatric diagnosis and victims' profiles: a study with the sample of a criminal-psychiatric ward in São Paulo" was carried out by E. H. Teixeira and P. Dalgalarrondo in 2005. The records of 269 patients were analyzed, considering only male patients whose medical reports had already been included in the criminal-psychiatric records. Psychotic disorders were the most common findings (58 %). The most common type of crime was murder or murder attempt (52,8 %), with a significant correlation between psychotic disorders and this type of crime ($p < 0.05$). These crimes led to death in 89,7 % of the cases, and in 34,5% the victim was a close relative. Mentally retarded patients committed proportionally more sexual crimes when compared to psychotic patients and considering only sexual crimes or murder attempts ($p<0.05$). In 78,5 % of all sexual crimes the victims were under 14 years old [19, p. 192-194].

Meanwhile according to the data received by J. Garbayo and M. J. Relvas Argôlo, the most prevalent diagnosis were psychotic disorders (67 %) followed by mental retardation (15,2 %), disorders due to the use of psychoactive substances (7,3 %), personality disorders (4,5 %), among others. Most of them (71 %) had been under previous psychiatric treatment [20, p. 247-252]. A group of scientists headed by S. Fazel, comparing the risk of increase of criminal behaviour among patients with established diagnosis "epilepsy" and among general population, has recorded such index increase 1,5 times among former [21].

We selected 1422 court verdicts from Unified Register of Court Rulings of Ukraine concerning persons who committed criminal offences under circumstances which allow to consider such persons as having limited sanity. It was observed that from 1406 persons who were actually consider as such 185 were registered as psychiatrists' patients with a diagnoses of mental deficiency, 222 – schizophrenia, 296 – imbecility, 74 – dementia combined with emotional-volitional instability, 148 – oligophrenia with psychopathic-like behavior, 148 – organic personality disorder, 185 – abnormal personality, 111 – epilepsy, 37 – exhibitionism and post-traumatic stress disorder. Thus it is possible to conclude that person considered as having limited sanity can have any mental or behavioral derangement, but the most common are F06. Other mental disorders due

to brain damage and dysfunction and to physical disease, F20. Schizophrenia, F65. Disorders of sexual preference, F70-F79. Mental retardation, F80. Specific developmental disorders of speech and language.

V. Batyrgareieva also underlines that mental disorders are common among the recidivists. By the results of her research 52,9 % recidivists who were subjected to forensic psychiatric examination were found to have certain psychical anomalies which do not exclude sanity. The most common of them were mental and behavioral derangements caused by use of psychoactive substances (namely alcohol and drugs). Proportion of recidivists with mental anomalies classifies to the chapter F1 of ICD-10 is 59,6 % among all examined by specialists [22]. Moreover, 22,2 % of all examined and found to have mental anomalies classifies to the chapter F6 of ICD-10 are also recidivists [22].

In the meantime either foreign scientists' researches or court rulings analyzed by us have no mention of ICD-10. That's why we consider as argumentative the conclusion that separation of legal from medical descriptors has the obvious advantage of freeing the law from the vagaries of the development of the medical sciences – avoiding the problems created by outdated terminology which plague Paragraph 20 of the German Criminal Code ('pathological mental disorder, profound consciousness disorder, debility or any other serious mental abnormality'). On the other side, the separation has the obvious disadvantage of potentially missing essential features of the relevant phenomena and of creating permanent problems of translation in the legal evaluation of expert opinions [13, p. 53]. On the contrary, explanations of certain types of mental derangements given in criminal legislation would allow avoiding complications in application of punishment to such persons.

Equally debatable is an issue of types of criminal offences committed by persons with mental derangements (most of such studies were conducted by scientists in Russia and in the USA). Instead we are interested in results received in other countries. According to data obtained by group of researches headed by M. P. Pondé, persons with mental derangements committed the following crimes in Brazil (according to its Penal Code): robbery (Article 157), kidnapping and extortion (Article 159), rape (Article 213), indecent assault (Article 214), theft (Article 155), rioting (Article 354), contempt (Article 331), illegal threats (Article 146), fraud (Article 171), conspiracy(Article 288), misappropriation (Article 168), extortion (Article 158), embezzlement (Article 312), use of fraudulent or counterfeit documents (Article 304), receiving stolen goods (Article 180), false identity (Article 309), crimes related to counterfeiting money (Article 290), intimidation (Article 147), escape of a legally imprisoned individual or of an individual submitted to a security measure (Article 351), corruption of minors (Article 218), resistance (Article 329), escaping prison through the use of violence against an individual (Article 352), bodily harm (Article 129), fraudulent misrepresentation (Article 299), kidnapping (Article 148), homicide (Article 121), crime of armed robbery and murder (first-degree murder in accordance with Article 157, Paragraph 3 of the penal code), drug trafficking crimes (as defined in Article 33 of Brazilian law 11.343/2006), torture (as defined in Article 1 of Brazilian Law 9.455/1997), illegal possession of weapons (as defined in Article 12 of Brazilian Law 10,826/2003) [23, c.10-13]. Other academics studying persons who committed crimes and were considered as having limited sanity note that such persons prone to violent crimes against life and health (murder, bodily injury etc.), sexual crimes or terrorists crimes.

At the same time joint research of D. J. Vinkers, E. de Beurs, M. Barendregt, T. Rinne and H. W. Hoek shows that total prevalence of mental disorders is highest when the main charge is a crime against property (58,0 %) and lowest when such charge is murder (40,0 %; $X2 = 5325,6$, $p < 0,001$). More specifically, the prevalence of psychotic disorders was relatively high in relation to battery (17,6 %) and / or manslaughter charges (16,0 %) and relatively low in respect of sexual crimes (3,2 %) and rape (5,6 %; $X2 = 5325,6$, $p < 0,001$). Developmental disorders were especially prevalent in defendants of sexual crimes (6,9 %; $X2 = 5325,6$, $p < 0,001$). Personality disorders were most common in defendants of battery (53,5 %) and property (51,7 %) and least common in defendants of sexual crimes (46,1 %) and assault (48,2 %; $X2 = 122,01$, $p < 0,001$). Cluster B personality disorders were more common in defendants charged with violent crimes (20,9–23,0 %), whereas cluster C personality disorders were more common in respect of sexual crimes (7,3 %; $X2 = 122,01$, $p < 0,001$). An IQ score of 85 and below, or intellectual functioning estimated as being below average, was more common in rape defendants (14,7 % vs 24,4 %; $X2 = 200,62$, $p < 0,001$), Alcohol abuse was more common in defendants charged with arson (27,3 %) and less common in defendants where the charges were sexual (8,9 %) or property related (7,8 %; $X2 = 2120,4$, $p < 0,001$). Abuse of both cannabis (13,0 %) and hard drugs (24,3 %) was especially high in relation to property crimes ($X2 = 2120,4$, $p < 0.001$) [24, p. 308].

Finally, according to the results obtained by J. Garbayo та M. J. Relvas Argôlo murder was the most common crime (44 %) followed by crimes against property (26 %), sexual crimes (11 %), crimes related to drugs (11 %) and others. Intrafamiliar murder was prevailing among mentally retarded population and psychotics. The former generally committed more sexual crimes than the latter [20, p. 247-252].

Similar results were obtained in some ways concerning situation in Ukraine. As our research shows, the most the most common of them are criminal offences against property (584 judgments of conviction, or 41 %, and 30 % of them are on charges of theft stipulated by Art. 185 of CC of Ukraine). Running second are criminal offences in the field of circulation of narcotic drugs, psychotropic substances, their analogues or precursors and other criminal offences against public health (298 judgments of conviction, or 20,7 %, and 15,5 % of them are on charges of illicit manufacture, making, acquisition, storage, transportation or shipment of narcotic drugs, psychotropic substances or their analogues

without the purpose of sale stipulated by Art. 309 of CC of Ukraine). In third place are criminal offences against public safety (221 judgments of conviction, or 15,5 %, and 6,3 % of them are on charges of knowingly false information about the threat to public safety, destruction or damage to property stipulated by Art. 259 of CC of Ukraine).

As for other criminal offences, no defendant was considered according to psychiatric examination reports as having limited sanity in cases of intentional murder (Art. 115 of CC of Ukraine); at the same time every third person charged with intentional grave bodily injury (Art. 121 of CC of Ukraine) was considered by psychiatric examination reports as having limited sanity.

Consequently, we consider at least debatable conclusions made by D.J. Vinkers, E. de Beurs, M. Barendregt, T. Rinne, H. W. Hoek concerning the fact that mental disorders are related to all types of crimes but especially to arson, battery and homicidal attempts or threats [24, p. 307], since any person having mental derangements and being at extreme situation could commit any unlawful actions.

It should be stressed that analysis of crimes committed by persons having mental derangements and considered as having limited sanity proves that one-third of them had been regularly and sufficiently treated as outpatients. Almost half of the offenders were diagnosed with alcohol abuse/dependence and two-thirds with any substance abuse/dependence. Furthermore, almost half were intoxicated during the index crime. Antisocial personality disorder was diagnosed in 25 % of the offenders. Almost half of the offenders were placed in involuntary special care for the ID, which lasted approximately 2 years. Among the last mentioned, two thirds of the nursing care plans lacked recommended structure [25]. In addition other results (which are in line with our outcomes) confirm that mental disorders are most common for men (almost 90 % from all persons considered as having limited sanity); the research made by O. Kozeratska shows that the correlation between men and women is 96,7 % to 3,3% respectively [26].

Publications on this issues and results obtained during our own research demonstrate that mental derangement could be taken into account by the court during sentencing (naturally as a mitigating circumstance as there is no such in the list of aggravating circumstances) and could by the ground for application of compulsory measures of medical care. However, the mechanism of such taking into account is still does not defined. In certain countries (for example, in Brazil and Denmark) compulsory measures of medical care are very seldom applied to persons who committed crimes and have limited sanity; instead they are referred to psychiatric clinics for treatment. Application of compulsory measures of medical care usually takes place when severe psychiatric illness is diagnosed or a violent crime was committed. In general they are applied only to 20 % of persons who have mental derangements and committed repeated crimes.

As to Ukraine, in almost 1000 judgments of conviction outpatient psychiatric care was compulsory applied at the place of residence, in 222 cases the same took place in correctional facilities; almost 200 judgments of conviction do not contain any mention of application of compulsory measures of medical care.

Consequently we can assume that lawmaker's specification of mental derangement as a mandatory element of limited sanity in criminal legislation was based on the principle of humanity and according to modern foreign tendencies of criminal law development inherent to many countries around the world. But criminal justice system not always has relevant mechanisms of influence on such people, and non-application of compulsory measures of medical care or correlational programs to them leads to commitment of repeated criminal offences.

CONCLUSIONS

This research allows concluding the existence of necessity to stipulate the list of mental derangements as a mandatory feature of limited sanity in criminal legislation. Unfortunately, bodies of criminal justice not always consider expedient to commission and conduct forensic psychiatric examination to establish presence (or absence) of mental derangements arguing that such examination is compulsory only in cases of certain criminal offences commitment. As a result person who was not a subject of such examination is still considered sane, could commit another criminal offence, and his (or her) mental derangement will become more severe.

Psychological progress in different illnesses diagnostics urges lawmakers in different countries to examine the possibility to release persons having mental derangements from criminal responsibility or consider existence of such derangements as a mitigating circumstance. Significance of such achievements proves criminal legislation dependence on psychology.

We can confidently affirm that persons with mental derangements who are considered as having limited sanity are inclined to recidivism of criminal offences. This postulates mandatory application of compulsory measures of medical care to such persons and normative regulation of duration of such application.

Whereas the quantity of people with mental derangements is increasing during last years, the necessity arises to develop on state level specific correlational programs for persons who are considered as having limited sanity to prevent commitment repeated criminal offences by them. These programs will help to substantiate approaches to treatment schemes, to define people to which urgent mental health care is necessary, to coordinate interaction between law enforcement bodies and local governance. Without such programs introduction the quantity of people with mental derangements who are considered as having limited sanity will only increase, as it is already observed in certain countries.

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