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DOCTORAL SCHOOL

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# MEDICAL MALPRACTICE – THE RESEARCH OF IMPACT AND CONSEQUENCES IN THE PRACTICE OF FAMILY DOCTORS IN ROMANIA DOCTORAL THESIS ABSTRACT

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#### **INTRODUCTION**

#### MOTIVATION FOR CHOOSING THE RESEARCH TOPIC

The introduction analyzes the motivation for choosing the research topic regarding the vulnerability of family doctors' practice in Romania to accusations of medical malpractice. The challenges and problems faced by the Romanian healthcare system, including underfunding, poor management, and malpractice-related issues, are highlighted. The topic is identified as insufficiently studied in Romania, with limited data regarding compliance with legislation and patient rights in medical practice.

The argument is made that the risk of malpractice accusations is real, and family medicine is just as vulnerable to these accusations as other specialties. The gradual introduction of medical law courses in Romanian medical and pharmacy universities (pioneered by UMFCD in 2013) to improve physicians' knowledge of legal regulations and medical responsibility is mentioned.

The importance and relevance of the topic at the international, national, and regional levels are underscored, highlighting concerns for proper and safe medical practice and the exchange of best practices between countries. The implications of the topic in the international, national, and regional contexts are discussed.

The hypothesis and research questions are outlined, focusing on assessing the risk of malpractice in the practice of family doctors in Romania, understanding medical legislation, and identifying major vulnerabilities in their practice, comparing 2023 with 2012.

The research objectives are presented, accompanied by a description of the applied research methodology and criteria for evaluating questionnaire responses. Additionally, a brief overview of the paper's contents is provided, emphasizing the results obtained from analyzing physicians' responses.

The interdisciplinary nature of the research is highlighted, stressing that addressing medical malpractice must consider both scientific/technical and legal/ethical aspects.

The conclusion mentions research limitations, such as variable interpretations of responses and the effects of the selected sample. The prospects for further research in this field are suggested.

#### GENERAL PART (CURRENT STATE OF KNOWLEDGE)

# CHAPTER 1. MEDICAL ACT RESPONSIBILITY - FROM ETHICAL AND MORAL PRINCIPLES TO THE LEGAL LIABILITY OF FAMILY DOCTORS

#### 1.1. Introductory considerations

The chapter analyzes aspects related to medical act responsibility, from ethical and moral principles to the legal liability of family doctors in cases of malpractice. It examines the definition of malpractice and the types of legal liability for medical personnel, including civil, criminal, disciplinary, and administrative.

#### 1.2. Definition of malpractice

Medical malpractice is defined as a professional error committed in the execution of medical acts, causing harm to the patient and requiring the civil liability of medical personnel and healthcare providers.

The text emphasizes that malpractice involves civil, not criminal, administrative, or disciplinary liability, and physicians are responsible for compensating patient harm, not punishing them. The importance of causality between medical error and patient harm is underlined.

#### 1.3. Etiology of malpractice

The etiology of malpractice is explored, linked to scientific/technical errors or violations of legal regulations governing medical practice. The text emphasizes that malpractice extends beyond medical errors to encompass ethical and legal violations in the doctor-patient relationship.

#### 1.4. From bioethics to malpractice

The connection between bioethics and malpractice is highlighted, indicating that avoiding malpractice requires professionalism in medical application and adherence to ethical and legal obligations towards patients. The development of bioethics is presented as a response to challenges posed by scientific and technological advancements.

#### 1.5. Abuses of Human Rights and Freedoms

The text discusses abuses of human rights and freedoms in the history of medical research and practice, including Nazi experiments and the thalidomide tragedy, emphasizing the need to protect patients and adhere to ethical and legal norms in medical practice. In conclusion, the text analyzes the complexity of medical responsibility, highlighting the relationship between ethics, law, and malpractice, and underscoring the importance of adhering to both bioethical principles and legal regulations to prevent patient harm and hold physicians accountable. In 1953, the World Medical Association (WMA) began developing a document for applying the principles of the Nuremberg Code to medical research. This document, known as the Helsinki Declaration, was issued in 1964 and establishes rules for therapeutic and non-therapeutic research. A tragic example of disregarding these principles is the thalidomide tragedy. In the 1950s, thalidomide was approved as a sedative in Europe but was not approved by the FDA in the US. In 1961, it was discovered that thalidomide was dangerous for fetuses in the first trimester of pregnancy, causing abnormal blood vessel development and limb malformations. Due to its teratogenic effects, the drug was globally banned. Although thalidomide received limited approval for certain indications, this tragedy led to changes in ethical codes and legislation, requiring informed consent from patients for clinical studies. The Tuskegee Study, conducted between 1932 and 1972, investigated the untreated progression of syphilis in 399 African American patients. Despite penicillin becoming the standard treatment for syphilis in 1947, researchers hid this information and continued the study to observe the effects of untreated disease. The study continued until 1972 and was only halted when the information became public. The Tuskegee Study was a serious ethical violation, and the Nuremberg Code and Helsinki Declaration did not prevent its execution. In the following years, ethical principles for clinical studies were developed, culminating in the 1979 Belmont Report, which formed the basis for FDA rules on clinical research. The three fundamental principles of this report are respect for persons, benefits outweighing risks in research projects, and justice in the distribution of costs and benefits.

#### 1.6. Emergence of Bioethics

The emergence of bioethics resulted from developments in medical and ethical fields, and the term "bioethics" was first used in 1971 by American oncologist Van Ransseler Potter. Bioethics aims to combine biological knowledge with human values and address ethical dilemmas in the medical field. It is based on various types of moral theories, including

utilitarianism, Kantianism, rights theory, and communitarianism. These theories led to the crystallization of the four major ethical principles of principialism: respect for autonomy, non-maleficence, beneficence, and justice. Thus, medical ethics developed within a complex framework, attempting to strike a balance between human values and scientific advances to ensure proper and ethical patient treatment. The text further discusses the principle of justice in the context of access to medical resources and the costs of medical services, highlighting the debate and controversy surrounding social justice in this field. It emphasizes that all theories of justice are rooted in the minimum requirement that "equals must be treated equally, and unequals must be treated unequally," but they do not provide precise criteria for determining equality and equal treatment ("formal" justice). The material principles of justice are presented, referring to the objective properties of distributing medical resources, including the need to distribute these resources based on needs. The text mentions multiple principles of fair distribution, such as equal distribution, distribution based on needs, effort, merit, and free-market exchanges. The challenges facing national healthcare systems are highlighted, particularly regarding the funding and distribution of medical services. The importance of improving efficiency and equity in these systems is emphasized, and a conflict between justice-based objectives and efficiency-based objectives is noted. The principles of bioethics (principialism) and how they guide physician-patient behavior and are translated into legal regulations regarding medical personnel's civil liability and clinical research in Romania are discussed.

# CHAPTER 2. CIVIL LIABILITY OF MEDICAL PERSONNEL – MEDICAL MALPRACTICE

#### 2.1. From Moral Principles to Legal Responsibility in Medical Practice

Continuing, the work focuses on analyzing the principle of autonomy in the context of informed patient consent and medical data confidentiality.

#### 2.1.1. The Principle of Autonomy

The conditions under which patients must express their informed consent and its content are described. Additionally, aspects related to confidentiality and how physicians should protect patients' medical information are detailed.

#### 2.1.2. The Benefit and Non-Maleficence Principles

The text then addresses the principles of beneficence and non-maleficence, highlighting that these principles complement each other in medical practice and that maintaining a balance between them can be challenging in certain situations. The phenomenon of "defensive medicine" is mentioned in the context of the imbalance between these principles in some countries.

#### 2.1.3. The Principle of Justice

Finally, the text discusses the principle of justice and how it applies at the national, institutional, and individual levels. The importance of fairness in distributing medical resources is emphasized, and the criteria for selecting patients under financial or other restrictions are explained. The paragraph focuses on the discussion around the principle of justice in accessing medical resources and services, as well as providing a detailed exposition of how bioethical principles and legal regulations apply in medical practice in Romania.

#### 2.2. The Legal Nature of Medical Liability

This section presents divergent opinions regarding the legal nature of medical civil liability. Some opinions suggest that it can be considered either contractual civil liability or tortious civil liability, depending on the context, while others assert that it is always a form of tortious civil liability. However, contractual liability is considered to operate in cases where the patient is tied to a private medical unit or in the relationships between the patient and individual physicians.

In contrast, the opinion that medical civil liability is always of a tortious nature is based on the argument that life, health, and physical or mental integrity cannot be the subject of a contract. Thus, even if legal acts were concluded, they would be deemed void under the Civil Code. This perspective underscores that physicians have general legal obligations to patients, and patients have civil subjective rights. Furthermore, liability disclaimers in medical contracts are often considered null in cases of tortious liability. This opinion is based on the idea that the subjects of the medical relationship cannot negotiate or limit liability prescribed by law or medical regulations.

#### 2.3. Medical Malpractice Insurance

In the section on "Medical Malpractice Insurance," the importance of professional civil liability insurance for medical personnel is discussed. This is also known as "malpractice

insurance." Malpractice insurance is seen as an essential mechanism for managing the financial risk associated with compensating patients affected by faulty medical acts. However, the text mentions that although malpractice insurance is mandatory in many cases, many insurance contracts have not provided adequate protection to both physicians and patients. Many physicians did not carefully read insurance contracts or perceived them only as formalities, signing them solely to maintain their right to practice. The text highlights that many physicians did not carefully choose malpractice insurance and often opted for insurance companies based on lower premium prices. Additionally, many contracts had clauses that limited payments for moral damages and compensation awarded as a result of multiple litigations. Physicians are advised to be more involved in the negotiation process of malpractice insurance contracts and pay attention to details, especially concerning coverage for moral damages and compensation for multiple litigations.

In conclusion, it is emphasized that these insurance contracts must be carefully analyzed to provide adequate coverage for the risk of malpractice. Physicians are encouraged to be proactive in negotiating contracts and to request coverage for moral damages and compensation related to multiple litigations, ensuring they are protected against the financial risks associated with medical practice.

#### 2.4. Correct Identification of Legal Liability Limits

The text discusses the limitations and types of legal liability for physicians in cases of medical malpractice. It is mentioned that there are several types of liability, such as civil, criminal, disciplinary, and administrative liability. In the case of civil liability for malpractice, the physician can be held responsible for damages caused to the patient due to scientific errors or violation of legal regulations. There are situations where the physician is not liable for damages, as they may be caused by the circumstances in which the medical act took place, and in such cases, liability may fall on the medical institution.

#### 2.5. Institutional Malpractice

Institutional malpractice cases are debated, where the medical institution may be responsible for damages suffered by the patient due to broader factors related to medical activity. This may include nosocomial infections, defects in medical devices, or non-compliance with internal regulations of the healthcare unit. It is emphasized that there are cases where liability may be solely attributed to the physician, solely to the institution, or

divided between the physician and the institution. Additionally, there is a possibility for the institution to be liable to the patient, while the physician ultimately bears the costs.

The importance of distinguishing between individual and institutional liability is highlighted, noting that institutions have an interest in protecting their medical practice by adhering to legal regulations and providing malpractice insurance. It is also emphasized that aligning medical practice with legal requirements is not just a protection mechanism but also a quality standard for medical services.

The text mentions that hospital accreditation processes are based on complying with quality standards, including respecting patients' rights and ensuring proper communication with them. The text concludes that adherence to legal requirements is not only a way to manage the risk of malpractice but also a modern and obligatory standard for the quality of medical practice.

#### **ORIGINAL PART (PERSONAL CONTRIBUTIONS)**

# CHAPTER 3. STUDY 1 - COMPLIANCE OF FAMILY DOCTORS' ACTIVITY IN ROMANIA WITH NATIONAL LEGISLATION REGARDING PATIENT RIGHTS

#### 3.1. Working Hypothesis and General Objectives

A 2023 research regarding the compliance of family doctors' activity in Romania with national legislation regarding patient rights is presented. The research aims to identify whether family doctors adhere to legal regulations and evaluate their practice in relation to patients. The research method used is quantitative, with an online opinion survey using a questionnaire containing 16 open and closed questions.

Within the research, questions related to the medical malpractice risk of family doctors at present, knowledge and compliance with the legal framework, as well as major vulnerabilities in the practice of family doctors in Romania in the year 2023, are formulated. According to the first hypothesis, it is considered that legal regulations are little known and respected by the doctors, and this lack of knowledge obviously leads to exposure to the risk of malpractice. The secondary hypothesis assumes that doctors are not aware of this lack of knowledge in their current practice.

#### 3.2. Scientific Objectives for Resolution within Scientific Research

The research analyzes the practice of family doctors in the 8 different economic development regions of Romania. It is mentioned that the number of family doctors in Romania has decreased until the year 2023, and the study focuses on data collected in 2012 and 2023. The research results will be compared to highlight any differences in compliance with legal regulations between these two periods.

#### 3.3. General Methodology of the Research

The analysis method includes regional comparisons, with attention to geographical peculiarities and university influences. Medical and pharmaceutical universities are considered important sources of training and education for family doctors in their respective regions regarding medical legislation and malpractice.

The importance of family doctors' knowledge and compliance with legal requirements is emphasized in order to avoid accusations of malpractice and to ensure proper and ethical medical practice in relation to patients.

#### 3.4. Researching Regional Specificities

The 8 development regions in Romania are discussed, and the analysis of medical practices of family doctors in these regions is presented. It is noted that the development regions include North-East, South-East, South, South-West, West, North-West, Center, and Bucharest-Ilfov, with details about population, area, density, and the largest city in each region. The presence of medical universities and faculties in these regions is also highlighted.

#### 3.5. Defining Criteria for Evaluating Questionnaire Responses

Reference is made to a 2023 doctoral research study that analyzes the responses of family doctors in Romania to questionnaires. They were asked to respond according to their daily practice, and then in the analysis, responses in line with the legislation were deemed correct.

#### 3.6. Results and Discussions

The research focuses on major areas of vulnerability in medical practice, such as informed consent, confidentiality of medical data, patient access to personal medical information, and others.

It is mentioned that none of the participating doctors answered "correctly" to all questions in the questionnaire, indicating non-compliance with the legal framework in medical practice.

Several tables containing data collected from the study and calculation formulas to evaluate correct answers to questions are presented, as well as a comparative analysis of data from the two time periods, 2012 and 2023. The use of the Chi-Square Test is detailed for evaluating correlations between nominal variables and trends over time in medical practices.

In conclusion, the obtained Chi-Square Test values from the statistical analysis were significant and suggest that the research methodology was valid and that significant relationships exist between the investigated variables in the medical practices of family doctors in different regions of Romania.

The results of the doctoral research study using the Chi-Square Test to evaluate correlations between correct answers to the same 16-question questionnaire, the economic development regions of Romania, and the years 2012 and 2023 are presented. Probability values p < 0.05 for the Chi-Square Tests highlight the differences between the responses in the two time periods, in different regions.

#### 3.7. Informed Consent

Within Question 5, which pertains to the collection and analysis of biological samples, response options are detailed, and it is mentioned that patient consent is necessary for collection. The results for Question 5 in different regions show a significant improvement in correct responses from family doctors in 2023 compared to 2012, especially in the case of North-East.

The discussion then moves to Question 6, which concerns informing patients about the risks of medical procedures. The relevant legal provision for this question is presented. A significant increase in correct responses among family doctors in 2023, nearly reaching 100%, is observed, representing the norm.

The overall results of the statistical analysis are further discussed, highlighting the high values of the Chi-Square Test and Phi coefficient, indicating a strong correlation between the analyzed variables. The importance of statistical relevance and its impact on understanding Romania's medical, educational, and socio-economic context is emphasized.

Additionally, graphical representations of the percentages of correct responses by region and year for Questions 5 and 6 are provided, highlighting trends and differences between different regions and time periods.

In conclusion, changes in the attitudes of family doctors from different regions are mentioned regarding informing patients about risks, obtaining written consent for high-risk medical procedures, and completing emergency reports in the years 2012 and 2023. Regarding obtaining patient consent for high-risk maneuvers, a significant improvement is observed in most regions in 2023 compared to 2012, while the situation is worse for completing emergency reports in the current year compared to 2012.

In the concluding paragraph, the importance of the Romanian Bioethics Society, founded in Iaşi in 2005, is emphasized in explaining some 2012 results. It organizes the National Bioethics Conference and publishes the Romanian Journal of Bioethics. It is also mentioned that certain regions, especially the North-East, had different attitudes towards bioethical aspects and medical legislation in 2012, which returned to average in 2023.

#### 3.8. Confidentiality of Medical Data

The doctoral study focuses in this subchapter on the aspect of respecting the confidentiality of medical data. The study results indicate that the number of family doctors who adhere to the confidentiality of medical data has increased from 38% in 2012 to 77% in 2023. However, certain regions, such as the North-East, continue to have less compliant responses regarding the confidentiality of medical data.

In conclusion, the study highlights that there are improvements in the adherence to certain aspects of medical data confidentiality among family doctors in Romania, but there are still educational and awareness needs in certain regions.

#### 3.9. Patient Access to Personal Medical Information

An important aspect in the medical field is further examined: patient access to personal medical information. For this topic, the questionnaire contains Question 11 regarding the provision of medical data, investigations, and treatment to the patient. Proposed responses include options like explaining at discharge or providing complete information. According to the law, patients have the right to unlimited access to their medical information.

The study highlights different percentages of correct responses to Question 11 in different regions and nationally for the years 2012 and 2023. It is noted that 35% of family

doctors in 2012 and 60% of those in 2023 ensure patient access to their medical information. A notable situation is observed in the Bucharest-Ilfov region, with a positive trend in 2012 and its continuation in 2023.

#### 3.10. Media Access

Regarding the relationship between doctors and mass media, Question 3 of the questionnaire is related to granting the press access to patients in the case of events with media impact. Response options include the need for patient consent or informing the public. Legally, patients must provide explicit consent for photography or filming in medical facilities.

The report reveals percentages of correct responses to Question 3 in different regions and nationally for the years 2012 and 2023. It is observed that 48% of family doctors in 2012 gave a correct response, while the percentage decreases to 41% in 2023. Significant variations are observed in the Bucharest-Ilfov region in a negative sense, and in the West and Center regions in a positive sense (more correct responses than the national average). The study emphasizes that, overall, doctors have differing positions regarding their relationship with the mass media, with a tendency towards worsening attitudes by 2023.

#### 3.11. Right to a Second Medical Opinion

The text refers to a study investigating the opinions and practices of family doctors regarding the right to a second medical opinion.

The study examines an important aspect in the medical context: patients' right to a second medical opinion. Question 10 of the questionnaire addresses how doctors respond to a patient's request for a second medical opinion from outside the primary care facility. Response options include facilitating the obtaining of the opinion or recommending that the patient transfer their medical records to another family doctor. According to the law, patients have the right to request a second medical opinion, and the attending physician cannot refuse this right.

The study presents percentages of correct responses to Question 10 in various regions and nationally for the years 2012 and 2023. It is observed that 73% of family doctors in 2012 and 72% in 2023 gave correct responses to this question. Detailed analysis of these percentages reveals variations between different regions and minor changes over time.

#### 3.12. Limitation to Own Specialty

Regarding limitation to their own specialty, Question 9 examines how doctors act when faced with conditions that exceed the competence of their specialty. Response options include providing medical care in emergency situations or consulting a specialist by the family doctor. Legislation stipulates that doctors cannot exceed the limits of their specialty but can intervene in emergency situations that meet certain conditions.

The doctoral study presents percentages of correct responses to Question 9 in different regions and nationally for the years 2012 and 2023. A significant increase in the percentages of correct responses in 2023 is noted, indicating a better understanding of regulations and available options in such situations.

#### 3.13. Conclusions

The results regarding the conformity of doctors' practice with legal requirements are presented.

Geographic differences are highlighted, with regards to family doctors' practice compliance with legal requirements regarding patient rights, being more pronounced in 2012.

The North-East region stands out for having the largest differences compared to the national average, both positively and negatively, in various aspects of medical practice in 2012.

For instance, doctors from the North-East region provided more correct responses regarding the collection of biological samples with patient's informed consent but fewer correct responses when it comes to explaining risks to patients in the case of a risky maneuver.

Attention is drawn to the significant concerns of the "Gr. T. Popa" University of Medicine and Pharmacy in Iaşi in the field of bioethics, being a national leader in this discipline of study, and how it might influence medical practice and compliance with legal requirements among its graduates.

Failure to obtain written consent before performing a medical procedure can lead to legal liability for doctors and a decrease in the quality of medical care.

The need for specific training for medical personnel in the field of bioethics on one hand and the application of medical legislation on the other hand is emphasized.

Proposed solutions include implementing specific training programs and hiring only personnel trained in this field in healthcare institutions.

It is noted that in medical school curricula, courses in medical bioethics do not fully address the problem of the risk of medical malpractice for doctors in Romania.

The conclusions suggest that knowledge of bioethical principles alone is not sufficient to avoid the consequences of malpractice and that knowledge of medical legislation and legal procedures is essential for this goal.

In conclusion, this study reveals important aspects of medical practice in Romania regarding the respect of patient rights and the necessity for education in the field of ethics and medical legislation. Geographic differences in doctors' practice compliance raise the question of possible distinct cultural patterns and suggest that educational measures and improvements in medical practice are necessary to ensure quality healthcare and compliance with laws in the field.

# CHAPTER 4. STUDY 2 - COMPLIANCE OF SCHOOL DOCTORS' PRACTICE IN ROMANIA WITH MEDICAL LEGISLATION

#### 4.1. Summary

In Chapter 4 of the thesis, the practice of school doctors is analyzed in terms of compliance with medical laws and norms.

#### 4.2. Introduction

Study 2 focuses on researching the compliance of school doctors' practice in Romania with legal regulations in the medical field. The practice of these doctors involves specific aspects regulated by laws, and knowledge and adherence to these norms are essential to ensure the rights of patients (school minors), avoid malpractice accusations, and guarantee the quality of medical care.

The research investigated whether the practice of school doctors complies with applicable requirements. The results indicated that all surveyed doctors do not fully comply

with legal requirements, making their practice vulnerable to potential malpractice-related issues.

School doctors have specific responsibilities related to medical care for children with chronic illnesses, managing medical emergencies in schools, and providing medical clearance for school sports competitions. These activities involve knowledge and compliance with specific regulations, and non-compliance can lead to legal problems for doctors.

#### 4.3. Research Objective

The research objective was to collect information about the compliance of school doctors' practice with applicable requirements and identify any trends in non-compliance.

#### 4.4. Material and Method

The research included a group of 25 school doctors from Bucharest (out of a total of 90 in 2020), and the data were collected through interviews and closed-ended questionnaires.

#### 4.5. Definition of Criteria for Evaluating Questionnaire Responses

Responses from school doctors were evaluated as "correct" or "incorrect" based on compliance or non-compliance with legal regulations, and response options were analyzed in detail to identify patterns of practice and justifications. For analysis, the IBM SPSS Statistics program, version 20, was used.

#### 4.6. Results and Discussions

#### 4.6.1. General Results

Data analysis revealed that none of the surveyed doctors fully adhere to the applicable legal framework of their profession.

#### 4.6.2. Specific Results

Areas where legal requirements are not met were identified, such as informed patient consent, confidentiality of medical data, patient access to personal medical information, and limitation of practice to their own specialty.

A specific example was Question 1 regarding the action to take when a patient requires medical care for a condition outside the doctor's specialty. The majority of responses indicated non-compliance with the legal framework, suggesting that many doctors provide

medical care beyond their competencies or consult specialists only in emergency cases, which is not in line with medical laws and regulations.

In conclusion, the study highlights that school doctors in Romania do not fully adhere to medical legislation in their current practice, raising concerns about malpractice and the quality of medical care.

Question 2 concerns communicating a patient's treatment information to third parties. Proposed response options include communication to non-governmental organizations, family members, or none of these. The correct answer, as per the law, is that patient health information must be kept confidential and cannot be disclosed to others outside the patient themselves. However, a significant number of responses (48%) are incorrect, suggesting that doctors believe they can communicate such information to patients' family members. This may reflect a lack of understanding of laws and regulations regarding medical data confidentiality.

Question 3 addresses the issue of informed consent for minor patients. The majority of responses (96%) are incorrect, indicating a lack of awareness that minor patients under certain circumstances can provide their consent for certain medical procedures. Even in this case, there are specific legal regulations, and this lack of awareness can be a vulnerability in current medical practice.

Question 4 relates to patient access to their medical data, including information about tests, diagnosis, and treatment. According to the law, the patient has the right to access this information, yet a significant number of doctors (44%) do not provide this unlimited access, indicating a compliance issue with legal requirements.

Question 5 discusses filming patients in medical facilities. The correct answer is that patients can be filmed with their identity protected and for educational or research purposes, but only with their consent (or that of parents/legal representatives). Many incorrect responses show a lack of understanding of the legal framework and requirements for such recordings.

#### 4.7. Conclusions

In conclusion, the research highlights several issues regarding the compliance of school doctors' practice with legal norms. These non-compliances can have legal consequences and can impact the quality of medical care. Further studies are necessary to

deeply understand these issues and develop educational measures to improve medical practice compliance with legal requirements.

# CHAPTER 5. STUDY 3 - LEGAL CHALLENGES FOR FAMILY MEDICINE PRACTITIONERS IN ROMANIA DURING THE COVID19 PANDEMIC

#### 5.1. Summary

This chapter analyzes the legal challenges faced by family medicine practitioners in Romania during the COVID-19 pandemic. Key questions addressed include the role and responsibilities of doctors in the pandemic context, as well as how they must adapt to legal changes and new medical practice requirements. The socio-economic context of the Romanian healthcare system is described, highlighting inequalities in access to medical services.

#### 5.2. Introduction

In accordance with international health regulations, the COVID-19 epidemic was declared a global public health emergency in January 2020, and pandemics pose significant tests for economies, politics, and country healthcare systems. An effective response to a pandemic involves various measures, including the essential contributions of family medicine practitioners, assessing their role within healthcare systems.

#### **5.3. Research Objectives**

In the pandemic context, questions arise about the role of family medicine. Topics such as the capacity of family doctors to assess patients' health without physical encounters, the legality and functioning of telemedicine in their practice, authorization to treat outside their specialization, and the possible influence of stress on legal liability in case of errors are addressed.

#### **5.4. Socio-Economic Context**

The healthcare system in Romania is characterized by underfunding and inefficiency in resource utilization, with uneven coverage and inequalities between urban and rural populations. Family medicine plays a critical role in the system, being tied to public healthcare services, while the private system allows direct access to services. Pandemics like COVID-19 stress economies, politics, and healthcare systems, and family medicine plays a

vital role in addressing these crises, alleviating pressure on acute care. However, challenges include a shortage of family doctors in many areas and a limit on the number of registered patients for each doctor.

#### 5.5. Roles and Responsibilities of Family Medicine during a Pandemic

The roles of family doctors during a pandemic include triage, treatment, and monitoring of suspected or confirmed patients, as well as providing preventive and continuous care for patients with chronic illnesses.

#### **5.6. Obligation to Provide Medical Care**

Doctors have an obligation to provide medical care to patients and can only refuse this in one strictly regulated situation, which involves disrespectful patient behavior. In such cases, the patient must be notified in writing at least 5 days before discontinuation of the doctor-patient relationship, and the patient must be assured of finding another doctor with the same specialization. Thus, the risk of SARS-CoV-2 coronavirus infection or other health-related reasons cannot justify the refusal of medical care, and it can only apply in cases of inappropriate patient behavior.

### 5.7. Limiting Medical Practice to Own Specialty. Conditions for Exceeding this Limit

Doctors are obligated to act within their professional competencies in their respective specialty, except in emergencies where necessary medical personnel are unavailable. During a pandemic, emergencies can meet legal conditions that allow practicing outside the limits of specialization in order to save lives or prevent patient health deterioration. However, illegal exceeding of competencies can lead to civil liability and malpractice insurance termination, requiring adequate scientific and legal preparation for such exceptional situations.

## 5.8. Informed Patient Consent. Refusal of Consent. Medical Interventions without Consent

The acquisition of informed consent from patients and the circumstances under which medical interventions can be carried out without patient consent are discussed. It's emphasized that legal violations can lead to the termination of doctors' professional liability insurance coverage. In exceptional situations, such as a pandemic, doctors may operate outside their specialization, but they must follow legal conditions to avoid legal

consequences. Thus, adhering to the law and the ethical principles of medical practice remains a priority despite the pandemic context.

#### 5.9. Telemedicine

Study 3 addresses several topics related to telemedicine, family medicine, and the impact of the COVID-19 pandemic on the healthcare system in Romania. Various aspects of Romania's healthcare system within the COVID-19 context are discussed. The importance of telemedicine in providing remote medical services, as defined by the WHO, is emphasized. In Romania, medical legislation has evolved to regulate telemedicine and remote consultations, although the Ministry of Health has not yet published the Methodological Norms for the application of changes to Law 95/2006 concerning telemedicine.

#### 5.10. Conclusions

The pandemic has amplified the role of family doctors as primary care providers, necessitating rapid adaptation to new protocols and guidelines. Although telemedicine has brought benefits, challenges in its use have arisen, including legal issues, technological difficulties, and patients' lack of experience.

Regarding COVID-19 vaccination, family doctor Cătălin Petrencic drew attention by refusing to treat patients who do not accept vaccination. In discussions with patients, he highlighted the importance of vaccination and following medical advice.

However, the principle of patient autonomy is presented in the context of the legal obligation to obtain informed patient consent before treatment, including vaccination. No one can be vaccinated against their will. Patients who refuse vaccination may face certain financial consequences.

Furthermore, the doctoral study recalls illegal "sink vaccination" practices by some family doctors in Romania (2021), where fraudulent COVID certificates were obtained, undermining vaccination efforts and leading to an increase in deaths caused by the pandemic (20,000 deaths in the Delta wave, September 2021 - January 2022).

In conclusion, the pandemic has underscored the importance of adapting the healthcare system and family doctors to new challenges. Telemedicine has become an essential tool, but also one with many challenges. Adhering to medical ethics and laws is crucial in addressing public health crises, to ensure the health and safety of the population.

#### **CHAPTER 6. FINAL CONCLUSIONS AND CONTRIBUTIONS**

#### **6.1. Final Conclusions**

Within the scope of the doctoral study on the vulnerabilities of family doctors' practices from different regions of Romania in the face of possible medical malpractice allegations, using a questionnaire applied in 2023 to a target group of 1121 family doctors (FDs) compared to the previous research in 2012 on a group of 1559 FDs, the following conclusions were drawn:

Geographical differences observed in 2012 regarding the compliance of family doctors' practices with legal requirements related to patient rights have diminished in 2023, and all FDs from various regions are exposed to the risk of malpractice accusations.

Family doctors in Romania are not sufficiently familiar with the legal framework governing their activity and their relationship with patients.

Failure to obtain written consent before a medical procedure can lead to legal liability for doctors and may impact the quality and safety of patient treatment. The situation worsened in 2023 compared to 2012.

Confidentiality of patients' medical information must be respected by family doctors, and this aspect's status in 2023 is less satisfactory than in 2012.

Access to patients' medical records is more consistently respected in 2023 compared to 2012, but deficiencies in practice still exist.

Media exposure represents an increased vulnerability to malpractice accusations, and the situation in 2023 is less compliant than in 2012.

The right to a second medical opinion within the same specialty is respected in 2023 at a level similar to 2012.

Limiting practice to one's own specialty remains a vulnerability for family doctors in Romania, the situation has slightly improved since 2012, but some violations of legal provisions persist.

Education in the field of medical malpractice has improved, but in 2023, fewer doctors recognize the real and current danger of malpractice accusations compared to 2012 (a dangerous phenomenon of vigilance lapse is observed).

Continuing education in preventing, managing, and mitigating the effects of malpractice accusations is essential for medical personnel.

#### 6.2. Own Contributions

This section discusses the study's own contributions, focusing on the results obtained in economically developing regions of Romania and the importance of bioethics in the medical context.

Analysis of regional differences: The study revealed significant differences between economically developing regions of Romania in 2012 regarding the adherence to legal and ethical requirements by family doctors in certain areas of practice vulnerability. Thus, particularities were highlighted concerning the confidentiality of medical information, patient access to personal medical information, respect for competence limits, and patients' right to a second medical opinion. Some regions showed more correct and law-ethical compliant responses, while others exhibited a lower level of compliance.

Role of bioethics: The importance of bioethics in medicine was emphasized. "Grigore T. Popa" University of Medicine and Pharmacy in Iaşi stood out for its involvement in the field of bioethics, including the organization of national bioethics conferences and the publication of a journal in this domain. Fundamental ethical principles such as autonomy, non-maleficence, beneficence, and justice were presented as moral guidelines for medical practice.

Difference between bioethics and medical legislation: The study underscores that while bioethics and medical legislation are interconnected, they have distinct roles. Bioethics promotes ethical actions and awareness, whereas medical legislation regulates actions and imposes sanctions in case of law breaches. This highlights that while understanding and applying ethical principles are important for the moral profile of any doctor, knowledge, comprehension, and adherence to laws are crucial for doctors when discussing medical malpractice.

Training courses as proposed solutions: The study concludes that to reduce the risk of medical malpractice, for future doctors as well as practicing physicians, immediate and long-term implementation of specific training programs is necessary at the national level, organized across three levels: university, residency, and postgraduate. Additionally, only personnel who have completed these training programs should be engaged in healthcare

institutions. The importance of an interdisciplinary approach encompassing both medical and legal notions is emphasized.

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