

## Pharmacy and Dentistry: A Multidisciplinary Study of the Risks of Circulation of Medicinal Products

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**Abstract.** The relevance of the work is confirmed by the statistics of drug circulation risks and medical errors in dentistry. A multidisciplinary study was conducted through an organizational and economic, forensic and pharmaceutical, criminal and legal, forensic and medical study of the risks of drug circulation and their side effects due to the provision of dental care on the basis of pharmaceutical and medical law. Taking into account the experience of the countries of the world, the risks of circulation of drugs of clinical and pharmacological, classification and legal, nomenclature and legal groups in dentistry have been studied. Medical errors in dental practice with fatal cases are summarized. The consequences of low-quality dental care were given: deterioration of the

patient's health; the development of complications (a sharp increase in temperature, worsening of breathing, dizziness, weakness, loss of consciousness, jaw pain, etc.). Cases of urgent invitation of emergency medical aid doctors to transport a patient to the intensive care unit due to medical errors and the use of low-quality drugs were noted. Forensic and pharmaceutical practice in dentistry with violation of criminal proceedings, recovery of material damages for the benefit of patients is described. Peculiarities of dentistry in children are given. Further research is ongoing.

**Keywords:** pharmacy, stomatology, pharmaceutical law, circulation, drugs, side effect of drugs, fatal cases, forensic pharmacy, criminal law, forensic medicine.

**Introduction.** Internet monitoring of dental clinic offers shows that private dental practice is successful, affordable, expensive, and widely advertised as a business in Ukraine. Certificates (diplomas) about the participation of doctors in seminars on dentistry (prosthetics), prices of services (from UAH 400 to UAH 37,000) are listed on the sites, but the following are not listed:

- ✓ authorized person responsible for incoming quality control of medicinal products;
- ✓ documents of the license register of the Ministry of Health of Ukraine on dental services of an individual entrepreneur;
- ✓ permission to carry out economic activity from medical practice in the specialty of children's stomatology;
- ✓ the algorithm of actions of doctors and medical personnel in emergency situations with patients and the nearest clinical institutions providing emergency medical assistance;

✓ certificates, diplomas, certificates of doctors of the model established by the Ministry of Health of Ukraine on the completion of cycles of specialization, internship, thematic improvement in matters of emergency medical care due to side effects of drugs during dental services; safe circulation (incoming quality control, dosage, contraindications, interaction) of medicinal products, clinical pharmacy and pharmacology based on the principles of medical and pharmaceutical law.

As a result, more articles published in the mass media about medical errors of doctors when providing dental services to children of various ages and adults, which cost parents and patients too much - lives (fatal cases). Most children and patients have a fear of the dentist's office. Some doctors inflict physical and neurological pain on patients, cause fear, emotional insecurity, and psychological suffering [1-4]. It is quite difficult to bring children to see a dentist [5]. After dental procedures and pharmaceutical manipulations (administration of drugs), the patient may continue to be bothered by pain of various genesis, chronic inflammation, fever, and psychoneurological disorders (depression, sleep, vision, hearing, breathing, etc.) [6]. Against the background of the coronavirus disease and infectious diseases, the risks in dental practice have increased. Only in the period from January 15 to 21, 2024, more than 140,000 cases of acute respiratory viral infections, influenza and COVID-19 were detected. More than 4,000 patients were hospitalized, of which more than 2,000 were children under the age of 17. Fatalities have been recorded. Among all registered patients, COVID-19 prevails. The risks of dental interventions are increasing. There are attempts to correct the situation at the level of the Verkhovna Rada of Ukraine Committee on Health Care. It was emphasized that the level of responsibility of health care institutions of all forms of ownership to patients should be increased simultaneously with the increase in funding of the health care sector. In Ukraine, more than 30 people die every day due to the mistakes of doctors, which could have been avoided. World judicial practice shows that every year doctors have to answer increasingly questioning in court to the claims of their patients, which indicates the need to involve lawyers to protect the rights of victims and doctors [7-28].

**The purpose of the study** was to research in the field of pharmacy and stomatology. A multidisciplinary study was conducted for the organizational and economic, forensic and pharmaceutical, criminal and legal, forensic and medical research of the risks of drug circulation and their side effects as a result of providing dental care on the basis of pharmaceutical and medical law.

**Materials and methods.** The basis of the research were the laws of Ukraine, resolutions of the Cabinet of Ministers of Ukraine, Orders of the Ministry of Health of Ukraine, information sources from medical, pharmaceutical, criminal law, forensics, forensic medicine, forensic pharmacy. Research methods: bibliographic, documentary, normative and legal, comparative, graphic, retrospective, systematic, tabular, forensic and pharmaceutical.

The research of the article is a fragment of research works of Lviv Medical Institute LLC on the topic of "Improving the system of circulation of drugs during pharmacotherapy on the basis of evidentiary and forensic pharmacy, organization, technology, biopharmacy and pharmaceutical law" (state registration number 0120U105348, implementation period 2021-2026); Luhansk State Medical University "Conceptual interdisciplinary approaches to pharmaceutical provision and availability of drugs, taking into account organizational and legal, technological, analytical, pharmacognostic, forensic and pharmaceutical, clinical and pharmacological, pharmacoeconomic, marketing, social and economic competencies" (state registration number 0123U101632, terms 2023-2027); Kharkiv Medical Academy of Postgraduate Education on "Improving the organizational and legal procedure for providing patients with drugs from the standpoint of forensic pharmacy, organization and management of pharmacy" (state registration number 0116U003137, terms 2016-2020) and "Pharmaceutical and medical law: integrated approaches to the system of drug circulation from the standpoint of forensic pharmacy and organization of pharmaceutical business" (state registration number 0121U000031, terms 2021-2026); Petro Mohyla Black Sea National University on the topic "Conceptual interdisciplinary approaches to the drug circulation system, taking into account organizational and legal, technological, biopharmaceutical, analytical, pharmacognostic, forensic and pharmaceutical, clinical and pharmacological, pharmacoeconomic, pharmacotherapeutic aspects" (state registration number 0123U100468, implementation period 2023-2028); Private Scientific

Institution “Scientific and Research Institution of Medical and Pharmaceutical Law” on the topic “Multidisciplinary research of post-traumatic stress disorders during war among patients (primarily combatants)” (State Registration No. 0124U002540, period 2024-2029).

**Results and discussion.** According to the data [29], the system of legal relations "doctor-patient" is the fundamental point of understanding the responsibility of the doctor to the patient for the harm caused. The essence of such a construction should form the basis for the formation of criminal-legal protection of the patient's rights. The basis of the ideology of relations in the "doctor-patient" system at the level of society should be the traditional (dogmatic and historical) foundations of the formation of such relations in the relevant society. As well as global modern (international requirements) standards for the protection of such rights. Criminal law protection against violation of patient rights should be understood as a system of measures of criminal law policy and criminal law aimed at protecting the patient from harm caused by violation of the patient's guaranteed rights by a doctor or other medical worker through the application of criminal law norms.

Need to note that advertising of dental services sometimes does not meet moral and deontological requirements [30]. According to statistical data [31], doctors make mistakes in every tenth patient. The specificity of medicine involves a large number of non-standard situations: 20% of medical errors are caused by the human factor; 80% – occur due to imperfection of medical technologies and lack of medical equipment. An analysis of citizens' complaints about the quality of medical and pharmaceutical care was carried out. Complaints were registered in the period from January 2012 to December 2019 on the telephone "hotline" of the Department of Health Care of the Kharkiv Regional State Administration. Citizens' appeals to the lawyers of the "Apotheosis" Bar Association, the "Association of Medical and Pharmaceutical Law", the Department of Medical and Pharmaceutical Law, General and Clinical Pharmacy of the Kharkiv Medical Academy of Postgraduate Education were analyzed. According to the criminal legal experience of foreign countries, 31% of US doctors were tried during their career. Doctors' risks of being sued differ significantly depending on specialty, gender, and age [32].

As noted by Sipherd R. [33], the third leading cause of death of patients in the USA is medical errors. Take the 3rd place among the causes of death after heart disease and cancer. More than 250,000 citizens in the United States die each year from medical errors. Human rights defenders insist on the need to strengthen legislation to increase the level of protection and safety of patients. A death due to a medical error is a death caused by inadequately trained personnel that could have been prevented. Includes computer breakdowns, medication dosing errors, surgical complications that go undiagnosed. About 9.5% of all deaths are due to medical error.

If the patient's dental problem was solved in another hospital, then, as O. Shevchenko notes, the culprits must reimburse the costs of repeated treatment, that is, the pre-trial dispute settlement procedure [34]. A patient who believes that he was provided with poor-quality dental service has the right to send a written appeal to the administration of the medical institution with a justification of all the facts that testify to poor-quality provision of medical service and a demand for free elimination of defects or a proportional reduction in the price of the provided service, full reimbursement of material costs and moral damage. The patient should attach evidence to this application (a contract with a medical institution, receipts for payment of medical services). If the administration of the medical facility refuses to meet the above-mentioned requirements, it is necessary to apply to the court with a demand for:

- free elimination of defects;
- free repeat procedure;
- reimbursement of compensation for low-quality service provided (in some cases, you can contact law enforcement agencies and some other agencies immediately).

The study was carried out by a group of scientists Zoppi M., Török M., Stoller-Güteryüz D., Winzenried P. during 1974-1980. It showed that 19 out of 17,285 inpatients of the internal medicine departments of two teaching hospitals had a problem associated with with a probable or certain adverse reaction of patients to medication. It was believed that this was the main cause of their death [35]:

- 7 patients had a decisive adverse reaction during their stay in the hospital;
- in 12 patients, adverse reactions were already present during hospitalization;
- overall mortality from adverse reactions is 0.040%.

For each pharmacotherapeutic group of drugs, the rate of mortality associated with taking the drugs was calculated. For:

- anticoagulants 0.047% (3/6378 inpatients);
- cardiac glycosides 0.016% (1/6368);
- analgesics/antirheumatic drugs 0.014% (1/7112);
- cytostatic drugs 0.38% (2/531).

Below are typical examples from modern forensic medicine, forensic and pharmaceutical practice (No. 1-3). Forensic and pharmaceutical examples testify to the cause-and-effect relationship between the administration of a drug by a doctor, an adverse reaction to the drug, fatal outcomes due to the doctor's negligence and failure to provide emergency medical care in a timely manner. Deaths in children and adults have been recorded in dental practice as a result of side effects of drugs.

*Example from forensic medical and forensic pharmaceutical practice No. 1.* The investigator of the investigative police department of the police department in the Dnipropetrovsk region, under the procedural guidance of the prosecutor's office, started a pre-trial investigation in criminal proceedings on the fact of improper performance of professional duties by medical workers, which caused serious consequences to a minor child Part 2 of Art. 140 of the Criminal Code of Ukraine [36].

During the pre-trial investigation, it was established that on February 4, 2024, a dentist extracted a tooth of a 14-year-old boy under the influence of local anesthesia in one of the hospitals of Kryvyi Rih. The boy from the dentist's office came home. I felt sick at home. He was hospitalized in the intensive care unit, where the boy died the next day.

The director of dentistry said that the boy came in with a toothache. The doctors acted according to the procedure. The child's tooth was removed [37]. Medical assistance is provided in full in accordance with regulatory documents. After providing medical assistance, the patient was discharged home. His relatives were present with him. After some time, the boy was hospitalized due to his worsening condition. Investigations are currently ongoing. All the circumstances are established and a forensic medical examination is ordered.

*Example from forensic medical and forensic pharmaceutical practice No. 2.* Police investigators in the Ternopil region, under the procedural guidance of the prosecutor's office, started a pre-trial investigation in criminal proceedings on the fact of improper performance of professional duties by a medical worker under Part 2 of Art. 140 KKKU [38, 39].

Established that on November 13, 2023, a boy (age 1 year and 10 months) became ill after dental treatment by dentists in the regional children's hospital in the city of Ternopil. After some time the boy died. The mother brought the child to the state clinical health care institution to remove caries from the teeth. Since the child is small, the doctors emphasized that such procedures are performed only under general anesthesia. For this, the doctors gave a referral to pass all the tests. An hour and a half after the start of the general anesthesia operation, the child's blood pressure began to drop and the patient was taken to the intensive care unit. However, the doctors could not bring the boy, who was in the intensive care unit, out of the effects of anesthesia on his body, and already in the evening, the doctors declared the child dead.

Investigators seized from the dental office, where the child's procedure was performed, all medications, certificates on the child's tests, which are intended for forensic medical examination. Preliminary cause of the boy's death: acute pulmonary heart failure and allergic reaction [40-44]

*Example from forensic medical and forensic pharmaceutical practice No. 3.* The police investigator in the Lviv region, under the procedural guidance of the prosecutor's office, initiated criminal proceedings on the improper performance of professional duties by a medical or pharmaceutical worker under part 2 of Article according to Art. 140 of the Criminal Code of Ukraine [45]. It was established that on December 8, 2023, a mother took her 5-year-old son to the dental clinic of LLC "O" in Lviv for the removal of two milk teeth. Dentists suggested that she perform an operation on the child under general anesthesia. The child cried a lot, did not want to put on the

anesthesia mask. Sometime after the start of the operation, the mother heard a commotion in the operating room, medical workers began to rush there, after about 20 minutes, two emergency medical teams arrived at the clinic. The director of the O LLC dental clinic reported that the child had a cardiac arrest during the operation. The child was transferred to the intensive care unit of a multidisciplinary clinical hospital. Later, doctors diagnosed the boy with brain death [46, 47]. A forensic and medical examination has been ordered on the case; the investigation is ongoing.

We still have tragic cases in dentistry throughout Ukraine: 5 deaths - in the city of Lviv, in the city of Rivne – a 50-year-old woman, in the city of Kyiv and in the city of Dnipro [48]. The given examples from forensic medicine and forensic pharmaceutical practice testify to the risks during the provision of dental care. The following issues need to be resolved [10, 12, 15, 49-51]:

- presence in dental clinics of an authorized person responsible for conducting incoming control of drugs in circulation (purchase, transportation, storage, administration, quality);
- provision of measures to ensure the quality of drugs, vaccines, oxygen, and medical items in accordance with the requirements of good GxP practices;
- execution by authorized persons of dental institutions of prescriptions of drug quality control bodies regarding the removal from circulation of falsified, substandard, low-quality drugs;
- compliance by dental institutions with the order of the Ministry of Health of Ukraine dated October 31, 2023 No. 1887 regarding the licensing of medical practice [52];
- when violations of the circulation of drugs are detected, to suspend the validity of the license for the conduct of economic activity in the field of medical practice;
- implementation of sedation in dentistry in accordance with the proper practices of evidence-based medicine and evidence-based pharmacy [53].

Let's analyze the sedation procedure for dentistry. There are 3 stages of sedation in dentistry: 1) light, superficial sedation - the patient is relaxed, but awake, in contact with the doctor; 2) average - the patient reacts to tactile stimuli, all functions and reflexes are within normal limits; 3) deep - reactions are observed only to strong stimulation, the patient does not react to sound stimuli, the cardiovascular system works normally.

To reduce the risk of developing negative consequences, it is necessary to undergo a preliminary examination. It is mandatory to do a general and biochemical blood test, tests for HIV and hepatitis, and an electrocardiogram. If you have a history of chronic diseases, get a doctor's permission. All patients need an anesthesiologist's consultation. Sedatives are used for pharmaceutical manipulations. Contraindications to sedation:

- ❖ age less than three years;
- ❖ allergy and intolerance to the active substances in the composition of sedative drugs;
- ❖ arterial hypertension, cardiovascular diseases, pregnancy, tuberculosis, hepatitis, mental and addictive disorders;
- ❖ special warnings and contraindications in pediatric dentistry [54].

Errors in dentistry are the most common cause of side effects of drugs [55, 56]: 60% of dentists were aware of errors in treatment; 66.7% of respondents noted a dosage error; 30% - that medical technologies can reduce medical errors.

Indian dental jurisprudence suggests that the most controversial dental practice has been oral surgical procedures; in 40% of cases dentists were to blame. The inclusion of literary evidence and expert opinion influenced the outcome of the trial [57].

Prescription drugs are the 3rd leading cause of death after heart disease and cancer [58]. Psychoactive prescription antidepressants may cause falls in elderly patients due to falls. Nonsteroidal anti-inflammatory drugs cause mortality due to bleeding gastric ulcer and myocardial infarction.

In the practice of surgical dentistry, life-threatening conditions occur [59]. According to WHO data [60]:

- more than 3 million deaths occur annually due to unreliable treatment and medical errors;
- in low- and middle-income countries, at least 4 out of 100 patients die from unsafe care;
- more than 50% of harm (1 in every 20 patients) is preventable;
- 50% of damage is attributed to medication;

➤ common mistakes – unsafe surgical procedures, healthcare-associated infections, diagnostic errors, patient falls, bedsores, patient misidentification, unsafe blood transfusions, and venous thromboembolism.

Factors leading to patient damage in dentistry:

- ➔ systemic and organizational factors (complexity of medical interventions, inadequate procedures, disruptions in the work process, resource limitations, insufficient staffing);
- ➔ technological factors (electronic medical records, drug administration);
- ➔ human factors (disruption of communication between medical workers, with patients and their families, ineffective teamwork, fatigue, exhaustion, and cognitive biases);
- ➔ factors related to the patient (limited medical literacy, non-compliance with the treatment regimen and medication dosage);
- ➔ external factors (conflicting regulations, economic and financial pressure, challenges related to the natural environment).

According to the WHO, patient safety is a global health priority [61]. The goal of patient safety is to achieve the greatest possible reduction in avoidable harm from unsafe healthcare worldwide. In support of the implementation of the Global Action Plan "Decade of Patient Safety 2021-2030".

Peculiarities of dental practice among children for doctors [62, 63]:

- ✓ pass specialization cycles in children's dentistry;
- ✓ pass cycles of thematic improvement in clinical pharmacy and pharmacology for the use of medicinal products of various clinical-pharmacological, classification-legal, nomenclature-legal groups;
- ✓ understand forensic and pharmaceutical, forensic and medical risks due to overdose, contraindications, side effects or use of low-quality, falsified drugs [64];
- ✓ comply with the requirements for the use of drugs in dentistry at the stages of circulation (storage in appropriate conditions, accounting, incoming quality control, purpose, safety profile, interaction, special warnings, adverse reactions, etc.);
- ✓ to ensure an atmosphere of comfort and trust in the children's clinic based on the principles of ethics and deontology.

Preventive visits to a children's dentist should be regular in accordance with the protection of the rights of patients and consumers [65]. Indications for which an appointment with a doctor becomes mandatory and emergency:

- appearance of dental plaque;
- the first signs of caries development in the form of spots and darkening;
- the appearance of a fistula on the gums (usually a consequence of inflammation);
- the appearance of a tumor on the gums or swelling of the cheek;
- complaints about painful sensations while eating;
- acute painful sensations, including with sleep disturbance;
- children after 6 years of age are shown regular visits to the dentist in order to control the preservation of permanent teeth, their strengthening;
- from the age of 6, the child's bite is usually corrected if necessary.

The most common dental problems of a child:

- Pulpitis. The development of inflammation inside the teeth, in which blood vessels and nerve endings are affected. Accompanied by sharp pains, reaction to hot, cold.
- Caries. Gradual destruction of the enamel layer. It is often provoked by lack of proper hygiene, abuse of sweets. The problem occurs in most children of preschool age, there is a risk of its transition to permanent teeth.
- Stomatitis. Inflammation of the soft tissues of the gums. It is manifested by the formation of characteristic ulcers of a white shade. Stomatitis is accompanied by pain, as a result of which the child may refuse food and become irritable.
- Bite deviation. Not only an aesthetic problem, improper formation of the tooth rows provokes the development of a number of physiological problems.

**Conclusions.** A multidisciplinary study was conducted through an organizational and economic, forensic and pharmaceutical, criminal and legal, forensic and medical study of the risks of drug circulation and their side effects due to the provision of dental care on the basis of pharmaceutical and medical law. Taking into account the experience of the USA, the risks of circulation of drugs of clinical-pharmacological, classification-legal, nomenclature-legal groups in dentistry were studied. Medical errors in dental practice with fatal cases are summarized. The consequences of low-quality dental care are given: deterioration of the patient's health; the development of complications (a sharp increase in temperature, worsening of breathing, dizziness, weakness, loss of consciousness, jaw pain, etc.). Cases of urgent invitation of emergency medical aid doctors to transport a patient to the intensive care unit due to medical errors and the use of low-quality drugs are noted. Forensic pharmaceutical practice in dentistry with violation of criminal proceedings, recovery of material damages for the benefit of patients is described. Peculiarities of dentistry in children are given. Further research is ongoing.

**Conflict of interest.** The authors declare that the study was conducted in the absence of any commercial or financial relationship that could be considered a potential or actual conflict of interest.

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