

VILNIUS UNIVERSITY

Sandra

MAŽEIKIENĖ

Ethical, legal, forensic medical
justification of deontological
examinations in the evaluation of
physician malpractice and errors

SUMMARY OF DOCTORAL DISSERTATION

Medical and Health Sciences

Medicine M 001

VILNIUS 2020

This dissertation was written between 2013 and 2019 in Vilnius University.

Academic supervisor:

Prof. Dr. Dainius Characienjus (Vilnius University, Medical and Health Sciences, Medicine – M 001).

Academic consultant:

Assoc. Prof. Dr. Algimantas Jasulaitis (Vilnius University, Medical and Health Sciences, Medicine – M 001).

Dissertation Defense Panel:

Chairman –**Prof. Dr. Janina Tutkuvienė** (Vilnius University, Medical and Health Sciences, Medicine – M 001).

Members:

Prof. Dr. Gražina Stanislava Drašutienė (Vilnius University, Medical and Health Sciences, Medicine – M 001),

Assoc. Prof. Dr. Daisuke Yajima (Chiba University, Japan, Medical and Health Sciences, Medicine – M 001),

Prof. Habil. Dr. Viktoras Justickis (Mykolas Romeris University, Social Sciences, Law – S 001),

Prof. Dr. Rimantas Stukas (Vilnius University, Medical and Health Sciences, Public Health – M 004).

This dissertation will be defended at a public meeting of the Dissertation Defence Panel at 12:00 on 25 September 2020 in the meeting room of the Faculty of Medicine of Vilnius University. Address: 21 M. K. Čiurlionio Street, Vilnius, Lithuania. Phone No.: +370(5) 239 8700: email: mf@mf.vu.lt.

The text of this dissertation can be accessed at the libraries of Vilnius University, as well as on the website of Vilnius University: www.vu.lt/lt/naujienos/ivykiu-kalendorius

VILNIAUS UNIVERSITETAS

Sandra

MAŽEIKIENĖ

Deontologinių ekspertizių etinis,
teisinis, teismo medicininis
pagrindimas, vertinant profesinius
gydytojų nusižengimus ir klaidas

DAKTARO DISERTACIJOS SANTRAUKA

Medicinos ir sveikatos mokslai,

Medicina M001

VILNIUS 2020

Disertacija rengta 2013– 2019 metais Vilniaus universitete.

Mokslinis vadovas:

prof. dr. Dainius Characiejus (Vilniaus universitetas, medicinos ir sveikatos mokslai, medicina – M 001).

Mokslinis konsultantas:

doc. dr. Algimantas Jasulaitis (Vilniaus universitetas, medicinos ir sveikatos mokslai, medicina – M 001).

Gynimo taryba:

Pirmininkė – **Prof. dr. Janina Tutkuvienė** (Vilniaus universitetas, medicinos ir sveikatos mokslai, medicina – M 001).

Nariai:

Prof. dr. Gražina Stanislava Drašutienė (Vilniaus universitetas, medicinos ir sveikatos mokslai, medicina – M 001),

Prof. dr. Daisuke Yajima (Chiba universitetas, Japonija, medicinos ir sveikatos mokslai, medicina – M 001),

Prof. habil. dr. Viktoras Justickis (Mykolo Romerio universitetas, socialiniai mokslai, teisė – S 001),

Prof. dr. Rimantas Stukas (Vilniaus universitetas, medicinos ir sveikatos mokslai, visuomenės sveikata – M 0014).

Disertacija ginama viešame Gynimo tarybos posėdyje 2020 m. rugsėjo mėn. 25 d. 12 val. Vilniaus Universiteto, Medicinos fakulteto, didžiojoje auditorijoje. Adresas: M. K. Čiurlionio g. 21, Vilnius. Lietuva, tel. (85) 239 8700; el. paštas mf@mf.vu.lt.

Disertaciją galima peržiūrėti Vilniaus universiteto bibliotekoje ir VU interneto svetainėje adresu: <https://www.vu.lt/naujienos/ivykiu-kalendorius>.

TURINYS

1. INTRODUCTION	7
1.1 Relevance of the research	7
1.2 Purpose of the reserach.....	9
1.3 Objectives of the research.....	9
1.4 Novelty and importance of the research	10
1.5 Supporting statements	10
2. METHODOLOGY OF THE RESEARCH	11
2.1 Stages of the research	11
2.1.1 Literature analysis.....	11
2.1.2 Charachteristics of the research group.....	11
2.1.3 Statistical analysis of data.....	12
2.2 Formulation of the diagnoses	12
2.2.1 Final rules for the comparison of clinical and forensic diagnoses	15
2.2.2 Classification of diagnostic discrepancies	16
3. BRIEF OVERVIEW OF LITERATURE RESEARCH	19
3.1 Legal assessment of deontological examinations	19
3.1.2 Legal regulation	21
3.1.3 International documents regulating the professional activities of doctors.....	23
3.1.4 Documents regulating the professional activities of doctors valid in Lithuania.....	23
3.1.5 Adverse outcomes and legal liability of medical staff	25
3.2 Legal peculiarities in Lithuania	26
3.2.1 Adverse events.....	26

4. INVESTIGATIVE PART	31
4.1 Analysis of complaints	31
4.2 Investigation of deontological examinations	35
4.2.1 Prevalence and dynamics in Lithuania	35
4.2.2 Distribution of deontological examinations by medical institutions and departments	39
4.2.3 Distribution and dynamics by output	47
4.2.4 Peculiarities of deontological examinations	50
4.2.5 Coincidences of diagnoses	52
CONCLUSIONS	60
RECOMENDATIONS	61
LIST OF AUTHOR 'S PUBLICATIONS	64
INFORMATION ABOUT THE AUTHOR	65
APPENDIX	66

1. INTRODUCTION

1.1 Relevance of the research

In a changing world every day, the healthcare system is changing rapidly. Advanced methods of research, prevention, diagnosis and treatment, modernizing the thinking of doctors promote a more accessible, faster provision of medical services. Technological innovation, increasing workload and pace of doctors, increasing the number of errors made, leads to more frequent misunderstandings between doctors and patients. Most often, patients and their family members are aware of the disease, the methods of investigation and treatment, the possible consequences are incomplete, or the interests of patients, preferences, forgetting medical ethics are ignored. Patients express their dissatisfaction with the services provided by complaints against doctors or treatment facilities treating them. The importance of deontological examinations remains significant and unabated in order to clarify the quality, expediency, correctness of treatment provided.

According to the scientific literature, the incursions between clinical and medical diagnoses range from 30% to 37% on average. One of the most common reasons - doctors incorrectly formulated diagnoses. In the scientific literature, little attention is paid to errors in the formulation of diagnoses in the detection of the underlying disease or injury. In order to correctly determine the final diagnosis of disease or injury and the cause of death, it is necessary to accurately determine the genesis of the disease/injury, and in the event of death - the mechanism of death caused by the disease, therefore the autopsy remains the golden standard for improving clinical diagnosis by formulating the correct clinical diagnosis.

In all economically and technologically developed countries, including Lithuania, advances and advances in medical science are observed, but treatment errors are inevitable. In 1960, A. Klasso, and later in 2011, and B. A. Koch, highlighted a paradoxical situation: in

the event of undeniable advances in medical science and the increasing likelihood of patients being healed and provided with quality health care, errors are inevitable, and the number of claims for inadequate healthcare is increasing. The introduction of new medicinal substances, diagnostic and therapeutic methods and technologies is an integral part of the progress that enables results to be achieved, but with progress also changing the old medical model - the generosity of the doctor's profession loses its meaning, giving way to the pursuit of material benefits. Medicine becomes a service.

Communication between the doctor and the patient is determined by the financial reward. Thus, the oath of the medical father Hippocrates acquires more historical than practical significance, so the need for medical ethics and deontology increases more than ever in order to restore, strengthen a sense of morality and duty in medicine, in close, resilient ways, like no other science related to the moments of human life, when a person is most vulnerable as a result of his illness and suffering, and therefore an extremely important understanding of the human person and objective assessment of the actions carried out. The main factor leading to the successful and good functioning of medical staff is good professional training, which allows patients to provide qualified assistance. High qualifications of medical staff must be based on high moral and ethical norms.

In modern society, many fictional myths glide about the work of doctors. It is thought that doctors have no right to make mistakes, because the mistake made is treated as a doctor's negligence or a lack of qualifications. In Lithuania, increasingly dissatisfied, outraged patients and their relatives complain of poor quality healthcare provided. Complaints range from inappropriate or rough treatment of a health worker to accusations of health disturbance, resulting in mutilation or even death. In the practice of forensic service most often we deal with cases when they end up in court, because of the poor quality of the services provided by the medical workers or the non-provision of those services. The court and the court proceedings

then have a number of questions where special medical knowledge is required, so the court appoints an examination, which is carried out and in the form of a deontological expert conclusions, provided by the State Forensic Medical Service (SFMS)formed panel of forensic experts and doctors of other medical specialties.

Since the 1930s, the term medical deontology has established itself in the medical literature, referring to the duty of medical staff to society, the sick and their relatives. This is a list of moral and ethical norms that is mandatory for every medical worker.

The rapid development of medical sciences in recent decades has influenced the review of moral and ethical criteria for the performance of medical staff. A new branch of science has emerged—biomedical ethics, the basics of which are studied in all medical educational establishments. Biomedical ethics was formed at the intersection of branches of biology, medicine, philosophy, ethics, law science. Its primary source is medical deontology.

1.2 Purpose of the reserach

Analyze deontological examinations carried out by the State Forensic Medical Service (SFMS) for the period of 1989-2016 and assess professional misconduct and errors of doctors in Lithuania from an ethical, forensic medical and legal point of view.

1.3 Objectives of the research

1. Analyze and summarise Lithuanian and foreign scientific literature on professional misconduct and errors of doctors.
2. Assess the prevalence and dynamics of deontological examinations carried out in Lithuania in 1989 - 2016.
3. Analyze and identify complaints and demographic characteristics of victims of professional misconduct and errors of doctors.
4. Identify the areas of personal health care where the highest number of deontological cases is observed.

5. Analyze the data obtained and identify discrepancies between clinical and forensic medical diagnoses.

1.4 Novelty and importance of the research

In Lithuania, very little attention is paid to the importance of deontological examinations. In this retrospective study, the most common discrepancies between clinical and forensic medical diagnoses, the most common departments of medical facilities with the highest number of discrepancies have been analyzed and presented. In the future, this can help reduce the likelihood of medical errors, avoid unnecessary complaints and improve the relationship between doctors and patients. In the scientific literature, very little attention is paid to errors in the formulation of diagnoses, identifying the direct cause of death and the underlying disease. Many of the studies carried out publish cases of clinically unsuspected conditions and diseases revealed during autopsy, and do not emphasize the principles of formulation of a diagnosis, where mistakes are most often made.

1.5 Supporting statements

1. The number of deontological examinations carried out in Lithuania is increasing.
2. The highest number of cases related to controversial deontological issues occurs in the groups of middle aged (working) males.
3. The majority of deontological examinations are carried out regarding emergency invasive medical procedures.
4. The most common professional medical specializations receiving deontological examinations are of emergency surgical profile.
5. Most often, diagnoses do not coincide when interpreting intracranial injuries, conditions.

2. METHODOLOGY OF THE RESEARCH

2.1 Stages of the research

2.1.1 Literature analysis

Literature on deontological examinations collected and analyzed using publications, databases, where the keywords used were *discrepancies between clinical and pathological diagnoses, errors in doctors and treatment, formulation of diagnoses, autopsies*. On the basis of the literature collected, data on discrepancies of clinical and forensic medical diagnoses, their prevalence, causes in the world and Lithuania are summarised.

2.1.2 Characteristics of the research group

The study analyzed deontological examinations conducted by the State Forensic Medical Service (SFMS) to detect doctor errors for the period of 1989-2016. During the study, 1007 questionnaires were collected, meeting the criteria for deontological examination. These criteria are:

Cases of professional misconduct or crime of medical workers are analyzed;

A panel of forensic experts and specialist doctors was formed to analyze the examination;

The examination indicated the circumstances of the patient's health disturbance or death;

The examination was assigned by court or the pre-trial investigation.

Data were collected using a questionnaire (see Appendix). The questionnaire consisted of the following indicators: place and speciality of the medical staff, time of the incident, gender and age of the victim, clinical and forensic diagnoses, reasons for the examination, composition of the expert commission, number of questions, examination report number (for data traceability). During the data collection, the start and end times of the examinations were

additionally noted, but only in order to determine the duration of the examinations.

Also, during the study, a retrospective statistical analysis of patients' statements (complaints) for 2011-2015 was performed according to the data provided by the Ministry of Health of the Republic of Lithuania. Data analysis was performed using MS Excell 2010. Complaints about dentistry and medical services were examined separately.

2.1.3 Statistical analysis of data

The method used is a retrospective selective questionnaire method for collecting and examining data. A computer file of this data is formed using a Microsoft Excel computer program. Statistical analysis package R. This program was chosen for data analysis because of its availability, reliability and extensive application. Statistically significant differences between the two groups were identified in the non-parametric *Mann - Whitney - Wilcoxon* test with a 95 % materiality level. This test was chosen because it is not known whether the data analysed are distributed according to any (in most cases normal) distribution. Likewise, that criterion mentions the likelihood of both first and second types of error, i.e. does not allow the admission of an incorrect or correct hypothesis. The calculated value of criterion p shows a statistically significant difference if p is less than 0.05. Statistically significant trends were assessed by the *Pearson* correlation coefficient test with a 95% significance level. This coefficient is chosen because it verifies the linear dependencies with sufficient informativeness. The estimated trend is statistically significant if the p value of the test is less than 0.05.

2.2 Formulation of the diagnoses

In forensic practice, when examining the deceased in medical institutions, the main question often asked to a forensic doctor is: "Was the disease or injury correctly diagnosed?" In determining the

cause of death, most common mistakes are made in misinterpreting the underlying disease and the direct cause of death caused by the complications of the underlying disease. The data from our study are almost identical to the discrepancy data between clinical and autopsy diagnoses in other countries. Diagnoses must be unified and exactly follow the formulation rules and their coding. When properly identifying the final diagnosis or cause of death, it is necessary to accurately determine the genesis of the disease, and in the event of death - tanatogenesis. The basic principles for determining the final diagnosis or cause of death should help to do this:

Diagnoses must be of the same shape and accurately comply with the formulating rules and their coding. The uniform names for diseases, syndromes or injuries must be used in the formulation of diagnoses, strictly in line with the proposed international classification of diseases (ICD) terms. Not all information and not all ICD codes can be used to describe the underlying disease. In the event of death only the one reason that caused death directly or through complications should be identified as the main disease. Diagnosis must consist of three points: 1) underlying disease or injury; 2) major complications of the disease or injury; 3) accompanying pathologies, conditions (indicating from the most important).

The underlying disease, injury, is a specific nosological form (or its equivalent) written in a certain term suggested by the International Classification of Diseases, which the doctor believes was the original cause of death, that is, whether or not a series of complications caused death. It is this term and the corresponding disease code that will be compared with the main disease or injury of the forensic medical diagnosis. Usually, the underlying disease or injury is a single nosological unit. However, there are cases where the underlying illness or injury is several different illnesses or injuries. In such cases, "combined major diseases" are indicated, which can be presented in three possible variants: competing, cumulative and background diseases.

Competitive diseases are those the deceased suffered simultaneously, and each of them individually could have undoubtedly caused death.

Cumulative diseases are those diseases that have developed in the patient at the same time, playing a key role in the genesis. These two diseases, combined with aggravating each other, caused death. And each of them, developing individually, would not have caused death.

Background diseases - so-called diseases that are not etiologically related to the main one, but in the general genesis was one of the reasons for its development, complicated the course and contributed to the development of fatal complications that caused death. For example, hypertension, diabetes are often acting as a background disease.

When formulating a basic, combined diagnosis, it is important to take into account that statistics can only assess the primary cause of death as the disease/injury written in the first place in the diagnosis. In such cases, experts suggest prioritizing the illness or injury that had the greatest significance in the genesis.

A complication of a major disease or injury is called a nosological unit, trauma, syndrome, or symptom that is directly or indirectly related to the underlying disease but is not its expression. The most important, fatal complications of a major illness or injury are the immediate causes of death, listed last.

Concomitant diseases, conditions, are one or more nosological units that were not directly involved in the underlying disease at the time of death and were not directly involved in pathogenesis, although these diseases were subject to certain treatment-diagnostic procedures during the last episode of medical care. It is important to note that concomitant diseases cannot have fatal complications. All concomitant diseases are classified according to their significance for a specific nosological form of the underlying disease. In addition to diseases, it is necessary to note other pathologies, such as different pathological conditions - previous injuries and their consequences,

removal of the appendicitis, data on stomach, eyes, limbs surgeries, etc.

2.2.1 Final rules for the comparison of clinical and forensic diagnoses

After the examination, if the person was treated in hospital, the forensic physicians must compare the final clinical (written in the medical records) and the forensic medical diagnosis according to all three options separately (underlying disease/injury; complications; concomitant diseases/conditions). If all nosological forms, their terms and codes at each of the points coincide, it is a question of overlap between clinical and forensic diagnoses. If not, a discrepancy in diagnoses is recorded. In the case of a combined underlying disease, in case any of the competing, cumulative, or background diseases have not been diagnosed, the hyperdiagnosis can lead to a divergence of diagnoses. Discrepancies in diagnoses are considered to be substantial discrepancies in nosological units of any of the diagnosis options according to localization, according to etiology, according to the nature of the pathological process, as well as subsequent, untimely diagnosis of the underlying disease or injury. Three categories of discrepancies are used in the clinical-expert analysis of erroneous clinical diagnoses:

- I diagnostic discrepancy category - recorded in the case of a short-term presence of a patient in a hospital, when the doctors of the relevant department, due to a short period of time, were not able to make a correct diagnosis, and the diagnostic error did not affect the outcome. The time required to make a clinical diagnosis is three days. The period of up to three days is relatively equivalent to the patient's short-term hospital stay.
- II diagnostic discrepancy category - determined in cases where a correct diagnosis was possible in the relevant medical institution, but the diagnostic error did not substantially affect the outcome of the disease.

- III diagnostic discrepancy category - determined in cases when it was possible to make a correct diagnosis in the respective medical institution, and the diagnostic error influenced the wrong treatment tactics, which had an important role in the development of the fatal outcome of the disease.

It is important to consider the cause of one or another diagnostic error. When analyzing diagnostic errors, objective and subjective causes are distinguished. The first category of discrepancies in diagnoses is always caused by objective reasons. Category II and III errors can be caused by objective and subjective reasons. There are 3 groups among the objective reasons, and 6 groups among the subjective ones.

Objective causes of diagnostic errors:

- short-term hospital stay;
- severe patient condition;
- other objective diagnostic difficulties: e.g. failure of diagnostic equipment during the examination, atypical or slight symptoms of the disease, rare nosological forms, etc.

Subjective causes of diagnostic errors:

- insufficient examination of the patient;
- poor collection and evaluation of anamnesis data;
- inadequate evaluation of clinical data;
- incorrect evaluation of research;
- improper assessment of the consultant's conclusion;
- improper formulation of the final clinical diagnosis.

2.2.2 Classification of diagnostic discrepancies

The most common methods for classifying diagnostic discrepancies have already been mentioned (reviewed), with their advantages and disadvantages. Although, according to the scientific

literature, there is no single gold standard for the identification and classification of inconsistent surgical pathological diagnoses, there is a practice of applying the standard method consistently. Most importantly, these data should be integrated into the quality assurance and quality improvement program in order to reduce errors and fully improve the quality of treatment.

Goldman classification:

- Class I - errors directly related to death. No major disease has been identified early detection (diagnosis) of which would have increased the chances of survival or recovery, e.g. unrecognized curable infection; unsuspected myocardial infarction with marked chest pain.
- Class II– errors indirectly related to death. No underlying disease has been identified early detection (diagnosis) of which could have led to an adjustment in treatment, which would increase the chances of survival or recovery, e.g. no pulmonary artery thromboembolism was observed in the presence of advanced malignancy; unsuspected myocardial infarction with cardiac arrest.
- Class III– errors where accidental autopsy findings are not directly related to death but are related to the terminal disease process, e.g. known myocardial infarction with unsuspected left ventricular atrial thrombus.
- Class IV is divided into 1 and 2.
 - o 1 - when the findings found at random during the autopsy are not related to the determined cause of death, e.g. known myocardial infarction with unsuspected lung cancer.
 - o 2 - when the findings found at random during the autopsy supplement the final diagnosis made in a patient with an incurable disease, e.g. aspiration

pneumonia is not suspected in a patient with incurable disease.

- Class V. Complete coincidence of diagnoses.

Modified Battle Classification:

Very important (significant) discrepancies

- Class I

Primary diagnosis discrepancy. A correct (timely) diagnosis before death would have changed the situation by prolonging survival or allowing the patient to be cured (e.g. pulmonary infarction treated as pneumonia, fungal pneumonia treated as bacterial).

- Class II

Inconsistent primary diagnosis. Correct (timely) diagnosis would not have prolonged survival even with appropriate treatment (e.g., heart failure, pulmonary embolism-induced aortic stenosis, correctly treated bacterial sepsis with multiple organ failure due to unrecognized (unnoticed) postoperative osteomyelitis in a patient with rheumatoid arthritis). Or there was no treatment available at the time (e.g. cytomegalovirus infection until the early 1980s).

Secondary (insignificant) discrepancies

- Class III

Inconsistent concomitant diagnosis not directly related to the cause of death but related to symptoms that had to be treated because it may have influenced (altered) the forecast (e.g., lung carcinoma in a patient with ruptured aortic aneurysm).

- Class IV

Inconsistent small (minor) concomitant diagnosis (undiagnosed) but possibly of epidemiological or genetic significance (e.g. asymptomatic gallstones, goiter).

No discrepancies

- Class V

There are no diagnostic discrepancies.

- Class VI

Patients died suddenly, within a short time of hospitalization, before the tests were performed, or the patient refused any diagnosis and treatment. The post-mortem study was non-informative (inappropriate), without any clear findings, and no diagnosis was made either clinically or in post-mortem studies.

3. BRIEF OVERVIEW OF LITERATURE RESEARCH

3.1 Legal assessment of deontological examinations

Increasingly, patients are blaming doctors for their mistakes, for not following the rules of careful treatment. Compensation of pecuniary and non-pecuniary damage is discussed. In order to clarify the validity of the allegations of treatment errors, expert assistance is needed. If the claim states that the patient died due to a treatment error, the court will order an examination of the deceased - an autopsy - to clarify such a case. The expertise report must state not only the treatment error, but also its significance for the occurrence of harm or the death of the patient. The usual term "doctor's error" has been replaced by "treatment error". A treatment error is considered when a doctor in the circumstances applies a necessary method of treatment, which is objectively recognized by medical science as a necessary means of treatment, in an unqualified manner,

he or she does this inattentively, irresponsibly. To make it sound shorter, it is called a "treatment error", "a violation of the generally accepted rules of medical science". Legal practice distinguishes between a simple and a harsh error of treatment. An example of *a simple treatment error* is damage to the lingual nerve by pulling a mental tooth. A *harsh treatment mistake* - when a doctor unequivocally violates the applicable rules of treatment or knowledge of medical science, makes a mistake that is objectively impossible to explain because he or she is simply not entitled to make such a mistake. For example, an X-ray shows a clearly visible fracture of the femoral neck, but the necessary treatment is not prescribed.

Legal issues are closely linked to ethical issues: the responsibility of physicians in diagnosing death, their rights and obligations to the living donor and sick recipients, the determination of indications for transplantation, the assessment of the degree of risk to the living donor and recipient, and many others. Ethical issues of biomedicine are especially relevant in interpreting the issues of artificial insemination, surrogacy, prenatal fetal gender diagnostics, paternity determination. Ethical issues arising with the evolving progress of intensive care and resuscitation should be singled out. As an example, the decision to stop artificial ventilation and blood circulation when the patient's cerebral cortex has died (decortication), who and when can and must make a decision to stop the life-support equipment? Another equally important ethical behavior is the relationship between physicians and their relationship with patients. It is a fundamental change in the doctor-patient relationship enshrined in the Constitution of the Republic of Lithuania: "Man, his right and freedom are the highest value. The recognition and protection of these rights and freedoms is mandatory." The Law on Health Care (Law on the Health System of the Republic of Lithuania) emphasizes that every citizen who has become a patient has the right to receive all information about his illness, its course, prognosis: the patient must give consent to

diagnostic and treatment interventions or refuse them in writing. Medical staff are prosecuted for disclosing confidential patient information (seeing a doctor, diagnosis, treatment predictions). Penalties do not apply when a patient has a serious infectious disease that could provoke an epidemic. The doctor must report any injuries of criminal origin to law enforcement and inform the responsible law enforcement authority. The law obliges the doctor to treat patients humanely and respectfully.

The formation and development of biomedical ethics is inextricably linked to established human rights, inviolable individual and patient rights. Biomedical ethics is one of the forms of protection of human rights: the right to life, to health care, to the free management of one's life. In recent years, many purely deontological issues have found a legal solution - the moral regulation of the actions of medical staff has become legal. For example, a deontological dispute over euthanasia performed. This issue is viewed from a moral-ethical point of view: categorically and unequivocally - legally, i.e. the laws of the Republic of Lithuania prohibit euthanasia and establish legal liability for its execution. One of the sources of the origins of biomedical ethics has been medical deontology, which has not lost its importance and remains one of the most important components of biomedical ethics to this day.

3.1.2 Legal regulation

Professional misconduct and errors are investigated and liability is determined or sanctioned by the competent authorities in accordance with the relevant legal instruments.

The oldest known legal regulation of physician liability is found in Sumerian civilization, i.e. ~ 2 thousand years BC. The Code of Hammurabi, which states that "if a doctor has treated a gentleman and it all has resulted in death, or if a doctor has opened the abscess of an eye to a gentleman and it has all ended in death, the doctor must have his hands cut off for all this." The oldest known case of "medical

negligence" was described in 1374: The surgeon (defendant) treated the patient's (plaintiff's) severely injured hand, the plaintiff claimed that the surgeon guaranteed full healing of her arm for the agreed remuneration, but after treatment her arm remained severely deformed. The claim back then was dismissed for procedural errors, but the judge established principles that are still recognized: the doctor should be held liable if the patient is injured due to the doctor's negligence, but if the doctor provided appropriate care, he/she should not be held liable, even if a positive treatment result was not achieved.

Most of the early cases were "breach of contract" cases - the plaintiff (patient) accused the doctor (defendant) that the end result of the treatment did not match the promised. The very term "malpractice" (malpractice - Latin: mala praxis, "bad practice") was first used only in 1765 in William Blackstone's "Comments on English Law" to distinguish medical negligence from simple breach of contract. In 1769 An English court set a standard by which a doctor's conduct was to be assessed. In order for the defendant (doctor) to be found guilty, another doctor had to testify that the medical service provided did not meet the standard. However, the court ruled that the certifying doctor ("expert") could only be from the same area.

19th century social and medical changes in science and practice have led to an increase in litigation for medical negligence. At the same time, it has led to the improving legal regulation of medical practice and negligence:

Between 1840 and 1860, the number of cases of medical negligence in the English courts of appeal increased by 95% (while the population increased by only 85%).

Medical science was poorly standardized, and doctors were poorly trained, leading to a decline in their social status.

There was a growing belief that human actions, not divine power, determine the course of events. As a result, suing the doctor for negligence was less radical than before.

Successful physicians were affluent, making them an attractive target for litigation.

Some physicians have seen benefits in advancing litigation as advances in medical science, regulation of practice, and quality assurance of services.

3.1.3 International documents regulating the professional activities of doctors

International Code of Medical Ethics (1949); Convention on Human Rights and Biomedicine (Oviedo, 1997); Declaration of Helsinki (1964, latest version 2013); Belmont Report (1979) - regulates the ethical principles of biomedical research in humans, Tokyo Declaration (1975) - regulates the duties of doctors in prisons, Oslo Declaration (1970) - regulates abortion for medical purposes.

3.1.4 Documents regulating the professional activities of doctors valid in Lithuania

- Code of Ethics of the Lithuanian Medical Association. Signed on 11/05/2015. It covers important issues such as the doctor-patient relationship, doctor-doctor relationships, doctors' rights, medical research, free and informed patient choice and scope, respect for patient privacy, confidentiality of patient and health information. Due to the special sensitivity of the doctor-patient relationship, the vulnerability of the patient, medicine is one of those areas of professional activity where codes of ethics have a very long tradition. Legal regulation alone is not enough to solve the problems that arise in the work of a doctor, therefore codes of ethics provide guidelines that reflect the values of the professional community, which help to find solutions in difficult situations.
- Law on the Health System of the Republic of Lithuania. This law regulates the Lithuanian national health system, its

structure, the limits of the legal regulation of health safety, health promotion and health recovery relations, the determination of the scope of health activities, the regulatory framework of healthcare organization, management, promotion and contracting activities, grounds for liability for violations of the legal norms of health care activities, rights and obligations of the population and health care entities.

- Law on Healthcare Institutions. This Law establishes the types of healthcare institutions, the regulatory framework of their establishment, reorganization, liquidation, activities, its state regulation, control measures, management and financing peculiarities, the nomenclature of Lithuanian national health system institutions, health care services and paid procedures for the provision of health care services in the institutions of the Lithuanian national health system, the relations between health care institutions and patients, the grounds for liability for violations of this Law.
- Medical Practice Act. This law establishes the conditions for the acquisition and exercise of the right of doctors to practice medicine; the procedure for the issue, registration, re-registration, suspension, renewal and revocation of licenses; the basic professional rights, duties and responsibilities of doctors.
- Medical norms. It is legislation that defines the rights, responsibilities, professional competencies, and operational requirements of personal health care professionals. Each medical norm is approved by the order of the Minister of Health, therefore it is obligatory for all specialists practicing in Lithuania with the relevant professional qualification, their employers, as well as institutions training, improving these specialists and controlling their activities.
- Patient Rights and Health Compensation Act. The purpose of this law is to establish the rights of patients and the procedure for the assessment and compensation of damage

caused to the health of patients when the damage to patients was caused by the lawful actions of a doctor or nurse (without their fault).

- Other documents (Civil Code of the Republic of Lithuania, Criminal Code of the Republic of Lithuania, Law on Death and Critical Conditions, Law on Burial of Remains, Law on Donation and Transplantation of Human Tissues and Organs, Law on Prevention and Control of Communicable Diseases, Law on Mental Health, Law on Assisted Reproduction.

3.1.5 Adverse outcomes and legal liability of medical staff

Reasons for adverse treatment outcomes:

Group I - causes independent of medical activity: congenital anomalies of the patient, incurable disease, atypical course of the disease, hypersensitivity of the patient to medication, delayed treatment, refusal of surgery or other prescribed treatment. Although complaints are quite common in such cases, doctors are not responsible for the unfavorable outcome of treatment.

Group II - directly or indirectly related to the professional and ethical activities of a physician:

- An accident is an adverse outcome the physician could neither anticipate nor prevent (e.g., death cases on the operating table when anesthesia was performed properly, and there were no contraindications; idiosyncratic reactions to medications that the patient did not know of or told the physician; complications of diagnostic procedures, etc.);
- Unintentional medical error (e.g. surgical error - unintentional nerve damage; delay in diagnosis due to lack of diagnostic capabilities and the like).

In such cases, the medical liability may be: moral, disciplinary, civil, criminal.

Moral responsibility - the doctor must feel moral responsibility even when the unsuccessful outcome of treatment is related to one of the group I reasons.

Disciplinary liability –a remark, a reprimand or dismissal (suspension or revocation of a license).

Civil liability - Some medical errors can be the subject of civil lawsuits, but the defendant is more often a legal person (such as a hospital) than a natural person (doctor).

Criminal liability - if a crime is committed in the course of one's professional activity, this act can be recognized as a criminal only if there are 4 compositional elements of the crime:

1. Entity (doctor or other health care provider).
2. Object (patient's health or life).
3. Objective element (act, such as criminal abortion, or lack of action, such as failure to provide medical care).
4. Subjective element (intentional action, negligence) - the most difficult to identify and prove. Attempts are made to prove that the causes of the unfavorable outcome exceeded the limits of an accident or medical error, and the physician acted intentionally with negligence, carelessness, overconfidence). In the investigation of cases, it is particularly important to identify the subjective element.

3.2 Legal peculiarities in Lithuania

Patient safety in healthcare is defined as healthcare structures and processes, the application of which reduces the probability of adverse events (hereinafter referred to as AEs) resulting from the influence of healthcare in Lithuania.

3.2.1 Adverse events

An adverse event is the result of an act that may have caused or has caused an adverse outcome (result) for the patient, more due to the provision and organization of medical care than to the patient's own

illness or condition. An adverse event is usually caused not by a single factor, but by the interaction of many circumstances and events. Data on the extent of adverse events in the healthcare systems of the Member States of the European Union are increasing. It is known that 8-12% of patients treated in EU hospitals experience adverse events when receiving healthcare. 2008 According to the European Commission, in the structure of adverse events, 23% are medication errors, 22% are diagnostic errors, 12% are medical device-related adverse events, 9% are nosocomial infections, and 5% are other adverse events. In Lithuania, the Minister of Health issued an order on 11 September 2018 to change the description of the mandatory registration procedure of adverse events, approved by the Minister of Health of the Republic of Lithuania on 6 May 2010 with the order "Regarding Approval of the List of Adverse Events Required for Registration and the Description of the Procedure for Registration", which entered into force on 1 January 2019. The adverse event monitoring profile governs the provision, analysis and dissemination of data on adverse events at national and local level. The purpose of adverse event monitoring is to ensure the monitoring of adverse events at the national level, to collect depersonalised data on adverse events, to analyze it, publicize and contribute to patient safety. The main principles according to which the monitoring of adverse events is carried out: expediency, systematicity, reliability, confidentiality. The new law expands the list of mandatory adverse events to be registered by establishing lists of adverse events for groups A and B. List A adverse events have already been regulated since 6 May 2010. These events are monitored by the responsible institutions: the State Accreditation Service for Health Care Activities under the Ministry of Health, the Ministry of Health of the Republic of Lithuania, etc. List B adverse events consists of 7 new groups of adverse events:

B1 - adverse events related to surgical, diagnostic and therapeutic invasive procedures;

B2 - adverse events related to the identification of patients or their body parts;

B3 - adverse events related to patient falls or falls in or around the healthcare institution;

B4 - adverse events related to patient behavior;

B5 - adverse events related to patient transportation;

B6 - nosocomial infection that caused the patient's death;

B7 - other adverse events.

The description stipulates that the Institute of Hygiene becomes a coordinating body for the monitoring of adverse events on the national level, prepares and publishes summary annual reports of the AEs. As of 1 January 2019, the national adverse event monitoring system that many European Union countries have has been in operation in Lithuania. Another important step in improving the monitoring of the AEs will be its computerization. The Public Health Monitoring Information System which will include an AEs module, to allow faster, more convenient and efficient monitoring of AEs on the national and local (personal health care institutions) level. The system will be created for the Institute of Hygiene by implementing the EU Structural Funds project "Improving the management of health sector processes through the development of public health monitoring" (2017-2020).

Both analyzing and evaluating general data on AEs makes it difficult to identify the dominant AEs for the following reasons:

- 1) different data collection methodology for each type of AE. Most AEs are registered throughout the year, but nosocomial infections are identified from three data sources: data collected in a one-time survey of the prevalence of infections and their risk factors, conducted annually in April; data collected in the surgical

departments of epidemiological surveillance of surgical wound infections, performed for at least 4 months per year; and data collected regarding nosocomial infections in resuscitation-intensive care units for at least 4 months per year⁴;

2) different providers of data on the incident. In most cases, AEs are reported by persons specified in the legislation (doctors, pharmacists, other healthcare professionals, patients). Infection control specialists collecting data on nosocomial infections are responsible for the epidemiological surveillance of nosocomial infections in personal health care institutions;

3) unequal scope and structure of information on the registered AE. Most of the information is collected through the registration of nosocomial infections detected in AEs related to the use of medicinal products. For other AEs, a minimum amount of information is collected, which is not sufficient for a general analysis of the AE.

Given the above characteristics of the data on AEs, the report only presents the total number of AEs by type, and each type of AE is analyzed separately. Information about registered AEs in Lithuania in 2017 was submitted by all specified institutions. Total number of registered AEs in 2017 was 890 (excluding established nosocomial infections), i.e. 1.2 times higher than in 2016 – 718 cases. The highest number of reported AEs related to the use of medicinal products - 861.18 AEs related to the use of medical devices were registered, AEs related to the preparation of blood transfusion and blood components and AEs related to radiation safety of patients, workers, the general public and radiological accidents - 5 each, and only one AE related to tissues, cell and organ donation and transplantation process. Compared to the reporting period of 2016, the number of the above-mentioned AEs increased 2.2 times.

One of the key conditions for changing the attitudes of physicians and the public towards errors in medicine is awareness and understanding of the problem. Assessing the analysis of patient

complaints and the cases of harm caused to patients in the media, it can be stated that adverse events in medicine are not uncommon. In 2008, The Institute of Hygiene implemented the Health Care Quality Assurance 2005-2010 program „Adverse events and their causes from the perspective of healthcare professionals and patients“. A study by the Institute of Hygiene found that one in ten doctors did not know what adverse events were, with only 4.5% of physicians admitting that adverse events in personal practice occur frequently (several times a month); over 80% of physicians said that adverse events are analyzed in their facilities, most often discussed within their department.

The main threats to patient safety worldwide are the inadequate number of competent healthcare professionals and the lack of knowledge about safe healthcare practices. In Lithuania, medical study programs are designed to develop clinical skills, the importance of service organization, leadership and healthcare team cooperation, quality assurance of healthcare services, and formation of risk factor management skills are not sufficiently emphasized. With today's requirements, patient safety and quality management are becoming a very important object of activity for all employees. Therefore, it is very important for university level and non-university educational institutions of both formal and non-formal education to respond to today's requirements.

In 2008, Minister of Health of the Republic of Lithuania, by the order No. V-338 “Regarding the Approval of the Description of Minimum Quality Requirements for Personal Health Care Services” obliges health care institutions to compulsorily record and analyze information on adverse events and their causes, take preventive measures to prevent and/or reduce adverse events.

Lithuania does not have a national patient safety policy, there is no coordinated action to improve patient safety at the national level. Adverse events are usually tackled in a less effective preventive way by 'firefighting': identifying the doctor who made the mistake, punishing him/her, compensating the patient, but not delving into the

real causes of such events. It is obvious that this solution is not valuable in a preventive sense, as adverse events are not systematically analyzed by identifying the root causes and implementing corrective actions to address them. Healthcare professionals avoid declaring a mistake for the fear of a hostile reaction from patients, punitive sanctions and disclosure of the situation, so the mistakes are hidden, and experience, whatever it may be, is not passed on. Punishment for mistakes do not encourage the sharing of experience and learning from mistakes. Errors reoccur, and their frequency and financial/non-financial losses increase. Punishments not only are unhelpful in avoiding mistakes and their consequences, but, on the contrary, force health managers and professionals to hide mistakes. This causes mistrust in healthcare and physicians in society.

4. INVESTIGATIVE PART

4.1 Analysis of complaints

For a long time, no statistical analysis of patients' complaints about inadequate or poor personal health care services was performed in Lithuania. We performed a retrospective statistical analysis of patients' statements (complaints) for 2011-2015 based on the data provided by the Ministry of Health of the Republic of Lithuania. (Data analysis was performed using MS Excell 2010). Complaints

regarding dentistry and medical services were examined separately. In both areas, complaints were broken down by the cities to which the healthcare facilities complained of belonged. Medical services are divided into medical fields. Applicants are divided according to whether the complaint was made by the patient himself or by the patient's relatives, including cases, according to the gender and age of the patient to whom the services were provided (minors, adults). The number of fatal cases was calculated. The panel decisions are divided into examined and unexamined statements, and the statements examined according to whether or not the complaint has been upheld. All satisfied complaints are divided according to the damage compensated to the complainant - pecuniary damage, non-pecuniary damage or both.

In 2011-2015, a total of 466 patient complaints were received regarding inadequate or poor quality care services. Of these, 101 (22%) were due to dentistry and 365 (78%) were due to medical services (Figure 1-4). A significant decrease or increase in the number of complaints is not distinguished either by taking the total number of complaints or by examining the services provided by dentistry and medicine separately.

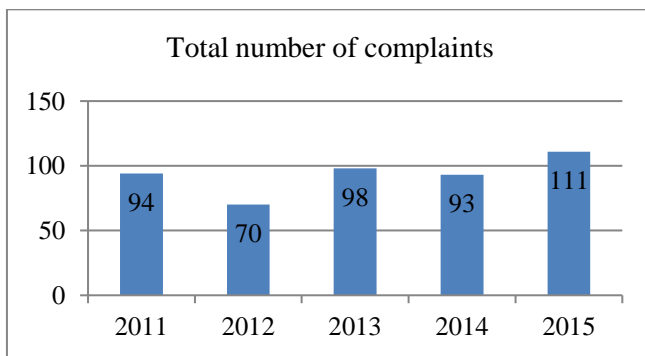


Fig. 1 Total number of complaints.

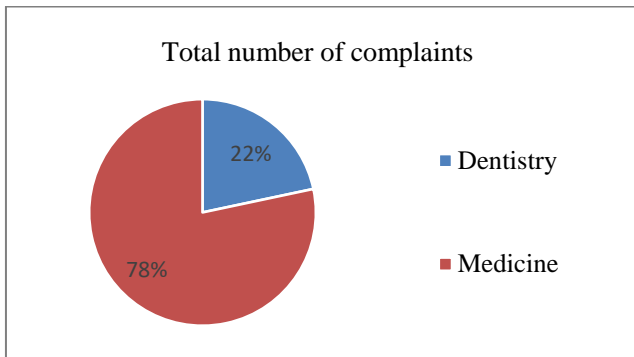


Fig. 2 Total number of complaints (%).

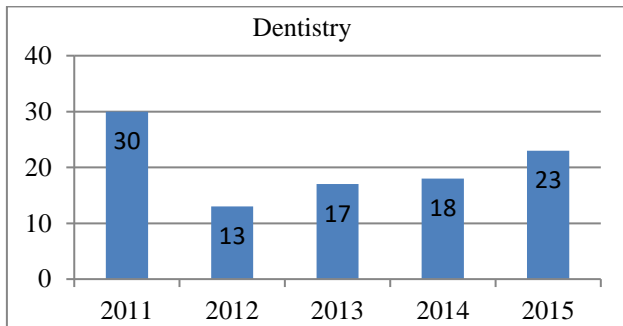


Fig. 3 Number of complaints due to services provided by dentists.

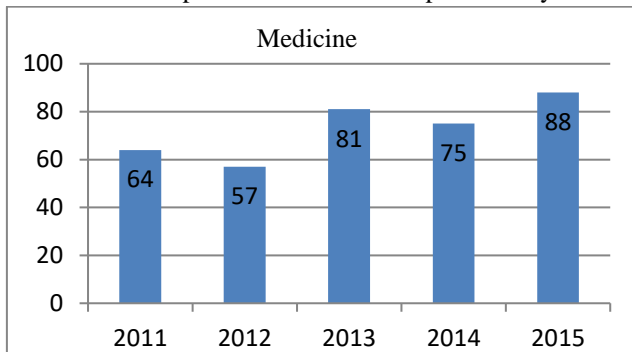


Fig. 4 Number of complaints due to services provided by medical specialists.

During the period of 2011-2015, out of all submitted statements regarding the complained dental and medical services - 314 (67%) complaints were submitted by the patient himself, 146 (31%) - by the patient's relatives, of which 83 complaints were regarding the patient's death (patient deaths were observed only in the medical services sector and accounted for 19% of all complaints). In 4 cases, both the patient and his relatives applied, and in 2 cases, the person was not indicated.

In 264 (57%) statements, the patients were female, in 187 (40%) were male, and in the remaining 15, the patient's gender was not indicated. The majority of 401 (86%) patient complaints were regarding inadequately or poorly provided healthcareservices for adults, 14 (11%) - for minors, and in 12 cases the patient's age was not indicated.

In the medical services sector, the largest number of patient complaints was received for medical services provided by therapy (n - 70), traumatology (n - 56), surgery (n - 76), gynecology and obstetrics (n - 43), and admissions (n - 29). A significant number of patients did not indicate the type of medical services complained of.

Conclusions:

1. There was no significant decrease or increase in the number of complaints regarding improperly provided healthcare services in the period of 2011-2015.
2. Complaints are usually made by the patients themselves, and their relatives usually apply in the event of the patient's death or represent minors.
3. The most frequently complained about are the personal healthcare services provided by therapy, traumatology, surgery, gynecology - obstetrics and the admission departments.
4. The majority of complaints end up unsatisfied or unresolved.

5. In almost all cases of satisfaction of complaints, non-pecuniary damage is compensated.

4.2 Investigation of deontological examinations

This study evaluates deontological examinations that were performed at the State Forensic Medicine Service. Deontological examinations performed between 1989 and 2016 were analyzed, when doctors were accused of the patient's death, improper provision of services, negligence in the treatment of the patient, health disorders due to improper treatment and other issues. The method used in the study is in the form of a descriptive questionnaire using unified questionnaires (see Appendix). The total number of deontological examinations meeting the above-mentioned criteria of deontological examinations during the period of 1989-2016 was 1007.

4.2.1 Prevalence and dynamics in Lithuania

The number of deontological examinations by year when the event in question occurred is presented in the diagrams (Figures 5 - 6). They show that the number of events considered tends to increase during the investigated period. This increase began after the restoration of Lithuania's independence. Some of the events that took place before 1989 had not been deontologically examined until then. The majority of events followed by deontological examinations occurred after 1995, although a significant increase was observed in the periods 1992-1994, 2001-2003, 2008-2011, and 2012-2015. A slanting increase in the number of events is observed until 2002. Since then, there has been an uneven change in their numbers. The largest number of deontological examinations in the period under review was performed in 2011 - 73 (7%), of which the largest number of events was registered in Klaipėda County - as many as 30 cases ($p < 0.001$). Over the last five years, the need for deontological examinations has remained very similar, neither declining sharply nor increasing.

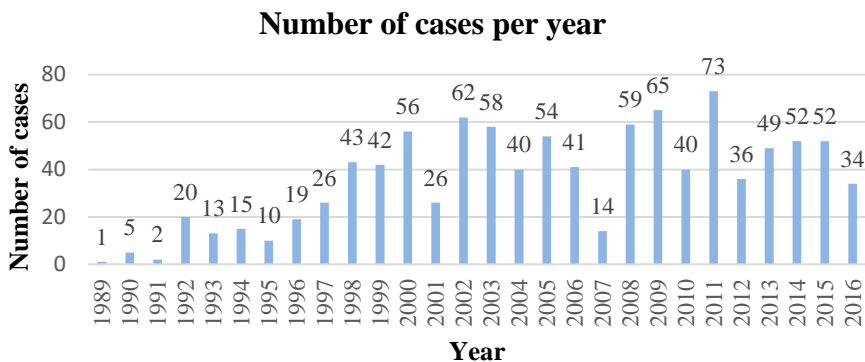


Fig. 5 Distribution of annual deontological examinations cases.

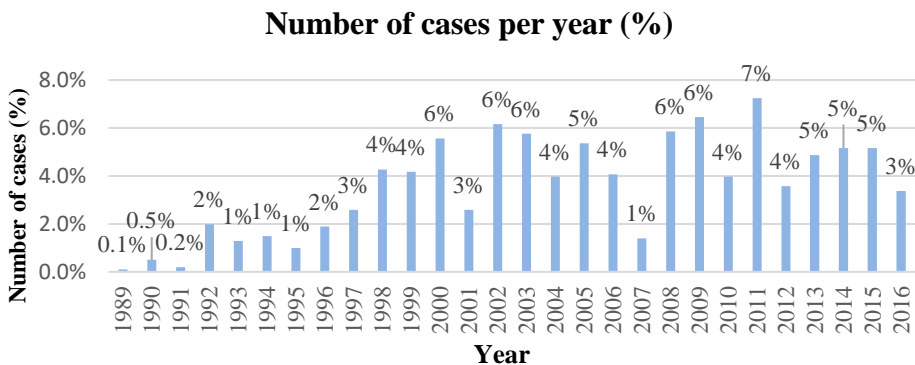


Fig. 6 Distribution of annual deontological examinations cases(%).

Assessing the age distribution of the number of victims in this study and comparing the age distribution of patients with the overall age structure of the Lithuanian population, we can see that the proportions of persons aged one year or older correspond to the overall population structure (correlation 0.53; $p < 0.001$). The share of persons under one year of age among the studied persons is higher than the share in the Lithuanian population ($p < 0.001$). The average

age of the subjects is increasing ($p = 0.002$). The growth trend of age is observed - 0.56 years per year.

Of all the deontological examinations analyzed, 600 (60%) cases were male and 407 (40%) were female (Figure 7). The number of cases of deontological examinations performed on male victims is one third higher.

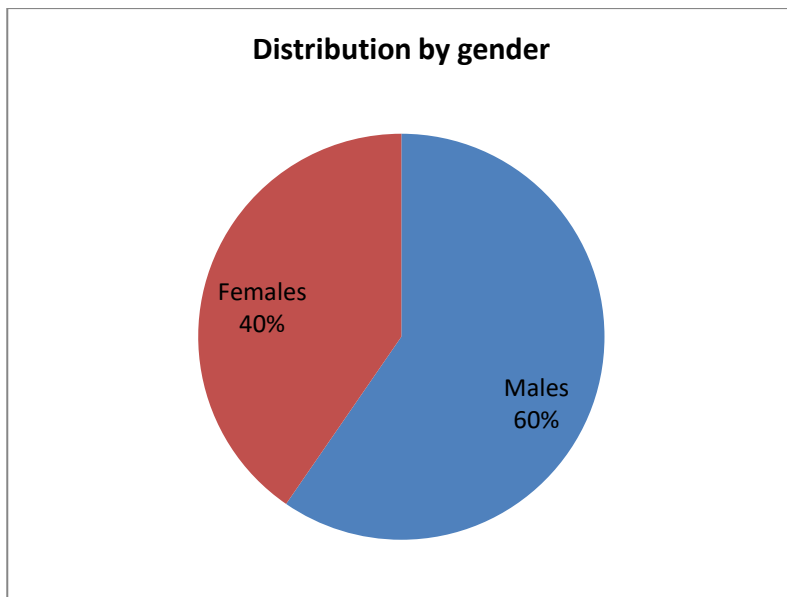


Fig. 7 Distribution of deontological examinations by gender of the victims.

A more detailed analysis of the distribution of deontological examinations by gender in each of the studied years (Figure 7) shows that male patients dominated throughout the year, only in 1992, 1996 and 2010 more examinations were performed on the females. The proportion of men was significantly higher in 2000 ($p = 0.033$). The number of subjects examined the following year did not differ significantly by gender ($p > 0.05$).

Distribution by annual number

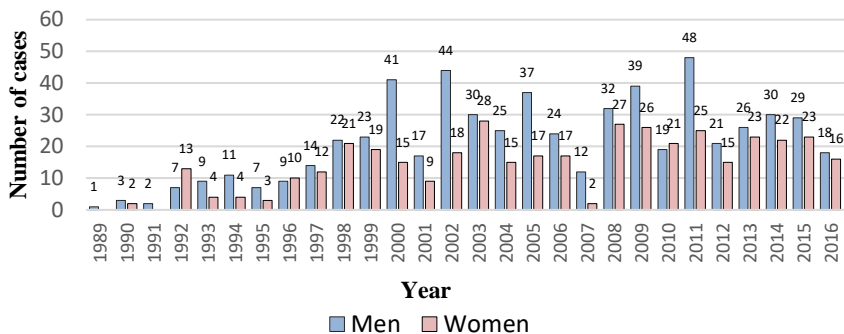


Fig. 8 Distribution of annual deontological examinations each year.

The analysis of the distribution of deontological examinations by age of men and women separately (Figure 9) show age groups, and only in a few groups was this number similar: 7 - 18 years of age, 30 - 39 years and the group of ≥ 70 years of age.

Age groups by gender

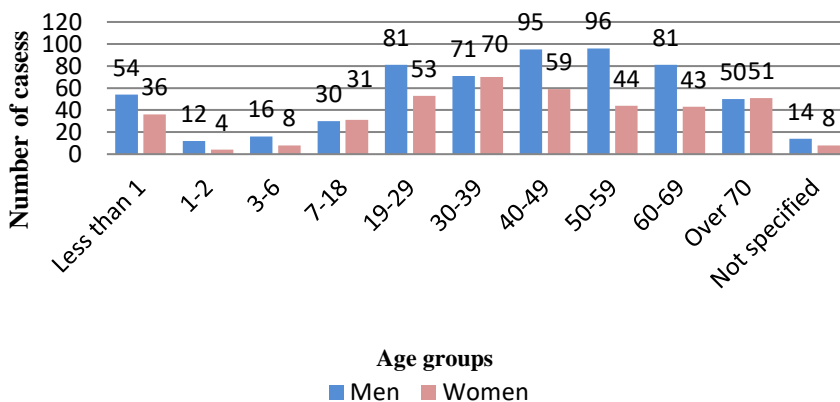


Fig. 9 Distribution of deontological examinations by gender and age of the victims.

When examining the number of cases by age groups selected according to physiological characteristics, the age of the injured patient was not indicated in 22 cases studied. 985 cases were divided into age groups according to the age of the subject at the time of the event for which the deontological examination was performed (Figure 10).

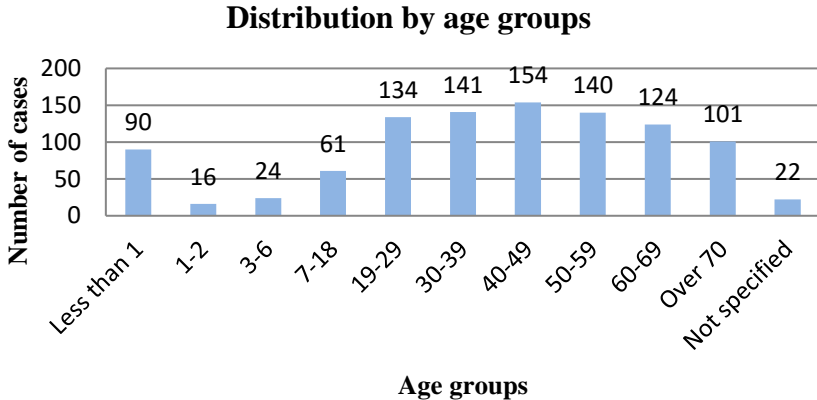


Fig. 10 Distribution of deontological examinations by age groups.

4.2.2 Distribution of deontological examinations by medical institutions and departments

The distribution of the whole sample according to the departments of medical institutions is very diverse, covering many fields of medicine. The presented bar chart shows the distribution of deontological examinations according to the department with the most controversial cases (Figure 11).



Fig. 11 Distribution of deontological examinations by department of medical institutions.

The highest number of cases was found in general surgery departments - 154 cases, in admission departments - 133 cases, resuscitation - in intensive care departments - 132 cases, slightly lower numbers in obstetrics - gynecology departments - 105 cases, in traumatology departments - 78 cases, and in neurosurgery departments - 58 cases. Such a high number of cases observed in these sections could be associated with a high flow of patients, as well as higher expectations of relatives regarding the condition of patients, stressful emergencies, complex cases, and so on. In all other departments, the number of disputed cases was significantly lower. In as many as 121 cases, departments of medical institutions were not specified. This may have been due to the fact that in some cases the charges were brought only to individual doctors or to the whole treatment facility, not mentioning any treatment unit, also in cases where the facility did not have a unit (such as a small outpatient clinic, etc.).

The bar charts below (Fig. 12 and Fig. 13) show the area of the medical professionals who provided health care services and were assigned deontological examinations. As many as 141 cases did not indicate the specialty of the doctor who provided the health care service (13%). This may be due to the fact that not in all cases the individual doctor was charged, and during the deontological examination only the name of the doctor was indicated and his specialization was not indicated. Deontological examinations were mostly performed for the services provided by surgeons - 151 cases (14%), obstetricians - gynecologists - 122 cases (11%), traumatologists - 90 cases (8%), anesthesiologists-resuscitators - 76 cases (7%), neurosurgeons - 75 cases (7%), therapists - 65 cases (6%). The same number of cases was regarding the services provided by neurologists, general practitioners and ambulance paramedics - 33 cases each (3% each). The numbers of deontological examinations were lower and did not differ much from each other due to the services provided by medical specialists of other specialties.

Distributing cases by gender, deontological examinations were mostly performed for males regarding services provided by surgeons ($p = 0.002$) and neurosurgeons ($p = 0.002$), therapists ($p < 0.001$), and for females—regarding the services of obstetricians and gynecologists ($p < 0.001$). It was also found that persons under one year of age were more likely to be examined for services provided by obstetricians and gynecologists ($p < 0.001$), patients aged 70 and older were more likely to be examined by surgeons ($p = 0.026$) and traumatologists ($p = 0.002$), services provided by anesthesiologists-resuscitators - for persons aged 1-18 ($p = 0.002$).

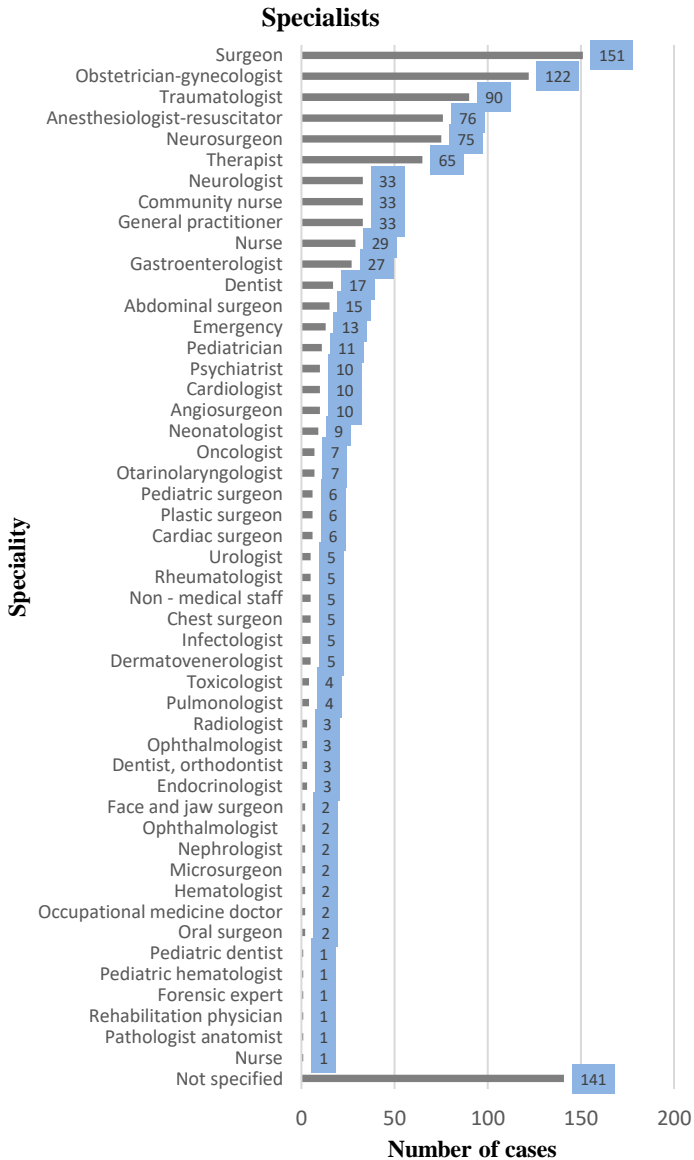


Fig. 12 Deontological examinations appointed for the medical services provided by these specialists.

Designated specialists

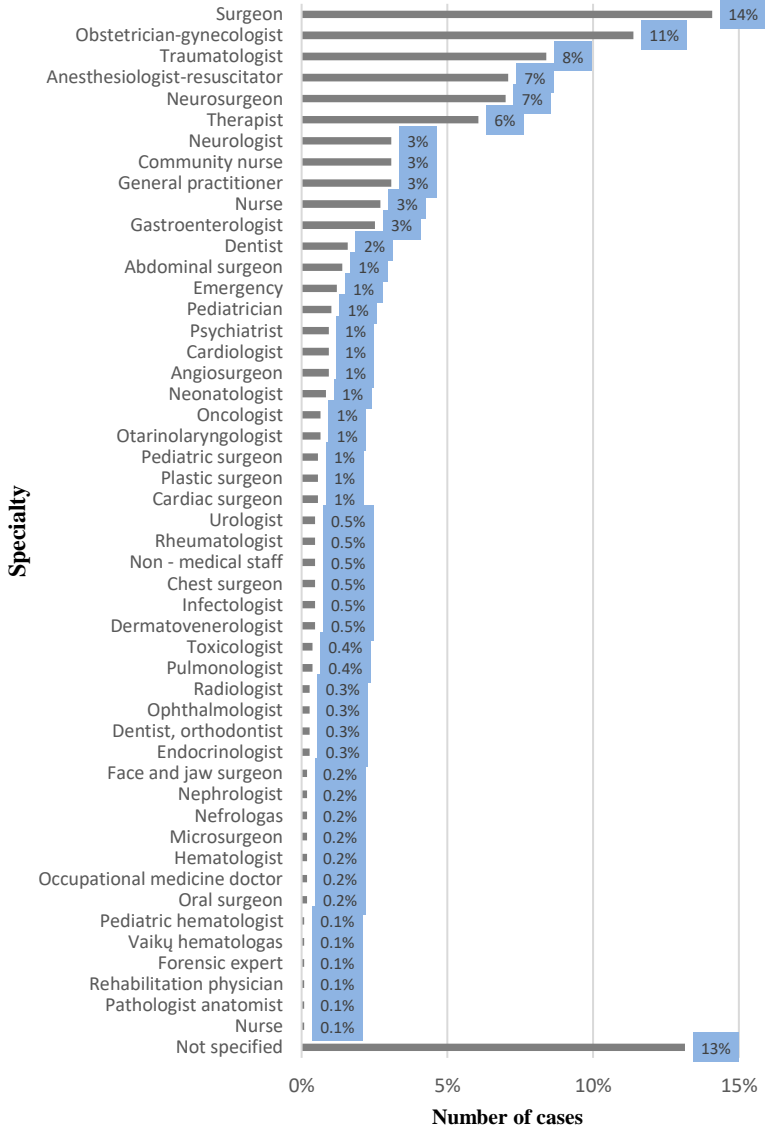


Fig. 13 Deontological examinations(%) appointed for the medical services provided by these specialists.

According to the research data, the institutions requiring the appointed deontological examinations regarding their specialist activities were analyzed (Fig. 14). In all cases evaluated, inpatient (tertiary) services were provided most often (855 cases), and outpatient services alone were provided many times less frequently (125 cases). In 5 cases, the type of service was not specified, and only in 16 cases both outpatient and inpatient services were provided.

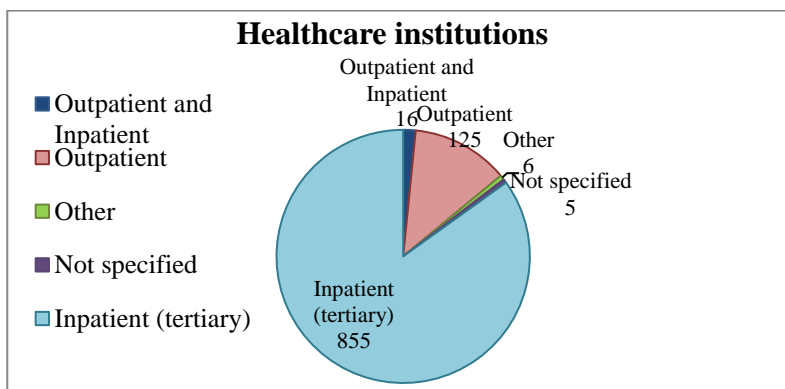


Fig. 14 Distribution by healthcare institutions

Deontological examinations for outpatient (primary and secondary) health care services were more often directed to females ($p = 0.001$). Due to inpatient (tertiary level) treatment, deontological examinations were more often prescribed to young people (up to 1 year of age) and persons over 70 years of age ($p = 0.003$). Outpatient (primary and secondary) services were more often limited to cases when the examination was provided only due to a health disorder ($p < 0.001$).

Examining the distribution of all services provided in major counties in Lithuania, we can notice that most of the deontological examinations were regarding inpatient services provided in Klaipėda and Kaunas medical institutions (Figure 15). In 2011, most events were registered in Klaipėda county ($p < 0.001$). All of them were due

to the chronic hepatitis C virus (this could be related to the higher number of foreigners arriving, unprotected sex, increased intravenous drug use, etc.). The highest number of discharged patients was also registered the same year ($p < 0.001$). All of them were hospitalized for chronic hepatitis C virus. Inpatient (tertiary level) treatment was more often needed by patients of Panevezys county ($p = 0.002$). Women were more likely to need consultations of more than one specialist ($p < 0.001$). Deontological examinations were more often performed regarding services provided by surgeons in Utena and Vilnius counties ($p < 0.001$), regarding obstetricians-gynecologists in Telšiai county ($p = 0.017$), anesthesiologists-resuscitators in Panevėžys and Šiauliai counties ($p = 0.007$). There was also a tendency regarding the services provided by obstetricians and gynecologists - patients were more often discharged from medical institutions ($p = 0.011$).

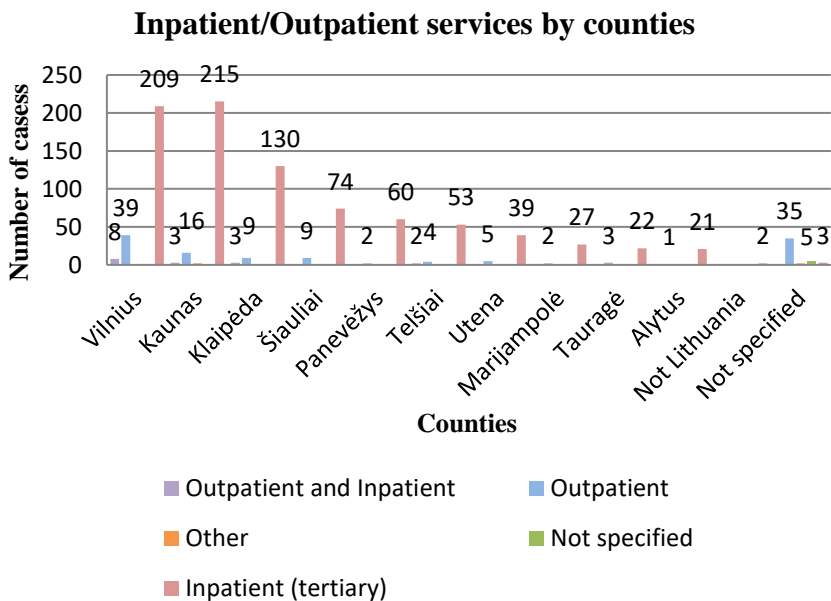


Fig. 15 Distribution of deontological examinations by outpatient/inpatient services in Lithuanian counties.

4.2.3 Distribution and dynamics by output

Assessing the distribution of deontological examinations according to the outcome of the provided health care services, we notice that out of all 1007 deontological examinations examined during this period, 715 cases (71%) were examined due to patient death and only 292 cases (29%) were due to improperly provided examinations of healthcare services, where victims were discharged from medical institutions (Figure 16).

Distribution by outcome

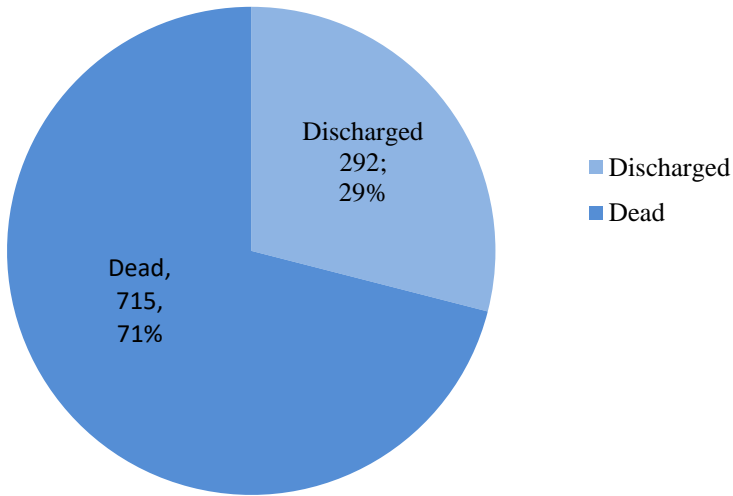


Fig. 16 Distribution of performed deontological examinations by output.

The distribution of identified outcomes by gender (Fig. 17) and age groups (Fig. 18) was also studied. The results of the study showed a higher number of deceased men - 475 (66.43%), and a higher number of women was among the discharged patients - 167

(57.20%) ($p < 0.001$). The graph shows that there are almost twice as many cases of deceased men - 475 (66.43%) than women - 240 (33.57%).

The graph shows that the number of deaths over the age of 30 remains very similar. The number of deaths was similar in three age groups: 30-39 years, 40-49 years and 50-59 years (97, 97 and 95 cases, respectively). The lowest number of deaths was found in the age group of 1-2 years, 14 cases. As many as 72 deaths were infants under the age of 1 year. The highest number of cases of victims who were discharged from medical institutions is seen in the age groups of 19-29 years and 40-49 years, 53 and 57 cases, respectively. Only in 2 cases of deontological examinations performed for children aged 1-2 years who were discharged from medical institutions. Mortality was higher in subjects aged 70 years and older than in younger ones ($p < 0.001$).

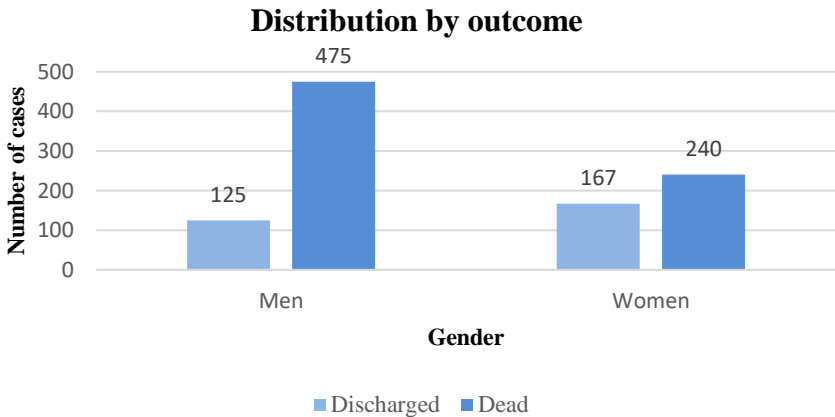


Fig. 17 Distribution of deontological examinations by gender.

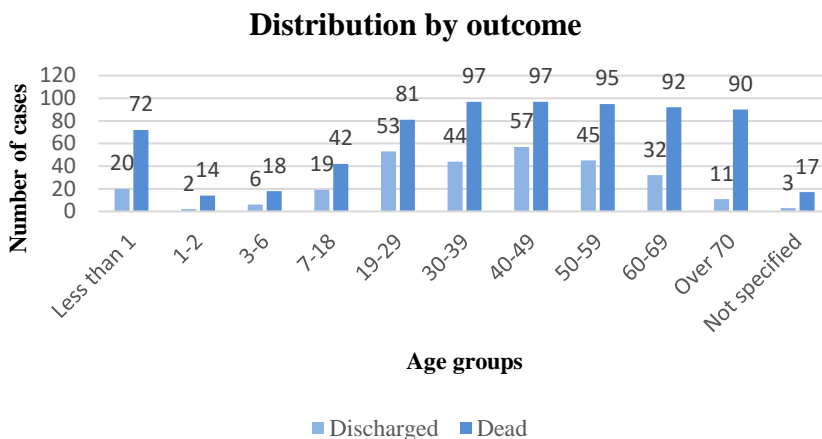


Fig. 18 Distribution of outcome by age.

An examination of the reasons for appointing a deontological examination (all cases examined including the ones where the reason is indicated in more than one option) revealed that in 928 cases, the most frequent deontological examination was appointed regarding improper provision of health care services, in 665 cases regarding the death of the patient during the applied treatment or absence of treatment, 85 deontological examinations were appointed for the diagnosis of a medical condition, 7 cases –regarding questionable diagnosis set at the primary healthcare institution and discrepancy or correctness of the diagnosis, regarding accuracy determining the extent of a health disorder (expert conclusions) - 3 cases, regarding other reasons (discrepancies in the mechanism of injury and time in the expert conclusions) - 4 cases.

The most common (92% of cases) examination was regarding inadequate provision of health care services. Examination regarding health disorders was more often given to women ($p < 0.001$). Men were more often examined for the death of a patient during the applied treatment/no treatment applied ($p = 0.017$). examination

regarding health disorders was more often given to younger (up to 40 years old) persons ($p = 0.015$), (Fig. 19).

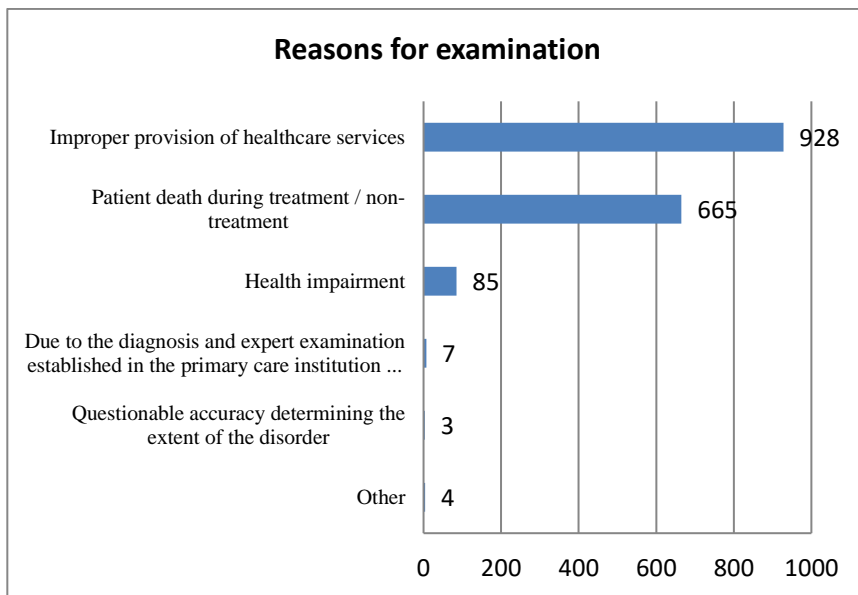


Fig. 19 Reasons for the deontological examination.

4.2.4 Peculiarities of deontological examinations

Examining the number of questions submitted to the panel of experts on deontological examinations for 1989-2016, it was found that 5 questions (114 cases) were most frequently asked, 3 questions were submitted in 108 cases and 4 questions were submitted in 107 cases. In five deontological examinations, the panel was asked more than 50 questions (these are mostly well-known cases).

The diagrams (Fig. 20 and Fig. 21) show the number of forensic experts and medical specialists who participated in the panel of deontological examinations and the most frequently invited consulting medical specialists invited in 1989-2016. In most cases, as many as 769, 2 forensic experts participated in the deontological examination panel, in 194 cases 1 forensic expert participated, and

even less often - in 44 cases - 3 forensic experts. The number of specialists invited by deontological examination panel ranged from 1 to 6 (Figure 21). In most cases - as many as 481, one specialist doctor participated, 318 cases - 2 specialist doctors, 113 cases - 3 specialist doctors, 38 cases - 4 specialist doctors, 8 cases - 5 specialist doctors and only 6 cases involved as many as 6 specialist doctors. During the research it was noticed that during 45 deontological examinations no medical specialist participated in the commission, and in 3 cases - the number of specialists who participated /did not participate was not indicated.

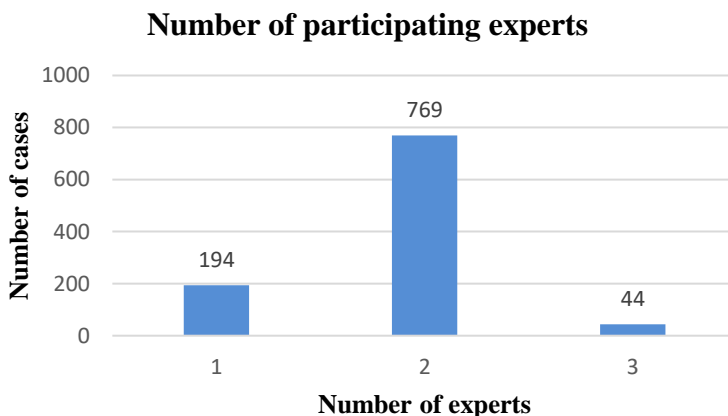


Fig. 20 Distribution of deontological examinations according to the number of forensic experts involved.

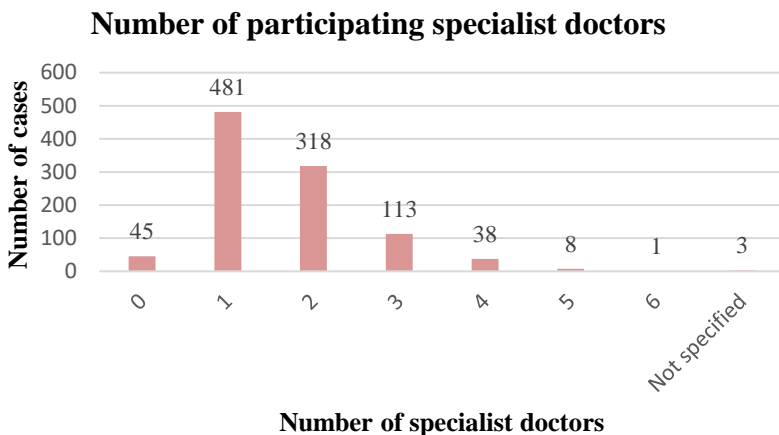


Fig. 21 Distribution of deontological examinations according to the number of specialists of the participating physicians.

During the research, the most common (most popular) specialties of medical consultants who participated in deontological examinations were evaluated. The most common specialties were an anesthesiologist-resuscitator (161 cases), a neurosurgeon (158 cases), an obstetrician's gynecologist (157 cases), a traumatologist (123 cases) and a surgeon (86 cases). All other specialties occurred much less often. Consultations with physicians of all these specialties were more often inpatient (tertiary level) than outpatient. Anesthesiologists-resuscitators, surgeons, obstetricians-gynecologists, traumatologists, neurosurgeons, etc. were the most frequently consulted physicians, their numbers are similar to the number of medical specialists who were under review of the deontological examinations for the health care services provided.

4.2.5 Coincidences of diagnoses

The coincidence of the diagnoses made during deontological examinations and the diagnoses made by the doctors who provided

health care services (i.e., clinical ones) was assessed (Fig. 22 and Fig. 23). In 796 (79%) cases the diagnoses coincided (class V according to Goldman), in 129 (13%) cases the diagnoses did not coincide (classes I and II according to Goldman), only in 67 (7%) cases the diagnoses partially coincided (III and Class IV by Goldman). In the other 15 (1%) cases, the coincidence of diagnoses could not be examined due to the lack of data submitted for deontological examination (for example, not all performed examinations were submitted to the expert panel, etc.).

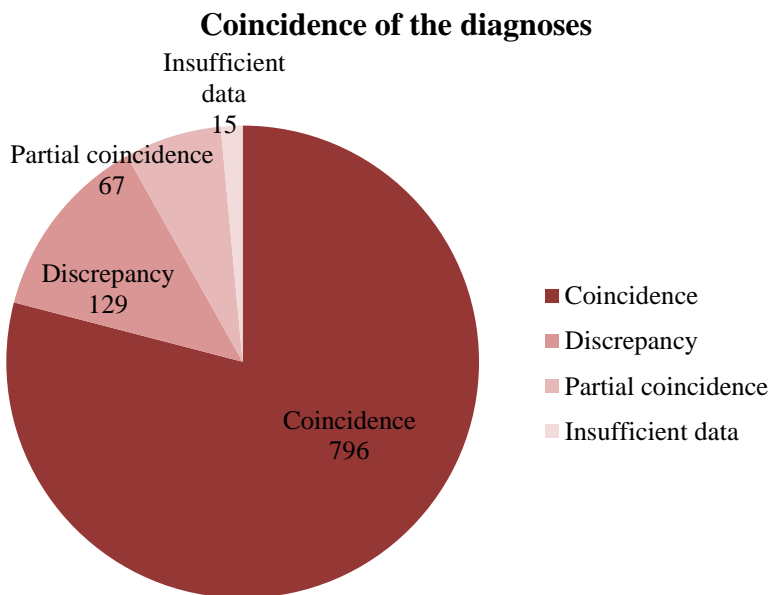


Fig. 22 Coincidence of conclusions of deontological examinations and conclusions of specialists who provided the services.

Coincidence of the diagnoses (%)

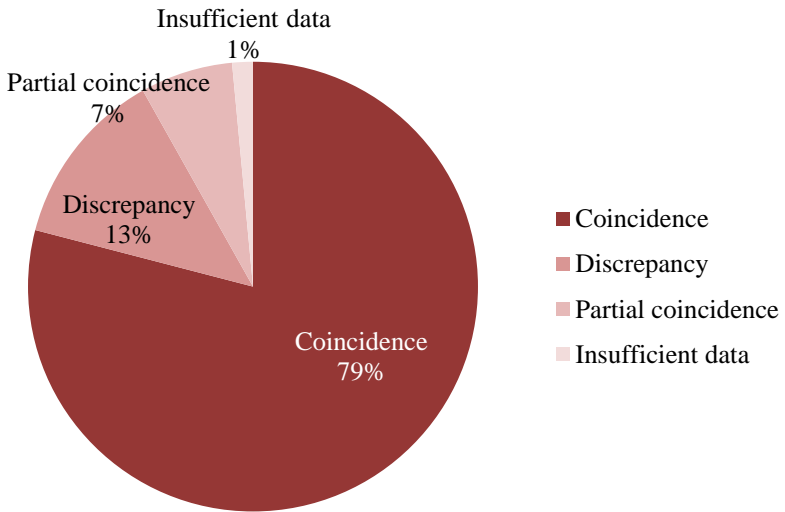


Fig. 23 Coincidence of conclusions of deontological examinations and conclusions of specialists who provided services (%).

The study assessed the distribution of diagnoses regarding age groups (Fig. 24). It was noticed that the diagnoses coincided more often in persons under 2 years of age and in persons older than 70 years of age ($p < 0.001$).

Diagnostic coincidence by age groups

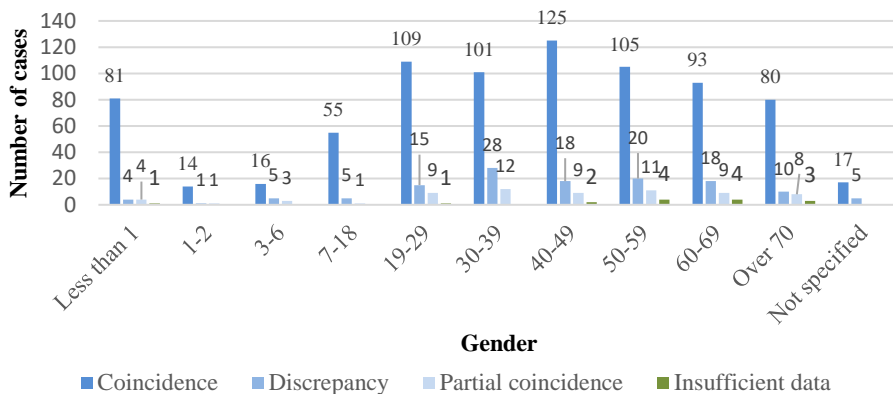


Fig. 24 Coincidence of conclusions of deontological examinations and conclusions of specialists who provided services by age groups.

Insufficient number of autopsies performed is one of the main reasons for the relatively large number of discrepancies in diagnoses. The number of autopsies performed during the study period varies throughout the year (Figure 25). Assessing the whole study period, an increase in the number of autopsies was observed - 1 case per year (correlation is strong, positive, $P = 0.007$), but the overall increase in cases is higher, i.e. 1.8 cases per year. Thus, the number of autopsies increases slower than the overall number of cases.

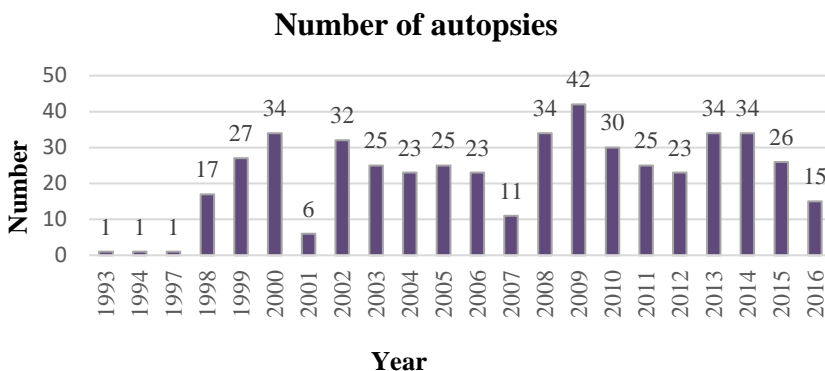


Fig. 25 Number of autopsies performed

The study assessed the distribution of coincidences / diagnostic discrepancies by gender (Figure 26). There were no significant differences, and the gender distribution was similar: both men (464 cases) and women (332 cases) accounted for the largest share of coinciding diagnoses. Discrepancies and partial coincidence between forensic and clinical diagnoses were found in almost twice as many women as in men (42 and 87 cases, 22 and 45 cases, respectively). This could be explained by the fact that in almost all cases during the period under review, the victims of the examined cases were mostly male.

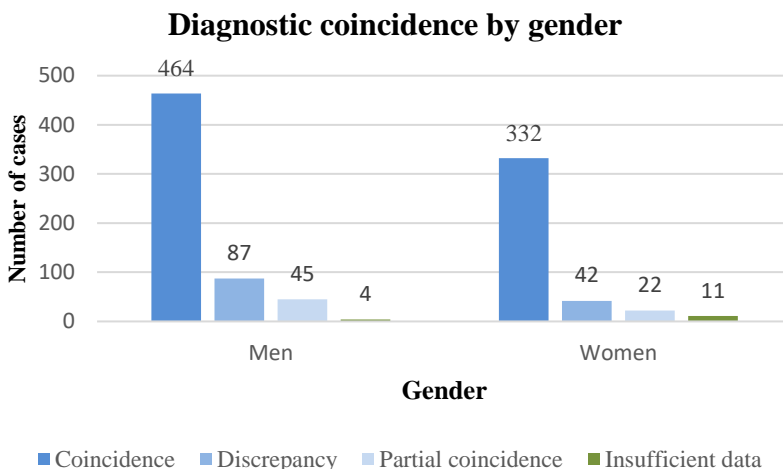


Fig. 26 Coincidence of conclusions of deontological examinations and conclusions of specialists who provided services by gender of the patients.

The study identified 129 cases (13%) of diagnostic discrepancies. According to the available data, the highest number of incorrectly identified injuries was intracranial injuries - 22 cases (22.9%), including: superficial head injuries, head wounds, cranial and facial bone fractures, unspecified intracranial injuries. The most common undiagnosed diseases and injuries: hemorrhage under the hard meninges - 10 cases, hemorrhage under the soft meninges - 2 cases, hemorrhage over the hard meninges - 1 case, purulent meningitis - 2 cases, damage to internal organs - 2 cases, polytrauma (multiple bodily injuries) - 1 case, injury to abdominal organs - 1 case.

During autopsies, 19 cases (19.8%) of intracranial injuries were detected, the diagnoses of which did not coincide with the clinical diagnoses. The most common undiagnosed diseases: unspecified head bruises, injuries - 11 cases, superficial bruising, wound - 2 cases, alcohol or medical poisoning, narcotic substances poisoning - 5 cases, stroke, brain aneurysm - 2 cases, epilepsy - 2 cases. Clinically suspected diagnoses - toxic effects of alcohol

(alcohol poisoning) were not confirmed in 5 cases, where undiagnosed diseases were hemorrhage under the hard meninges - 3 cases, hemorrhages under the hard meninges - 1 case, toxic liver disease - 1 case. Cardiovascular diseases identified in the pathological (autopsy) study in 5 cases were not suspected in the clinical investigation, when intercostal nerve neuralgia, post-syncope condition, death due to an unknown cause were diagnosed.

The study examined the cases whether the deontological examination revealed / confirmed the doctor's error or, conversely, it was denied (Fig. 27). The aim was to find out how many allegations were made regarding the doctor's mistakes, how many of them were admitted as the actual doctor's mistake, and whether the mistakes identified were the cause of the harm to the patient.

Determination of activity

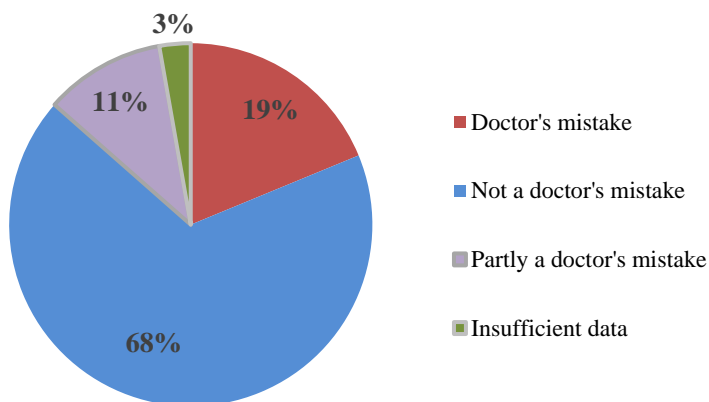


Fig. 27 Conclusions of deontological examinations.

Data analysis showed that most physician errors were confirmed in 1992 (11 cases), 2000 (27 cases), and 2002 (36 cases), (Figure 28). Out of all deontological examinations performed in 1989-2016, in more than half of the cases, 684 (68%), the guilt of doctors was

denied / not confirmed. The evaluation of the available data shows that there is an increase in the number of cases when the doctor's error is denied ($p < 0.001$). The growth trend of such cases is observed - 1.75 per year.

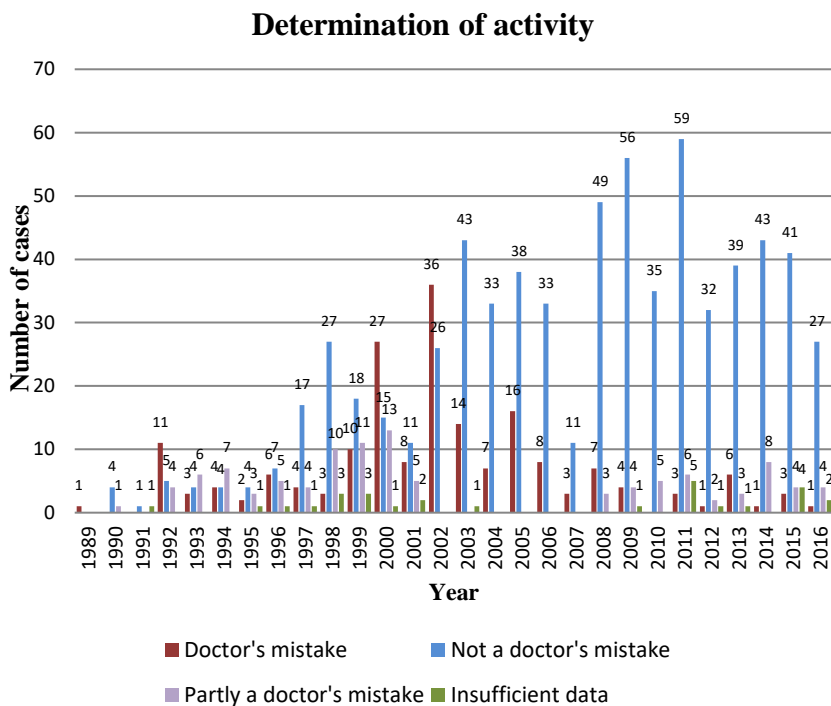


Fig. 28 1989 - 2016 conclusions of deontological examinations (%).

CONCLUSIONS

1. Summarizing the results of the data analyzed in the study, it can be seen that the number of deontological examinations in the analyzed period of 1989-2016 has a slight tendency to increase, the increase began after the restoration of Lithuania's independence. A trendy increase in the number of events is observed until 2002.
2. Having examined the deontological examinations of the researched period, we notice that the male gender predominated, it also dominated the distribution by gender each year. In the group of middle-aged (working-age) men (40-69 years), cases related to controversial deontological issues are more common.
3. Assessing the departments of medical institutions where the affected were treated, it can be stated that the areas of emergency and invasive medicine are leading in terms of the number of deontological cases, i.e. surgery, admission, resuscitation-intensive care, slightly smaller numbers in obstetrics-gynecology and traumatology departments.
4. Surgeons, obstetricians-gynecologists, traumatologists, anesthesiologists-resuscitators, neurosurgeons are the leaders of assessed professional medical specializations of medical staff who were appointed deontological examinations for the healthcare services provided.
5. During the period under review, the highest number of incorrect diagnoses was regarding intracranial injuries - 22 cases (22.9%), which includes diagnoses such as: superficial head injuries, head wounds, cranial and facial bone fractures, unspecified intracranial injuries. The most common undiagnosed diseases and injuries are: hemorrhage under the hard covering of the brain, bleeding under the soft covering of the brain, bleeding over the hard covering of the brain, purulent meningitis.

RECOMENDATIONS

In recent years, there has been an increased need for systematic recording, analysis of "incidents" and "errors" due to the provision of poor quality healthcare. For the sake of future patients, it is beneficial to take certain preventive measures: error recording and avoidance systems. Of particular strategic importance is the readiness of doctors and support staff to carry out such work and further development of it. To this end, a wide range of instructions to achieve the required medical standards, algorithms such as service instructions, catalogs, reference lists could be useful; careful personal approach to your duties performed is also important.

Familiarization with physician training and development programs should also include "classic" mistakes in a variety of disciplines.

Work on identifying and preventing medication errors can be seen as a contribution to risk management. For example, the German Association of Health Insurance Funds has an anonymous information system since 2005. In the future, treatment error management modules should be introduced into the licensing methodology for hospitals and doctors' offices. Annual reports could be provided on cases of medical negligence. As global practice shows, patients' complaints regarding improper treatment increase every year, so it would be appropriate to analyze and find out the most common reasons for this. Recently, there have been more and more heated discussions in Lithuania about the possible provision of inappropriate treatment, the damage caused and the fact that the Lithuanian legal system, its regulation, assessment of the conditions of liability itself are debatable, unacceptable due to obvious interpretation shortcomings.

Modern medicine is evolving rapidly with the introduction of the latest health care technologies that overcome past seemingly insurmountable health problems. At the same time, however, a health sector with a high risk and high potential for error can also distress

the patient. Increasingly, the media is hearing about patients' dissatisfaction with the health care provided, the distress they have suffered in hospitals, and illnesses that have not been diagnosed in time. Patient safety has recently become a topical issue in the healthcare system.

A very relevant problem in Lithuania is the lack of communication skills of doctors with patients, which leads to complaints and lawsuits, and one of the ways to avoid this could be communication training programs to help medical staff and patients. Consideration should be given to the possibility of legalizing in Lithuania the obligation for medical institutions and staff to inform the patient and his family members about medical errors and accidents that have harmed the patient's health or even resulted in death. In Lithuania, there is a lack of legal regulation in order to provide maximum protection for the doctor, so that he or she could reveal the mistakes made without fear, and such cases would not remain "hidden" from the public. Following the example of other countries, an apology and explanation policy could be applied. When using this tactics, patients often forgive doctors when the latter immediately sympathize and fully reveal their mistakes and guarantee that steps will be taken to prevent this from happening again to another patient.

Over the last ~ 50 years, the number of autopsies has decreased significantly, thus it is unrealistic to expect the situation to improve. There should be a change in the attitudes of treating physicians themselves and in the attitudes of pathologists towards this situation, as they have influenced themselves by abandoning autopsies as a method in their daily practice and giving priority to biopsies. And most importantly, the training of new medical professionals should be associated with a changed approach to the importance of autopsies.

Before assessing a treatment error, a violation of the recognized rules of medical care should first be identified, so the treatment error itself must be identified. For example, when the most common

treatment errors are known to be misdiagnosis, failure or inadequacy of initial examination, failure to perform tests, incorrect choice of treatment, etc., then one must find out whether the error found was the cause of the harm to the patient. And only when information is sufficient, having identified and analyzed all the causes of the errors, is it necessary to decide, if the error exists or not. Communication, information transfer, avoidance of concealment of results must be ensured. We could recommend a similar practice in Lithuania. Making all errors public, discussion in lectures, conferences, etc., detailed discussions could help reduce the recurrence of errors in the future.

The establishment of error database and error archive should be considered. However difficult it may be to recognize, adverse effects in healthcare cannot be avoided, but they can be reduced through risk management measures. One way to reduce the negative consequences of treatment is to record the adverse events (errors) that have occurred during the treatment process, and then to analyze them in order to identify and eliminate the causes. However, until now, medical institutions in Lithuania avoid registering adverse events. Another way to improve the effectiveness of health care is to assess whether the patient has received the expected outcome of treatment, but such assessment is not yet practiced.

LIST OF AUTHOR 'S PUBLICATIONS

Articles in peer-reviewed scientific publications

1. Discrepancies between forensic and clinical medical diagnoses in Lithuania. Sandra Mažeikienė, Sigitas Laima, Algimantas Jasulaitis, Jana Bytautaitė, Vilma Baranauskaitė, Gerda Andriuškevičiūtė, Sigitas Chmieliauskas. *Laboratorinė medicina* 2014; 16(3): 116-119.
2. Deontological examination: clinical and forensic medical diagnosis discrepancies. Sandra Mazeikiene, Sigitas Laima, Sigitas Chmieliauskas, Dmitrij Fomin, Gerda Andriuskeviciute, Mante Markeviciute, Audrone Matuseviciute, Algimantas Jasulaitis, Jurgita Stasiuniene. *Egyptian Journal of Forensic Sciences* 2016;6(4):323–327.

Articles in ISI Web of Science peer-reviewed scientific publications with citation rate on the topic of the dissertation

Deontological examination as a criterion for the assessment of personal healthcare professional quality. ASTROBE-compliant retrospective study. Sandra Mazeikiene, Jurgita Stasiuniene, Diana Vasiljevaite, Sigitas Laima, Sigitas Chmieliauskas, Dmitrij Fomin, Rokas Simakauskas, Algimantas Jasulaitis. *Medicine*. 2020;99(3):e18770.

INFORMATION ABOUT THE AUTHOR

Name, surname	Sandra Mažeikienė
Date of birth	1983 Feb 18
Email	s.matickaite@gmail.com
Education	2001 secondary school – Panevezys Vytautas Zemkalnis Gymnasium 2007 university – Kaunas Medical University, professional qualification of a doctor 2008 -Internship at Public Institution Panevezys Hospital 2013 -Forensic medicine qualification diploma 2018 -Included in the list of experts of the Republic of Lithuania
Work experience	Since 2013 until now - forensic medicine expert at the State Forensic Medicine Service under the Ministry of Health of the Republic of Lithuania

APPENDIX

Deontological examination research questionnaire

Hospital			
Department			
Date:		Days in hospital	
Patient	Male []	Female[]	Age:
Home address:		Tautybè:	
Patient::	discharged []	died[]	
Doctor's specialization			
Clinical diagnosis:	Underlying disease:		
	Complications:		
	Concomitant diseases:		
Appointed regarding:	Regarding a health disorder [] Provision of inadequate services [] Death of the patient []		
Forensic diagnosis:	Underlying disease:		
	Complications:		
	Concomitant diseases:		

Clinical diagnosis:	Coincidence []	Discrepancy []
Number of questions		Ekspertizès
Specialization of the doctor specialist invited to the examination		Examination report/record number
Number of experts:		Number of specialists:
Work experience of the expert in years:		Eksperto speciality :

NOTES

NOTES

NOTES

Vilniaus universiteto leidykla
Saulėtekio al. 9, III rūmai, LT-10222 Vilnius
El. p.: info@leidykla.vu.lt, www.leidykla.vu.lt
Tiražas 30 egz.