

# Does a doctor have a right to error? Medical and legal view on the problem

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**Abstract.** The aim of the article is analysis of the problem of medical error, namely the lack of a single definition and understanding of conceptual categories. The complexity of the problem of the medical error is due to its intersection in two fields — medicine and law, where, on the one hand, the subject is human rights, including health as the highest social value, and on the other one — the quality of care and conscientious attitude of doctors to their professional responsibilities. Definition of a unified approach to solving the problem and analysis of the factors of formation of medical errors will reduce the impact of the latter and improve the quality of the medical care.

**Key words:** medical error, diagnostic errors, legal views, medical views, medical care.

## Introduction

A human being, its life, health, honor, dignity, inviolability and safety are recognized as the highest social values in Ukraine according to Article 3 of the Constitution of Ukraine [1].

The state exists to form such conditions, under which it will be possible to implement the abovementioned values. An important way for the state to achieve this goal is to create and administrate the healthcare system including conditions for qualitative, effective and affordable medical treatment. According to the World Health Organization, the quality of healthcare services is a measure of how the medical care is provided to particular individuals and communities and improves desired patients' health outcomes. One of the core criteria of qualitative medical care is its safety that minimizes possible harm to recipients, including preventable injuries, and reduces the possibility of medical errors (ME) [2, 3].

In Ukraine, one third of acute myocardial infarction cases are not diagnosed in time, although the number of cardiologists is not inferior to similar figures in the Netherlands and Poland. It is known that early diagnosis of myocardial infarction and proper treatment significantly increases patient's chances for recovery. It is not clear how many of these diagnostic errors are the results of insufficient qualification of a doctor. The issue about the fact how many Ukrainians believe to have suffered from ME has not been deeply studied. There is a study on ME, conducted in Ternopil region, that says: ME were found in 92 out of 112 provided medical care cases, which is 82.1% [4].

According to the WHO, 6–7 patients die every day in Ukraine due to medical negligence and three times more become disabled. At the same time, only about ten medical workers are prosecuted each year [5]. Instead, statistics shows that in the EU countries, frequency of ME and negative effects caused by medical care is 8–12% of all hospitalizations. At the same time, 23% of the EU citizens claim that they were injured due to a ME, of which 18% — a serious ME, 11% were prescribed wrong treatment. According to statistics, 50.0–70.2% of such errors could have been avoided [4].

According to the Spanish Association of Victims of Medical Negligence, where mainly the state healthcare system exists, about 5,000 deaths have been recorded due to ME over the past 10 years [5, 6].

In the United States, ME take the third place in the rate of death causes [7]. Every 15 min in this country 5 people die from ME or unscrupulous medical staff. There are about 3–15% of ME made in the United States. Mortality from the ME reaches the number around 50–100 thousand per year [3, 5, 6].

In the United Kingdom, up to 70,000 people die each year from ME. The overall incidence of ME is around 5% [5, 6]. Analyzing the accuracy of the diagnosis and treatment of 5412 patients treated in hospital emergency departments in England and Wales from 2013 to 2015 found 2288 (42%) cases of ME including of 315 (14%) cases of wrong diagnoses and 1973 (86%) cases of delayed diagnoses [8].

According to reputable medical scientists, the mistakes made by doctors due to complexity of the medical science and individual characteristics of the patients are legitimate [6, 9]. The increase of the frequency of the ME is caused by the expansion of the range of diagnostic tools and methods of treatment, the use of complex types of surgical interventions. In modern conditions, the analysis of ME that takes into account the factors of their occurrence is unexplored and relevant, as reduction of impact of the errors will improve quality of the medical care [10]. It is necessary to study calculation of the frequency and structure of the ME, which will make it possible to develop a strategy of their reduction.

One of the priority factors that complicate the implementation of improving the quality of healthcare is the lack of a single common definition and understanding of ME. The term «medical error» is not enshrined in any of the documents governing the healthcare. Nevertheless, this definition is widely used in practice and is a frequent subject of controversy in academia, especially among physicians and lawyers. Taking into account different professional approaches, interpretation of the term «medical error» has diametrically opposite meanings. Given the wide variety of definitions of «medical error» and pluralism of opinions on its understanding, the problem remains relevant and needs further study.

**Aim:** to analyze modern medical and legal views on the definition and understanding of the term «medical error».

## Object and methods of the research

To achieve this goal, modern literature on the problem of the ME was analyzed. The hypothesis of the presented study concerned the existence of a single definition of the term «medical error», as well as a single approach in its definition among physicians and lawyers?

## Results

### Analysis of factors causing ME

It is believed that the characteristic features of the ME are:

- deviation of a doctor from medical standards while choosing of treatment method, dosage of pills;
- incorrect diagnosis and appointment of further incorrect treatment;
- improper diligence of a doctor;
- insufficient experience of a doctor in application of new surgical techniques;
- violation of the principle of timeliness of the medical care;
- violations in the monitoring of the course and consequences of treatment, as well as in the conduct of rehabilitation therapy [5, 6, 9, 11–13].

It is assumed that the doctor acts contrary to the standards and local protocols of medical care in the field of the health-care, which leads to errors due to subjective or objective factors. It is believed that the objective factors cause around 30–40% of the errors, the subjective ones — 60–70% [5]. The objective factors are most often associated with a change in views on the treatment of the disease and the general lack of development of medicine for certain diseases.

Objective causal factors include the following:

- late hospitalization and severity of patient's condition, inability to obtain clear and complete answers of the patient;
- lack of opportunity to conduct a full examination of the patient, performance of clinical and laboratory studies, special diagnostic methods, consultations of related specialists if necessary;
- objective difficulties in diagnosing some diseases due to their rarity, atypical development, lack of pronounced clinical manifestations or individual anatomical features of development, abnormalities in the structure or function of the patient's body;
- unpredictable reactions of the patient's body to certain pills, provided that the patient is in critical condition or is under medical intervention in an emergency caused by a natural disaster.

Subjective factors include:

- mistakes made by the doctor in the process of communicating with the patient due to non-compliance with basic deontological principles;
- inattentive examination (incomplete anamnesis), insufficient or late examination of the patient, ignoring the data or previous medical examinations;
- inadequate evaluation of clinical and laboratory studies, lack of data of special research methods when there is a possibility of obtaining them, or overassessment of their results and diagnostic capabilities;
- disregard or overassessment of results of consultation opinion or results of concilium, lack of consultation when it is necessary and available;
- careless performance of operations or other treatment and prophylactic measures of patient care, prescribing symptomatic treatment instead of radical measures;

- low level of qualification of a doctor and his personal qualities such as insecurity in knowledge or excessive self-confidence, weak clinical thinking, insufficient knowledge in related specialties, absence or lack of experience, practical skills, arrogance;
- narrowing of diagnostic point of view of a doctor of narrow specialization;
- lack of understanding of the impact and interaction of multiple risk factors.

It is an important point — to determine the cause of the ME, as it is one of the conditions for determining doctor's responsibility. Thus, when it comes to ME, which are based on the subjective reasons (misinterpretation of the results of laboratory and instrumental research, insufficient experience), it is necessary to provide liability of medical workers [9, 13].

In addition to the abovementioned classification, including the cause of the «medical error», there also some other ones.

According to the principle of phased provision of medical care distinguish: ME in diagnosis, ME in organization of the treatment process, ME of ethical and deontological nature.

Taking into account the cause of «medical errors» are divided into: tactical (underestimation of the patient's condition, incorrect diagnosis, inappropriate choice of treatment method, incorrectly defined indications for surgery, etc.), technical (error in the dose of prescribed pills, improper manipulation or surgery).

Conditionally «medical errors» are divided according to the following characteristics:

- diagnostic errors (errors in recognizing the disease and its complications, misdiagnosis, incorrect diagnosis, incomplete examination, hurry at the examination);
- treatment errors (associated with an incorrect clinical diagnosis, when the patient is prescribed treatment that does not correspond to the true disease and at the same time necessary therapy is not conducted);
- technical errors (miscalculations during diagnostic and therapeutic procedures and operations);
- organizational (shortcomings in the organization and other types of medical services);
- deontological errors (in the doctor's behavior, communication with patients, i.e. non-compliance with the ethics of medical practice by a doctor);
- errors in filling out medical records.

Obviously, the lack of a single classification is due to the lack of a common view on the definition of the «medical error» term.

### Medical views on the interpretation of the term «medical error»

According to one of the most cited definition ME should include only a conscientious error of a doctor, which is based on imperfections of current state of medical science, its research methods or caused by peculiarities of disease of an individual or the one that is explained by the lack of knowledge or experience of a doctor. It's considered the ME to be a purely conscientious one, which precluded his criminal liability [6, 9].

Often a ME is defined as a wrong action or inaction of doctors in the performance of their professional duties, errors in diagnosis of a disease, organization and conduct of treatment. Although it is obvious that the problem of ME can not be narrowed only to issues of diagnosis and treatment. The severity of the error depends on its consequences, which can be very severe up to the death of the patient [5, 6, 9].

A ME is a conscientious mistake of a doctor, which has caused some damage to the patient's health, a sincere delusion of the doctor without elements of negligence, carelessness and

malicious professional ignorance. The ME includes ignorance or inability to use existing knowledge in practice [5, 6, 9, 12, 13].

A. Herzen in his study, considering the ME from a medical point of view, defines it as a certain conscientious behavior (actions or inaction) of a medical worker, the negative consequences of which are caused by atypical development of the disease, unpredictable reactions of the patient to certain pills, deficial state of medical science and technology, lack of professional experience, which is not associated with negligence in their duties, and therefore excludes the possibility of prosecution [9].

The ME is sometimes considered to be an action that occurred as a result of a combination of difficult circumstances in the performance of all regulated provisions, which led doctor to delusion and therefore it was not a result of a negligent, irresponsible attitude of the doctor to his duties, ignorance or a kind of criminal action.

In practice, the ME is a non-criminal delusion of the doctor in his professional activity, if it excludes negligence, unscrupulousness, self-confidence or indifference [5, 6, 9].

### **Legal views on the interpretation of the term «medical error»**

Despite the large number of cases of ME in medical practice, from a legal point of view, the term «medical error» does not exist, it is not mentioned in any legal document [5]. The term «medical error» is not a legal concept and is not mentioned in the Civil Code of Ukraine, so this concept is medical.

According to the Law of Ukraine «Fundamentals of the Legislation of Ukraine on Health Care», Article 78 (a) states that medical workers are obliged to promote the protection and improvement of human health, to prevent and treat diseases, provide timely and qualified medical and rehabilitation care [14]. Thus, the law forbids being unchanging, dishonest, inattentive, unscrupulous.

Most lawyers in the interpretation of the term «medical error» take a categorical accusatory position, insisting on the mandatory presence of guilt in the actions of medical workers [9, 11–13]. However, even among them there is no single point of view on the qualification of the ME.

Thus, proponents of the legal field claim that ME is erroneous, negligent, dishonest, and careless and uneducated actions of a doctor, methods of providing medical care to patients, which resulted in harm (bodily injury) or death of the patient or prolongation, worsening of the disease, loss of favorable time for proper treatment, which could have been foreseen and eliminated in the process of providing medical services. Medical error covers both culpable action and culpable inaction, which in case of adverse consequences for the patient is the basis for bringing a medical worker to justice. A ME should be considered as an action or inaction of a healthcare worker that has led to negative consequences for the patient's health or life, namely, mistakes made by healthcare professionals who unreasonably deviate from established medical standards, act carelessly, self-confidently or allow unreasonable risk, having lack of experience or knowledge [9, 11, 13].

According to the definition of I. Seniuta, the ME — is a type of a defect in the provision of medical care, which is improper performance (non-performance) of duties by a medical worker due to subjective or objective mistake, not related to negligent and dishonest attitude towards them, which caused harm to patient's health [13].

Characteristic signs of the ME are: 1) the onset of civil liability due to legal qualification of the act; 2) a fine line with professional crimes and difference in the amount of damage: when crimes are committed there are serious consequences, which is an evaluative concept, but, as a rule, they involve death, severe and moderate bodily injuries. In addition, the difference lies in the good faith of

the error, not related to negligent and dishonest attitude to the performance of professional duties; 3) «Academic explanatory dictionary of the Ukrainian language» explains the word «error» as «incorrectness, inaccuracy in any mechanism, device, in any scheme, map, etc.» [13].

Only ME that have caused harm to the life or health of a citizen have legal significance. However, a ME does not necessarily leads to any complications. From the legal point of view, absence of treatment effectiveness is can by no means be defined as a ME. Even if the health care worker has made an incorrect diagnosis, but the treatment prescribed by him has not worsened patient's condition, the patient can not make any claims.

### **Determination of guilt in making ME**

The divergence of numerous definitions of «medical error» among lawyers and physicians lies in different interpretations and establishing guilt. Despite the long existence of the term and its numerous interpretations, the definition of the «guilt» is highly controversial. In general, guilt is a subjective (mental) state of a person who commits an illegal act. At the same time, some lawyers argue about the ability to realize, others — about intention and knowledge, the third ones — about awareness and desire, the fourth — about the condemned mental state, the fifth — about any mental state... There is no clear decision on the concept of guilt in the criminal law of the United States, England, Germany, and France.

According to Article 23 of the Criminal Code of Ukraine: «Guilt is a mental attitude of a person to an act or inact, stated in this Code, and its consequences, expressed in the form of intent or negligence» [15]. Intent is a conscious socially dangerous act that has entailed predictable socially dangerous consequences, and negligence is a criminal unlawful arrogance or carelessness, when a person foresaw the possibility of socially dangerous consequences of the action (action or inaction) or should and could have foreseen them [15].

Thus, the question arises, can a factor of guilt be seen in doctor's actions?

If the doctor in the process of providing medical care intends to create socially dangerous consequences of their actions (direct intent) or consciously understands the possibility of their occurrence (indirect intent), it is unlikely to be associated with his professional qualities. Moreover, there is no connection with illegal arrogance and negligence: if a person foresaw the possibility of socially dangerous consequences of his actions or should and could have foreseen them (carelessness), it is shouldn't be qualified as the ME.

Thus, the ME is an innocent act that is not related to intentional criminal actions and negligence. Only the presence of guilt in the commission of a ME by a person is the basis for bringing him to civil liability. The impossibility of predicting negative results that are causally related to illegal behavior in the legal literature is qualified as a case. This limits responsibility.

However, in rare cases in medicine, factor of chance, which is impossible to predict, may play some role but it can lead to unforeseen consequences. Such situations a related to the case (casus), which according to part 1 of Article 617 of the Civil Code of Ukraine is the basis for release from liability for breach of obligation [16]. The casus is defined as a consequence that is causally related to the action (or inaction) of a person who, however, not only did not foresee the possibility of occurrence, but also could not foresee it. In medical practice, accidents are understood as an unfavorable outcome of the patient's treatment due to a coincidence that does not depend on the actions of the doctor, which the doctor could not have foreseen and prevented. Such results are most often associated with the individual reaction of the patient to certain drugs, diagnostic procedures, operations, deficiencies in the

operation of medical equipment that can not be predicted, even in the case of appropriate attitude of medical staff to their duties.

The identification of the terms «medical error» and «accident» is erroneous. A feature that separates these terms is the presence of additional unforeseen circumstances in the accident and the inability of a doctor of any specialty to anticipate them and prevent their consequences [11–13].

A separate type of offense is a gross negligence, the feature of which is the failure to follow the due diligence of the health-care worker in performing his professional duties, which led to serious consequences for the life and health of the patient and has legal qualifications, resulting in compensation. Gross negligence is the result of gross inattentiveness. Gross negligence includes elementary errors that violate the diagnostic and therapeutic basic rules, which should always be followed [11, 12].

## Conclusion

The analysis of modern sources of the medical and legal scientific information, legal acts of Ukraine show the lack of a common view on the definition of the «medical error» both from legal and medical point, resulting in its indifference to legal and expert practice.

The lack of a common understanding of the term «medical error» causes a large number of contradictions and uncertainties regarding the responsibility of medical workers, the elimination of which is possible only through improvement of legislation on regulation of the rights and obligations of doctors. It is important and necessary that meanings of the terms «medical care», «medical services»; «medical error» are legally defined, etc., as well as regulation mechanisms of the legal status of patients and doctors, legal relations that arise between them in the process of providing medical care and medical services, health care agreements, grounds and types of liability.

A necessary condition for reducing the frequency of the ME is the constant improvement of the level of professional knowledge and skills of doctors, and this duty is not only moral but also legal.

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## Чи має лікар право на помилку? Медико-правовий погляд на проблему

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**Анотація.** У статті проаналізовано проблему лікарської помилки, а саме відсутності єдиного визначення та розуміння понятійних категорій. Складність проблеми зумовлена її положенням на перетині двох галузей знань — медицини та юриспруденції, де, з одного боку, предметом розгляду є права людини, зокрема здоров'я як найвища соціальна цінність, з іншого — якість надання медичної допомоги та сумлінне ставлення лікарів до виконання професійних обов'язків. Визначення єдиного підходу до вирішення проблеми та аналіз чинників формування лікарських помилок дозволить знизити вплив останніх та підвищити якість надання медичної допомоги.

**Ключові слова:** медична помилка, діагностичні помилки, юридичні погляди, медичні погляди, медична допомога.

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