

# GEORGIAN MEDICAL NEWS

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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии  
საქართველოს სამედიცინო სიახლენი

# GEORGIAN MEDICAL NEWS

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თანამშრომლობითა და მისი პატრონაჟით

**ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ  
ТБИЛИСИ - НЬЮ-ЙОРК**

**GMN: Georgian Medical News** is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board and The International Academy of Sciences, Education, Industry and Arts (U.S.A.) since 1994. **GMN** carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

**GMN** is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

**GMN: Медицинские новости Грузии** - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией и Международной академией наук, образования, искусств и естествознания (IASEIA) США с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения.

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**GMN: Georgian Medical News** – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

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3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

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2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემაჯამებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრამების ფოტოასლები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალებების შედეგების ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფხიხლებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემაში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.



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уровни обучения. При этом качество подготовки по программам медицинского образования напрямую зависит от интернационализации медицинского образования и уровня профессорско-преподавательского состава.

#### რეზიუმე

სამედიცინო უნივერსიტეტების საგანმანათლებლო საქმიანობის რეიტინგული შეფასება, როგორც სტიმულირების ინსტრუმენტი გლობალურ რეიტინგებში შესვლისა და ჯანდაცვის სისტემის კადრის მომზადების ხარისხის გაუმჯობესებისათვის

<sup>1</sup>ე.კოიკოვი, <sup>12</sup>ა.უმბეტქანოვა, <sup>2</sup>გ.დერბისალინა, <sup>13</sup>ზ.ბაიგოვინა, <sup>12</sup>უ.ბებერგენოვა

<sup>1</sup>ჯანმრთელობის დაცვის განვითარების რესპუბლიკური ცენტრი; <sup>2</sup>არაკომერციული სააქციო საზოგადოება "სამედიცინო უნივერსიტეტი, ასტანა", ნურ-სულტანი, ყაზახეთი

ეროვნული უნივერსიტეტებისათვის გლობალურ საუნივერსიტეტო რეიტინგებთან წვდომის არარსებობა ბევრ განვითარებად ქვეყანაში, მათ შორის – ყაზახეთში აქტუალურ პრობლემას წარმოადგენს. ეს გარემოება განსაზღვრავს ეფექტური გზების ძიებას ეროვნული უნივერსიტეტების კონკურენტუნარიანობის ამაღლებისა და გლობალურ საუნივერსიტეტო რეიტინგებში მოხვედრისათვის.

კვლევის მიზანს წარმოადგენდა სამედიცინო უნი-

ვერსიტეტების საგანმანათლებლო საქმიანობის ეროვნული რეიტინგული სისტემის შემუშავება და მისი გამოყენება ჯანდაცვის ეროვნული სისტემის პირობებში. სამედიცინო უნივერსიტეტების საგანმანათლებლო საქმიანობის ეროვნული რეიტინგული შეფასების ავტორების მიერ შემუშავებული სისტემა მოიცავდა უნივერსიტეტების შეფასებას 4 ინდიკატორით (სამედიცინო საგანმანათლებლო პროგრამებით მომზადების ხარისხი, კურსდამთავრებულთა მოთხოვნადობა, სამედიცინო განათლების ინტერნაციონალიზაცია, პროფესორ-მასწავლებელთა შემადგენლობის დონე). კვლევის ფარგლებში 2018-2019 სასწავლო წელს საგანმანათლებლო საქმიანობის მიხედვით შეფასდა ყაზახეთის 12 სამედიცინო უნივერსიტეტი.

კვლევის შედეგებმა გამოავლინა ავტორების მიერ შემუშავებული საგანმანათლებლო საქმიანობის ეროვნული რეიტინგული შეფასების სისტემის, როგორც გლობალურ რეიტინგებში შესვლის ინსტრუმენტისა და ჯანდაცვის სისტემის კადრების მომზადების ხარისხის გაუმჯობესების, პრაქტიკული გამოყენების შესაძლებლობა. კორელაციური ანალიზით დადგენილია, რომ სამედიცინო საგანმანათლებლო პროგრამებით მომზადების ხარისხსზე პირდაპირაა დამოკიდებული უნივერსიტეტების კურსდამთავრებულთა შრომითი მოწყობა და მათი დაშვება განათლების შემდეგ საფეხურზე. ასევე, სამედიცინო საგანმანათლებლო პროგრამებით მომზადების ხარისხი პირდაპირაა დამოკიდებული სამედიცინო განათლების ინტერნაციონალიზაციასა და პროფესორ-მასწავლებელთა შემადგენლობის დონეზე.

## HEALTH CARE SECTOR'S FINANCIAL, CIVIL, CRIMINAL AND ADMINISTRATIVE LIABILITY IN EU MEMBER STATES AND UKRAINE: RESULTS OF COMPARATIVE RESEARCH

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The reform of the health care system in Ukraine requires, among other things, an improvement of the mechanism of liability in this sector, like that existing in the EU countries. Ukraine, having ratified the Association Agreement between Ukraine and the EU (the Agreement), has undertaken to bring its legislation in line with the EU documents in this sector. The following are the main documents adopted by the Council of Europe: 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) (1997); European Charter of Patients' Rights (2002); Convention on the Counterfeiting Medical Products and Similar Crimes involving Threats to Public Health (2011).

Everyone in Ukraine, in accordance with the Constitution of Ukraine, has the right to health care, medical care, health insurance, and the state must ensure the proper level of their provi-

sion to citizens and protect the patients' rights by the institution of liability for the violation of these rights. However, there are currently such negative factors as the provision of poor health services and medical care, mal adaptation of health care professionals, etc., in the health care system of Ukraine, as well as of some EU countries. According to WHO, medical errors in most EU countries occur in 8-12% of inpatient cases and every 10 patients is misdiagnosed (incorrect treatment) [4]. Thus, over 30,000 patients die annually in the UK; 90,000 patients are affected in Italy, respectively 13% and 23% respectively in Greece and Germany because of medical errors [11]. For comparison, 6-7 patients die every day in Ukraine, and 18-21 become disabled [16]. This is one of the reasons for the increase in the number of appeals of Ukrainian citizens to the ECHR, to the Ombudsman of Verkhovna Rada of Ukraine (2018 – 706 appeals) [23], to the court [16], to the Ministry of Health of Ukraine (2017 – 1287,

2018 – 1673 appeals) [1]. The reasons for appeals include violations of patients' rights, improper provision of medical care, other unlawful acts, which provide liability according to the Art. 80 of the Fundamentals of Ukrainian Legislation on Healthcare (Fundamentals) (1992).

It is worth noting that the institution of responsibility in the field of healthcare has recently undergone significant changes in the EU countries. Thus, prospective appeals to personal health responsibility – are often understood as encouragements to take responsibility for one's health [40].

Following the adoption of the Recommendations of the Committee of Ministers of the Council of Europe to Member States on patient safety management and prevention of adverse events in the health care sector (2006), it is recommended to use a fair rather than punitive system of incidents notice of patients' safety and their research and to encourage health care facilities, their staff for information. The Committee of Ministers of the Council of Europe also recommends to obtain information about medical errors by the example of the United Kingdom, Denmark, Ireland, through the Patient Complaint Registry System [4], since only the patient who can identify and report on feeling safe or unsafe in relation to their own definition of safety [38].

Confirmation of the correctness of this approach is the judgment of the ECHR "Birzykowski v. Poland" dated from June 27, 2006, which contains provisions for the prompt identification of errors caused by healthcare professionals and the immediate dissemination of information about this to the staff of the medical institution, in order not to avoid the repetition of negative experience in the future and to guarantee patients with the provision of better medical services [17].

The European integration processes in Ukraine, the implementation of the provisions of the Agreement are pushing for changes in this direction, in order to approximate the legal regulation of the relations in the health care sector to the standards existing in the EU countries. Therefore, establishing the system for reporting and monitoring medical errors, as well as the system for reporting patients' complaints, should be one of the priorities of the health care reform in Ukraine. The mentioned along with the improvement of the legislation of Ukraine in regard to liability in the health care sector, will certainly contribute to the creation of effective guarantees of ensuring, realization and protection of the rights of participants of legal relations in this sector, and, therefore, it is urgent and socially significant scientific search of the present day.

The aim of the article is to undertake a comparative and legal study of liability in the health care sector in the EU countries and Ukraine. Accordingly, the following objectives have been identified along with the aim: to analyze the experience of the EU countries in regulating liability in the health care sector; to offer the adoption of the norms on the system of reporting of medical errors and their monitoring in Ukraine taking into account the Council of Europe's Recommendations, the judgments of the ECHR; to determine certain ways of improving the legislation of Ukraine on financial, civil, criminal and administrative liability in this sector, using the experience of the EU Member States.

**Material and methods.** The EU legislation and the EU countries, as well as the WHO information, cases of the ECHR, Results of Ukraine's execution of the second phase of European research on compliance with the EU standards on Patients' Rights (European Research Results) (2012). Also information has been obtained from the Unified State Register of Judgments, the Office of the Prosecutor General, the Ombudsman of Verkhovna Rada, the Ministry of Health of Ukraine, decisions of the Ac-

counting Chamber are the materials for comparative and legal research on liability in the health care sector in the EU countries and Ukraine.

A complex of theoretical (systematization method, comparative and legal method) and empirical (analysis and generalization of statistical data) methods were used to solve the objectives and for achieving the set aim. The systematization method was used to analyze the system of different types of liability in the health care sector; methods of analysis and generalization of statistical data – to determine the effectiveness of the application of different types of liability; comparative and legal method – to analyze the regulation of liability issues in the health care sector in the EU countries and Ukraine and to identify the ways to improve the legislation of Ukraine on this issue.

**Results and discussion.** EU health policy serves to complement national policies, and to ensure health protection in all EU policies and has aim to protect and improve the health of EU citizens, preventing human illness and diseases, pool resources and overcome shared challenges, support the modernization of health infrastructure, improve the efficiency of Europe's health systems. In addition to formulating EU-wide laws and standards for health products and services, it also provides funding for health projects across the EU [42].

According to the Prosperity Rating of 2019 among 167 countries in the world, the 20 best health care systems in terms of efficiency include 12 countries from 27 EU member countries, namely: Iceland (7th place), Denmark (8th place), Kingdom of the Netherlands (9th place), Austria (10th place), Germany (12th place), Malta (14th place), Spain (13th place), Sweden (15th place), France (16th place), Italy (17th place), Luxembourg (19th place), Ireland (20th place)[40]. Such indicators of the effectiveness of the health care system of European countries indicate that the EU countries have established sustainable national health care systems and seek to strengthen national capacity. However, along with this, some of the biggest challenges facing modern EU healthcare are drug abuse and medical interventions, patient safety and rising costs [43]. EU countries hold primary responsibility for organizing and delivering health services and medical care. Financial, civil, criminal and administrative liability is most commonly used for offenses in this sector.

Regarding financial liability, we will focus on the two most relevant types: violations related to budget financing of health care, including during public procurement, and violations for tax offenses. As is known, health financing is a key health system function. There are two main types healthcare systems in Europe. The tax-funded model (e.g. Scandinavia) is a single-payer, predominantly public, system with salary or capitation reimbursements, where patients have a choice of providers and specialty access is regulated through General Practitioners. The social insurance model (e.g. Germany, Netherlands, France) has both multiple payers and owners of provider assets with fees being levied for services, where patients have a choice of insurers and direct access to specialists. Thus, financing can be divided into several subfunctions according to the way the money flows in the health system: from households, which are the ultimate source of health revenues, through financial intermediaries, which manage budgets, to health care organizations, which provide services to patients [39].

According to Eurostat, Health in the European Union - Facts and Figures, public funding for health care in Denmark is 84% of total funding, Sweden – 83,7%, Iceland – 81,5%, Italy – 73,7%, Ireland – 72,9%, Spain - 66%, Portugal - 65%, Malta – 63,3%, Finland – 61,6%, Austria – 29,7%, Belgium – 21,2%, Germany

- 6,3%, France – 5,3% [28]. Thus, health care systems in most EU countries are funded through government schemes, which require effective control over the efficiency of public funds.

There are budgetary control agencies in the EU countries, such as the Accounting Chamber in Ukraine, which are responsible for conducting efficient audit and other control measures, including in the field, is being analyzed. It is related to the fact that all health systems face budget constraints to a greater or lesser degree, making rationing a necessity. Rationing is more likely to have negative consequences for health system performance if it is implicit rather than explicit [29]. Analysis of the activities of these agencies in the EU countries has demonstrated that the main idea of efficient audit is to create effective control over the effective use of budgetary funds and it should be carried out either by an independent agency (Poland, Hungary, Germany) or an agency empowered with judicial power (Germany) or included in the judicial system (France) [5]. This affects the high efficiency of budgetary control in these countries in detecting violations of budgetary legislation.

For comparison, the Accounting Chamber in Ukraine also conducts efficient audit, in particular in 2019, on the use of subsidies from the State budget to local budgets for reimbursement of medicinal products for the treatment of certain diseases (April 23, 2019, No. 10-1), for implementation of measures aimed at developing the health care system in rural areas (November 12, 2019, No. 32-1). The published Audit Results reported the facts on the use of subsidy funds (UAH 154.7 million and UAH 134.8 million respectively) in violation of the law [15]. The Accounting Chamber also conducted audits on public procurement in the health care sector and found a significant number of violations [6]. As a result, the Accounting Chamber in accordance with its powers, informed the Verkhovna Rada of Ukraine, law enforcement and other agencies about detected violations. Usually, the consequences of taking them into account are negligible, since only one indictment was pronounced for the period of its existence [15].

Everything indicated above testifies to the ineffectiveness of the activity of the Accounting Chamber, and, consequently, to the need (in the light of the experience of France, Germany, Italy, Poland) to amend the Budget Code of Ukraine (BC of Ukraine), the Law of Ukraine “On the Accounting Chamber”, which should strengthen the status of its independence, safeguards impartiality in control, extend the powers to conduct audit of local budget funds, strengthen accountability for impeding auditors’ work during the audit. It is also advisable to make the auditor responsible for detecting violations of budget law by initiating the prosecution of the perpetrators, execute the minutes, prepare the report for applying financial sanctions to budgetary institution.

With regard to financial liability for tax offenses in the health care sector, the democratic and preventive European approach (compared to the Western one) deserves, first and foremost, to be studied and borrowed. The result of this approach, aimed at harmonizing the relationship between taxpayers and tax authorities, is the increase of conscientious taxpayers (80% of such taxpayers in Sweden) and the minimum number of tax evasion. To this end, they also apply the following: in the UK – the signing by the taxpayer of tax control claim; in Belgium – assistance of tax authorities in determining the list of taxpayer’s taxes; in the Netherlands, Belgium – simple and accessible forms of tax reporting (1 page of VAT declaration); in the UK, the Czech Republic – income tax report is submitted once a year. Besides, transparency and simplicity provide a single tax bill (Belgium, United Kingdom, Denmark, Sweden) [10].

The situation in Ukraine is somewhat different. Thus, the single tax bill will only be introduced from January 1, 2021. Due to imperfect provisions of the Tax Code of Ukraine (TC of Ukraine), in particular in regard to reporting, the taxpayers often evade taxes or do not pay them in full. Therefore, the experience of the EU countries discussed above is valuable for improving the tax mechanism in Ukraine.

With regard to the size of the sanctions, it depends on the existence of the intention and can be fixed (Great Britain, Germany, Switzerland) or as a percentage of the reduced (unpaid) tax (maximum 80% (France), 240% (Italy)). In contrast to Ukraine, a fine for ignoring tax requests (500-600 euros for each request) is applied in Italy.

At the same time, according to the experience of these countries, there are quite often cases of using duplicative fine along with a fine (Germany), a higher tax rate (Austria, Denmark, Finland). There is a public disclosure of the fact of a tax offense in an officially printed publication (France) [10]. These provisions may be useful in improving the Tax Code of Ukraine and adopting norms on the differentiated amount of the fine, depending on the form of tax evasion of the taxpayer, the definition of the term of “evasion on paying compulsory payments”, comparing it with “concealment” and “under declaration” of incomes (earnings).

Another reason for tax evasion is the imperfect mechanism of tax exemptions from the personal income tax, the value added tax in the legislation of Ukraine. For this reason, it is possible to borrow from the experience of Germany, where taxpayers are provided with benefits for income tax payers who care about health, family, and the payer is assigned a more favorable category [5].

In regard to the value added tax benefits for healthcare services, then the issues of their effectiveness and validity have been the subject matter of an appropriate audit by the Accounting Chamber (March 19, 2019, No. 6-5) [15]. The audit revealed the facts of conducting medical practice activity without proper state registration and accounting in tax authorities, not reporting to them on the received tax benefits of certain medical facilities-taxpayers. One of the reasons for these violations is the poor standards of supervision in the health care sector and tax control. There are also cases of improper charging of value added tax and penalties to medical facilities during the inspections conducted by the agencies of the State Tax Service of Ukraine (STS of Ukraine). Therefore, it is advisable to revise the norms on the personal responsibility of officials and public servants of the Ministry of Health of Ukraine, STS of Ukraine for improper supervision and control, for wrongful decisions in the direction of its strengthening. We believe that the adoption of these and other norms in the legislation of Ukraine will reduce the number of violations of the budget and tax legislation by participants of legal relations in the health care sector.

The experience of the EU countries demonstrates the existence of three models of legal regulation of civil and criminal liability in the health care sector. The first one is applied in the United Kingdom and provides civil settlement of disputes as a result of harming the life and health of the patient while performing professional duties, including as a result of medical negligence. And criminal liability of medical professionals for improper performance of professional duties is most likely applied as an exception [22].

The essence of the second model, which is used by almost all post-Soviet states, is the use of criminal law measures. Instead, the third model used by most EU countries, in particular Italy, Germany, is a combination of civil and criminal measures [22]. Let’s consider the peculiarities of their application in the EU countries and in Ukraine.

Where criminal law and medicine intersect, complexity arises [25]. Healthcare in Europe is one of the areas particularly vulnerable to corruption. Today, corruption in the health sector occurs in all EU Member States and that both the nature and the prevalence of corruption typologies differ across the Member States. The most common crimes related to corruption in the health sector include: bribery in medical service delivery; procurement corruption; improper marketing relations; misuse of (high) level positions; undue reimbursement claims; fraud and embezzlement of medicines and medical devices. Bribery in medical service delivery occurs most frequently, and is considered systemic, in (former) transition economies of Central and Eastern Europe, in Western European countries bribery in medical service delivery is rarer and restricted to specific areas such as isolated cases in pre- and post-surgery treatment. So for instance, Czech Republic, Latvia, Croatia, Slovakia, Romania, Italy, Bulgaria and Greece are considered having a widespread corruption problem and seem to encounter more bribery in medical service delivery, procurement corruption and misuse of (high) level positions. Healthcare procurement corruption seems to occur less frequently in countries where public procurement is highly regulated [27].

Also, counterfeit pharmaceuticals pose a growing threat to the EU, affecting a large number of Member States. Organized crime groups might produce counterfeit pharmaceuticals in clandestine laboratories, import counterfeit medicines or sell illegally diverted medicines using falsified branding and packaging [30]. The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health is the first international criminal law instrument to oblige States Parties to criminalize: the manufacturing of counterfeit medical products; supplying, offering to supply and trafficking in counterfeit medical products; the falsification of documents; the unauthorized manufacturing or supplying of medicinal products and the placing on the market of medical devices which do not comply with conformity requirements [26]. However, this convention has been ratified by only a few EU countries, including Belgium, Croatia, France, Hungary, Spain.

Medical errors are a serious public health problem in EU countries. It is a difficult problem as it is challenging to uncover a consistent cause of errors and, even if found, to provide a consistent viable solution that minimizes the chances of a recurrent event. For example, error of omission as a result of action not taken or error occur as a result of wrong action taken [36]. European data, mostly from European Union Member States, consistently show that medical errors and health-care related adverse events occur in 8% to 12% of hospitalizations. While 23% of European Union citizens claim to have been directly affected by medical error, 18% claim to have experienced a serious medical error in a hospital and 11% to have been prescribed wrong medication. Evidence on medical errors shows that 50% to 70,2% of such harm can be prevented through comprehensive systematic approaches to patient safety [44].

Medical errors (including fatal errors) are an inevitable feature of the delivery of health care [34]. The fact that human error may have tragic consequences does not (of itself) mean that the errors were therefore a crime, but it does justify every effort to reduce recurrence of those errors. This depends, amongst other things, on a culture of open reporting and active engagement in the continuous improvement of patient safety [33].

State public health law, criminal law, and tort law play discrete and specific roles in upholding public health goals, providing incentives, and establishing consequences [35]. Laws do

not address preventable harms and adverse events uniformly. In general terms tort law is organized around corrective justice, distributive justice and prevention or deterrence [32].

The focus in civil liability analysis will be on protecting patients' rights to compensation for caused harm. It should be noted that the mechanism for the application of civil liability in the EU countries is based on the Articles 13 and 14 of the European Charter of Patients' Rights (2002) on their right to appeal against unlawful decisions and actions of healthcare professionals and the guaranteed right to adequate compensation (if possible in the short term) of moral and psychological harm as a result of medical treatment, regardless of the severity of the harm and its causes – even in cases where it is not possible to determine precisely those responsible persons.

According to the legislation of Ukraine the guilty person can be brought to civil liability, and the injured patient or his family members (in case of the patient's death) have the right to file a civil action for the compensation of material and moral harm caused by improper medical care.

The results of European studies have also demonstrated a very low level of the realization of the patients' right to compensation for harm in Ukraine. At the same time, they have demonstrated the high and medium level of the opportunity of EU citizens to implement these rights that corresponds to the state of both the health care system and the legal enforcement system in these countries [20]. Therefore, it is advisable to bring the legislation of Ukraine on patients' rights, including the right to compensation for harm, into conformity with the European Charter of Patients' Rights. To accomplish this, it is necessary to consolidate the concept of "medical error", distinguishing between admissible (innocent) and inadmissible (guilty) medical errors and to adopt the norm on civil liability of medical employees for medical errors [12].

With regard to the regulation of these issues by Italian law, there is civil liability for medical malpractice, which causes harm to the patient's health. There is criminal liability (as well as in German law) for causing harm to patient's health by medical employees as a result of negligence. It is worth noting that about 3000 criminal proceedings are initiated in Germany every year [22].

For comparison, Section II "Crimes against Person's life and health" of the Criminal Code of Ukraine (CC of Ukraine) (2001) covers the Articles 130-145. According to the data of the "Unified Report on Criminal Offenses over the State for December 2019", the Office of the Prosecutor General for 2019 there were 669 criminal offenses under the Art. 140 "Improper performance of professional duties by medical or pharmaceutical practitioners" and only one case was sent to the court with an indictment. The data in regard to other Articles in this Section is the following: 13 and 3 (the Art. 130); 221 and 125 (the Art. 135); 28 and 1 (the Art. 136); 58 and 4 (the Art. 137). It should be noted that according to the Articles 131-134, 138-139, 141-145 of the Criminal Code of Ukraine there were respectively reported 2, 3, 0, 3, 8, 55, 1, 0, 2, 1, 10 criminal offenses, but no case was sent to the court with an indictment [7]. In addition, an analysis of judicial practice in recent years shows that 4 persons were prosecuted for improper performance of professional duties by a medical or pharmaceutical worker in 2017 and 2 in 2018 [18].

Regarding to the adoption of the Law of Ukraine "On Amendments to Some Legislative Acts of Ukraine on Simplifying Pre-Trial Investigation of Certain Categories of Criminal Offenses" (2018) and introduction of the Institution of Criminal Offenses in view to improve it, the provisions of the Act of the Republic

of Poland “On Liability of Collective Formations for Prohibited Punitive Actions”, the Penal Code of the Republic of Estonia on criminal influence on legal entities in the form of quasi-criminal liability [24, p. 50] constitute the interest.

However, scholars consider optimization of the institution of administrative liability of medical employees as one of the priority directions for improving national legislation in the sphere of ensuring the rights of patients [9]. It is also due to the results of European studies, according to which patients’ rights to respect for private life and privacy are not adequately secured in Ukraine, and one of the least secured is the patient’s right to qualitative medical care (the right to quality standards) [20]. Besides, the quality control over medical care with the participation of the public and patients’ organizations is not conducted in Ukraine, there are no sanctions for the violation of unified medical standards (clinical protocols) [20], part of physicians are not familiar with those standards (do not apply). But instead, the procedures applied hitherto are also susceptible to fraud and corruption – treatment of certain diseases with expensive and inadequate medicines results not so much from the actual health needs, but more from informal arrangements that give financial benefits to specific persons» [37]. That is why healthcare is one of the most corrupt sectors in the country [31]. The experience of Spain, Italy, Finland, Sweden and most of the Central and Eastern European countries on total quality management of health care sector may be useful [21].

An urgent issue is the provision of certain types of medical care to patients without their informed consent to intervene in the violation of the Convention on Human Rights and Biomedicine. According to the conducted research, physicians informed only 15.7% of patients among orderly hospitalized about the nature of the intended study and only 1.4% of patients consented to informed intervention, 62.8% of patients did not receive information about the essence of research methods, and 92.6 % did not give their consent at all [3].

Therefore, we support the proposition set in the Code of Ukraine on Administrative Offenses (CUAO) to provide administrative liability: for the violations of state medical standards (clinical protocols) by health employees, norms and regulations while providing medical care to a patient; for the disclosure of medical secrets by a person who has become aware of it in connection with the performance of professional (official) duties, if such an act did not cause grave consequences; for the violation of patients’ rights, conditions and procedure for providing him or her medical care: for conducting clinical trials of medicinal products without the written consent of the patient (his legal representative) or related to a minor (incapacitated), if these actions did not lead to the death of the patient or caused other serious consequences [9].

The structure of the Code on Administrative Offenses of the Republic of Latvia, which contains a separate Article on administrative liability of a legal entity, and propositions of O. S. Dotzenko, S. V. Knysh to consolidate the corpus delicti of administrative offenses in the health care sector (public health) within one Section (chapter) of the Code of Ukraine on Administrative Offenses under the title “Administrative Medical Offenses” [8], is believed valuable for consideration for the improvement of the Code of Ukraine on Administrative Offenses.

It is also worth supporting the idea of adopting the Medical Code of Ukraine with a separate Section “Liability for the Violations of Healthcare Legislation” [19], because Medical Codes in France, Germany, Italy with the norms on liability have been already adopted [21].

Finally, let us address the currently relevant issue of responsibility in the context of measures aimed at preventing the occurrence and spread of coronavirus disease. It should be noted that Verkhovna Rada of Ukraine adopted on March 17, 2020 several laws, in particular “On Amendments to Certain Legislative Acts of Ukraine aimed at Preventing the Occurrence and Spread of Coronavirus Disease (COVID-19)”, No. 530-IX (Law No. 530-IX) [13] and the Law of Ukraine “On Amendments to the Tax Code and Other Laws of Ukraine on Supporting the Taxpayers for the Period of Conducting Measures to Prevent the Occurrence and Spread of Coronavirus Disease (COVID-19)”, No. 533-IX (Law No. 533-IX) [14].

The Law No. 533-IX amended the Tax Code of Ukraine [14]. In particular, it is provided for the period from March 1 till May 31, 2020 for violation of tax legislation during this period (except cases specified in the Law): not to apply penalties; not to charge the fine (charged, but not paid fine during this period is subject to write-off); to establish a moratorium on documentary and factual verifications; to stop the limitation period. In addition, there is no charge and no payment for land for land owned or used by individuals or legal entities and used by them for business purposes. Persons are also temporary exempted (except cases specified in the Law) from the calculation, accounting and payment of a single contribution, penalties are not applied, no fine is charged (the assessed penalty for these periods is subject to writing off) and a moratorium on documentary verifications is established from March 1 till April 30, 2020.

Under these conditions the EU countries impose mainly administrative penalties (Italy – 206 €, Slovakia – 1659 €, Austria – 2180 €, United Kingdom – 1000 £, Czech Republic, Austria - 100 000 €), and only Italian law provides imprisonment starting from 3 months [2]. It was established in Ukraine by the Law No. 530-IX in the form of a fine for citizens from 1 up to 2 thousand non-taxable minimum incomes of citizens (NTMI) and for officials – starting from 2 up to 10 thousand NTMI. The same law provides criminal liability – for the violation of rules and norms established for the prevention of epidemic and other infectious diseases, as well as mass non-communicable diseases (poisoning) and their combating, if such actions caused or knowingly could cause the spread of these diseases in the form of a fine from 1 up to 3 thousand NTMI, or imprisonment up to 3 years, or imprisonment from 5 to 8 years (if these actions resulted in the death of people) [13]. As one can see, the size of the fine is quite significant, which should assist in preventing the spread of coronavirus disease.

These norms have already entered into force in Ukraine. March 21, 2020, the court first imposed a fine on a citizen of Ukraine for violating quarantine restrictions – selling products in unspecified place. Besides, the prosecutor’s office initiated a case against a private clinic in Kyiv for not reporting to the Ministry of Health of Ukraine about a coronavirus patient in accordance with the prescribed form (to the Ministry of Health of Ukraine will withdraw licenses from medical facilities for such actions).

Therefore, further reform of the institution of liability in the health care sector of Ukraine should be aimed at: the implementation of the provisions of the Council of Europe documents in this field into the legislation; the use of the mechanisms of such liability existing in the practice of the EU Member States while amending the Budget and Tax Codes of Ukraine; the improvement of the powers of the Accounting Chamber, the State Tax Service of Ukraine, and the Ministry of Health of Ukraine to exercise control functions.

**Conclusions.** As a result of studying liability in the health care sector, it has been proved that the mechanism of such liability by the law of EU countries is defined in such a way that it is possible to comply with the legislation by almost all parties involved in the health care sector, including through the use of preventive measures. While reforming this institution in Ukraine, it is important to adopt the optimal model of its legal regulation by aligning Ukrainian legislation with EU documents. It should be also noted that it is possible to use positive experience in regulating this issue in certain EU Member States.

It has been offered to improve the mechanism of financial liability for the violation of budget legislation (to amend the Budget Code of Ukraine, the Law of Ukraine "On the Accounting Chamber"), for tax offenses (to amend the Tax Code of Ukraine), taking into account the norms of the EU legislation on the amount of the fine (United Kingdom, Italy, France, Germany, Switzerland); repeated fine (Germany); the use of an increased tax rate (Austria, Denmark, Finland); public disclosure of a tax offense (France).

Analysis of the law of the EU countries has led to a conclusion on the need for improvement and norms on the application of other types of liability in the health care sector, using the experience of these countries: on civil and criminal liability for malpractice (Italy); criminal liability of medical professionals for the harm to the health of patients while providing medical care, including negligence (Germany); on the liability of legal entities (Latvia); on the regulation of liability issues in Medical Codes (France, Germany, Italy). It is also advisable to introduce in Ukraine the total quality management of the health care sector by the example of Spain, Italy, Finland, Sweden.

Therefore, finding an effective model of legal regulation of liability in the health care sector and bringing it closer to the EU standards is an urgent task. The provisions formulated in the article may serve as separate directions for research in regard to the liability in the health care sector.

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## SUMMARY

### HEALTH CARE SECTOR'S FINANCIAL, CIVIL, CRIMINAL AND ADMINISTRATIVE LIABILITY IN EU MEMBER STATES AND UKRAINE: RESULTS OF COMPARATIVE RESEARCH

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The aim is a comparative and legal study of liability in the health care sector in the EU countries and Ukraine. Materials of the research are the EU legislation, laws of the EU countries, Ukraine, statistical information. The authors of the study have used the systematization method, comparative and legal method, analysis and generalization of statistical data.

Ensuring an adequate level of health care, providing affordable health care service and medical care to citizens is one of the main tasks of any country, including Ukraine. It is the reason why the state controls this sector through the institution of liability, which does not fully meet the standards of the present day existing in the EU Member States, and therefore needs to be improved.

The authors of the article have summarized the experience of the EU countries and Ukraine in regard to liability in the health care sector and have determined some ways to improve Ukrainian legislation. The authors have established the necessity to borrow the experience of certain EU countries in regulating financial (France, Germany, Italy, Poland), civil (Italy), criminal (Germany), administrative liability (Latvia) in the health care sector.

**Keywords:** health care, medical error, financial liability, civil liability, criminal liability, administrative liability.

## РЕЗЮМЕ

### ФИНАНСОВАЯ, ГРАЖДАНСКАЯ, УГОЛОВНАЯ И АДМИНИСТРАТИВНАЯ ОТВЕТСТВЕННОСТЬ В СФЕРЕ ЗДРАВООХРАНЕНИЯ В СТРАНАХ-ЧЛЕНАХ ЕС И УКРАИНЫ: РЕЗУЛЬТАТЫ СРАВНИТЕЛЬНЫХ ИССЛЕДОВАНИЙ

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Целью статьи является сравнительно-правовое исследование ответственности в сфере здравоохранения в стра-

нах ЕС и Украины. Материалом исследования являлись законодательство ЕС, стран ЕС, Украины, статистическая информация. В процессе исследования применен метод систематизации, сравнительно-правовой метод, анализ и обобщение статистических данных.

Сделан вывод, что обеспечение надлежащего уровня здравоохранения, предоставление доступного медицинского обслуживания и медицинской помощи гражданам является одной из основных задач любого государства, в том числе и Украины. Поэтому государство осуществляет контроль этой сферы через институт ответственности,

который по сей день не полностью отвечает стандартам стран-членов ЕС, а, следовательно, нуждается в усовершенствовании.

В статье обобщен опыт стран ЕС и Украины относительно ответственности в сфере здравоохранения и определены отдельные пути совершенствования законодательства Украины. Установлена необходимость заимствования опыта отдельных стран ЕС по регулированию финансовой (Франция, ФРГ, Италия, Польша), гражданской (Италия), уголовной (ФРГ), административной ответственности (Латвия) в сфере здравоохранения.

### რეზიუმე

საფინანსო, სამოქალაქო, სისხლის სამართლის და ადმინისტრაციული პასუხისმგებლობა  
ჯანმრთელობის დაცვის სფეროში ევროკავშირის წევრ ქვეყნებსა და უკრაინაში:  
შედარებითი კვლევის შედეგები

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<sup>1</sup>ტერნოპილის ეროვნული ეკონომიკური უნივერსიტეტი; <sup>2</sup>კიევის ვადიმ გეტმანის სახ. ეროვნული ეკონომიკური უნივერსიტეტი; <sup>3</sup>იაროსლავ მუდრის სახ. ეროვნული იურიდიული უნივერსიტეტი, ხარკოვი, უკრაინა

კვლევის მიზანს წარმოადგენდა ჯანმრთელობის დაცვის სფეროში პასუხისმგებლობის კვლევა ევროკავშირის ქვეყნებსა და უკრაინაში. კვლევის მასალას წარმოადგენდა ევროკავშირის, ევროკავშირის ქვეყნების და უკრაინის კანონმდებლობა, სტატისტიკური ინფორმაცია. კვლევისას გამოყენებულია სისტემატიზაციის და შედარებით-სამართლებრივი მეთოდები, ანალიზი და სტატისტიკური მონაცემების განზოგადება.

ავტორები დაასკვნიათ, რომ ჯანმრთელობის დაცვის სათანადო დონის უზრუნველყოფა, მოქალაქეებისათვის ხელმისაწვდომი სამედიცინო მომსახურების და სამედიცინო დახმარების შეთავაზება ნებისმიერი სახელმწიფოს, მათ შორის – უკრაინის, ერთ-ერთ ძირითად ამოცანას წარმოადგენს. ამიტომ სახელმწიფო ამ სფეროს კონტროლს ახორციელებს პასუხისმგე-

ბლობის ინსტიტუტის გზით, რომელიც დღეს სათანადოდ ვერ შეესაბამება ევროკავშირის ქვეყნებში არსებულ სტანდარტებს და, ამდენად, სრულყოფას მოითხოვს.

სტატიაში განზოგადებულია ევროკავშირის ქვეყნების და უკრაინის გამოცდილება პასუხისმგებლობის მიმართებით ჯანმრთელობის დაცვის სფეროში და განსაზღვრულია უკრაინის კანონმდებლობის დახვეწის ცალკეული გზები. დადგენილია ევროკავშირის ცალკეული ქვეყნების გამოცდილების გაზიარება ჯანმრთელობის დაცვის სფეროში საფინანსო (საფრანგეთი, გერმანიის ფედერაციული რესპუბლიკა, იტალია, პოლონეთი), სამოქალაქო (იტალია), სისხლის სამართლის (გერმანიის ფედერაციული რესპუბლიკა) და ადმინისტრაციული (ლატვია) პასუხისმგებლობის საკითხებში.

## ВРАЧЕБНАЯ ЭКСПЕРТИЗА КАК МЕТОД ОЦЕНКИ КАЧЕСТВА МЕДИЦИНСКОГО ОБЕСПЕЧЕНИЯ СОТРУДНИКОВ ПОЛИЦИИ РЕСПУБЛИКИ АРМЕНИЯ

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Анализ данных литературы показывает, что вопросы управления качеством медицинской помощи изучали многие ученые и врачи-организаторы здравоохранения. В течение длительного периода они пытались повысить качество медицинской помощи экстенсивными методами за счет увеличения числа медицинского персонала и емкости медицинских учреждений [8,12].

Некоторые исследователи считают, что управление качеством медицинской помощи возможно осуществить сово-

купностью мер организационного, экономического, правового, научного и медицинского характера, направленных на обеспечение адекватного выполнения медицинских технологий, снижение риска ухудшения состояния пациентов и устранение неблагоприятного социального прогноза вследствие оказанной медицинской помощи, на оптимизацию расходов ресурсов медицинских учреждений [11]. Российские ученые предполагают, что для успешного развития медицины высоких технологий необходимо не только