

Medical Errors in Health Care Institutions: an Interdisciplinary Study of the Competences of Specialists Based on Medical and Pharmaceutical Law

Valentyn Shapovalov (Doctor of Pharmaceutical Sciences, Professor, LLM, Luhansk State Medical University, Advocates Company "Apotheosis" – Ukraine)

*Corresponding author: Valentyn Shapovalov

Received: November 01, 2023

Published: December 14, 2023

Abstract. In global medical practice, physicians have faced criminal charges such as manslaughter, reckless endangerment, or negligent homicide following fatalities of patients. A comprehensive and interdisciplinary study was carried out, involving forensic and pharmaceutical, medical and immunological, as well as criminal and legal expertise. This study focused on the competencies of healthcare facility professionals, guided by medical and pharmaceutical law within the legal framework of interactions between doctors, patients, pharmacists, and lawyers. It specifically addressed medical mistakes made in the field of gynecology. The research encompassed an

analysis of how leading countries worldwide handle medical errors. It categorized common medical missteps, including hazardous surgical methods, infections from medical care, diagnostic inaccuracies, and risky blood transfusions. The forensic and pharmaceutical practices related to gynecological medical errors were scrutinized. Furthermore, the study led to the proposition of normative initiatives for amendments and additions to Article 140 of the Criminal Code of Ukraine, aiming to address these issues more effectively.

Keywords: medical errors, forensic pharmacy, forensic medicine, medical law, pharmaceutical law, legal guardianship.

Introduction. Fatalities during the provision of medical care are rarely classified as homicides. As noted by Duncanson E., Richards V., Luce K.M., Gill J.R., some doctors have been prosecuted for manslaughter, reckless endangerment, or negligent homicide as a result of patient deaths [1]. Such cases are based on:

- forensic and medical conclusions;
- principles of the forensic and medical system during the investigation of the deaths of patients in health care institutions;
- protection of public health, prevention of causes and conditions causing medical errors.

Protection of the rights and freedoms, life, and health of doctors [2, 3], citizens of all age groups in the system of legal relations "doctor-patient-pharmacist-lawyer" are in the plane of interdisciplinary forensic and pharmaceutical, medical and immunological, criminal and legal, forensic and medical researches based on the principles of medical and pharmaceutical law in accordance with the recommendations of WHO and ICD-11 [4-27].

It is the police (operative officers, investigators) and prosecutors who perform the functional duties assigned to them by the state. They play a key role in maintaining a high level of law and order and legality in the state, as well as in judicial protection [28]. This is an important guarantee of ensuring the rights and freedoms, life and health of a person, a citizen, and a patient during the provision of assistance by doctors in health care institutions with the use of medicinal products during pharmacotherapy and treatment in inpatient or outpatient settings [29]. Therefore, the activity of a doctor and pharmacist is based on the principles of medical and pharmaceutical law, which is regulated by Art. 4 of the Law of Ukraine "On the Basics of the Legislation of Ukraine on Health Protection" [30].

Need to note that the role of forensic medical examination in determining the legal responsibility of medical workers was considered in 2016 at the Department of Forensic Medicine and Medical Law of Bohomolets National Medical University [31]. In our opinion, there is a need for an interdisciplinary forensic and pharmaceutical, forensic and medical, medical and immunological study of the causes and conditions that cause medical errors to be committed in health care institutions on the basis of medical and pharmaceutical law.

The purpose of the study was an interdisciplinary forensic and pharmaceutical, forensic and medical, medical and immunological, criminal and legal study of the competences of specialists in the system of legal relations "doctor-patient-pharmacist-lawyer" regarding medical errors committed by doctors for the protection of rights and freedoms, life and health I women during lactation, pregnancy and childbirth (before and after) on the basis of medical and pharmaceutical law.

Materials and methods. The research is based on interdisciplinary studies based on: the Constitution of Ukraine, constitutional law, medical law, pharmaceutical law, criminal law, procedural criminal law, forensic medicine and toxicology, forensic pharmacy, forensic narcology, forensic psychiatry, forensic pharmaceutical forensics, evidentiary medicine, evidence-based pharmacy, clinical pharmacy, medical chemistry, drug technology, organization and management of health care and pharmacy, pharmaceutical analysis, infectious diseases, immunology, internal medicine, administrative law, labor law.

Research methods were used [32-34]: forensic identification, documentary, regulatory, retrospective, comparative, graphic, system, tabular, and forensic pharmaceutical.

The study of the article is a fragment of modern research works of the State Institution "Luhansk State Medical University" on the topic "Conceptual interdisciplinary approaches to pharmaceutical supply and availability of medicinal products, taking into account organizational-legal, technological, analytical, pharmacognostic, forensic and pharmaceutical, clinical and pharmacological, pharmaco-economic, marketing and socio-economic competences (state registration number 0123U101632, term 2023-2027).

Results and discussion. In today's environment, the health care and pharmaceutical industry faces numerous challenges associated with increased risks during the provision of medical care and the use of drugs during treatment. Side effects, contraindications, and use of drugs with psychoactive properties without a doctor's prescription affect women before and after pregnancy and childbirth. Therefore, a doctor's understanding of the clinical-pharmacological, classification and legal, nomenclature and legal aspects of the circulation of medicinal products (primarily use, administration, risks) requires in-depth knowledge of the rules of use, dosage, interaction with other drugs, side effects, adverse reactions, contraindications for use [35]:

- firstly, the combination of medicines with food and drinks; if the recommendations are not followed, less of the necessary active substances may enter the blood due to destruction by stomach enzymes; the medicine should not be taken with certain food or drinks (do not drink citrus juice, do not use energy and alcoholic drinks (beer, wine, liquor, etc.), narcotic drugs, tobacco products, etc.);
- secondly, the time and frequency of medication administration; missing a dose or too long intervals between taking medications can reduce the amount of the drug in the body and negatively affect the treatment; if the instructions say to take pills 3-4 times a day, the interval between doses must be evenly distributed over 24 hours; with a two-time intake, the medicine is taken after 12 hours;
- thirdly, compatibility and interaction of drugs; it is an element of medical and immunological interaction between medicinal products and the body's immune system; some drugs during the interaction can make the drug less effective or even dangerous (you can't take a sleeping drug (sedative) and an allergy drug (antihistamine) at the same time, because it slows down the body's reaction and the woman may not be able to drive a car.

According to experts of the World Health Organization, 6-7 patients die from medical errors during treatment and pharmacotherapy, and 25-30 citizens become disabled [36, 37]:

- 1 out of 10 patients receive medical care, and more than 2 million deaths occur annually due to inadequate treatment;
- at least 4 out of 100 people die from unsafe care in low- and middle-income countries;
- 50% of harm (1 out of 20 patients) is preventable; half of this harm is attributable to medication;
- 4 out of 10 patients are harmed in primary and outpatient settings, while up to 80% (23.6-85%) of this harm is avoidable;

- harm to patients potentially reduces global economic growth by 0.7% per year. Globally, the indirect cost of damage is in the trillions of US dollars every year.

Common adverse events that can lead to avoidable patient harm are medication errors; dangerous surgical procedures; infections associated with the provision of medical care; diagnostic errors; fall of the patient; bedsores; incorrect patient identification; dangerous blood transfusion and venous thromboembolism.

The results of studies cited by Alkema L., Chou D., Hogan D., Zhang S. indicate that [38]:

- annual number of maternal deaths in the world decreased from 532 thousand (1990) to 303 thousand (2015). The highest proportion of maternal deaths was recorded in 2015 in sub-Saharan Africa. Between 1990 and 2015, 10.7 million women worldwide died before, during and after pregnancy;
- worldwide, the lifetime risk of maternal mortality has decreased by more than half: from 14 maternal deaths per 1,000 women (1990) to 6 maternal deaths (2015);
- reduction of maternal mortality will be impossible without clinical and non-clinical interventions, as well as political and legal, medical and pharmaceutical, socio-economic measures of the state, on the example of countries that have already significantly reduced maternal mortality in a short period of time;
- each country will have a different strategy for "Maternal mortality reduction and prevention", and for this, adaptive, highly effective measures to improve women's health before, during and after pregnancy are proposed;
- discussion of interventions should be based on the content and quality of the provided medical care (taking into account the level of provision of medicines);
- development of working questions to define and outline what constitutes high-quality health care that is expected to reduce mortality and morbidity among women.

Human rights defenders in the USA insist on the need to strengthen the legislation in order to increase the level of patient safety, protect their lives, health, and proper treatment, which is based on research by specialists from the Johns Hopkins Center (USA) [39]:

- ❖ more than 250,000 people in the USA die from medical errors every year, according to other data, this figure reaches 440,000 citizens;
- ❖ medical errors are the third leading cause of death after heart disease and cancer.

Although, according to Podlisny E. and Mkrtychev M., there are no corresponding official statistics on medical errors in Ukraine; there are no clear criteria that would classify medical errors; Ukrainian legislation does not even define the very concept of "medical error" [40]. There are proposals to use the term "medical error" instead, as it is broader. That is, mistakes can happen not only due to the fault of the doctor, but also of other persons working in the health care institution.

Quite often, as Mkrtychev M. adds, a medical error occurs where there is no regulatory regulation in general (absence of clinical guidelines, medical standards, and clinical protocols). Or such regulation is outdated and needs to be updated. Or lack of access to modern and effective medical technologies, insufficient study of new and rare diseases, insufficiently high level of training of a specific medical worker, etc. [41]. The main task during the protection of a patient or a doctor is the collection of documentation (to confirm the qualification of the doctor, his work activity, as well as documents that record the patient's clinical route, his medical history). In practice, most documents either do not exist, or they are not kept, or they are kept with violations. It should be understood that in the event of a medical error, establishing the presence or absence of a case is possible only after an assessment of the quality of medical care and the corresponding forensic examination. The results of the examination can explain whether there was a medical error or not. The actions of a specialist should be qualified as a medical crime when:

- ✓ most medical errors in Ukraine occur due to the imperfection or insufficiency of medicines or medical equipment, and not due to the influence of the human factor;
- ✓ other circumstances, independent of doctors and medical institutions, can be: insufficient knowledge of science with a specific disease (which is extremely relevant today in view of vaccination against coronavirus), peculiarities of the patient's body, improper informing of

the doctor about all important circumstances of the state of health or his negligence and improper implementation of instructions during treatment;

- ✓ insufficient qualification of medical personnel, incorrect diagnosis, and incorrect recommendations. All of these factors affect the final decision as to whether medical malpractice has occurred and, if so, what the financial compensation will be or whether the doctor will be held liable.

According to Pletenetska A., the main problems in the investigation of crimes related to the professional activities of medical workers include the actions provided for in Articles 139 and 140 of the Criminal Code of Ukraine, which include the absence [42]:

- joint legal and forensic approach to the creation of an evidence base in the investigation of the specified crimes;
- rules for conducting examinations in cases of bringing medical workers to criminal liability for "professional offenses", which would clearly formulate a unified approach and procedure of actions of a forensic medical expert;
- representatives of investigative and judicial bodies have a clear idea about the specifics of professional crimes of medical workers, causing difficulties in determining and proving the form of guilt of a particular medical worker, which does not allow investigative and judicial bodies to qualify the crime;
- unified forensic medical criteria for assessing defects in the provision of medical care and establishing the presence/absence of their cause-and-effect relationship with the effect;
- practical shortcomings of the expert's conclusions to the results of the departmental inspections of the relevant Department or the Office of Health Care, regardless of the correctness of the latter, which in the end result ends in the concealment of offenses committed by colleagues from the medical field, and is direct evidence of the dependence of forensic medical examination institutions on of the Department/Management of Health Care not only in an administrative and economic sense, but also in an expert sense, which is unacceptable;
- regarding the impossibility of experts to make a correct assessment of the provision of medical care, it shows, first of all, the pressure on forensic medical experts from the representatives of the Health Care Departments, which violates the principles of legality, independence, objectivity and completeness of conducting examinations, therefore there is a proposal to consider the issue of subordination to judicial medical expert service in Ukraine, at least at the regional level, as well as solving a number of issues regarding the status of forensic medical expertise in general.

Highly qualified specialists from different fields (forensic doctors, pharmacists, experts, criminologists, lawyers) can work together during forensic examinations. Thus, the given examples from forensic and medical practice No. 1-5 provide an idea of the reasons and conditions that caused the gynecologist to commit a specific crime. Forensic-pharmaceutical analysis of the given examples from forensic-gynecological practice contributes to improving the quality of life, safety, and efficiency of treatment of women, reducing harmful effects during childbirth, childbirth, or emergency gynecological operations.

Example from forensic and medical practice No. 1. The investigator of the Supreme Court of Ukraine in the Kharkiv region, under the procedural leadership of the Kharkiv regional prosecutor's office, notified the doctor of the suspicion that the medical worker had improperly performed his professional duties as a result of negligent treatment of them, which caused grave consequences for the minor under part 2 Art. 140 of the Criminal Code of Ukraine [43]. During the pre-trial investigation, it was established that on May 10, 2022, a woman gave birth to a premature baby girl in the Kharkiv maternity hospital. The child was not eating well, she had rashes on her neck and cheeks. The girl's mother reported this to the head doctor of the department. The doctor did not observe the premature newborn child and did not leave her in the hospital. On the day of discharge, the girl felt sick, she screamed. Her skin turned dark red, but the doctor, after examining the child and listening to her carefully, did not pay attention to the health condition and prematurely discharged the child as healthy on the fourth day of life, together with the mother. Upon arrival home, the child could

not be fed, she had no sucking reflex. The girl behaved restlessly, kept looking in different directions and never fell asleep again. After some time, she had an attack in the form of respiratory arrest. The mother immediately went to the hospital, but the child died at the hospital on the night of May 17, 2022. Forensic medical experts noted that "...timely diagnosis and initiation of appropriate timely treatment, which was part of the suspect's duties, could have prevented the development of complications and prevented the death of the newborn girl...". The pre-trial investigation continues, the issue of choosing a preventive measure for the suspect is currently being resolved, forensic examinations have been scheduled.

Example from forensic and medical practice No. 2. Investigators of the State Department of Ukraine under the procedural guidance of the Prosecutor General's Office notified two doctors of suspicion under Part 1 of Art. 140 of the Criminal Code of Ukraine [44]. On April 19, 2023, investigators of the National Police sent a formal accusation to the court against the doctors for improper performance of professional duties in the case of the patient's death after surgery. During the pre-trial investigation, it was established that in December 2020, after establishing a diagnosis, doctors at a private clinic recommended that the 48-year-old patient undergo a planned operation. The woman died after the operation. The reasons were that doctors did not provide:

- proper preparation of the patient for surgery;
- necessary postoperative monitoring.

Investigators were assigned a forensic medical examination. It was established that improper performance of professional duties by doctors - obstetrician-gynecologist and anesthesiologist - led to the death of the patient.

Example from forensic and medical practice No. 3. The investigator of the Obolon State Police Department in Kyiv, under the procedural guidance of the Obolon District Prosecutor's Office of Kyiv, informed the doctor about the suspicion of committing a crime, provided for in Part 1 of Art. 140 of the Criminal Code of Ukraine [45, 46]. During the pre-trial investigation, it was established that in February 2023, an obstetrician-gynecologist at a private clinic in Kyiv made an incorrect diagnosis. Failed to urgently hospitalize a 34-year-old patient, thus causing her serious consequences. During the examination of the patient, the obstetrician-gynecologist established that: the woman had an early pregnancy and did not report any abnormalities; the patient returned to her workplace, where her health deteriorated, she became ill and lost consciousness; the victim was taken to the hospital by "ambulance"; doctors immediately performed an operation after examining the woman; during surgical interventions and obtained test results, a final diagnosis was established regarding the disruption of the course of pregnancy with internal bleeding; a doctor at a private clinic misdiagnosed the patient; having the results of the tests, did not carry out urgent hospitalization, as a result of which the pregnant woman suffered. The investigators seized the documentation and appointed a forensic medical examination, the investigation is ongoing.

Example from forensic and medical practice No. 4. Under the procedural guidance of the prosecutor's office, the investigators of the Supreme Court of Ukraine in the Odesa region entered information into the Unified Register of Pretrial Investigations under Part 2 of Article 115 (intentional murder marked as "natural death") and Part 2 of Art. 140 (improper performance of professional duties by a medical or pharmaceutical worker) of the Criminal Code of Ukraine [47]. During the pre-trial investigation, it was established that on October 20, 2023, in the health care facility of the city of Yuzhne, Odesa district, Odesa region, after a woman gave birth to a child, she and the baby were taken by ambulance to one of the medical institutions of Odesa for providing the newborn with the necessary medical care. While in the intensive care unit, on the fifth day after birth, 10/24/2023, the baby died. Investigators are establishing all the circumstances of the events, the relevant documents have been seized and a forensic medical examination has been ordered, which will establish the cause of the child's death. Investigations are ongoing. At the same time, it should be noted that according to the mother of the dead baby, the doctors are to blame for the tragedy due to their negligence [48]: the police initially did not plan to start an investigation, believing that the child's death was natural; law enforcement officers found no signs of violent death on the child's body.

Example from forensic and medical practice No. 5. Under the procedural guidance of the prosecutor's office, the investigator of the Volochysky District Police Department of the State Police in Khmelnytskyi Region entered information into the Unified Register of Pretrial Investigations under Part 2 of Art. 140 of the Criminal Code of Ukraine [49]. During the pre-trial investigation, it was established that on August 28, 2023, the police received a statement from the victim that as a result of the obstetrician-gynecologists negligent attitude to his professional duties during childbirth, serious consequences were caused to the health of the woman in labor and her newborn child:

- about abuse during childbirth, after which the newborn child ended up in intensive care;
- during childbirth, the doctor and other midwives "squeezed" (Krysteller's reception) the baby out of her, hit her in the face and poured water on her, called her names and accused her of "pushing incorrectly";
- on the 6th day after giving birth, the woman was discharged, but was forbidden to get out of bed for a month, without a child, crippled, in a difficult psychological state;
- newborn boy has been in intensive care for 49 days in a critical condition;
- every morning, the man goes to the intensive care unit, buys all vital medicines as prescribed by the doctor, and goes to Ternopil to buy medicines that are not available in Khmelnytskyi.

The pre-trial investigation is ongoing. Documentation has been removed. A forensic medical examination was appointed [50].

When discussing the given examples from forensic medical practice No. 1-5, it was concluded that a woman during childbirth experiences great stress and suffering. Obstetricians and gynecologists and the administrative apparatus of the health care institution (chief physician, head of the department) are responsible for the correct organization of childbirth, safe, high-quality, effective, and modern provision of gynecological care; provision of essential medicines in the hospital free of charge.

As Zozulya N. states, the process of bringing a medical worker to criminal responsibility is a rather lengthy process, accompanied by a series of procedures defined by the Criminal Procedure Code of Ukraine [51]:

- actions regarding the appeal of a dissatisfied patient to the police are not aimed at actually bringing the medical worker to justice, but are only a means of putting pressure on the medical institution;
- doctor must be ready to defend his rights and express his vision of the situation to the investigator;
- increase in the number of acquittals of courts regarding the clinical actions of doctors indicates the development of judicial practice in this area, which will undoubtedly have a positive effect on the consideration of similar criminal proceedings in the future.

Most forensic examinations, as Pletenetska A.O., Kondratenko V.L., and Legedza A.V. note, related to obstetrics – 84.7% (172 cases). Of these, 42.3% (86 cases) were defects in the provision of medical care that were directly causally related to an adverse outcome [52]:

- in all cases, doctors had an actual opportunity to prevent serious consequences, as 65.3% of cases occurred in large cities of Ukraine;
- when evaluating the provision of medical care at various stages, it was found that at the pre-hospital (in the polyclinic) defects were allowed in 65.5%; in hospital - in 72.8%, of which during resuscitation measures – in 38.7%;
- in 38 examinations, defects in the provision of medical care were directly causally related to the child's death;
- at 21 – with extirpation of the uterus (severe bodily injuries) and the onset of fetal death;
- at 12 – with the onset of serious consequences for both the woman and the child (serious physical injuries in both);
- at 11 – with damage to the child's central nervous system (severe physical injuries);
- in 2 cases were made up of shortcomings during the abortion in direct causal connection with the occurrence of serious consequences (removal of the kidney) – serious bodily injuries;

- in 2 cases when untimely diagnosis of fetal malformations led to the impossibility of timely termination of pregnancy;
- 25.6% (52 examinations) related to neonatology, among which in 15.4% (in 8 cases) a direct cause-and-effect relationship was seen between defects in the provision of medical care and the death of the child;
- in all cases there was an incorrectly chosen delivery tactic, as well as in most cases (65.3%) – untimely provision or non-provision of medical assistance;
- the reason for the wrongly chosen delivery tactics was insufficient examination of pregnant women, underestimation of examination data.

During the statistical analysis of the data from examinations conducted in the forensic and medical department of the "Main Bureau of Forensic and Medical Examination of the Ministry of Health of Ukraine", Pletenetska A.O. found that among all examinations, the total number of examinations for "medical cases" increased from $19.16 \pm 1.46\%$ in 2012 to $23.56 \pm 1.46\%$ in 2014 [53]. The largest specific weight of medical examinations belonged to obstetrics and gynecology and surgery specialties - $28.44 \pm 2.44\%$ and $22.9 \pm 2.44\%$, respectively. The largest number of examinations (34) was from Kharkiv Bureau and Odesa Bureau (33 examinations). The following were highlighted among the shortcomings assumed during the examination: the absence of any information from the current regulatory documents in the protocol parts of the conclusions, and in some cases, the names of these documents; the lack of wording in the experts' opinions about the presence or absence of defects in the provision of medical care, as well as a cause-and-effect relationship between the adverse effect and the actions (inaction) of the doctor; shortcomings of the expert work: the cover letters of the "Expert's Opinion" and "Forensic Medical Examination Act" continued to be written not in accordance with the forms approved by the order of the Ministry of Health of Ukraine on August 5, 1999. No. 197; the numbering of the answers was missing or did not coincide with the numbering of the questions of the resolution; information about the expert was not provided in full, or instead of the name of the position held – "forensic and medical expert" – "forensic expert" was indicated, which is incorrect; when drawing up the summaries, attention was often drawn to the unreasonable brevity of the statement of opinion, or, on the contrary, the cumbersomeness and confusion of expert judgments.

Conducting commission of forensic and medical examinations on "medical cases" on the basis of "Odesa Regional Bureau of Forensic Medical Examination", according to Kryvda G.F., Plevinskis P.V., Kryvda R.G., Slyusarenko O.O. Umansky D.O., is a small percentage (from 4.2 to 5.6%) of the total number of examinations conducted during the period 2011–2015 [54]. When conducting forensic examinations of medical personnel, diagnostic, medical and tactical errors were most often found, which led to the death and disability of patients.

Patient safety is the top priority of healthcare facility management [55]:

- strong teams of doctors working in a healthcare facility;
- reduction of the level of infection, thanks to the work of the staff;
- establishing checks to prevent errors;
- proper planning of operations and analysis regarding the quality, timeliness, and completeness of their implementation;
- ensuring reliable communication between the staff of the health care institution, in the system of legal relations "doctor-staff of the institution-patient-pharmacist-family".

But in some health care institutions, there is no team of doctors, technical staff, professional management that would cooperate well and guarantee the patient's safety when providing medical and pharmaceutical care. Patients can develop dangerous complications, recover more slowly, and some patients even die without cause.

Risk factors associated with medication errors in obstetrics and gynecology, in Klemann D., Rijkx M., Mertens H., Merode F.V. and Klein D., contain several categories [56]:

- delay in providing medical and pharmaceutical assistance;
- coordination and management of medical and pharmaceutical assistance;
- shortage of pharmaceutical supplies, personnel, and knowledge.

One of the risks for the health of pregnant patients, as noted by Foti T.R., Green A., Altschuler A., is the use of marijuana as a means of controlling mood and medical symptoms [57]. Patients believed that prenatal cannabis use was safer than using prescription drugs. Obstetrician-initiated conversations about prenatal cannabis use, advice on ceasing cannabis use during pregnancy, and examining readiness to transition to physician-recommended interventions for pregnancy-related symptoms may benefit patients.

The experience given by Weintraub K. about the work of the US Department of Health and Social Services was studied [58, 59]. The Leapfrog Hospital Safety Assessment, conducted every six months, is recognized as a tool to highlight successes and track safety gaps to focus improvement efforts. Leapfrog specialists provided a rating, of which:

- 30% of hospitals received an "A" grade (over 800 hospitals, which is significantly less compared to the period before the KVID-19 pandemic);
- grade "B" - 26% (700 hospitals);
- grade "C" – 39.9% (1100 hospitals);
- grade "D" – 6% (170 hospitals)
- 1% of hospitals did not receive evaluations, they failed to provide proper medical care to patients.

According to research by the Centers for Disease Control and Prevention, on any given day, 1 out of every 31 hospitalized patients is infected during hospitalization. It costs healthcare systems \$28.4 billion each year and accounts for an additional \$12.4 billion in lost productivity and premature death.

The American Academy of Pediatrics provides the following recommendations for preventing pediatric medical errors [60]:

1. Increasing awareness, professionalism, and improving practical knowledge regarding pediatric patient safety issues and best practices in the pediatric community;
 - 1.1. Education and training of a wide range of clinicians;
 - 1.2. Network at national and regional meetings;
 - 1.3. Creating a safety culture that informs, supports, and educates about ensuring the safety of pediatric patients;
 - 1.4. Implementation and use of standardized disease-specific care protocols, including checklists, clinical practice guidelines, and compliance monitoring;
 - 1.5. Expanding the focus: Bringing pediatric health care professionals to safety in outpatient settings, including family medical homes and other settings where children receive care.
2. Act and advocate to minimize preventable pediatric medical harm by using information about specific pediatric risks for patient safety;
 - 2.1. Develop pediatric error reports; stimulate leadership by maintaining awareness, professionalism, and accountability for patient safety issues;
 - 2.2. Improve family-oriented care by actively involving patients and families in safety at all points (stages) of providing medical and pharmaceutical care.
3. Improve the outcomes of medical and pharmaceutical care for children by following proven best practices to improve the safety of pediatric patients;
 - 3.1. Follow best practices and disseminate proven patient safety interventions;
 - 3.2. Targeted safety of drugs used in pharmacotherapy, cooperation of doctors and pharmacists with regulatory bodies;
 - 3.3. Help redesign clinical systems by implementing security design concepts when updating or building patient care systems and processes.

It is important to cite the results of the research by Gutorov N.O. and Pashkov V.M., on the imperfection of the legislative construction of Art. 140 of the Criminal Code of Ukraine in terms of the differentiation of criminal liability based on qualifying features [61]:

- ✓ criminal liability of a doctor for improper performance of duties during childbirth, as a result of which both the woman and the fetus died, occurs under Part 1 of Art. 140 of the Criminal Code of Ukraine and is less severe than for an act resulting in severe bodily harm to a newborn;

- ✓ necessity to deepen the differentiation of criminal responsibility with the help of such qualifying features as the death of the patient and the death of the fetus;
- ✓ criminal liability of doctors for improper performance of professional duties during childbirth according to Art. 140 of the Criminal Code of Ukraine in the vast majority of cases (83.3%) takes only the form of state condemnation with the corresponding moral impact on the guilty person, without actually serving the sentence imposed by the court on the basis of the expiration of the statute of limitations, amnesty, or exemption from serving the sentence with probation;
- ✓ situation that has developed indicates insufficient effectiveness of measures of criminal law regulation of relations that arise in the specified area.

So, for example, according to the verdict of the Rivne city court, the anesthesiologist of the regional hospital, who was accused of the death of a 39-year-old patient, was acquitted. According to the version of the investigation under the procedural guidance of the prosecutor's office, the doctor provided assistance to the patient in an untimely manner. The patient died in a health care facility. The husband and mother of the dead woman asked the court to impose the maximum punishment on the doctor and filed civil lawsuits for compensation of UAH 1.5 million in moral compensation. The court did not satisfy the claim. The factor that led to the untimely provision of qualified medical care to the patient was recognized as the improper organization of the treatment process in the Rivne Regional Clinical Hospital named after Yuriy Semenyuk of the Rivne Regional Council [62].

To solve the identified problems of applying the provisions of Article Art. 140 of the Criminal Code of Ukraine as a rule-making initiative, we propose changes and additions to Article 140 of the Criminal Code of Ukraine [63]:

- reword the part 1 with the introduction of qualifying features "causing light bodily harm or moderate bodily harm to the patient" and increase the punishment;
- present the part 2 in a new version with the introduction of qualifying signs "severe bodily injuries to the patient", including a minor or a minor and increased punishment "with confiscation of property"
- add to the part 3 with the introduction of the qualifying feature "death of the patient" and strengthening of the punishment "imprisonment for a term of up to five years" "with confiscation of property".
- add to the part 4 with the introduction of the qualifying features "death of two or more patients" and strengthening of the punishment "imprisonment for a term of up to ten years", "with confiscation of property".

In our opinion, these regulatory initiatives will contribute to the provision of financial compensation to patients due to medical errors at the expense of health care institutions or doctors.

Conclusions. An interdisciplinary forensic and pharmaceutical, forensic and medical, medical and immunological, criminal and legal study of the competences of health care facility specialists based on medical and pharmaceutical law in the system of legal relations "doctor-patient-pharmacist-lawyer" regarding medical errors committed by doctors in gynecology was conducted. practice It is substantiated that the doctor's understanding of the clinical and pharmacological, classification and legal, nomenclature and legal aspects of the circulation of medicinal products contributes to the reduction of medical errors. The experience of the leading countries of the world regarding medical errors has been studied. Forensic pharmaceutical practice regarding medical errors in gynecology was analyzed. Normative initiatives regarding changes and additions to Article 140 of the Criminal Code of Ukraine were proposed.

Conflict of interest. The author declare that the study was conducted in the absence of any commercial or financial relationships that could be considered a conflict and/or potential conflict of interests.

Funding. The author state, that this research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

References.

1. Duncanson E., Richards V., Luce K.M., Gill J.R. Medical homicide and extreme negligence. *Am J Forensic Med. Pathol.* 2009. Vol. 30. No.1. P. 18-22. URL: <https://pubmed.ncbi.nlm.nih.gov/19237847/>
2. Polupan O.O., Lysenko S.E., Barannik S.V. The right of medical workers to protection from illegal encroachments on their life and health. *Health-ua.com.* 25.02.2018. URL: <https://health-ua.com/article/35296-pravo-medichnih-pratecnykv-na-zahist-vid-protipravnyh-posyagan-na-hn-zhittya>
3. Tytikalo R.S., Sekelyk L.V., Gluzman S.F. etc. The right of medical workers to protection against illegal encroachments on their life and health. *Health-ua.com.* 18.03.2018. URL: <https://health-ua.com/article/35645-pravo-medichnih-pratecnykv-na-zahist-vid-protipravnyh-posyagan-na-hn-zhittya>
4. Rights and responsibilities of citizens in the field of health care. Communal non-commercial enterprise "Shostka Central District Hospital" of the Shostka City Council. 23.06.2023. URL: <https://crl.com.ua/index.php/list-likariv/prava-i-obov-yazki-gromadyan-v-sferi-okhoroni-zdorov-ya>
5. Rokhanskyi A. Human rights in the field of health care. *Ukrainian Helsinki Group.* 07.03.2017. URL: <https://www.helsinki.org.ua/prava-lyudyny-v-haluzi-okhorony-zdorov-ya-a-rohanskyj/>
6. Ryshchenko O.O., Shapovalov V.V., Shapovalova V.O., Kapelnikova E.V. Organizational and legal implementation of recommendations of the World Health Organization regarding pharmaceutical correction of patients with chronic pain syndrome on the basis of medical and pharmaceutical law. *Ukraine Journal of Psychoneurology.* T. 23. Is. 2 (83). P. 100-104. URL: <https://uvnnp.com.ua/arkhiv-nomeriv/2015/tom-23-vipusk-2-83/organ-zats-yno-pravova-mplementats-ya-rekomendats-y-vse-sv-tno-organ-zats-okhoroni-zdorov-ya-shchodo>
7. Radionova V.O., Shapovalov V.V., Shapovalova V.O. et al. Forensic pharmacy: study of modern causes of alcohol addiction and its consequences in women. *Ukraine Journal of Psychoneurology.* 2014. T. 11. Is. 1 (78). P. 125-128. URL: <https://uvnnp.com.ua/arkhiv-nomeriv/2014/uvp-t1-vip-1-46-2014/sudova-farmats-ya-vivchennya-suchasnykh-prichin-formuvannya-alkogolno-zalezhnost-ta-nasl-dk-v-u-zh-n>
8. Shapovalova V. The ICD-11 for the twenty-first century: the first view from the organizational, legal, clinical and pharmacological aspects. *SSP Modern Pharmacy and Medicine.* 2022. Vol. 2. No. 1. P. 1-13. URL: <https://doi.org/10.53933/ssppm.v2i1.37>
9. Forensic pharmacy, evidentiary pharmacy and pharmaceutical legislation as components of pharmaceutical law in the program of implementation of state policy in the field of combating crime and violations of the rules of circulation of psychoactive substances for 2011-2017: materials VII International. science and practice conf. (November 19-20, 2010, Kharkiv). Edited by Shapovalov V.V., Shapovalova V.O. Kharkiv. 2010. 190 p.
10. Knysh E.G., Ponomarenko M.S., Alekseeva I.M. et al. Provisional glossary of basic pharmaceutical terms and concepts (in-depth comparative analysis of current health legislation). Zaporizhzhia: Zaporizhzhia DMU. 2010. 104 p.
11. Shapovalova V.O., Shapovalov V.V., Galatsan O.V. et al. Unified programs in medical and pharmaceutical law, forensic pharmacy, pharmacy organization and management, general pharmacy, clinical pharmacy. Kharkiv: KhMAPO. 2014. 204 p.
12. Shapovalova V.O., Shapovalov V.V., Khalin M.M. et al. Pharmaceutical legislation: education. manual with the seal of the Ministry of Education and Culture of Ukraine (series: Pharmaceutical law). Kharkiv. 2010. 142 p.
13. Shapovalova V.O. Subject "Medical and pharmaceutical law". Interaction with medical, pharmaceutical and legal disciplines. Legislation of health care in Ukraine. Slobozhanskii readings. Pharmaceutical and medical law of Ukraine: innovations, accessibility and prospects for the development of the pharmaceutical business organization: materials of the 15th interdisciplinary of science and practice conference with the participation of international specialists, November 15-16, 2018, Kharkiv. 2018. P. 85-91.

15. Shapovalova V.A., Shapovalov V.V., Stefanov A.V. et al. Clinical use of medicinal products. Medicines in neurology, psychiatry and narcology. Kharkiv, "Fact." 2003. P. 228-438.
16. Shapovalov V.V. (Jr.), Tairova K.Y., Shapovalova V.A. et al. Introduction to pharmaceutical law: parameters of the control regime and stages of medicines circulation: 9th International youth conference "Perspectives of science and education". New York. USA. 2019. P. 133-142.
17. Shapovalova V.V., Shapovalov V.V., Vasina Ju.V. et al. Legislation in pharmacy, forensic pharmacy and evidence-based pharmacy: Study book (series: Pharmaceutical law). Kharkiv. 2011. 160 p.
18. Shapovalova V.O., Sosin I.K., Shapovalov V.V. et al. Pharmaceutical law in narcology. Kharkiv: "Fact". 2004. 800 p.
19. Shapovalova V.O., Shapovalov V.V., Peresyphkin O.V. The order of control and authorization circulation of precursors on the basis of pharmaceutical law: training. manual with the seal of the Ministry of Education and Culture (series: Pharmaceutical law). Kharkiv. 2011. 56 p.
20. Kulikova O.V., Shapovalov V.V., Shapovalova V.O. Organizational and legal foundations of the formation of the science of medical and pharmaceutical law in Ukraine. Scientific and practical materials. conf. "Theoretical and legal foundations of the formation of modern medical law in Ukraine". Poltava: "Firma "Techservice" LLC. 2015. P. 17-23. URL: http://pli.nlu.edu.ua/doc/20151127_medical_law_conference_part_1.pdf
21. Vasina Yu.V., Shapovalov V.V., Shapovalova V.O. et al. Pharmaceutical law: problematic issues of circulation of extemporaneous medicinal products. Scientific and practical materials. conf. "Theoretical and legal foundations of the formation of modern medical law in Ukraine". Poltava: "Firma "Techservice" LLC. 2015. P. 8-10. URL: http://pli.nlu.edu.ua/doc/20151127_medical_law_conference_part_1.pdf
22. Rogozhnikova O.V., Shapovalov V.V., Shapovalova V.O. Improvement of state principles in the field of circulation of medicinal products under preferential prescriptions on the basis of pharmaceutical law. Scientific and practical materials. conf. "Theoretical and legal foundations of the formation of modern medical law in Ukraine". Poltava: "Firma "Techservice" LLC. 2015. P. 41-43. URL: http://pli.nlu.edu.ua/doc/20151127_medical_law_conference_part_1.pdf
23. Shapovalov V.V., Shapovalova V.O., Khmelevskiy M.O. Pharmaceutical law as the basis of state policy regarding risks in the organization of rural pharmacies. Pharmacist. 2013. No. 3. P. 87-90. URL: http://sphu.org/wp-content/uploads/2017/01/Farmacom_3_2013.pdf
24. Shapovalov V.V. (Jr.), Linsky I.V. Evidence-based pharmacy: definition of the control regime for the medicines in the pharmaceutical correction schemes of the opioid dependence. *Pharmaceutical Journal*. 2013. No. 3. P. 35-40. URL: <https://pharmj.org.ua/index.php/journal/article/view/399>.
25. Shapovalov V., Linsky I. Forensic pharmacy: the study of disposition to health addictive disorders pf the drug addiction patients with deviant behavior. *Farmatsevychnyi Zhurnal*. 2011. No. 6. P. 30-34. URL: <https://pharmj.org.ua/index.php/journal/article/view/564>.
26. Shapovalov V., Linsky I. Forensic pharmacy, forensic narcology: scoring method of the predisposing to psychical and behavioral frustrations health by reason of psychoactive substances abusing. *Farmatsevychnyi Zhurnal*. 2010. No. 1. P. 36-41. URL: <https://pharmj.org.ua/index.php/journal/article/view/864>.
27. Shapovalov V., Linsky I. Forensic and pharmaceutical study of the pharmacotherapy of opioid withdrawal syndrome among patients-offenders with different levels of opium addiction on a base of evidence-based pharmacy. *Farmatsevychnyi Zhurnal*. 2012. No. 1. P. 20-27. URL: <https://pharmj.org.ua/index.php/journal/article/view/546>.
28. Musoev S. M., Shapovalov V. V., Shapovalova V.O. Licensing of pharmaceutical activity in the Republic of Tajikistan on the basis of pharmaceutical law. Methodical recommendations. Dushanbe-Kharkiv. 2012. 22 p.
29. Bakirova I.O. The state-legal mechanism for ensuring the constitutional right of a person and a citizen to judicial protection and the place of the justice bodies of Ukraine in the administration of justice. Ministry of Justice of Ukraine. 23.06.2023. URL: https://minjust.gov.ua/m/str_9254

30. Kysylova K.V. Provision of human rights and freedoms by police bodies through implementation of the rule of law principle. Materials of international science and practice conf. "Modern European policing and the possibilities of its use in the activities of the National Police of Ukraine." Kharkiv: KhNUVS. 2019. P. 126-128. URL: <https://dspace.univd.edu.ua/items/d4eee4b2-2e15-4651-817e-1780e8b691d1>
31. Law of Ukraine "On the Basics of the Legislation of Ukraine on Health Care". Information of the Verkhovna Rada of Ukraine. 1993. No. 4. Article 19. Editorial from 01.10.2023. URL: <https://zakon.rada.gov.ua/laws/show/2801-12#Text>
32. The role of forensic medical examination in determining the legal responsibility of medical workers. Materials of the student conference. Ed. Mykhailychenko B.V., Ergard N.M. Kyiv: Department of Forensic Medicine and Medical Law of Bohomolets National Medical University, 2016. 100 p.
33. Modern methods of forensic medical examination of traces of biological origin. Pidru4niki. 2023. URL: https://pidru4niki.com/89913/meditsina/suchasni_metodi_sudovo-medichnoyi_ekspertizi_slidiv_biologichnogo_pohodzhennya
34. Ergard N.M. Forensic medicine: lecture notes. Kyiv: Ukr. DGR. 2023. 119 p.
35. Mishalov V.D., Khokholeva T.V., Bachynskiy V.T. et al. Electronic textbook "Forensic Medicine". 08/29/2022. 575 p. URL: <https://www.nuozu.edu.ua/s/np/k/sudovoi-medytsyny/navchalna-robota/3535-elektronnij-pidruchnik-sudova-meditsina-za-zagalnoyu-redaktsieyu-profesora-v-d-mishalova>
36. Morozova M. Instructions for medicines: what you should pay attention to so that the treatment is safe and effective. Ukrainian Pravda. 29.12.2022. URL: <https://life.pravda.com.ua/columns/2022/12/29/252064/>
37. Patient safety. WHO. 11.09.2023. URL: <https://www.who.int/news-room/fact-sheets/detail/patient-safety>
38. Medical errors. Kill five people per minute, 2.6 million people every year: press release. Counter currents.org. 11.12.2019. URL: <https://countercurrents.org/2019/12/medical-errors-kill-five-people-per-minute-2-6-million-people-every-year/>
39. Alkema L., Chou D., Hogan D. et al. Global, regional, and national levels and trends in maternal mortality between 1990 and 2015, with scenario-based projections to 2030: a systematic analysis by the UN Maternal Mortality Estimation Inter-Agency Group. *The Lancet*. 2016. Vol. 387. P. 462-474. URL: <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2815%2900838-7>
40. Sipherd R. The third-leading cause of death in US most doctors don't want you to know about. CNBC. 22.02.2018. URL: <https://www.cnbc.com/2018/02/22/medical-errors-third-leading-cause-of-death-in-america.html>
41. Podlisny E., Mkrtycheva M. The problem: to mistake for health. Ukrainian legislation does not provide for medical errors. Ukrainian Lawyer. 2021. No. 7-8 URL: <https://www.legalalliance.com.ua/publikacii/ukrainske-zakonodavstvo-ne-peredbae-likarskih-pomilok/>
42. Mkrtycheva M. Problem: Mistake for health. Ukrainian Lawyer. 2021. No. 7-8. URL: <https://jurist.ua/?article/2263>
43. Pletenetska A. Criminal liability of doctors outside the law? Sector of life. 29.11.2016. URL: http://www.sektorlife.info/2016/11/blog-post_29.html
44. In Kharkiv, the doctors of the maternity hospital declared suspicion due to the death of the baby. Regionnews.ua. 19.06.2023. URL: <https://regionnews.ua/ukr/news/harkovshchina/1687189308-u-harkovi-likartsi-pologovogo-budinku-ogolosili-pidozru-cherez-smert-nemovlyati>
45. Two doctors will be tried because of the death of a patient after an operation. Regionnews.ua. 19.04.2023. URL: <https://regionnews.ua/ukr/news/ukraine/1681904590-dvoh-likariv-suditimut-cherez-smert-patsientki-pislya-operatsiyi>
46. Kostyrin V. In a private clinic in Kyiv, a pregnant patient was seriously injured due to the doctor's actions. RBC-Ukraine. 12.02.2023. URL: <https://www.rbc.ua/rus/styler/privatniy-klinitsi-kieva-cherez-diyi-likarki-1676213585.html>

47. Neschetna S. Didn't notice the deviations: in Kyiv, a pregnant woman was seriously injured as a result of the actions of a private clinic doctor. TSN. 12.02.2023. URL: <https://kyiv.tsn.ua/ne-pomitila-vidhilen-u-kiyevi-vnaslidok-diy-likarki-privatnoyi-kliniki-seryozno-postrazhdala-vagitna-2263579.html>
48. Investigators have started criminal proceedings following the death of a newborn in an Odesa hospital. The official web portal of the State Government of Ukraine in the Odesa region. 25.10.2023. URL: <https://od.npu.gov.ua/news/za-faktom-smerti-novonarodzenoho-v-likarni-odesy-slidchi-rozpochal-y-kryminalni-provadhennia>
49. In Odesa, a newborn baby died in a hospital: an investigation has begun. Odessa life. 25.10.2023. URL: <https://odessa-life.od.ua/uk/news-uk/v-odesi-u-likarni-pomerla-novonarodzhena-ditina-pochalos-rozsliduvannja>
50. Barsukova O. In Khmelnych region, a woman accused doctors of abuse during childbirth, the police opened a case. Ukrainian Pravda. Life. 29.08.2023. URL: <https://life.pravda.com.ua/society/2023/08/29/256218/>
51. Order of the Ministry of Health of Ukraine dated 17.01.1995 No. 6 "On the development and improvement of the forensic medical service of Ukraine". Registered in the Ministry of Justice of Ukraine on July 26, 1995 under No. 278/784. Verkhovna Rada of Ukraine. 17.01.1995. URL: <https://zakon.rada.gov.ua/laws/show/z0248-95#Text>
52. Zozulya N. Peculiarities of bringing doctors to criminal responsibility. Ukrainian law. 03/04/2019. URL: https://ukrainepravo.com/scientific-thought/legal_analyst/osoblyvosti-prytyagnennya-likariv-do-kryminalnoyi-vidpovidalnosti
53. Pletenetska A.O., Kondratenko V.L., Legedza A.V. Peculiarities of conducting forensic medical examinations when evaluating the provision of obstetric and gynecological medical care. 2019. URL: <http://ir.library.nmu.com/bitstream/123456789/833/1/PletenetskaMedGynecol.pdf>
54. Pletenetska A.O. Analysis of forensic medical examinations in criminal cases in relation to medical workers in connection with the performance of professional duties according to the data of the "Main Bureau of Forensic Medical Examination of the Ministry of Health of Ukraine". Ukrainian Journal of Medicine, Biology and Sports. 2015. No. 2 (2). P. 156-159. URL: <https://jmbs.com.ua/pdf/1/2/jmbs0-2016-1-2-156.pdf>
55. Kryvda G.F., Plevinskis P.V., Kryvda R.G. et al. Analysis of the prevalence of defects in the provision of medical care based on the results of forensic medical commission examinations in the Odesa region during 2011-2015. Achievements in biology and medicine. 2016. No. 1 (27). P. 45-48.
56. Errors, Injuries, Accidents, Infections. Hospital safety grade. 2023. URL: https://www.hospitalsafetygrade.org/what-is-patient-safety/errors-injuries-accidents-infections?gad_source=1&gclid=CjwKCAiAjfyqBhAsEiwA-UdzJOHxmyhT5kkaTOtZ79JM2fPsgWV9AjmUigmmtOR50G36JTgukXCNgxoCWRAQAvD_BwE
57. Klemann D., Rijckx M., Mertens H. et al. Causes for medical errors in obstetrics and gynecology. *Healthcare*. 2023. Vol. 11. No. 11. e1636. DOI: <https://doi.org/10.3390/healthcare11111636>.
58. Foti T.R., Green A., Altschuler A. More patient perceptions of prenatal cannabis use and implications for clinicians. *Obstetrics Gynecology*. 2023. Vol. 142. No 5. P. 1153-1161. URL: <https://journals.lww.com/greenjournal/toc/2023/11000>
59. Weintraub K. Medical errors kill thousands of people each year. But are hospitals getting any safer? *USA Today*. 03.05.2023. <https://www.usatoday.com/story/news/health/2023/05/03/are-hospitals-getting-safer-new-report/70158933007/>
60. Weintraub K. Medical errors kill thousands of people each year. But are hospitals getting any safer? *AHRQ*. 17.05.2023. URL: <https://psnet.ahrq.gov/issue/medical-errors-kill-thousands-people-each-year-are-hospitals-getting-any-safer>
61. Mueller B.U., Neuspiel D.R., Fisher E.R.S. AAP Council on quality improvement and patient safety, committee on hospital care. Principles of pediatric patient safety: reducing harm due to medical care. *Pediatrics*. 2019. Vol. 143. No.2. e20183649

62. Gutorova N.O., Pashkov V.M. Liability for improper performance of professional duties by a doctor during childbirth, which caused serious consequences (analysis of judicial practice). Medical law. 2019. No. 2 (24). P. 9-25. DOI: <https://doi.org/10.25040/medicallaw2019.02.009>
63. Bugayenko T. The court acquitted the accused in the death of a patient of an anesthesiologist from Rivne. ZAXID.Net. 06/08/2023. URL: https://zaxid.net/news/https://zaxid.net/sud_vipravdav_obvinuvachenogo_u_smerti_patsyentki_anesteziologa_z_rivnogo_n1565123
64. Criminal Code of Ukraine. Information of the Verkhovna Rada of Ukraine. 2001. No. 25-26. Art. 131. Edition of 05.10.2023. URL: <https://zakon.rada.gov.ua/laws/show/2341-14#Text>.