UDC: 343.625:343.85:614.253.83]:614.256

Legal consequences, measures of prevention and reduction of medical malpractice cases (errors)

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Key words: medical errors, health care, legal liability.

Pathologia 2019; 16 (1), 124–130

DOI: 10.14739/2310-1237.2019.1.166616

This work is purposed for determining grounds for legal consequences to come when any medical malpractice cases occur.

Aim. The goal of our research is to determine the quintessence features of "medical malpractice (error)" in the medical-legal context so to determine legal consequences of medical malpractices (errors), and to classify the regulatory measures of prevention of medical malpractice cases and reduction of these problems.

Methods: Semiotical, synergetic, anthropological and hermeneutical, method of normative comparison.

Results. Detecting the current medical malpractice (medical error) becomes more complicated due to its definition as highly significant differences in interpreting, understanding, qualifying, finding defects, medical errors and provability of these failures result in the complication of producing efficient legal guarantees for protection of the patient`s right. The peculiarity of this medical and legal substrate is that it synthesizes the awareness of rights and medicine both through the lens of their achievements. A clear vision of such a phenomenon as medical malpractice (error) has a priori significance for the legal environment. It is a sparkling example of the epistemological and gnoseological interaction of the medical and legal knowledge as to determine criteria of medical malpractices is to set "boundaries" of the legal regulation. Here we mean the occurrence of legal consequences in committing an error of law.

Conclusions. For a more complete understanding of cases of legal consequences the following regulatory measures of prevention of medical malpractice cases are necessary: establishment of an effective system of prudential internal control of defects in the medical care; specialised training for medical personnel on methods of detection of medical malpractices, their prediction and prompt elimination of possible consequences; instrumental, functional and system-structural measures for reducing risks of medical malpractice, namely: actions for reducing medical errors caused by system determinants (failures, disorders, etc.), actions for reducing medical errors made in prescribing and applying medicaments, medical errors happened because of the medical intervention, surgical in particular; improvement of the legal support of guarantees of patients and doctors rights for a safe delivery of medical aid and prevention of medical errors.

Ключові слова: лікарська помилка, медична допомога, цивільно-правова відповідальність.

Патологія. – 2019. – Т. 16, № 1(45). – С. 124–130

Правові наслідки, засоби превенції та редукування лікарських помилок

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Робота присвячена визначенню підстав для настання правових наслідків при здійсненні лікарської помилки.

Мета роботи – встановлення основних ознак «лікарської помилки» в медико-правовому аспекті, а також класифікація організаційно-правових заходів превенції лікарських помилок і редукування цих проблем.

Методи. Комплексно-критичний, семіотичний, синергетичний, антропологічний, герменевтичний, порівняльно-правовий і метод нормативного порівняння.

Результати. Визначення наявності лікарської помилки ускладнюється її поняттєво-термінологічною константою. Адже принципові відмінності в інтерпретації, розумінні, кваліфікації, встановленні дефектів, лікарських помилок і доведенні цих помилок призводить до ускладнення вироблення ефективних правових гарантій захисту прав і пацієнтів, і лікарів. Особливість цього медико-правового субстрату – він синтезує в собі знання як про право, так і про медицину через призму їх досягнень. Чітке уявлення про таке явище, як лікарська помилка має апріорне значення для правового поля. Це яскравий приклад гносеологічної та епістемологічної взаємодії медичних і правових знань. Адже визначення критеріїв медичної помилки є визначенням «меж» правового регулювання, тобто настання правових наслідків при здійсненні правової помилки.

Висновки. Для превенції та правильного кваліфікування правових наслідків лікарських помилок необхідні організаційно-правові заходи: удосконалення системи пруденційного внутрішнього контролю дефектів медичної допомоги; спеціалізована підготовка медперсоналу за технологією виявлення лікарських помилок, їх прогнозування та оперативного усунення можливих наслідків; заходи інструментальної, функціональної та системно-структурної спрямованості зі зниження ризиків скоєння лікарських помилок, а також їх редукування; удосконалення правового забезпечення гарантій прав пацієнтів і лікаря на безпечне й ефективне надання медичної допомоги.

Правовые последствия, средства превенции и редуцирования врачебных ошибок

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Работа посвящена определению оснований для наступления правовых последствий при совершении врачебной ошибки.

Цель работы – определение основных признаков «врачебной ошибки» в медико-правовом срезе, а также классификация организационно-правовых мер превенции врачебных ошибок и редуцирования этих проблем.

Методы. Комплексно-критический, семиотический, синергетический, антропологический и герменевтический, сравнительно-правовой, метод нормативного сравнения.

Результаты. Определение наличия допущенной врачебной ошибки усложняется ее понятийно-терминологической константой. Принципиально существенные отличия в интерпретации, понимании, квалификации, установлении дефектов, врачебных ошибок и доказуемости этих ошибок усложняет выработку эффективных правовых гарантий защиты прав и пациентов, и врачей. Особенность этого медико-правового субстрата – он синтезирует в себе знание как о праве, так и о медицине через призму их достижений. Четкое представление о таком явлении, как врачебная ошибка имеет априорное значение для правового поля. Это яркий пример гносеологического и эпистемологического взаимодействия медицинских и правовых знаний. Определение критериев медицинской ошибки является определением «границ» правового регулирования, т. е. наступлением правовых последствий при совершении правовой ошибки.

Выводы. Для превенции и правильной квалификации правовых последствий врачебных ошибок необходимы организационно-правовые меры: усовершенствование системы пруденциального внутреннего контроля дефектов медицинской помощи; специализированная подготовка медперсонала по технологии выявления врачебных ошибок, их прогнозирования и оперативного устранения возможных последствий; меры инструментальной, функциональной и системно-структурной направленности по снижению рисков совершения врачебных ошибок и по редуцированию врачебных ошибок; усовершенствование правового обеспечения гарантий прав пациентов и врача на безопасное и эффективное оказание медицинской помощи.

Ключевые слова: врачебная ошибка, медицинская помощь, гражданско-правовая ответственность.

Патология. – 2019. – Т. 16, № 1(45). – С. 124–130

Today, we have a common opinion among the representatives of the legal and medical communities as regards the determination and significance of medical malpractices (errors); there is also no official statistics of legal offences in the field of medical aid, because of which patients had their health harmed.

Presently, it is common when the mass media publicizes practical cases that are often based on the preliminary data received from the law enforcement agencies. At the legal level, there is no defined notion and signs of "medical malpractice cases (medical errors)", and a clear definition of this term is absent in the medical literature, too. "Medical malpractice (error)" is an unintended misconception of doctors (or any other healthcare practitioners) in the course of their professional activities if negligence and unfairness are excluded herewith.

In compliance with Article 12 of the International Covenant on Economic, Social and Cultural Rights, every man has a right for getting the medical aid and care in case of his illness. It is an inalienable human right reflected in Part One of Article 49 of the Constitution of Ukraine, which accentuates, that everyone has a right for his health protection, medical aid and medical insurance.

In the medical reform environment in our country the medical care problems come to the boil today. The number of so-called "defects in the medical care", which is just partially reflected by the number of judicial proceedings, actualizes this problem even more and determines the importance of scientific understanding of the meaning, nature, types and peculiarities of this complex term. The type of "defects in the medical care", which is the most difficult to identify, is another medical-legal notion – "medical malpractice". Therefore, the most complicated problem in the medical law theory is a legal qualification of medical care defects.

The problem of "defects in the medical care" is closely related to the peculiarities of the liability incurrence in the healthcare sphere as a question about liability may arise according to the results of determining consequences of the medical care delivery. Cases from the medical practice, which have an unfavourable outcome, are subject to the evaluation concerning the determination of a type of defects, every of which causes various legal consequences. Regulatory voids, law enforcement collisions in the judicial practice tellingly show the problems and necessity to apply the complex approach in their resolution.

The complexity of the legal regulation of this problem also lies in the fact that far from every patient seeks protection of his/her rights when an inadequate medical aid is delivered. People consider it related to the poor legal culture of medical activities. In Ukraine, the percentage of winning cases on litigations with doctors is extremely low. The public protection of doctors may also be a cause of it. This protection consists in the official recognition of "abdication of liability". It is related to the fact the labour legislation is on side of their protection, and abdication of liability should be just excluded with the opportunity to appeal to a court. If a person doubts the quality of services, he/she may decline them in advance. For getting a legally correct distinction of legal offences from "allowable professional errors in the medical activities", first, it is necessary to determine the notion "medical malpractice (medical error)" in the medical law.

The topic selected for our research is scientifically relevant and is an object of investigation for the national and foreign representatives of the medical and legal science, among which are S. Antonov, V. Viter, I. Davydovskyi, T. Zavarza, I. Ogarkov, R. Maidannyk, Ya. Radysh, A. Savytska, I. Seniuta, Yu. Sizyntsova, S. Stetsenko, R. Titikalo and many others. The scientific publications show this problem fragmentally: the concept and types of medical malpractices (errors) are revealed at most, but legal consequences, measures of prevention and reduction of medical malpractice cases (errors) requiring a thorough investigation and further regulation stay almost uninvestigated.

The goal

The goal of our research is to determine the quintessence features of "medical malpractice (error)" in the medical-legal context so to determine legal consequences of medical malpractices (errors), and to classify the regulatory measures of prevention of medical malpractice cases and reduction of these problems.

Materials and methods

While studying the notion of medical malpractice (medical error), the authors based on the fundamental of the complex critical method of existing viewpoints on the medical malpractice nature.

The authors used some methodological approaches, such as semiotical, synergetic, anthropological and hermeneutical approaches. There are some examples from the court practice given in the work, and it makes it possible for us to show not just a theoretical, but a practical aspect of this problem as well.

Results

The main problem of defining the notion "medical malpractice (medical error)" consists in that there is no clear definition in the legislation of Ukraine, so the focus is made on the doctrine of medical law.

A. A. Ponkina [1] shows the quintessence of medical malpractices (medical errors) and their qualifying and deontological features in the following approaches: 1) Approach based on the understanding and interpretation of medical errors as innocent fair actions of doctors (I. V. Davydovskyi; O. Yu. Aleksandrova, N. F. Gerasymenko, Yu. I. Grygoriev and I. K. Grygoriev; I. F. Ogarkov; S. G. Stetsenko; S. S. Shevchuk; I. Ya. Seniuta; O. Zairatiants, L. Kakturskyi, A. Vertkin and E. Vovk; P. V. Mazyn and V. P. Mazyn; many foreign authors); 2) Approach based on the dual understanding of medical malpractices – it is asserted that such errors may be both "legitimate and innocent" and illegitimate (A. S. Mnatsakanian; M. N. Maleina; V. T. Palchun and others); 3) Approach based on the understanding and interpretation of medical errors as torts, as wrongdoing (Ya. Leibovych; R. K. Rigelman; A. V. Kudakov; A. V. Tykhomirov and others). We should agree with A. A. Ponkina that such essential differences in interpreting, understanding, qualifying, detecting medical defects and provability of these defects result in the complicated elaboration of legal guarantees for protecting the patient`s rights.

By analysing the available approaches to interpreting the legal-semantic understanding of "medical malpractices (medical errors)" through the lens of "weaknesses" and "strengths" of every approach, it should be pointed out that "medical malpractice (error)" is an occurred or eventual situation came or may come as a result of negligence or late actions of a doctor, medical personnel, when he/they shall deliver medical aid to a patient or provide him with medical services, which subsequently cause events unfavourable for a patient (health damages, death, etc.), but are characterised as innocent actions.

The medical error specifics is the doctor's inability to anticipate and subsequently predict coming consequences of a delivered medical aid and/or provided medical service (only medical service must be considered as an element of the medical care structure). When excluding negligence, carelessness, unfairness, a doctor's error is considered as a unintentional harming a patient and/or a present random factor, which was difficult to foresee, but it results in the coming adverse consequences.

Medical error is "a child" of medical law. This area of law is specific as it synthesises the medical and legal knowledge. Therefore, the approach to understanding the nature of medical malpractices (medical errors) has a dual role: legal and medical. Medically speaking, a human body has not been entirely studied by the medicine yet, and it is not possible due to appearing new diseases, modification of viruses, etc., so a medical worker is not able to foresee and predict a 100 % treatment outcome as every human body is unique. As a result, a medical malpractice (error) is an outcome of the concurrence of circumstances or imperfection of the medicine and technologies, but not of a doctor`s negligent, irresponsible attitude to his/her duties. That means that this error is not caused by a medical worker, and there is no offence against the laws, so legal consequences do not come.

Legal practitioners do not agree with the aforementioned approach. Most of them take a cold accusatory stance. However, there is no single viewpoint as regards the qualification of medical errors among legal practitioners though. In some cases, a medical malpractice case (medical error) is deemed just as a guilty action of a medical worker that caused a patient`s health damage, and as an accidental caused damage in other cases. Sometimes, this error is considered as a circumstance that can slacken a doctor`s responsibility. Thus, here is a thesis of supporters of "the legal aspects": medical errors are careless, unfair, negligent actions and maneuvers in delivering medical aid (services), an outcome of which is an injury or death of a patient. It means that medical malpractice cases (medical errors) always invoke civil liability. But from this perspective, in our opinion, a doctor`s role is impinged in the convergent process "doctor ↔ patient".

Causes of medical malpractice cases (medical errors) may be subjective (depending on professional skills and knowledge of a doctor) and objective (depending on reformulated "insights" of the medical science in treatment methods of diseases and so forth). Subsequently, they arise out of "the medical science imperfection". From the viewpoint of the synergetic paradigm, defects and improvements present a path of perfection.

The law of Sweden states that "physical harm" means sufferings, injuries or moral harm, and diseases and death similarly, according to the current Law, which might be averted, or appropriate measures might be taken in the patient`s contacting with the healthcare system. Grievous bodily harm to a patient means that consequences caused by this are constant and cannot be eliminated, or it caused a significant increase of a patient`s needs for a continuing medical care, or if a patient died [2]. We should remember that the kind of professional responsibility is legal liability for causing harm to the patient`s health.

Legal liability is highly specific. First, legal liability depends on the case circumstances; second, it depends on the fact existence and degree of harm to the patient`s health, which are identified by taking into account causal connections, actions or inactions of a doctor and medical personnel, what becomes more complicated due to the determination of these connections (for instance, a patient did not follow all recommendations, or a doctor did not exercise a patient`s right for the voluntary informed consent to the full extent); third, "adequacy" of a situation, relevance, justifiability and promptitude of actions of a doctor, medical personnel or a patient himself should be

considered; fourth, a decision on applying legal liability is made by a court on grounds of circumstances of a case, which are reviewed on merits.

The judicial practice in Ukraine contains examples when medical workers are made liable for deeds done that are qualified as "medical malpractices (errors)". For example, the Court of Appeal of Dnipro Region, having heard a civil case, in an open session, on the appeal on the claim by PARTY_2 third parties: PARTY_3, PARTY_4 about the compensation of pecuniary and non-pecuniary damages, passed a judgment and left the decision of the first instance unchanged; the claim of PARTY_2 was sustained partially – a compensation in an amount of 10.000 UAH was paid by the defendant in her favour; 8 UAH 50 Kop. – expenses for paying the state duty; 30 UAH – costs for the IT support of the case hearing; 150 UAH – services of the lawyer. As indicated in the judgment, "the Chamber deems that the first instance court justifiably noted that the chest X-ray reading was made unprofessionally, a medical malpractice case (medical error) happened to be, which occurred because of an undiagnosed present mass in the mediastinum, which was caused by the emotional distress overcome by the plaintiff; but it was mistakenly based on the circumstances happened to be in 2002, to which the court applied the provisions of Article 1172 of the Civil Code of Ukraine" [3].

Attention should be paid to the semiotic difference between the concepts of "*medical error*" and "*defect of medical care*". These concepts are not identical. To tell the difference between the said concepts, semiotic interpretation of the word should be addressed first: a *defect* is a deficiency, shortcoming or flaw, while an *error* is an unintentional deviation from correct actions through forgetfulness, wrongness of behaviour, thoughts or acts. As a result, when implementing these concepts in the medical plane one can conclude that a *defect* of medical care means a failure or poor quality of medical care due to a violation of the process of diagnostics, medical care organization or treatment, which led or may lead to the patient's health deterioration or death. In the scientific literature, the concepts of "defect of medical care" and "improper provision of medical care" are sometimes identified.

Thus, when separating the concepts of *medical error* as the unintentional harm caused to the patient by a particular person, a doctor, and *defect of medical care,* it is important to note that the latter is most often caused by defects in the multi-stage medical care provision in an institution, i.e. not through the fault of a particular doctor, but often because of the auxiliary staff or the management of the institution that have not insured full provision of medical care technically or medicamentally on time. It is reasonable to state that the administrative or civil responsibility may intersect in terms of causal connections and circumstances of the happened fact in the structure of distribution of conditions for the legal liability incurrence due to the malpractice or defect in the medical care. It is a common phenomenon in the cases when an iatrogenic defect in the medical care combines one or several medical errors and medical negligence, carelessness, which may become more complicated by the present technical errors of the medical equipment and patient`s actions. It is obvious that criminal liability may be imposed on a doctor and (or) other medical personnel for actions caused a defect in the medical care in cases of negligence, carelessness and other actions that caused harm to the patient`s life and health and have features of a crime, what is prescribed by Articles 115–145 of the Criminal Code of Ukraine [4].

In studying the matter of legal consequences of medical malpractice cases (errors), we pay our attention to the analysis of legal consequences of a defect in the medical care in terms of its compensation. Unfortunately, today the legislation of Ukraine in the healthcare aspect does not contain any special prescriptions about legal consequences of medical malpractice cases (errors), and the main legal enactments as Law of Ukraine (hereinafter – "the LU") "Fundamentals of the healthcare legislation", LU "On transplantation of human anatomic materials", Criminal Code of Ukraine, Civil Code of Ukraine do not contain necessary specific provisions, but just declaratively cover the problem of legal consequences of medical malpractice cases and medical errors.

Article 1172 of the Civil Code of Ukraine envisages a right to file a lawsuit for compensation of harm inflicted on the person`s life and/or health, when medical aid is delivered, against medical institutions, where a doctor worked or works, who caused harm to the patient`s health and/or life [5]. Compensation of harm caused to the life and/or health of citizens shall not release medical and pharmaceutical workers from their liability, as prescribed by the Ukrainian laws. Nevertheless, the current regulations of the civil legislation, administrative and criminal laws do not ensure the filling of the legal gaps. Unfortunately, there is also no appropriate legal regulation of legal consequences of medical malpractice cases (medical errors) in the national subordinate legislation. Thus, the Ukrainian laws are unsatisfactory and partially fix guarantees of patients` rights for being protected from medical malpractices and medical care defects in general.

In compliance with Part 2 of Article 1166 of the Civil Code of Ukraine, a person caused harm shall be released from compensation of harm if it proves that harm is not caused by its fault, but the Law may herewith stipulate this compensation of harm, when there is no guilt of a causer of harm [5]. Just in this case, liability of healthcare institutions for violating rights in the healthcare aspect is determined by a caused harm to the life and/or health while delivering medical aid to patients. Nevertheless, this very article does not specify a scope, nature and procedures on setting legal consequences, civil liability; it just refers to the fact that this liability comes "according to the laws of Ukraine".

By analysing the current laws, we may come to the conclusion that legal consequences occur in the form of civil liability, compensation of harm caused to a patient, for healthcare institutions where harm was caused to the patient`s health and/or life as a result of a defect in the medical care, i.e. medical malpractice. But herewith, a doctor shall prove that harm was not caused by his fault. Medical malpractice cases of a particular doctor, which are frequently registered by the administration of healthcare institutions, will be a reason for rejecting his services. It should also be considered what measures were taken by a healthcare institution for reducing and eliminating negative consequences of a medical error for

the patient`s health by taking into account their relevance and promptitude. A healthcare institution shall design and implement a set of measures of prevention and reduction of medical malpractice cases.

For determining legal consequences, it is very important to consider regulatory measures for preventing medical malpractices and reducing this problem.

For reducing, preventing and correcting medical errors, the healthcare system should generalise, systemise them in the retro- and perspectives so to reduce the problem of such a defect in the medical care as medical malpractice (error).

Here a question comes: how to do this? Due to the unattainability of a result of a thorough study of the biological and social human nature, errors will be inevitable. The foreign experience shows that reducing problems of medical malpractices and defects in the medical care is quite possible in general. For a more advanced result, on the basis of scientific researches, it is necessary to engineer, structure, organise and implement a set of measures aimed at eliminating, preventing defects in the medical care. Engineering of a strategy for implementing the prevention and reduction procedures with defects in the medical care shall be based on the fundamental understanding of the medical malpractice (error) nature and multi-vector nature of generation of a system complex of different preventing and reducing measures. By taking into account the existing scientific researches in this field and approaches presented in them [6], we suggest identifying the following blocks of measures and procedures on the basis of the criterion "purposefulness":

Purpose 1. To form a powerful system of prudential internal control of defects in the medical care. In our opinion, it is the most effective way to prevent medical malpractices and errors.

In introducing complex measures to the prevention of medical malpractice cases (errors), an effective way is to create such systems that will assists in constricting incorrect actions, cognitive errors of medical workers before their causing harm to the patient`s health.

Prudential internal control of medical malpractices is a predominant preventive control that makes it possible to identify, register, analyse and predict potential opportunities, risks of violations, complications and problems in the activities of medical establishments and doctors, which cause or may cause harm to the health and life of patients as a result of medical malpractices (errors) or cases leading to this; this control includes a system monitoring of causes and conditions of medical malpractices (errors) and implementation of regulatory measures and a mechanism for "catching" (preventive correction and neutralisation of corresponding conditions and causes) medical errors before their occurrence or for reducing harms caused by medical malpractices and errors [7].

The system of measures of prudential internal control of defects in the medical care shall be formed on the basis of sanitation for ensuring the patients` safety, value of the delivered medical aid, but not on the basis of a causal, restriction approach (i.e. a focus is made on transition from the general to the specific, and not from the specific to the general).

It shall include the following:

– creation of a unified information space (complex data banks), where reports of detected medical malpractice cases, analysis and evaluation of causes, factors of their occurrence will be given. It might assist in designing a single strategy for their elimination. For instance, with the assistance of the Swiss Medical Association (Fédération des médecins suisses), a unified system of reports about the most significant incidents in the healthcare that covers all the aspects of medicine have already been created [8];

– creation of a system for identifying anticipated causes and conditions of occurring medical defects, medical errors in order to forecast, detect and eliminate ("constrict") them;

– designing of special procedures for "constricting" ("catching") and eliminating consequences of medical malpractice cases (medical errors) that have already come.

Purpose 2. Specialised training of medical personnel in techniques for detecting medical malpractices, their forecasting and prompt elimination of possible consequences. This complex should include the following actions:

– development of training programs for medical personnel on the subject of the medical malpractice nature, advanced training of medical officers by introducing to the study process modern methods of detection and correction of medical errors (medical malpractice), their threat assessment, study of effective ways of reaction, firstly, through the lens of "practical value" (e.g. modelling of scenarios and situations of medical malpractice cases and errors), and not just theoretically: arrangement of a system control in identifying competences of medical personnel;

– advanced training with special exercisers and computer simulation software for medical malpractice cases.

Problems. Mistakes are a dole of our existence. As Paul A. Glack states, it is impossible to completely advert or minimise the characteristic human feature to make mistakes as regards medical malpractice cases and errors just by making efforts in fulfilling personal professional duties on the part of every particular doctor. The system of medical services should be arranged so that it could complicate, reduce chances of undue actions to be done, and, in contrast, increase opportunities of due actions to be done by applying computer technologies [9]. The statement by I.V. Davydovskyi that "a number of errors (medical malpractice cases) rather increase than fall in the course of advanced trainings" [10] has a real matter of fact in a wider study, though it causes doubts due to its brevity and paradoxical features. E. Yu. Lozynskyi, I. I. Shmykova and M. E. Lozynskyi interpret this viewpoint in the following way: "a qualified doctor has to think a lot over difficult patients, who were often treated and handled by many other specialists before him" [11]. However, the researches of numerous medical malpractice cases and errors, which were held in 2009, showed that most young doctors committed a small number of medical errors as compared with a total number of medical officers [12]. Furthermore, as estimated by Yu. V. Kaminskyi and V. S. Tymoshenko, a great portion of a total number of iatrogenic pathologies consists of medication side effects registered in 10–20 % of indoor patients. The risk of medical errors becomes higher due to the sophistication of medical technological facilities either [13].

Purpose 3. Instrumental, functional and system-structural procedures for minimising risks of medical malpractices (errors).

This block of actions is classified in accordance with a medical specialisation (medical errors caused by various system determinants, for instance, disorders, failures; application and prescription of medications; medical errors occurred as a result of medical intervention – surgical, in particular).

3.1. Measures for reducing medical errors caused by system determinants (disorders, failures, etc.):

– creation of unified standardised medical aid algorithms;

– designing of supplementary control "fast filling" reports;

– development and updating of the database of a patient`s information reflected in the patient`s electronic medical chart (anamnesis, treatment methods, medication, substance abuse, lifestyle);

– improvement of the system of access of medical workers to necessary medical information;

– creation of new regulations, procedures for medical personnel to acquire behavioural skills for situations that tend to cause medical errors;

– training of patients and/or persons looking after them to properly handle the medical equipment;

3.2. Measures for reducing medical errors happening when certain medications are prescribed and applied:

– arrangement of the medical personnel advanced training in the field of pharmacology and application of medications;

– creation of an automated information system of compatibility testing of medicaments and drugs prescribed to patients;

– increase in control by both the government and parties involved of the quality of medicaments and drugs;

– creation of a system of control of prescription and delivery of medicaments, management of medication records of patients, where some detailed information of side effects of medicaments and drugs, individual allergic reactions of patients could be indicated;

– opening of a 24/7 hotline pharmaceutical hotline.

Problems. Basing on the principle of pluralistic monism, an excessive fragmentation and detailing of medical errors, which are set, for example, by means of unification and standardization, may lead to an opposite result. As new approaches, evaluations and/or views may provoke critics or limitation for scientifically substantiated and reasonable and initiative actions of doctors, which may lower their effectiveness. But, in doing so, when classifying medical errors, one should also consider "factors" affecting results. The problem consists in the fact that these "factors" can be both constant and variable. Moreover, in an ideal scenario, a doctor will never be able to predict and fully consider these "factors" as a human body is a living system with its functional features. That is why a doctor needs to monitor and detect principles of displayed constant "factors" (invariables). Herewith, as indicated by Ramon Masia Gomes, there is always a risk of failures of any barrier of this system for various reasons in actual life: it may be either errors of the equipment, which is a technological barrier, or human errors influencing the correct functioning, for example, of a barrier formed by other participants of a medical procedure [14]. Medicine is not a STEM field, but it is "a creative arena"; for example, the doctor`s current knowledge, skills and experience may "not work" for a new patient, so the situation will demand from him (doctor) showing initiative, be "creative" so to break the mould and conventional approaches [15].

We should also mention "hidden pitfalls" of this aspect. As reasonably proved by N. de Trizio, B. Vergari, doctors "are mentioned" in a so-called "defensive medicine" with endless reports, excessive controls impeding a priori estimate of possible accusations as unfounded to the prejudice of patients and public expenditures. This situation is common for all the western countries as the USA and European countries face similar problems [16]. We think that ignorance and, subsequently, inadequate regulation of the complex of these problems may result in a complete "collapse" of the healthcare system.

Purpose 4. Improvement of the legal support of guarantees of patients` and doctors rights for a safe delivery of medical aid and prevention of medical errors.

Problems. The Law "Basis of the legislations of Ukraine about healthcare" No. 2978-XII of 03.02.1992 incompletely envisages guarantees of patients as compared with the European standards in this area; first, it is referred to the guarantees adopted by the European Charter of Human Rights (European Union), European Convention on Human Rights and biomedicine (Council of Europe) [17]. Due to the relevance of this sphere of the legal life, it would be logical for the Supreme Court of Ukraine to carry out an objective, multi-vector analysis of legal proceedings in the matter of harm caused to the human life and health in the context of defects in the medical care, and to take a single legal stance in these problems.

Conclusions

1. Constant control and registration of medical malpractice cases and errors, their public discussion in the professional community may assist in increasing the medical aid quality. It should be pointed out that legal relationships in the medical field, considering their specifics, have a number of peculiarities and distinctions, and require special standards in the legislation that could govern relations among public healthcare authorities, healthcare institutions, medical workers, patients, a necessary reformation of laws in the healthcare realm and amendments made in a number of statutory and regulatory enactments. If to treat this matter optimistically, we should rely on the experience of certain European countries and adopt a Medical Code.

2. The characteristic features of medical malpractices (errors) are as follows: civil liability according to results of the legal qualification of deeds; a fine line with professional crimes and distinctions in the size of harm: in crimes – severe consequences, which are an evaluative notion, but usually stipulate death, grievous and medium-gravity bodily harm. Furthermore, distinctions consist in integrity of medical errors, which is not related to a negligent and dishonest attitude to professional duties. An important

factor in the legal qualification of defects in the provision of medical care is the presence of a causal link between the actions of the medical worker and the negative consequences for the patient's health.

3. For a more complete understanding of cases of legal consequences, we suggest the following regulatory measures of prevention of medical malpractice cases: establishment of an effective system of prudential internal control of defects in the medical care; specialised training for medical personnel on methods of detection of medical malpractices, their prediction and prompt elimination of possible consequences; instrumental, functional and system-structural measures for reducing risks of medical malpractice, namely: actions for reducing medical errors caused by system determinants (failures, disorders, etc.), actions for reducing medical errors made in prescribing and applying medicaments, medical errors happened because of the medical intervention, surgical in particular; improvement of the legal support of guarantees of patients and doctors rights for a safe delivery of medical aid and prevention of medical errors; development of a trust, constructive communication of a doctor and a patient; reconsideration of the general attitude of the medical and civil societies to the problem of medical malpractice; increasing the level of legal and medical literacy both by patients and doctors. In each said aspect, we analyse the problems with the proposals on reducing and/or narrowing the occurrence of legal consequences when medical errors are made.

Prospects of the future researches. The research data may be used both theoretically and practically so to elaborate and implement recommendations on reducing medical errors in the medical legal environment.

Conflicts of interest: authors have no conflict of interest to declare.
Конфлікт інтересів: відсутній.

Надійшла до редакції / Received: 22.02.2019
Після доопрацювання / Revised: 28.03.2019
Прийнято до друку / Accepted: 02.04.2019

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References

[1] Ponkina, A. A. (2012). *Vrachebnaya oshibka v kontekste prav cheloveka [Medical error in the context of human rights].* Moscow. [in Russian].
[2] (2010). *Patientsäkerhetslag*. Retrieved from http:https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/patientsakerhetslag-2010659_sfs-2010-659
[3] *Yedynyi derzhavnyi reiestr sudovykh rishen [The only state register of court decisions].* Retrieved from http://reyestr.court.gov.ua/ [in Ukrainian].
[4] (2001). Kryminalnyi kodeks Ukrainy [The Criminal Code of Ukraine]. *Vidomosti Verkhovnoi Rady Ukrainy*. Kyiv: Parlam. vyd-vo. [in Ukrainian].
[5] (2003). Tsyvilnyi kodeks Ukrainy [Civil Code of Ukraine]. *Vidomosti Verkhovnoi Rady Ukrainy.* Kyiv: Parlam. vyd-vo. [in Ukrainian].
[6] MacCourt, D., & Bernstein, J. (2009) Medical error reduction and tort reform through private, contractually-based quality medicine societies. *American Journal of Law & Medicine,* 35(4), 505–61.
[7] Stucky, E. R. (2003) Prevention of Medication Errors in the Pediatric Inpatient Setting. Committee on Drugs and Committee on Hospital Care of the American academy of pediatrics. *Pediatrics*, 112(2), 431–6.
[8] Voropaeva, L. S., & Parkanov, N. Yu. (2015). Vrachebnye oshibki: e´-ticheskij aspekt [Medical errors: ethical aspect]. *Byulleten' medicinskikh internet-konferencij,* 5, 569. [in Russian].
[9] Jalal, Poorolajal, Shirin, Rezaie, & Negar, Aghighi (2015). Barriers to medical error reporting. *Int J Prev Med*., 6(1), 97. doi: 10.4103/2008-7802.166680
[10] Pigolkin, Yu. I., Morozov, Yu. E., & Globa, I. V. (2018) Kompetenciya vracha i yurista v ustanovlenii vrachebnoj oshibki [Competence of a doctor and a lawyer in establishing a medical error]. *Aktual'nye problemy mediciny i biologii*, 2, 58–59. [in Russian]. doi: 10.24411/2587-4926-2018-10018
[11] Klimenko, O. V. (2016) *Derzhavne rehuliuvannia medychnoi praktyky v Ukraini: henezys i tendentsii rozvytku* (Dis… dokt. med. nauk). [State regulation of medical practice in Ukraine: genesis and development trends Dr. med. sci. diss.] Kyiv. [in Ukrainian].
[12] Ludupova, E. Y. (2016) Medicinskie oshibki. Literaturnyj obzor [Medical errors. Literature review]. *Bulleten' Rosszdravnadzora*, 2, 6–15. [in Russian].
[13] Kalinin, R. E., & Barinov, E. H. (2018) Rol' sudebno-medicinskoj e'kspertizy materialov ugolovnogo dela v opredelenii e'lementov i priznakov «yatrogennogo» prestupleniya [Role of forensic medical examination of materials of criminal case in defining the elements and signs of "iatrogenic" crime]. *Zhurnal sudebnoj mediciny*, 2, 30–35. [in Russian].
[14] Maciá Gómez, R. El error de diagnóstico y el error de tratamiento médico en el derecho español. Retrieved from http://www.porticolegal.com/pa_articulo.php?ref=333
[15] Khubulava, G. G. (2016). O filosofii vrachebnoj oshibki [On the philosophy of «Doctor's Error»]. *Medicinskij al'manakh*, 1(41), 26–29. [in Russian]. doi: 10.21145/2499-9954-2016-1-26-29
[16] Nevzgodina, E. L. (2015) Yuridicheskaya kvalifikaciya medicinskoj oshibki yeye pravovye posledstviya [Legal qualification of medical error and legal implications]. *Vestnik Omskogo universiteta. Seriya «Pravo»*, 2(43), 137–144. [in Russian].
[17] Holquist, C. Medication errors: an FDA perspective. European Union Regulatory Workshop on Medication Errors. Retrieved from http://www.ema.europa.eu/docs/en_GB/document_library/resentation/2013/03/WC500139886.pdf